FORM 10-Q

Quarterly report pursuant to sections 13 or 15(d)

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FILER

CIMA LABS INC

CIK:**833298**| IRS No.: **411569769** | State of Incorp.:**DE** | Fiscal Year End: **1231**
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SIC: **2834** Pharmaceutical preparations

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SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

☑ Quarterly Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended March 31, 2002

☐ Transition report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from _____ to _____

Commission File Number 0-24424

CIMA LABS INC.

(Exact name of registrant as specified in its charter)

Delaware	**41-1569769**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
10000 Valley View Road, Eden Prairie, MN 55344-9361	**(952) 947-8700**
(Address of principal executive offices and zip code)	(Registrant' s telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months, and (2) has been subject to such filing requirements for the past 90 days.

Yes ☑ No ☐

Indicate the number of shares outstanding of each of the issuer' s classes of common stock, as of the latest practical date.

Common Stock, $.01 par value	14,152,571
(Class)	(Outstanding at May 8, 2002)

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CIMA LABS INC.

All other trademarks used in this report are the property of their respective owners. We have registered "CIMA®," "CIMA LABS INC.®," "OraSolv®," "OraVescent®," "DuraSolv®" and "PakSolv®" as trademarks with the U.S. Patent and Trademark Office. We also use the trademarks "OraSolv®SR/CR," "OraVescent®SL/BL" and "OraVescent®SS." "Triaminic®" and "Softchews®" are trademarks of Novartis. "Zomig®," "Zomig-ZMT®" and "Rapimelt™" are trademarks of AstraZeneca. "Remeron®" and "SolTab™" are trademarks of Organon. "Tempra®" is a registered trademark of a Canadian affiliate of Bristol-Myers Squibb. "FirsTabs™" is a trademark of Bristol-Myers Squibb. "NuLev™" is a trademark of Schwarz Pharma. "Actiq®" is a registered trademark of Anesta Corporation. "Claritin®" and "Reditabs®" are registered trademarks of Schering Corporation. "Maxalt-MLT®" is a registered trademark of Merck & Co., Inc. "Zydis®" is a registered trademark of Cardinal Health, Inc. "FlashDose®" is a

registered trademark of Biovail Corporation. “WOWTab®” is a registered trademark of Yamanouchi Pharma Technologies, Inc. “Flashtab®” is a registered trademark of Ethypharm.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Balance Sheets
CIMA LABS INC.

	March 31, 2002 (Unaudited)	December 31, 2001 (See note)
Assets		
Current assets:		
Cash and cash equivalents	$9,408,191	$ 1,879,647
Available-for-sale securities	40,722,456	20,085,284
Trade accounts receivable, net	7,875,127	8,963,105
Interest receivable	1,688,389	2,127,151
Inventories, net	3,718,074	3,770,807
Deferred taxes	700,000	700,000
Prepaid expenses	569,067	170,516
Total current assets	64,681,304	37,696,510
Other assets:		
Available-for-sale securities	92,793,302	127,539,806
All other, net	6,262,968	5,933,652
Total other assets	99,056,270	133,473,458
Property and equipment:		
Property, plant and equipment	44,798,175	37,490,871
Accumulated depreciation	(10,344,562)	(9,729,963)
	34,453,613	27,760,908
Total assets	$198,191,187	$ 198,930,876
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$847,949	$ 1,607,378
Accrued expenses	1,638,394	1,771,849
Deferred revenue	499,167	775,000
Total current liabilities	2,985,510	4,154,227
Stockholders' equity:		
Convertible preferred stock, $.01 par value; 5,000,000 shares authorized; none outstanding	–	–
Common stock, $.01 par value; 60,000,000 shares authorized; 14,769,279 and 14,739,116 shares issued and outstanding (including 619,425 and 533,700 treasury shares), respectively	147,693	147,391
Additional paid-in capital	237,465,697	237,271,364
Accumulated deficit	(23,598,614)	(27,003,219)

Accumulated other comprehensive income	1,190,793	2,217,364
Treasury stock	(19,999,892)	(17,856,251)
Total stockholders' equity	195,205,677	194,776,649
Total liabilities and stockholders' equity	$198,191,187	$198,930,876

Note: The balance sheet at December 31, 2001 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

See accompanying notes.

Statements of Operations
CIMA LABS INC.

(Unaudited)

	For the Three Months Ended March 31,	
	2002	2001
Operating revenues:		
Net sales	$4,237,464	$3,296,173
Product development fees and licensing	2,307,253	1,868,217
Royalties	1,838,161	791,661
	8,382,878	5,956,051
Operating expenses:		
Cost of goods sold	3,356,127	2,601,428
Research and product development	2,051,993	1,486,228
Selling, general and administrative	1,476,681	1,117,638
	6,884,801	5,205,294
Operating income	1,498,077	750,757
Other income:		
Investment income	1,736,085	2,504,134
Other income (expense)	2,946	(78,541)
	1,739,031	2,425,593
Income before provision for income taxes	3,237,108	3,176,350
Provision for income taxes (benefit)	(167,497)	–
Net income	$3,404,605	$3,176,350
Net income per share:		
Basic	$.24	$.22
Diluted	$.23	$.20
Weighted average shares outstanding:		
Basic	14,159,399	14,458,728
Diluted	14,654,844	15,612,056

See accompanying notes.

