ANIKA THERAPEUTICS INC
Form 10-Q/A
March 13, 2003

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q/A

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

For the quarterly period ended September 30, 2002

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

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 x No o

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the last practicable date.

At October 28, 2002 there were 9,934,280 outstanding shares of Common Stock, par value $.01 per share.

Introductory Note

This amendment on Form 10-Q/A amends and supercedes the registrant s quarterly report on Form 10-Q for the period ended September 30, 2002, and is being filed to reflect the restatement of the registrant s consolidated financial statements for the three- and nine-month periods ended September 30, 2002, which was publicly announced on January 28, 2003. The items amended in this 10-Q/A are Items 1 (Financial Statements and Notes 2, 4 and 7), 2 and 4 of Part I. Information regarding the restatement and the effect of the restatement on the registrant s results of operation is included in Note 2 to the consolidated financial statements included in Item 1. Except for Item 4, the items that have been amended have been amended only to reflect the restatement referred to above, and no other updates or changes have been made.

PART I: FINANCIAL INFORMATION

ITEM 1: FINANCIAL STATEMENTS

Anika Therapeutics, Inc. and Subsidiaries

Consolidated Balance Sheets

	September 30, 2002 (Unaudited, Restated)	December 31, 2001
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,201,085	$ 9,064,977
Restricted cash	313,160	
Short-term marketable securities	4,500,000	3,994,401
Accounts receivable, net of reserves of $35,000 and $25,000 at September 30, 2002 and December 31, 2001, respectively	1,976,538	2,240,929
Inventories	2,932,974	3,726,982
Prepaid expenses and other current assets	310,564	540,476
Total current assets	17,234,321	19,567,765
Property and equipment, at cost	9,605,252	9,530,047
Less: accumulated depreciation	(7,402,765)	(6,583,175)
	2,202,487	2,946,872
Long-term deposits	143,060	148,160
Notes receivable from officers	178,000	253,000
Total assets	$ 19,757,868	$ 22,915,797
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 777,082	$ 954,585
Accrued expenses	1,785,901	1,842,399
Deferred revenue	959,889	15,001
Total current liabilities	3,522,872	2,811,985
Stockholders equity:		
Preferred stock, $.01 par value; 1,250,000 shares authorized, no shares issued and outstanding		
Common stock, $.01 par value; 30,000,000 shares authorized, 9,991,943 shares issued	99,919	99,919
Additional paid-in capital	31,640,234	31,640,234
Treasury stock (at cost, 57,663 shares)	(279,756)	(279,756)
Accumulated deficit	(15,225,401)	(11,356,585)
Total stockholders equity	16,234,996	20,103,812
Total liabilities and stockholders equity	$ 19,757,868	$ 22,915,797

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 September 30,		Nine Months Ended September 30,	
	2002 (Restated)	2001	2002 (Restated)	2001
Product revenue	$ 2,889,942	$ 3,045,779	$ 8,690,536	$ 8,143,431
License revenue	15,686	8,000	25,686	8,000
Total revenue	2,905,628	3,053,779	8,716,222	8,151,431
Cost of product revenue	1,974,807	2,553,582	6,263,539	6,631,579
Gross profit	930,821	500,197	2,452,683	1,519,852
Operating expenses:				
Research and development	999,137	826,378	3,139,437	3,095,573
Selling, general and administrative	900,192	1,100,180	3,368,524	4,347,544
Litigation settlement costs				950,716
Total operating expenses	1,899,329	1,926,558	6,507,961	8,393,833
Loss from operations	(968,508)	(1,426,361)	(4,055,278)	(6,873,981)
Interest income	61,095	94,324	186,462	573,105
Net loss	$ (907,413)	$ (1,332,037)	$ (3,868,816)	$ (6,300,876)
Basic and diluted net loss per common share	$ (0.09)	$ (0.13)	$ (0.39)	$ (0.63)
Shares used to calculate basic and diluted net loss per common share	9,934,280	9,934,280	9,934,280	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 Nine Months Ended

(Unaudited)

	September 30, 2002 (Restated)	September 30, 2001
Cash flows from operating activities:		
Net loss	$ (3,868,816)	$ (6,300,876)
Adjustments to reconcile net loss to net cash used by operations:		
Depreciation	819,590	797,456
Amortization of deferred compensation		143,753
Reserve for uncollectible accounts	10,000	
Forgiveness of note receivable from officer		129,000
Changes in operating assets and liabilities:		
Accounts receivable	254,391	(310,941)
Inventories	794,008	803,431
Prepaid expenses and other current assets	229,912	247,804
Accounts payable	(177,503)	10,598
Accrued expenses	(56,498)	590,767
Deferred revenue	944,888	401,475
Net cash used in operating activities	(1,050,028)	(3,487,533)
Cash flows from investing activities		
Proceeds from sale of short-term marketable securities	4,494,401	17,460,095
Purchase of short-term marketable securities	(5,000,000)	(11,378,240)
Increase in restricted cash	(313,160)	
Purchase of property and equipment	(75,205)	(865,056)
Repayment of note receivable from officer	75,000	
Deposits	5,100	5,940
Net cash provided by (used in) investing activities	(813,864)	5,222,739
Increase (decrease) in cash and cash equivalents	(1,863,892)	1,735,206
Cash and cash equivalents at beginning of period	9,064,977	8,265,936
Cash and cash equivalents at end of period	$ 7,201,085	$ 10,001,142

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, 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 Surgical, which are HA products used as viscoelastic supplements in ophthalmic surgery. The Company also manufactures CoEase™ for Advanced Medical Optics, Inc., STAARVISC®II for STAAR Surgical Company and ShellGel™ for Cytosol Ophthalmics, Inc., all of which are injectible ophthalmic viscoelastic products.