Statements of Cash Flows
CIMA LABS INC.

(Unaudited)

	For the Three Months Ended March 31,	
	2002	2001
Operating activities:		
Net income	$3,404,605	$3,176,350
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	650,434	520,333
Income tax benefit of stock options exercised	26,000	–
Deferred income taxes	(330,450)	–
Gain on sale of investment securities	(87,817)	–
Changes in operating assets and liabilities:		
Accounts receivable	1,087,978	3,335,252
Interest receivable	438,762	(347,672)
Inventories	52,733	(1,817,800)
Other assets	(398,551)	(58,886)
Accounts payable	(759,430)	895,069
Accrued expenses and other	(133,454)	313,355
Deferred revenue	(275,833)	20,833
Net cash provided by operating activities	3,674,977	6,036,834
Investing activities:		
Purchases of property, plant and equipment	(7,307,303)	(3,646,203)
Patents and trademarks	(34,702)	(29,057)
Purchases of available-for-sale securities	(9,025,637)	(82,606,668)
Proceeds from sales of available-for-sale securities	22,196,216	3,935,003
Net cash provided by (used in) investing activities	5,828,574	(82,346,925)
Financing activities:		
Proceeds from exercises of stock options	118,473	1,534,319
Purchases of treasury stock	(2,143,641)	–
Issuance of common stock related to employee stock purchase plan	50,161	–
Net cash (used in) provided by financing activities	(1,975,007)	1,534,319
Increase (decrease) in cash and cash equivalents	7,528,544	(74,775,772)
Cash and cash equivalents at beginning of period	1,879,647	91,587,716
Cash and cash equivalents at end of period	$9,408,191	$16,811,944

See accompanying notes

CIMA LABS INC.
Notes to Financial Statements
(Unaudited)

1. Basis of Presentation

CIMA LABS INC. (the "Company"), a Delaware corporation, develops and manufactures fast-dissolve and enhanced-absorption oral drug delivery systems. OraSolv and DuraSolv, the Company' s leading proprietary fast-dissolve technologies, are oral dosage forms incorporating taste-masked active drug ingredients into tablets, which dissolve quickly in the mouth without chewing or the need for water. The Company develops applications for technologies that are licensed to pharmaceutical company partners. The Company currently manufactures and packages five pharmaceutical brands incorporating its proprietary fast-dissolve technologies. Revenues are comprised of three components: net sales of products it manufactures; product development fees and licensing revenues for development activities conducted through collaborative agreements with pharmaceutical companies; and royalties on the sales of products sold by pharmaceutical companies under license from the Company.

The accompanying unaudited financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. These financial statements do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accruals, which are considered necessary for fair presentation, have been included. Operating results for the three months ended March 31, 2002 are not necessarily indicative of the results that may be expected for the year ended December 31, 2002. For further information, you should refer to the audited financial statements and accompanying notes contained in our Annual Report on Form 10-K for the year ended December 31, 2001.

2. Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires us to make estimates and assumptions that may affect the amounts we report in our financial statements and accompanying notes. Actual results could differ from those estimates.

3. Cash Equivalents and Investments

The Company' s investments in available-for-sale securities are carried at fair value, with unrealized gains and losses included in accumulated other comprehensive income as a separate component of stockholders' equity. As of March 31, 2002, the amortized cost and estimated market value of available-for-sale securities, all of which have contractual maturities of three years or less, are as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Market Value
As of March 31, 2002:				
Asset backed securities	$28,070,495	$235,033	$27,796	$28,277,732
Corporate bonds and notes	77,215,513	709,597	240,572	77,684,538
Euro notes	14,383,136	477,446	–	14,860,582
Floating rate notes	10,591,562	70,104	–	10,661,666
U.S. government securities	2,064,259	–	33,019	2,031,240
Totals - March 31, 2002	$132,324,965	$1,492,180	$301,387	$133,515,758
As of December 31, 2001:				
Asset backed securities	$30,476,440	$377,781	$14,235	$30,839,986
Corporate bonds and notes	85,770,912	1,371,649	52,536	87,090,025
Euro notes	14,392,231	537,290	–	14,929,521
Floating rate notes	12,696,395	17,283	–	12,713,678
U.S. government securities	2,071,748	–	19,868	2,051,880
Totals - December 31, 2001	$145,407,726	$2,304,003	$86,639	$147,625,090

4. Income Per Share

Income per share for the three months ended March 31, 2002 and 2001 are summarized in the following table:

	Three Months Ended	
	March 31, 2002	March 31, 2001
Numerator:		
Net income	$ 3,404,605	$ 3,176,350
Denominator:		
Denominator for basic earnings per share - weighted average shares outstanding	14,159,399	14,458,728
Effect of dilutive stock options	495,445	1,153,328
Denominator for diluted earnings per share - weighted average shares outstanding	14,654,844	15,612,056
Basic earnings per share	$ .24	$ .22
Diluted earnings per share	$ .23	$ .20

5. Comprehensive Income

Comprehensive income consists of net income and net unrealized gains (losses) on available-for-sale securities.

	Three Months Ended	
	March 31, 2002	March 31, 2001
Net income	$ 3,404,605	$ 3,176,350
Unrealized (loss) gain on available- for-sale securities	(1,026,571)	1,539,291
Total comprehensive income	$ 2,378,034	$ 4,715,641

6. Inventories

Inventories are stated at the lower of cost (first in, first out) or fair market value.

	March 31, 2002	December 31, 2001
Raw materials	$ 3,229,178	$ 3,659,288
Work in process	88,194	–
Finished products	400,702	111,519
	$ 3,718,074	$ 3,770,807

7. Tax Expense

Provisions for income taxes for the three-month period ended March 31, 2002, reflect provisions for U.S. federal and state income taxes. At December 31, 2001, the Company had a valuation reserve of $16.2 million and a net deferred tax asset of $22.4 million. As of March 31, 2002, the Company had a valuation reserve of $14.7 million and a net deferred tax asset of $21.4 million.

8. Segment Information – Major Customers

The Company operates within a single segment: the development and manufacture of fast-dissolve and enhanced-absorption oral drug delivery systems. Revenues are comprised of three components: net sales of products utilizing the Company' s proprietary fast-dissolve technologies; product development fees and licensing revenues for development activities conducted by the Company through collaborative agreements with pharmaceutical companies; and royalties on the sales of products manufactured by the Company, which are sold by pharmaceutical companies under licenses from the Company. Less than 10 percent of the Company' s revenues are earned from activities conducted outside the United States.

Revenues as a percentage of total revenues from major customers are as follows:

	Three Months Ended

	March 31, 2002		March 31, 2001	
AstraZeneca	22	%	39	%
Organon	30		23	
Novartis	17		19	
Unnamed company	12		–	

	Three Months Ended			
	March 31, 2002		March 31, 2001	
Schwarz Pharma	6		11	
Other	13		8	
Total	100	%	100	%

Trade accounts receivable at March 31, 2002 of approximately $7,875,000 were comprised primarily of the following customers: Organon (27%), Schwarz (7%), Novartis (19%), Unnamed company (8%), and AstraZeneca (19%).

9. Reclassifications

Certain amounts presented in the 2001 financial statements have been reclassified in order to conform with the 2002 presentation. These reclassifications have no impact on the net income or shareholders' equity as previously reported.

Item 2. Management' s Discussion and Analysis of Financial Condition and Results of Operations

Forward-Looking Statements

We make many statements in this Quarterly Report on Form 10-Q under the captions Management' s Discussion and Analysis of Financial Condition and Results of Operations, and Factors That Could Affect Future Results and elsewhere, which are forward-looking and are not based on historical facts. These statements relate to our future plans, objectives, expectations and intentions. We may identify these statements by the use of words such as believe, expect, will, anticipate, intend and plan and similar expressions. These forward-looking statements involve a number of risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those we discuss in Factors That Could Affect Future Results and elsewhere in this report. These forward-looking statements speak only as of the date of this report, and we caution you not to rely on these statements without considering the risks and uncertainties associated with these statements and our business that are addressed in this report.

These forward-looking statements include statements relating to the expected growth in operating revenues in 2002; the timing of expected improvements to our Eden Prairie manufacturing facility; the timing for completion of improvements to our Brooklyn Park R&D center, including the construction of a second manufacturing facility; future expense levels; the timing of availability of products; expected demand for products using our technologies and the adequacy of our production capacity; and future research and development activities relating to our current or new technologies. We are not under any duty to update any of the forward-looking statements after the date of this report to conform these statements to actual results, except as required by law.

Overview

We develop and manufacture pharmaceutical products based on our proprietary OraSolv and DuraSolv fast dissolve technologies. We currently manufacture five pharmaceutical brands utilizing our fast dissolve technologies: three prescription and two over-the-counter brands. These products include Triaminic Softchews for Novartis, Tempra FirsTabs for a Canadian affiliate of Bristol-Myers Squibb, AstraZeneca' s Zomig-ZMT and its equivalent for the European market, Zomig Rapimelt, Remeron SolTab for Organon and NuLev for Schwarz Pharma. The FDA is currently reviewing Wyeth' s (formerly known as American Home Products) regulatory submission for an orally disintegrating dosage form of loratadine that we developed. We are also currently developing other oral drug delivery technologies for ourselves and for others. We operate within a single business segment, the development and manufacture of fast dissolve and enhanced-absorption oral drug delivery systems. Our revenues are comprised of three components, including net sales of products we manufacture for pharmaceutical companies using our proprietary fast dissolve technologies, product development fees and licensing revenues for development activities we conduct through collaborative agreements with pharmaceutical companies, and royalties on the sales of our products which are sold by pharmaceutical companies under licenses from us.