2. Restated Financial Results

On January 28, 2002, Anika announced the restatement of previously-reported results for the three- and nine-month periods ended September 30, 2002. This restatement involves revenue recognized for the sale in the third quarter of 2002 of certain units of Anika s product used in the treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine osteoarthritis, HYVISC®. A new clean room at Anika s facility that does 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, revenue from that sale should not have been recognized. As a result of the restatement, the revenue for the three months ended September 30, 2002 is reduced by $326,480 to $2,905,628. The net loss for that period increased by $169,770, or $0.02 per share, to a net loss of $907,413 or $0.09 per share. The revenue for the nine months ended September 30, 2002 is reduced by $326,480 to $8,716,222. The net loss increased for that period by $169,770, or $0.02 per share, to a net loss of $3,868,816 or $0.39 per share. The Company s inventory at September 30, 2002 has been increased by the cost of the affected units. As a result of the restatement, the Company s total HYVISC® inventory at September 30, 2002, is $173,326, which includes $156,710 in HYVISC® inventory from the restated transaction, and $16,616 in HYVISC® inventory produced in the new clean room which was previously included in the Company s pre-restatement inventory.

Because revenues were reduced as described above, the revenues derived from sales to Pharmaren AG increased to 10.2% of the Company's total revenues for the nine months ended September 30, 2002. For this reason, the Company has listed Pharmaren AG in the sections of this 10-Q/A that describe which of the Company's customers accounted for greater that 10% of the Company's revenues for that period.

A summary of the impact of such restatement on the financial statements for the three- and nine-months ended September 30, 2002, is as follows:

	As Previously Reported	Adjustment	As Restated
Consolidated Statement of Operations Data:			
Quarter Ended September 30, 2002			
Revenue	$ 3,232,108	$ (326,480)	$ 2,905,628
Cost of product revenue	2,131,517	(156,710)	1,974,807
Gross profit	1,100,591	(169,770)	930,821
Net loss	$ (737,643)	$ (169,770)	$ (907,413)
Basic and diluted net loss per common share	$ (0.07)	$ (0.02)	$ (0.09)
Shares used to calculate basic and diluted net loss per common share	9,934,280		9,934,280
Nine Months Ended September 30, 2002			
Revenue	$ 9,042,702	$ (326,480)	$ 8,716,222
Cost of product revenue	6,420,249	(156,710)	6,263,539
Gross profit	2,622,453	(169,770)	2,452,683
Net loss	$ (3,699,046)	$ (169,770)	$ (3,868,816)
Basic and diluted net loss per common share	$ (0.37)	$ (0.02)	$ (0.39)
Shares used to calculate basic and diluted net loss per common share	9,934,280		9,934,280

	As Previously Reported	Adjustment	As Restated
Consolidated Balance Sheet Data:			
September 30, 2002			
Accounts receivable, net	$ 2,303,018	$ (326,480)	$ 1,976,538
Inventories	2,776,264	156,710	2,932,974
Total assets	19,927,638	(169,770)	19,757,868
Total stockholders equity	16,404,766	(169,770)	16,234,996

3. 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 September 30, 2002, the results of its operations for the quarter and nine months ended September 30, 2002 and 2001 and its cash flows for the nine months ended September 30, 2002 and 2001.

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, 2001. The results of operations for the quarter and nine months ended September 30, 2002 are not necessarily indicative of the results to be expected for the year ending December 31, 2002. See Risk

Factors and Certain Factors Affecting Future Operating Results.

4. 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 subsidiaries, Anika Securities, Inc. and Anika Therapeutics UK, Ltd. All intercompany transactions and balances have been eliminated in consolidation.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and 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*. Short-term marketable securities consist of investments with maturities within twelve months of the balance sheet date. The Company classifies these marketable securities as held to maturity, and accordingly they are carried at amortized cost. Aggregate fair value, amortized cost and average maturity for marketable securities held at September 30, 2002 and December 31, 2001, respectively, are as follows:

	September 30, 2002		
	Amortized Cost	**Gross Unrealized Holding Gain(Loss)**	**Fair Value**
Commercial Bond (12 month maturity)	$ 2,000,000	$ (2,320)	$ 1,997,680
Municipal Bond (12 month maturity)	2,500,000	775	2,500,775
Total	$ 4,500,000	$ (1,545)	$ 4,498,455

	December 31, 2001		
	Amortized Cost	**Gross Unrealized Holding Gain(Loss)**	**Fair Value**
Commercial Paper (weighted average maturity of 5.5 months)	$ 3,994,401	$ 39,802	$ 4,034,203

During the nine months ending September 30, 2002, securities classified as held to maturity, with an aggregate amortized cost of $4,532,000, including interest and realized gains of $103,849, matured.

Revenue Recognition

Product revenue is recognized upon shipment to the customer as long as there is persuasive evidence of an arrangement, the sales price is fixed or determinable and collection of the related receivable is probable. ORTHOVISC® has been sold through several distribution arrangements as well as two outsource order processing arrangements (logistics 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 up-front or milestone payments received as part of supply, distribution, and marketing arrangements ratably over the terms of the agreements to which the payments apply. Amounts received or billed prior to meeting the Company s revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheet.

Reporting Comprehensive Income

SFAS No. 130, *Reporting Comprehensive Income*, establishes standards for reporting and display of comprehensive income (loss) and its components in the financial statements. Comprehensive income (loss) is the total of net income (loss) 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 other items of comprehensive income (loss) for the quarter and nine months ended September 30, 2002 and 2001, except for its reported net loss.

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-makers, in making decisions regarding how to allocate resources and assess performance. The Company s chief decision-making group consists of two individuals: the chief executive officer and president and the chief financial officer. 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 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:

	Quarter Ended September 30,			
	2002 (Restated)		2001	
	Revenue	Percent of Revenue	Revenue	Percent of Revenue
United States	$ 2,428,200	83.6%	$ 2,272,834	74.4%
Middle East	52,220	1.8	91,337	3.0
Other/Europe	425,208	14.6	689,608	22.6
Total	$ 2,905,628	100.0%	$ 3,053,779	100.0%

	Nine Months Ended September 30,			
	2002 (Restated)		2001	
	Revenue	Percent of Revenue	Revenue	Percent of Revenue
United States	$ 6,979,580	80.1%	$ 5,669,109	69.5%
Middle East	141,335	1.6	103,287	1.3
Other/Europe	1,595,307	18.3	2,379,035	29.2
Total	$ 8,716,222	100.0%	$ 8,151,431	100.0%

Since early 2001, sales of product for the Turkish market have been made to a European-based entity and have accordingly been classified in the Other/Europe category since that time.