Revenues from product sales and from royalties will fluctuate from quarter to quarter and from year to year depending on, among other factors, demand by consumers for the products we produce, new product introductions, the seasonal nature of some of the products we produce to treat seasonal ailments, pharmaceutical company ordering patterns and our production schedules. Revenues from product development fees and licensing revenue will fluctuate depending on, among other factors, the number of new collaborative agreements that we enter into, the number and timing of product development milestones that we achieve under our collaborative agreements and the level of our development activity conducted for pharmaceutical companies.

Critical Accounting Policies and Estimates

General

The following discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to bad debts, inventories, income taxes, and contingencies and litigation. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

Revenue Recognition

We recognize revenue in accordance with the Securities and Exchange Commission' s Staff Accounting Bulletin No. 101, or SAB 101, "Revenue Recognition in Financial Statements." SAB 101 requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an agreement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed and determinable; and (4) collectibility is reasonably assured. Revenues from our business activities are recognized from net sales of manufactured products upon shipment; from product development fees as the contracted services are rendered; from product development milestones upon completion and acceptance; from up-front product development license fees as they are amortized over the expected development term of the proposed products; and from royalties on the sales of products sold by pharmaceutical companies under license from us. The determination of SAB 101 criteria (3) and (4) for each source of revenue is based on our judgments regarding the fixed nature and collectibility of each source of revenue. Revenue recognized for any reporting period could be adversely affected should changes in conditions cause us to determine that these criteria are not met for certain future transactions.

Deferred Taxes

The carrying value of our net deferred tax assets assumes that we will be able to generate sufficient taxable income in the United States, based on management' s current estimates and assumptions. We record a valuation allowance to reduce the carrying value of our net deferred tax assets to the amount that is more likely than not to be realized. While we have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing the requirements for the valuation allowance, in the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of our net recorded amount, an adjustment to the deferred tax asset would increase net income in the period such determination is made. Likewise, should we determine that we would not be able to realize all or part of our net deferred tax asset in the future, an adjustment to the net deferred tax asset would decrease net income in the period such determination is made. On a quarterly basis, we evaluate the realizability of our deferred tax assets and assess the requirements for a valuation allowance. For the three months ended March 31, 2002, we have recorded a $14.7 million valuation allowance related to our net deferred tax assets of $21.4 million, compared to a valuation allowance of $16.2 million related to our net deferred tax assets of $22.4 million for the year ended December 31, 2001.

Results of Operations

Three Month Periods Ended March 31, 2002 and 2001

Operating Revenues. Our total operating revenues were $8.4 million in the first quarter of 2002, compared to $6.0 million in the first quarter of 2001. Operating revenues from AstraZeneca, Organon and Novartis, our three largest pharmaceutical company partners, together represented 69% and 81% of our total operating revenues in first quarters of 2002 and 2001, respectively. The 41% increase in total operating revenues resulted from increases in all three of our revenue components: (1) royalties on the sales of our products which are sold by pharmaceutical companies under licenses from us, (2) revenues from the sales of products we manufacture, and (3) product development fees and licensing revenue.

Revenues from net sales of products we manufacture totaled $4.2 million in the first quarter of 2002, compared to $3.3 million in the first quarter of 2001. The increase of $941,000 or 29% was due primarily to higher manufacturing volumes of Remeron SolTab for Organon. For the first quarter of 2002, branded prescription product sales increased more than $600,000 from the same period last year. Sales of branded prescription products represented 72% of our total product sales in the first quarter of 2002, compared with 74% in the first quarter of 2001.

Product development fees and licensing revenues were $2.3 million in the first quarter of 2002, compared to $1.9 million in the first quarter of 2001. The increase of $439,000 or 24% resulted from agreements for proposed new products, our achievement of certain milestones under existing agreements and an overall increase in development activity. Product development fees and licensing revenues included amortization of deferred revenue of $76,000 and $79,000 in the first quarters of 2002 and 2001, respectively. Product development fees and licensing revenues in

subsequent quarters will depend on our success in signing new license and development agreements with pharmaceutical companies and our success in achieving milestones set forth in existing agreements. In 2002, we expect combined revenues attributable to product development fees and licensing revenues to increase by approximately 20 to 25% from 2001 levels.

Revenues from royalties were $1.8 million in the first quarter of 2002, compared to $792,000 in the first quarter of 2001. The increase of $1.0 million or 132% was due primarily to increased end-customer sales by AstraZeneca of Zomig Rapimelt in Europe and Zomig-ZMT in the U.S. and to increased end-customer sales by Organon of Remeron SolTab. Royalties represented 22% of our total operating revenues in the first quarter of 2002, compared to 13% in 2001. In 2002, we expect royalties to increase by approximately 100% from 2001 levels.

Cost of goods sold. Cost of goods sold was $3.4 million in the first quarter of 2002, compared to $2.6 million in the first quarter of 2001. The increase of $755,000 was principally due to higher production volumes over the same period in 2001, with increased production of Remeron SolTab for Organon accounting for most of the increase.

Gross profits on product sales, defined as net sales less cost of goods sold, were $881,000 in the first quarter of 2002, compared to gross profits of $695,000 in the first quarter of 2001. The $186,000 improvement was principally due to increased production volumes of higher margin branded prescription products. Gross profits on product sales were 21% of total product sales in the first quarter of both 2002 and 2001 because the mix of branded prescription and over-the-counter sales was essentially the same in both periods. In 2002, we expect gross profits on product sales to increase from 2001 levels in terms of dollar amounts and as a percentage of product sales.

Research and product development expenses. Research and product development expenses were $2.1 million in the first quarter of 2002, compared to $1.5 million in the first quarter of 2001. The increase of $566,000 was due primarily to additional staffing, development activity for our proprietary products, including OraVescent fentanyl, and infrastructure investments. In 2002, we expect research and product development expenses to increase by approximately 50% from 2001 levels due to a significant increase in development work for our pharmaceutical partners, as well as internally funded development efforts related to OraVescent fentanyl.

Selling, general and administrative expenses. Selling, general and administrative expenses were $1.5 million in the first quarter of 2002, compared to $1.1 million in the first quarter of 2001. The increase of $359,000 was due primarily to costs associated with increased professional staffing. In 2002, we expect selling, general and administrative expenses to increase 30% to 50% from 2001 levels as we continue to make investments in people and systems to support our anticipated growth.

Other income (expense). Other income was $1.7 million in the first quarter of 2002, compared to $2.4 million in the first quarter of 2001. Other income consists primarily of investment income comprised of interest earned on securities and gains realized on the sale of securities. The decrease of $687,000 was due primarily to lower levels of cash available for investment and from lower interest rates on our investments. In 2002, we expect other income to decrease by approximately 40% from 2001 levels due to lower interest rates and our expected use of cash for capital expenditures, which will reduce the level of cash available for investment.

Liquidity and Capital Resources

We have financed our operations to date primarily through private and public sales of equity securities, other income, and from operating revenues consisting of product sales, product development fees and licensing revenues, and royalties.

Working capital increased from $33.5 million at December 31, 2001, to $61.7 million at March 31, 2002. The increase of $28.2 million resulted primarily from the reclassification of $20.6 million of non-current available-for-sale securities to current available-for-sale securities when the maturities of those securities became less than one year. Cash and available-for-sale securities, including both current and non-current securities, were $142.9 million at March 31, 2002, compared to $149.5 million at December 31, 2001. This decrease of $6.6 million resulted from $7.3 million of capital expenditures made by the Company (including $5.7 million used to purchase our Eden Prairie corporate headquarters and manufacturing facility), and common stock repurchases of $2.1 million, partially offset by $3.7 million of cash generated from our operating activities. We invest excess cash in interest-bearing money market accounts and investment grade securities.

During the next nine months, we plan to spend approximately $25.0 to $30.0 million to complete various improvements to our Eden Prairie manufacturing facility, improvements to our Brooklyn Park R&D center, and to complete a second manufacturing site, which will be located at our Brooklyn Park R&D center. We expect this second manufacturing site to be operational in 2003. In addition, we expect to fund additional product development activities related to our OraVescent technology and to develop proprietary products using our OraSolv and DuraSolv technologies. We may also acquire technologies that complement our current portfolio of oral drug delivery technologies. We believe that our cash and cash equivalents and available-for-sale securities, together with expected revenues from operations, will be sufficient to meet our anticipated capital requirements for the foreseeable future. However, we may require additional funds to support our working capital requirements or for other purposes and may seek to raise such additional funds through public or private equity financings or from other sources. We cannot be certain that additional financing will be available on terms favorable to us, or at all, or that any additional financing will not be dilutive.

Factors That Could Affect Future Results

Certain statements made in this Quarterly Report on Form 10-Q are forward-looking statements based on our current expectations, assumptions, estimates and projections about our business and our industry. These forward-looking statements involve risks and uncertainties. Our business, financial condition and results of operations could differ materially from those anticipated in these forward-looking statements as a result of certain factors, as more fully described below and elsewhere in this Form 10-Q. You should consider carefully the risks and uncertainties described below, which are not the only ones facing our company. Additional risks and uncertainties also may impair our business operations.

The Loss Of One Of Our Major Customers Could Reduce Our Revenues Significantly.

Revenues from AstraZeneca, Organon and Novartis together represented approximately 80% and 69% of our total operating revenues for the year ended December 31, 2001, and for the quarter ended March 31, 2002, respectively. The loss of any one of these customers could cause our revenues to decrease significantly, resulting in losses from our operations. If we cannot broaden our customer base, we will continue to depend on a few customers for the majority of our revenues. We may be unable to negotiate favorable business terms with customers that represent a significant portion of our revenues. If we cannot, our revenues and gross profits may not grow as expected and may be insufficient to allow us to achieve sustained profitability.