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

	Quarter Ended September 30,		Nine Months Ended September 30,	
	2002	2001	2002	2001
	(Restated)		(Restated)	
Bausch & Lomb Surgical	67.7%	69.3%	54.0%	60.4%
Advanced Medical Optics	14.3%		6.6%	
Boehringer Ingelheim	1.3%	3.3%	10.5%	6.2%
Pharmaren AG	13.0%	13.8%	10.2%	18.6%
	96.3%	86.4%	81.3%	85.2%

5. 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 (loss) per share amounts are based on the weighted average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share amounts are based on the weighted average number of shares of common stock and the potential common stock outstanding 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, the dilutive effect of outstanding options totaling 126,875 and 416,500, respectively, at September 30, 2002 and 2001, are excluded from the calculation of diluted weighted average shares outstanding because to include them would have been antidilutive for the periods presented.

6. Restricted Cash

At July 19, 2002, in connection with the issuance of an irrevocable letter of credit to one of the Company s vendors the Company had deposited $313,160 with its bank to collateralize the letter of credit. These funds are restricted from the Company s use during the term of the letter of credit, which by its terms was to expire in November 2002, although the Company is entitled to all interest earned on the funds. On October 23, 2002, the letter of credit was drawn upon and the restricted funds were released.

7. Inventories

Inventories consist of the following:

	September 30, 2002	December 31, 2001
	(Restated)	
Raw materials	$ 1,453,563	$ 1,542,511
Work-in-process	1,021,909	1,971,067
Finished goods	457,502	213,404
Total	$ 2,932,974	$ 3,726,982

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.

8. Notes Receivable from Officers

Notes receivable from officers of $178,000 at September 30, 2002, consists of loans made to one officer and one former officer. The note receivable from the officer accrues interest at 6.22%. At September 30, 2002 the note receivable from the former officer was secured by a mortgage on his primary residence, accrued interest at an annual rate of 6.0% and was due on August 12, 2004. The note receivable, in the amount of $119,000, from the former officer was repaid early, on October 17, 2002. A

note in the amount of $75,000 from the Company s former chief executive officer was repaid on June 12, 2002.

9. Licensing and Distribution Agreements

In July 2000, the Company entered into a seven-year supply agreement with Bausch & Lomb Surgical, a unit of Bausch & Lomb (the BLS Agreement), superceding an existing supply contract with Bausch & Lomb Surgical that was set to expire December 31, 2001 (the Old BLS Agreement). Under the terms of the BLS Agreement, effective January 1, 2001, the Company became Bausch & Lomb Surgical s exclusive provider of AMVISC® and AMVISC® Plus, ophthalmic viscoelastic products, in the U.S. and international markets. The BLS Agreement expires December 31, 2007. The BLS Agreement is subject to early termination and/or reversion to a non-exclusive basis under certain circumstances. The BLS Agreement lifted contractual restrictions on the Company s sales of certain ophthalmic products to other companies contained in the Old BLS Agreement, subject to payment of royalties to Bausch & Lomb Surgical by the Company. The Company agreed to a reduction in unit selling prices effective April 1, 2000, and the elimination of minimum unit purchase obligations by Bausch & Lomb Surgical. Under the terms of the BLS Agreement, the price for units sold in a calendar year is dependent on total unit volume of sales of certain ophthalmic products to Bausch & Lomb Surgical and other companies during the year. Accordingly, unit prices for sales to Bausch & Lomb Surgical occurring in the nine months ended September 30, 2002 are subject to possible retroactive price adjustments when the actual annual unit volume for 2002 becomes known. Therefore, in accordance with the Company s revenue recognition policy, the amount of revenue subject to the contracted price adjustment is recorded as deferred revenue until the annual unit volume becomes known and the sales price becomes fixed. Those sales amounts received in excess of revenue recognized is recorded as deferred revenue. At September 30, 2002, the deferred revenue under the BLS Agreement amounted to approximately $840,000.

10. Legal Matters

Securities and Exchange Commission Investigation. The SEC has issued a formal order of investigation and has required the Company to provide information in connection with certain revenue recognition matters. The Company has been cooperating fully. These matters, relating to the Company s historical accounting for and disclosures concerning sales of ORTHOVISC® under a long-term supply and distribution agreement with Zimmer, were also the subject of the Company s March 15, 2000 disclosure concerning an informal SEC inquiry and the restatement of results for 1998 and the first three quarters of 1999. As reported on August 14, 2001, as a result of the SEC s ongoing investigation, the Company, in conjunction with its former independent auditors, determined to again restate its financial results for the fourth quarter of 1998 and the first quarter of 1999. As a result of the SEC s investigation, the Company has been informed that the staff of the Boston District Office of the SEC (the Staff) is considering recommending that the SEC authorize civil injunctive actions against the Company and others, including former officers of the Company, concerning these matters. The Company was invited by the Staff to submit its views as to why a civil injunctive action against the Company should not be instituted, and the Company did so. The Company is currently in discussions with the Staff concerning possible resolution of the matter by settlement. The Company is not in a position to predict whether such a settlement will be reached. In addition, if the Company expends substantial additional costs and fees in responding to this matter, then the matter may have an adverse effect on the Company s financial position.