We Rely On Third Parties To Market, Distribute And Sell The Products Incorporating Our Drug Delivery Technologies And Those Third Parties May Not Perform.

Our pharmaceutical company partners market and sell the products we develop and manufacture. If one or more of our pharmaceutical company partners fails to pursue the marketing of our products as planned, our revenues and gross profits may not reach our expectations, or may decline. We often cannot control the timing and other aspects of the development of products incorporating our technologies because our pharmaceutical company partners may have priorities that differ from ours. Therefore, our commercialization of products under development may be delayed unexpectedly. Because we incorporate our drug delivery technologies into the oral dosage forms of products marketed and sold by our pharmaceutical company partners, we do not have a direct marketing channel to consumers for our drug delivery technologies. The marketing organizations of our pharmaceutical company partners may be unsuccessful, or they may assign a low level of priority to the marketing of our products that is different from our priorities. Further, they may discontinue marketing the products that incorporate our drug delivery technologies. If marketing efforts for our products are not successful, our revenues may fail to grow as expected or may decline.

If We Do Not Enter Into Additional Collaborative Agreements with Pharmaceutical Companies, We May Not Be Able To Achieve Sustained Profitability.

We depend upon collaborative agreements with pharmaceutical companies to develop, test and obtain regulatory approval for, and commercialize oral dosage forms of, active pharmaceutical ingredients using our drug delivery technologies. The number of products that we successfully develop under these collaborative agreements will affect our revenues. If we do not enter into additional agreements in the future, or if our current or future agreements do not result in successful marketing of our products, our revenues and gross profits may be insufficient to allow us to achieve sustained profitability.

We face additional risks related to our collaborative agreements, including the risks that:

any existing or future collaborative agreements may not result in additional commercial products;

additional commercial products that we may develop may not be successful;

we may not be able to meet the milestones established in our current or future collaborative agreements;

we may not be able to successfully develop new drug delivery technologies that will be attractive in the future to potential pharmaceutical company partners; and

our pharmaceutical company partners may exercise their limited rights to terminate their collaborative agreement with us.

If We Cannot Increase Our Production Capacity, We May Be Unable To Meet Expected Demand For Our Products And We May Lose Revenues.

We must increase our production capacity to meet expected demand for our products. We currently have two production lines and are planning to add a bottling line and other manufacturing equipment by 2003. If we are unable to increase our production capacity as scheduled, we may be unable to meet expected demand for our products, we may lose revenues and we may not be able to maintain our relationships with our pharmaceutical company partners. Production lines in the pharmaceutical industry generally take 16 to 24 months to complete due to the long lead times required for precision production equipment to be manufactured and installed, as well as the required testing and validation process that must be completed once the equipment is installed. We may not be able to increase our production capacity quickly enough to meet the requirements of our pharmaceutical company partners.

If We Do Not Properly Manage Our Growth, We May Be Unable To Sustain The Level Of Revenues We Have Attained Or Effectively Pursue Additional Business Opportunities.

Compared to the corresponding periods a year earlier, our operating revenues increased 34% and 41% for the year ended December 31, 2001, and for the three month period ended March 31, 2002, respectively, placing significant strain on our management, administrative and operational resources. If we do not properly manage the growth we have recently experienced and expect in the future, our revenues may decline or we may be unable to pursue sources of additional revenues. To properly manage our growth, we must, among other things, implement additional (and improve existing) administrative, financial and operational systems, procedures and controls on a timely basis. We will also need to expand our finance, administrative and operations staff. We may not be able to complete the improvements to our systems, procedures and controls necessary to support our future operations in a timely manner. We may not be able to hire, train, integrate, retain, motivate and manage required personnel and may not be able to successfully identify, manage and pursue existing and potential market opportunities. Improving our systems and increasing our staff will increase our operating expenses. If we fail to generate additional revenue in excess of increased operating expenses in any fiscal period we may incur losses, or our losses may increase in that period.

We May Be Unable To Achieve Our Anticipated Revenues and Profits Because The Markets For The Products We Develop And Manufacture For Our Pharmaceutical Company Partners Are Subject To Market Risks From The Introduction of Generic Prescription Products, The Pricing

Strategies Of Generic Competitors And From Regulatory Strategies That Could Switch A Prescription Product To An Over-The-Counter Product.

In January 2002, Mylan Laboratories and Teva Pharmaceutical Industries announced that they received tentative approval from the FDA for mirtazapine tablets, which are expected to be generic substitutes for Organon' s Remeron standard tablets. In March 2002, Akzo Nobel NV, Organon' s parent company, reported that Organon sued seven generic pharmaceutical companies, including Teva and Mylan, for the infringement of Organon' s U.S. patent for Remeron (mirtazapine standard tablets). In May 2002, Organon announced that it sued Barr Laboratories, Inc. for infringing on its U.S. patent for Remeron SolTab (mirtazapine orally disintegrating tablets). The U.S. market launch of generic mirtazapine standard tablets by Mylan Laboratories, Teva Pharmaceutical Industries, and five other unnamed generic pharmaceutical companies, as well as the U.S. market launch of generic orally disintegrating mirtazapine tablets by Barr Laboratories, is subject to final FDA approval, which could occur after the resolution of all legal and patent issues related to Organon' s patent rights. Organon is vigorously defending its patent rights, which it believes apply through June 2017. There can be no assurance that Organon' s market for Remeron SolTab would not be negatively affected by generic mirtazapine competition due to the potential impact of lower product pricing resulting from generic competition from either or both standard and orally disintegrating tablets. Due to the large number of variables and high degree of uncertainty, we are unable to predict the timing for the market introduction of a generic mirtazapine standard tablet or a generic mirtazapine orally disintegrating tablet, and the effect of such generic product introductions on our business.

Another product that involves a high degree of uncertainty is loratadine, which is currently a prescription product. We have developed for Wyeth (formerly known as American Home Products) a fast dissolve formulation of loratadine, which Wyeth is expected to market as a generic alternative to Claritin Reditabs in 2003, unless Schering Corporation is successful in its efforts to secure extended exclusive rights to market Claritin. Schering Corporation, the loratadine patent holder, is vigorously defending its legal and patent rights against Wyeth and other generic competitors.

In May 2001, a joint committee of the FDA' s Nonprescription Drugs Advisory Committee and Pulmonary-Allergy Drugs Advisory Committee made a non-binding recommendation that loratadine, the active drug ingredient in Claritin, has a safety profile acceptable for over-the-counter marketing. In March 2002, Schering Corporation announced that the FDA has accepted for filing its application to switch all formulations of Claritin to over-the-counter products. In April 2002, the FDA' s Nonprescription Advisory Committee endorsed Claritin (loratadine) for over-the-counter treatment in chronic idiopathic urticaria, or chronic hives of unknown cause.

The ongoing litigation against Wyeth and others by Schering Corporation to prevent or delay the market entry of a generic loratadine product, as well as Schering Corporation' s application to switch loratadine to the over-the-counter market, could affect our anticipated revenues and profits. The potential switch of loratadine from the prescription market to the over-the-counter market affects pricing, distribution channels, advertising, insurance reimbursement and a variety of other marketing and regulatory factors. The effects of a delayed market entry of Wyeth' s generic alternative to Claritin Reditabs and the potential switch from the prescription market to the over-the-counter market involve a high degree of uncertainty and we are unable to predict the effect of such changes on our business.

We May Experience Significant Delays In Expected Product Releases While Our Pharmaceutical Company Partners Seek Regulatory Approvals For The Products We Develop And, If They Are Not Successful In Obtaining The Approvals, We May Be Unable To Achieve Our Anticipated Revenues And Profits.

The federal government, principally the U.S. Food and Drug Administration, and state and local government agencies regulate all new pharmaceutical products, including our existing products and those under development. Our pharmaceutical company partners may experience significant delays in expected product releases while attempting to obtain regulatory approval for the products we develop. If they are not successful, our revenues and profitability may decline. We cannot control, and our pharmaceutical company partners cannot control, the timing of regulatory approval for the products we develop.

Applicants for FDA approval often must submit extensive clinical data and supporting information to the FDA. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a drug product. Changes in FDA approval policy during the development period, or changes in regulatory review for each submitted new drug application, also may cause delays or rejection of an approval. Even if the FDA approves a product, the approval may limit the uses or "indications" for which a product may be marketed, or may require further studies. The FDA also can withdraw product clearances and approvals for failure to comply with regulatory requirements or if unforeseen problems follow initial marketing.

Manufacturers of drugs also must comply with applicable good manufacturing practices requirements. If we cannot comply with applicable good manufacturing practices, we may be required to suspend the production and sale of our products, which would reduce our revenues and gross profits. We may not be able to comply with the applicable good manufacturing practices and other FDA regulatory requirements for manufacturing as we expand our manufacturing operations.

If our products are marketed in foreign jurisdictions, we, and the pharmaceutical company partners with which we are developing our technologies, must obtain required regulatory approvals from foreign regulatory agencies and comply with extensive regulations regarding safety and quality. If approvals to market our products are delayed, if we fail to receive these approvals, or if we lose previously received approvals, our revenues would be reduced. We may be required to incur significant costs in obtaining or maintaining foreign regulatory approvals.

Our Commercial Products Are Subject To Continuing Regulations And We May Be Subject To Adverse Consequences If We Fail To Comply With Applicable Regulations.

Even if our products receive regulatory approval, either in the U.S. or internationally, we will continue to be subject to extensive regulatory requirements. These regulations are wide-ranging and govern, among other things:

adverse drug experience reporting regulations;

product promotion;

product manufacturing, including good manufacturing practice requirements; and

product changes or modifications.