11. Recent Accounting Pronouncements

In July 2002, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards, or SFAS, No.146, Accounting for Costs Associated with Exit or Disposal

Activities. SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized at its fair market value when the liability is incurred, rather than at the date of an entity s commitment to an exit plan. The provisions of SFAS No.146 are effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of SFAS No. 146 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/A 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;*
- *the rate at which we use cash and the amounts used;*
- *possible negotiations or renegotiations with existing or new distribution and collaboration partners; and*
- *the possible resolution of the Securities and Exchange Commission, or SEC, investigation by settlement, and the effect of the SEC investigation on our financial position if we expend substantial additional costs and fees in our response to the investigation.*

Statements identified by words such as will, likely, may, believe, expect, anticipate, intend, 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/A. 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, in our Annual Report on Form 10-K for the year ended December 31, 2001 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, we announced a restatement of our previously-reported results for the three- and nine-month periods ended September 30, 2002. This restatement involves revenue recognized for the sale in the third quarter of 2002 of certain units of our product used in the treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine osteoarthritis, HYVISC®. A new clean room at our facility that does 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 have determined and our independent public accountants have concurred that revenue from that sale should not have been recognized. As a result of the restatement, the revenue for the three months ended September 30, 2002 is reduced by $326,480 to $2,905,628. The net loss for that period increased by $169,770, or $0.02 per share, to a net loss of $907,413 or $0.09 per share. The revenue for the nine months ended September 30, 2002 is reduced by $326,480 to $8,716,222. The net loss increased for that period by $169,770, or $0.02 per share, to a net loss of

$3,868,816 or $0.39 per share. Our inventory at September 30, 2002 has been increased by the cost of the affected units. As a result of the restatement, our total HYVISC® inventory at September 30, 2002, is $173,326, which includes $156,710 in HYVISC® inventory from the restated transaction, and $16,616 in HYVISC® inventory produced in the new clean room which was previously included in our pre-restatement inventory.

Because revenues were reduced as described above, the revenues derived from sales to Pharmaren AG increased to 10.2% of the Company's total revenues for the nine months ended September 30, 2002. For this reason, the Company has listed Pharmaren AG in the sections of this 10-Q/A that describe which of the Company's customers accounted for greater that 10% of the Company's revenues for that period.

A summary of the impact of such restatement on our financial statements for the three- and nine-months ended September 30, 2002, is as follows:

	As Previously Reported	Adjustment	As Restated
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Cost of product revenue	6,420,249	(156,710)	6,263,539
Gross profit	2,622,453	(169,770)	2,452,683
Net loss	$ (3,699,046)	$ (169,770)	$ (3,868,816)
Basic and diluted net loss per common share	$ (0.37)	$ (0.02)	$ (0.39)
Shares used to calculate basic and diluted net loss per common share	9,934,280		9,934,280

	As Previously Reported	Adjustment	As Restated
Consolidated Balance Sheet Data:			
September 30, 2002			
Accounts receivable, net	$ 2,303,018	$ (326,480)	$ 1,976,538
Inventories	2,776,264	156,710	2,932,974
Total assets	19,927,638	(169,770)	19,757,868
Total stockholders equity	16,404,766	(169,770)	16,234,996

We have 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 .

Until the required regulatory approval of the new clean room for use in the production of HYVISC® is received from the FDA, we are using the clean room previously used in the production of HYVISC®, which has the required regulatory approval.

We have initiated discussions with the FDA regarding the shipment of HYVISC® described above. There can be no assurance that the FDA will respond to the our efforts cooperatively or will not bring regulatory or other actions or proceedings against us. Additionally, in the past, some companies (including Anika) that have restated their financial information have been subject to inquiry or investigation by the Securities and Exchange Commission (SEC), and to private securities litigation. Any inquiry, investigation, action or proceeding by a governmental agency or any private securities litigation could have a material adverse effect on our business, financial conditions or results of operations. There is a risk that any such inquiry, investigation, action, proceeding or litigation could result in substantial costs and divert management attention and resources from our business.

Results of Operations

Product revenue. Product revenue for the quarter ended September 30, 2002 was $2,889,942, a decrease of $155,837, or 5.1%, from $3,045,779 for the quarter ended September 30, 2001. Product revenue for the nine months ended September 30, 2002 was $8,690,536, an increase of $547,105, or 6.7%, from $8,143,431 for the nine months ended September 30, 2001. The decrease in product revenue for the quarter compared to the same period last year is primarily due to lower sales of ORTHOVISC® and lower sales of HYVISC® partially offset by higher ophthalmic product sales. The increase in product revenue for the nine months ended September 30, 2002 compared to the same period last year is primarily due to higher ophthalmic product sales and higher sales of HYVISC® partially offset by lower sales of ORTHOVISC®.

Revenue from sales of ophthalmic products increased $204,180, or 9.4%, for the quarter ended September 30, 2002, compared to the same period last year, primarily due to sales under a new supply agreement with Advanced Medical Optics, Inc. which recorded initial sales in the second quarter of 2002, partially offset by a reduced average selling price per unit on increased volume to Bausch & Lomb Surgical in accordance with their agreement. Revenue from sales of ophthalmic products increased $873,247, or 16.9%, for the nine months ended September 30, 2002, compared to the same period last year, primarily due to sales under the supply agreements with Advanced Medical Optics, Inc. and Cytosol Ophthalmics, Inc. partially offset by a reduced average selling price per unit on increased unit volume to Bausch & Lomb Surgical in accordance with their agreement. Revenue from sales of HYVISC® decreased $65,300, or 64.3%, for the quarter and increased $410,740, or 81.4%, for the nine months ended September 30, 2002 compared to the same periods last year. The decrease of $303,517, or 38.9%, and $745,682, or 30.0%, in revenue from sales of ORTHOVISC® for the quarter and nine months ended September 30, 2002, respectively, compared to the same periods last year is primarily attributable to lower sales for the Turkish market.

We derive a substantial portion of our revenue from the sales of ophthalmic products to Bausch & Lomb Surgical. For the quarter and nine months ended September 30, 2002, sales to Bausch & Lomb Surgical accounted for 67.7% and 54.0% of product revenue, respectively, compared to 69.3% and 60.4% of product revenue for the quarter and nine months ended September 30, 2001.

Revenues by geographic location in total and as a percentage of total revenues are as follows:

	Quarter Ended September 30,			
	2002 (Restated)		2001	
	Revenue	Percent of Revenue	Revenue	Percent of Revenue
United States	$ 2,428,200	83.6%	$ 2,272,834	74.4%

Middle East	52,220	1.8		91,337	3.0
Other/Europe	425,208	14.6		689,608	22.6
Total	$ 2,905,628	100.0%	$	3,053,779	100.0%

	Nine Months Ended September 30,			
	2002 (Restated)		2001	
	Revenue	Percent of Revenue	Revenue	Percent of Revenue
United States	$ 6,979,580	80.1%	$ 5,669,109	69.5%
Middle East	141,335	1.6	103,287	1.3
Other/Europe	1,595,307	18.3	2,379,035	29.2
Total	$ 8,716,222	100.0%	$ 8,151,431	100.0%

Since early 2001, sales of product for the Turkish market have been made to a European-based entity and have accordingly been classified in the Other/Europe category since that time.

License revenue. License revenue was $15,686 and $25,686 for the quarter and nine months ended September 30, 2002, respectively, compared to $8,000 for the quarter and nine months ended September 30, 2001. License revenue includes amortization of up-front and annual maintenance payments associated with five year supply agreements with two purchasers of our ophthalmic products.

Gross profit. Gross profit for the quarter ended September 30, 2002 was $930,821, or 32.0% of revenue, an increase of $430,624, or 86.1%, from a gross profit of $500,197, or 16.4% of revenue, for the quarter ended September 30, 2001. Gross profit for the nine months ended September 30, 2002 was $2,452,683, or 28.1% of revenue, an increase of $932,831, or 61.4%, from a gross profit of $1,519,852, or 18.6% of revenue, for the nine months ended September 30, 2001. Gross profit for the quarter and nine months ended September 30, 2002, as compared with same periods last year, benefited from improved manufacturing cost performance as a result of cost cutting initiatives we implemented during the latter half of 2001 which continued into 2002 combined with our efforts over the past year to reduce work-in-process inventories and increased sales volumes.

Research and development. Research and development expenses for the quarter ended September 30, 2002 was $999,137, an increase of $172,759, or 20.9%, compared to $826,378 for the quarter ended September 30, 2001. Research and development expenses for the nine months ended September 30, 2002 was $3,139,437, an increase of $43,864, or 1.4%, compared to $3,095,573 for the nine months ended September 30, 2001. Research and development expenses include costs for the current Phase III clinical trial for ORTHOVISC®, our product for treatment of osteoarthritis of the knee, which is currently limited to investigational use in the U.S. The increase in research and development expense for the quarter and nine months ended September 30, 2002 compared to the same period last year is primarily due to higher costs related to the ORTHOVISC® clinical trial partially offset by a decrease in employee related costs due to lower headcount. The increase in costs related to the ORTHOVISC® clinical trial for the nine months ended September 30, 2002 compared to the same period last year was partially offset by expenditures in the first quarter of last year related to the preparation for initiation of a clinical trial for INCERT®, a therapy for preventing post-surgical adhesions. As previously disclosed, we determined not to commence a clinical trial for INCERT® during 2001.

Selling, general and administrative. Selling, general and administrative expenses for the quarter ended September 30, 2002 was $900,192, a decrease of $199,988, or 18.2%, compared to $1,100,180 for the quarter ended September 30, 2001. The decrease is primarily due to lower professional service fees in 2002 compared to 2001. Selling, general and administrative expenses for the nine months ended September 30, 2002 was $3,368,524, a decrease of $979,020, or 22.5%, compared to $4,347,544 for the nine months ended September 30, 2001. The decrease is primarily attributable to separation costs of $515,000 incurred in the first nine months of 2001 related to management changes we implemented in June 2001 combined with

lower professional service fees and lower ORTHOVISC® selling expenses in foreign markets in 2002 compared to 2001.

Litigation settlement costs. Litigation settlement costs for the nine months ended September 30, 2001 included a charge of $850,000, which is the portion of the $1.25 million settlement amount contributed by us related to a putative class action suit. For the nine months ended September 30, 2001, professional fees related to the putative class action suit were $100,716.

Interest income. Interest income for the quarter ended September 30, 2002 was $61,095, a decrease of $33,229, or 35.2%, compared to $94,324 for the quarter ended September 30, 2001. Interest income for the nine months ended September 30, 2002 was $186,462, a decrease of $386,643, or 67.5%, compared to $573,105 for the nine months ended September 30, 2001. The decrease in interest income is primarily due to lower interest rates on investments combined with lower average cash balances during the quarter and nine months ended September 30, 2002, compared to the same periods last year.

Liquidity and Capital Resources

Liquidity is defined as the ability to meet current and future financial obligations of a short-term nature. Historically, we have funded our cash requirements from available cash and short-term marketable securities.

At September 30, 2002, we had cash, cash equivalents and short-term marketable securities, including restricted cash of $313,160, of $12.0 million and working capital of $13.7 million compared to cash, cash equivalents and short-term marketable securities of $13.1 million and working capital of $16.8 million at December 31, 2001. Short-term marketable securities at September 30, 2002 consist of a commercial bond and a municipal bond each with an original maturity of one year.

Aggregate cash used in operating activities was $1,050,028 for the nine months ended September 30, 2002 and $3,487,533 for the nine months ended September 30, 2001. Cash used in operating activities for the nine months ended September 30, 2002 included net loss, adjusted for depreciation and amortization, of $3,039,226. This cash used in operating activities was partially offset by cash provided by a reduction in accounts receivable of $254,391 and a reduction of inventories of $794,008 and an increase in deferred revenue of $944,888. Cash used in operating activities for the nine months ended September 30, 2001 included net loss, adjusted for depreciation and amortization and forgiveness of officer loan, of $5,230,667. This cash used in operating activities was partially offset by cash provided by a reduction in inventories of $803,431, an increase in accounts payable and accrued expenses of $601,365 and an increase in deferred revenue of $401,475. The increase in deferred revenue for the nine months ended September 30, 2002 and 2001, largely relates to unit pricing provisions under our supply agreement with Bausch & Lomb Surgical (see Note 9 of the Consolidated Financial Statements included herein). Based on our contractual obligations through 2002 under our supply agreements, we currently expect that a significant portion of our deferred revenue balance will be recognized as revenue in the fourth quarter of 2002. No assurance can be made, however, that retroactive price adjustments under the unit pricing provisions of our supply agreement with Bausch & Lomb Surgical will not be required and may result in a cash rebate to Bausch & Lomb Surgical equal to the related deferred revenue balance.

Capital expenditures were $75,205 for the nine months ended September 30, 2002 and $865,056 for the nine months ended September 30, 2001. Capital expenditures in 2002 include spending for small equipment, computers, and furniture and fixtures associated with normal operations. We anticipate that use of cash in 2002 will be significantly less than cash used in 2001.

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 product development 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; and
the development of strategic alliances for the marketing of certain of our products.

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 nine months ended September 30, 2002, Bausch & Lomb Surgical, Boehringer Ingelheim and Pharmaren AG accounted for 54.0%, 10.5%, and 10.2%, respectively, of product revenues. At September 30, 2002, Bausch & Lomb Surgical accounted for 82% of our accounts receivable balance. On March 11, 2002, Bausch & Lomb Surgical s senior debt and short-term debt ratings were downgraded. Although Bausch & Lomb Surgical 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.

There can be no assurance that we will record profits in future periods. However, we believe that our cash and investments on hand will be sufficient to meet our requirements at least through September 30, 2003. See Risk Factors and Certain Other Factors Affecting Future Operating Results.

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. No assurance can be given that any additional financing will be made available to us or will be available on acceptable terms should such a need arise.

Critical Accounting Policies

In December 2001, the SEC requested that reporting companies discuss their most critical accounting policies in management s discussion and analysis of financial condition and results of operations. The SEC indicated that a critical accounting policy is one that is important to the portrayal of a company s financial condition and operating results and requires management s most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

We have identified the policies below as critical to our business operations and the understanding of our results of operations. The impact and any associated risks related to these policies on our business operations is discussed throughout Management s Discussion and Analysis of Financial Condition and Results of Operations where such policies affect our reported and expected financial results. For a detailed discussion on the application of this and other accounting policies, see Note 2 in the Notes to the Consolidated Financial Statements of our Annual Report on Form 10-K for the year ended December 31, 2001. Our preparation of this Quarterly Report on Form 10-Q/A requires us to make estimates

and

assumptions that affect the reported amount of assets and liabilities, disclosure of contingent assets and liabilities at the date of our financial statements, and we cannot make any assurances that actual results will not differ from those estimates.

Revenue Recognition. Product revenue is recognized upon shipment to the customer as long as there is (i) persuasive evidence of an arrangement, (ii) the sales price is fixed or determinable and (iii) collection of the related receivable is probable. Amounts billed or collected prior to recognition of revenue is classified as deferred revenue. Determination of criteria (ii) and (iii) are based on management s judgments regarding the fixed nature of the product fee and collectibility of those fees. Under our agreement with Bausch and Lomb Surgical, the price for units sold in a calendar year is dependent on total unit volume of sales of certain ophthalmic products 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 our revenue recognition policy, the amount of revenue subject to the 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. We recognize 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.

Reserve for Obsolete/Excess Inventory. Inventories are stated at the lower of cost or market. We regularly review raw materials and work-in-process inventories and record a provision for excess and obsolete inventory if the inventory has not progressed through the manufacturing process for a period of time in excess of the typical inventory cycle period. The reserve is adjusted in subsequent periods to reflect the current movement of the inventory through the manufacturing process.

In connection with the aforementioned restatement, we evaluated whether the $173,326 of HYVISC® inventory produced in the new clean room that did not have the required regulatory approval from the FDA for the manufacture of HYVISC® required an adjustment to state it at the lower of cost or market. We believe that no adjustment is required to the cost basis of the inventory based on current facts and circumstances. In making this determination, we considered various factors including the likelihood of receiving regulatory approval to sell the inventory, the timing of receiving such approval relative to the product s two-year shelf life, the expected customer demand for this product and our historical and expected profit margin associated with this product. There can be no assurance, however, that (i) the FDA will grant regulatory approval to sell the inventory, (ii) if the FDA grants regulatory approval to sell the inventory, that is will do so in time for us to sell the inventory, given the inventory s shelf life; or (iii) that our customer will ultimately purchase the inventory or purchase the inventory at a price in excess of our cost. We evaluate the value of inventory on a quarterly basis and may, based on future changes in facts and circumstances, determine that a write-down of inventory is required in future periods.

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 or financial condition.

Product development and approval within the Food & Drug Administration framework takes a number of years and involves the expenditure of substantial resources. There can be no assurance 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.

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. 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. We have evaluated available information and in February 2001, we commenced another Phase III clinical trial of ORTHOVISC®. The trial is being conducted in up to 25 centers in the U.S. and Canada, with approximately 360 patients enrolled, and with evaluation over a six-month period following treatment. Patient enrollment was completed during the second quarter of 2002. There can be no assurances that:

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

There also can be no assurance 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; and
- we may not be able to achieve meaningful sales of ORTHOVISC® in the U.S.

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 any changes that 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 that affect safety and effectiveness may be deemed approved after a 30-day notice unless the FDA requests a 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 Good Manufacturing Practices/Quality System Regulations (GMP/QSR). Ongoing compliance with GMP/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. There can be no assurance 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 there can be no assurance 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 PMA s 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. There can be no assurance that we will be able to achieve and/or maintain compliance required for 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. There can be no assurance 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 in 1999, 2000, and 2001, we have incurred annual operating losses. As of September 30, 2002, we had an accumulated deficit of approximately $15.2 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. There can be no assurance 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 uncertainties in the Turkish market from economic, regional, political, and competitive factors. As a result, we are uncertain of the extent of our future sales in this market.

Our clinical trials may not support a PMA filing.

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. Although we have received IDE approval from the FDA for ORTHOVISC® there can be no assurance that:

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

There can be no assurance 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 BLS Agreement, effective January 1, 2001, we became Bausch & Lomb Surgical s exclusive provider of AMVISC® and AMVISC® Plus, ophthalmic viscoelastic products, in the U.S. and international markets. The BLS Agreement expires December 31, 2007. The BLS Agreement is subject to early termination and/or reversion to a non-exclusive basis under certain circumstances. The BLS Agreement lifted contractual restrictions on our sales of certain ophthalmic products to other companies contained in the Old BLS Agreement, subject to our payment of royalties to Bausch & Lomb Surgical. We agreed to a reduction in unit selling prices effective April 1, 2000, and the elimination of minimum unit purchase obligations by Bausch & Lomb Surgical. Under the terms of the BLS Agreement, the price for units sold in a calendar year is dependent on total unit volume of sales of certain ophthalmic products to Bausch & Lomb Surgical and other companies during the year. Accordingly, unit prices for sales to Bausch & Lomb Surgical occurring during the year are subject to possible retroactive price adjustments when the actual annual unit volume for the year becomes known. Therefore, in accordance with our revenue recognition policy, the amount of revenue subject to the contractual price adjustment is recorded as deferred revenue until the annual unit volume becomes known and the sales price becomes fixed. Those sales amounts received in excess of revenue recognized is recorded as deferred revenue. Based on our known contractual obligations through 2002 under our supply agreements, we expect that all of our deferred revenue of $840,000 attributable to the BLS Agreement will be recognized as revenue in the fourth quarter of 2002, although no assurance can be made that the retroactive price adjustments under the BLS Agreement will not be required and that may result in a cash rebate to Bausch & Lomb Surgical equal to the related deferred revenue balance. In addition, under certain circumstances, Bausch & Lomb Surgical 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.

The reduction in unit selling prices resulted in a decrease in our revenue and gross profit from Bausch & Lomb Surgical in 2001. For the years ended December 31, 2001 and 2000, sales of AMVISC® products to Bausch & Lomb Surgical accounted for 65.2% and 54.1% of product revenues, respectively. For the nine months ended September 30, 2002, sales to Bausch & Lomb Surgical amounted to 54.0% of our revenue. We expect revenue from sales to Bausch & Lomb Surgical in 2002 to be consistent with 2001. 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 a relationship with a logistic agent (outsource order processing providers) to distribute ORTHOVISC® to customers in certain European countries previously served by Zimmer, Inc. a subsidiary of Bristol-Myers Squibb Company. We have entered into new distribution agreements for ORTHOVISC® in Canada and the U.K. We are seeking to establish long-term distribution and marketing relationships with new distribution partners in additional countries. There can be no assurance that we will be able to identify or engage appropriate distribution or collaboration partners or effectively transition to any such partners. There can be no assurance 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 payors. 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. There can be no assurance that our new products will achieve significant market acceptance. 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. There can be no assurance 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 U.S. Patent and Trademark Office to determine priority of invention (see below), 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. Submission 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. There can be no assurance that in the event that any claims with respect to any of our patents, if issued, will not be 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, we could be subject to significant liabilities to such third party, or we 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, there can be no assurance 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, no assurance can be given 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. Our issued patents and any patents, which arise from our licensed application, would provide competitive protection, if at all, only in the United States.

Other entities have filed patent applications for or have been issued patents concerning various aspects of HA-related products or processes. There can be no assurance that the products or processes we develop 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. 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 development or marketing of INCERT® for this use. No assurance can be given 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 and the third party may enforce patent rights against us which could prohibit the sale and use of INCERT® products.

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. There can be no assurance 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, there can be no assurance that, despite precautions taken by us, others have not and will not obtain access to our proprietary technology. Further, there can be no assurance that third parties will not independently develop substantially equivalent or better technology.

Pursuant to the BLS Agreement, we have agreed to transfer to Bausch & Lomb Surgical, upon expiration of the term of the BLS agreement on December 31, 2007, or in connection with earlier termination in certain circumstances, our manufacturing process, know-how and technical information, which relate to AMVISC® products. Upon expiration of the BLS Agreement, there can be no assurance that Bausch & Lomb Surgical will continue to use us to manufacture AMVISC® and AMVISC® Plus. If Bausch & Lomb Surgical discontinues using 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. 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. There can be no assurance that such growth can be achieved or, if achieved, can be sustained. There can be no assurance 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; or
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 other markets, health care providers, such as hospitals and physicians, that purchase health care products, such as our products, generally rely on third party payors, 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 of our products to secure reimbursement and reimbursement approvals. Reimbursement by third party payors may depend on a number of factors, including the payor 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 payor 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 separately to each payor. Significant uncertainty exists as to the reimbursement status of newly approved health care products, and third party payors 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. There can be no assurance that third party reimbursement coverage will be available or adequate for any products or services we develop. 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 payors 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 short-term marketable securities of approximately $12.0 million as of September 30, 2002. 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; and
the development of strategic alliances for the marketing of certain of our products.

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 that 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. No assurance can be given 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 there can be no assurance 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, there can be no assurance that material claims will not arise in the future or that our insurance will be adequate to cover all situations. Moreover, there can be no assurance 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 the first half of 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 March 25, 2002, we appointed a new Senior Vice President of Sales and Marketing and 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. 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. There can be no assurance 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, 2001 and 2000, approximately, 27.9% and 20.2%, respectively, of our product sales were sold to international distributors. During the nine months ended September 30, 2002 approximately 19.9% 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 to supply the Turkish market. The Turkish economic situation has been volatile and the impact of this volatility on future sales of ORTHOVISC® are uncertain. Such changes in the volume of sales may continue to have adverse effects 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, 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 our 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. 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.

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No person is under any obligation to make a market in our common stock or to publish research reports on us, and any person making a market in our common stock or publishing research reports on us may discontinue market making or publishing such reports at any time without notice. There can be no assurance 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 its National Market. 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 the NASDAQ. 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 National Market. If our common stock is delisted, the delisting would most likely have a material adverse effect on the price and liquidity 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 any attempt to acquire 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, and 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 our Board of Directors.

The SEC commenced an investigation concerning our revenue recognition matters.

The SEC has issued a formal order of investigation to us and has required us to provide information in connection with certain revenue recognition matters. We have been cooperating fully. These matters, relating to our historical accounting for and disclosures concerning sales of ORTHOVISC® under a long-term supply and distribution agreement with Zimmer, were also the subject of our March 15, 2000 disclosure concerning an informal SEC inquiry and the restatement of results for 1998 and the first three quarters of 1999. On August 14, 2001, as a result of the SEC s ongoing investigation, we, in conjunction with our independent auditors, determined to again restate our financial results for the fourth quarter of 1998 and the first quarter of 1999 as discussed in Note 15 of the consolidated financial statements included in the company s Annual Report on Form 10-K for the year ended December 31, 2001. As a result of the SEC s investigation, we have been informed that the staff of the Boston District Office of the SEC (the Staff) is considering recommending that the SEC authorize civil injunctive actions against us and others, including former officers, concerning these matters. We were invited by the Staff to submit our views as to why a civil injunctive action against us should not be instituted, and we have done so. We are currently in discussions with the Staff concerning possible resolution of the matter by settlement. We are not in a

position to predict whether such a settlement will be reached. In addition, if we expend substantial additional costs and fees in responding to this matter, then the matter may have an adverse effect on our financial position.

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 we are. For the nine months ended September 30, 2002, Bausch & Lomb Surgical, Boehringer Ingelheim and Pharmaren AG accounted for 54.0%, 10.5%, and 10.2%, respectively, of product revenues. At September 30, 2002, Bausch & Lomb Surgical accounted for 82% 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 adversely affect our business. On March 11, 2002, Bausch & Lomb Surgical s senior debt and short-term debt ratings were downgraded. Although Bausch & Lomb Surgical emphasized at that time it was not facing any issues with respect to liquidity, any such issues that impact their ability to pay 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, in any future negotiations, we may be subject to the perceived or actual advantage the customers may have, given their relative size and importance to us. 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, Spain, Portugal, Turkey, and Israel. Due to the result of the unfavorable results of the U.S. ORTHOVISC® Phase III clinical trial announced on May 31, 2000, marketing efforts in these countries have been and may continue to be negatively affected. There can be no assurance 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 September 30, 2002, we do 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 our investments consist of money market funds, commercial paper that are carried on our books at amortized cost which approximates fair market value and municipal bonds. Accordingly, we have no quantitative information concerning the market risk of participating in such investments.

Primary Market Risk Exposures

Our primary market risk exposures are in the areas of interest rate risk and foreign currency exchange rate risk. Our investment portfolio of cash equivalent and short-term investments is subject to interest rate fluctuations, but we believe this risk is immaterial due to the short-term nature of these investments. Our 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 ended September 30, 2002. Currently, we do not engage in foreign currency hedging activities.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of 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 a date within 90 days prior to the filing of this report (Evaluation Date).

Prior to that evaluation, and as a result of the events that led to the restatement described elsewhere in the 10-Q/A, the Company made certain changes to its disclosure controls and procedures for this 10-Q/A. First, the internal document used in the manufacture of the Company s products now contains a field that requires manufacturing personnel to affirmatively indicate the clean room used in the production of the product, and to check (against a checklist that lists each product and the clean room or rooms approved for manufacture of that product) whether the clean room is approved for the manufacture of that product. After the product is manufactured, Anika s Quality Assurance (QA) department reviews that document to ensure that the product was manufactured in accordance with Anika s specifications. Finally, before revenue is recognized on the product, Anika s finance department will, among other things, make sure that QA has conducted its review. Second, the Company has instituted a system under which the Company s Regulatory Affairs department will issue a memorandum indicating the status of all pending regulatory submissions at the end of each calendar month. This memorandum will include the reason for each regulatory submission, the product or products to which each submission applies, the agency (and division of that agency, if applicable) responsible for review of each submission, and whether each submission has been approved. The memorandum will be distributed to relevant Company personnel.

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

We currently are in the process of further reviewing and documenting our disclosure controls and procedures, including our internal controls and procedures for financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

(b) Changes in internal controls.

Subsequent to the Evaluation Date, there were no significant changes in internal controls or in other factors that could significantly affect internal controls.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

See Note 10, Legal Matters in the consolidated financial statements included herein. 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

None.

Item 5. Other Information

Effective October 1, 2002 we appointed American Stock Transfer & Trust Company, or AST, as transfer agent and registrar for our capital stock.

On November 5, 2002, we substituted AST as successor rights agent under our Shareholder Rights Agreement, dated as of April 6, 1998, between us and Firstar Trust Company and amended the terms of our Shareholder Rights Agreement to facilitate this substitution.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibit No.	Description
(3)	Articles of Incorporation and Bylaws:
3.1	The 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	Amendment to the Amended and Restated Articles of Organization of the Company, dated January 8, 1997 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. 001-14027), filed with the Securities and Exchange Commission on August 14, 2002.
3.3	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.
3.4	Amendment to the Amended and Restated Articles of Organization of the Company, incorporated herein by reference to the Company s quarterly report on Form 10-QSB for the quarterly period ending September 30, 1998 (File no. 001-14027), filed with the Securities and Exchange Commission on August 14, 1998.
3.5	Amended and Restated By-laws 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. 001-14027), 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.
(10)	Material Contracts
(11)	Statement Regarding the Computation of Per Share Earnings
11.1	See Note 5 to the Consolidated Financial Statements included herewith.

* filed herewith

(b) Reports on Form 8-K:

The Registrant filed the following Reports on Form 8-K during the quarter ended September 30, 2002:

1. Current Report on Form 8-K filed July 9, 2002, as amended by Current Report on Form 8-K/A filed July 22, 2002, announcing that the Company had engaged PricewaterhouseCoopers LLP as independent auditor.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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 in Woburn, Massachusetts on March 13, 2003.

Anika Therapeutics, Inc.

March 13, 2003

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

CERTIFICATION PURSUANT TO SECTION 302(a)

OF THE SARBANES-OXLEY ACT OF 2002

I, Charles H. Sherwood, Ph.D, certify that:

1. I have reviewed this quarterly report on Form 10-Q/A of Anika Therapeutics, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

   c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent function):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 13, 2003

/s/ Charles H. Sherwood
Charles H. Sherwood, Ph.D
Chief Executive Officer and President

CERTIFICATION PURSUANT TO SECTION 302(a)

OF THE SARBANES-OXLEY ACT OF 2002

I, William J. Knight, certify that:

1. I have reviewed this quarterly report on Form 10-Q/A of Anika Therapeutics, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

   c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent function):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 13, 2003

/s/ William J. Knight
William J. Knight
Chief Financial Officer

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