If we fail to comply or maintain compliance with these laws and regulations, we may be fined or barred from selling our products. If the FDA determines that we are not complying with the law, it can:

issue warning letters;

impose fines;

seize products or order recalls;

issue injunctions to stop future sales of products;

refuse to permit products to be imported into, or exported out of, the U.S.;

totally or partially suspend our production;

withdraw previously approved marketing applications; and

initiate criminal prosecutions.

We Have A Single Manufacturing Facility And We May Lose Revenues And Be Unable To Maintain Our Relationships With Our Pharmaceutical Company Partners If We Lose Its Production Capacity.

We manufacture all of the products that we produce on our existing production lines in our Eden Prairie facility. If our existing production lines or facility becomes incapable of manufacturing products for any reason, we may be unable to meet production requirements, we may lose revenues and we may not be able to maintain our relationships with our pharmaceutical company partners. Without our existing production lines, we would have no other means of manufacturing products incorporating our drug delivery technologies until we were able to restore the manufacturing capability at our facility or develop an alternative manufacturing facility. Although we carry business interruption insurance to cover lost revenues and profits in an amount we consider adequate, this insurance does not cover all possible situations. In addition, our business interruption insurance would not compensate us for the loss of opportunity and potential adverse impact on relations with our existing pharmaceutical company partners resulting from our inability to produce products for them. Although we currently plan to add a second manufacturing site at our Brooklyn Park, Minnesota facility to reduce this risk, we may encounter unforeseen difficulties or delays in doing so.

We Rely On Single Sources For Some Of Our Raw Materials And We May Lose Revenues And Be Unable To Maintain Our Relationships With Our Pharmaceutical Company Partners If Those Materials Were Not Available.

We rely on single suppliers for some of our raw materials and packaging supplies. If these raw materials or packaging supplies were no longer available we may be unable to meet production requirements, we may lose revenues and we may not be able to maintain our relationships with our pharmaceutical company partners. Without adequate supplies of raw materials or packaging supplies, our manufacturing operations may be interrupted until another supplier could be identified, its products validated and trading terms with it negotiated. We may not be able to identify an alternative supplier in a timely manner, or at all. Furthermore, we may not be able to negotiate favorable terms with an alternative supplier. Any disruptions in our manufacturing operations from the loss of a supplier could potentially damage our relations with our pharmaceutical company partners.

If We Cannot Develop Additional Products, Our Ability To Increase Our Revenues Would Be Limited.

We intend to continue to enhance our current technologies and pursue additional proprietary drug delivery technologies. If we are unable to do so, we may be unable to achieve our objectives of revenue growth and sustained profitability. Even if enhanced or additional technologies appear promising during various stages of development, we may not be able to develop commercial applications for them because:

the potential technologies may fail clinical studies;

we may not find a pharmaceutical company to adopt the technologies;

it may be difficult to apply the technologies on a commercial scale; or

the technologies may be uneconomical to market.

If We Cannot Keep Pace With The Rapid Technological Change And Meet The Intense Competition In Our Industry, We May Lose Business.

Our success depends, in part, on maintaining a competitive position in the development of products and technologies in a rapidly evolving field. If we cannot maintain competitive products and technologies, our current and potential pharmaceutical company partners may choose to adopt the drug delivery technologies of our competitors. Fast dissolve tablet technologies that compete with our OraSolv and DuraSolv technologies include the Zydis technology developed by R.P. Scherer Corporation, a wholly-owned subsidiary of Cardinal Health, Inc., the WOWTab technology developed by Yamanouchi Pharma Technologies, the Flashtab technology developed by Ethypharm and the FlashDose technology developed by Fuisz Technologies Ltd., a wholly-owned subsidiary of Biovail Corporation. We also compete generally with other drug delivery, biotechnology and pharmaceutical companies engaged in the development of alternative drug delivery technologies or new drug research and testing. Many of these competitors have substantially greater financial, technological, manufacturing, marketing, managerial and research and development resources and experience than we do and represent significant competition for us.

Our competitors may succeed in developing competing technologies or obtaining governmental approval for products before us. The products of our competitors may gain market acceptance more rapidly than our products. Developments by competitors may render our products, or potential products, noncompetitive or obsolete.

If We Cannot Adequately Protect Our Technology And Proprietary Information, We May Be Unable To Sustain A Competitive Advantage.

Our success depends, in part, on our ability to obtain and enforce patents for our products, processes and technologies and to preserve our trade secrets and other proprietary information. If we cannot do so, our competitors may exploit our innovations and deprive us of the ability to realize revenues and profits from our developments. We have been granted ten patents on our drug delivery and packaging systems in the U.S., which will expire beginning in 2010.

Any patent applications we may have made or may make relating to our potential products, processes and technologies may not result in patents being issued. Our current patents may not be valid or enforceable. They may not protect us against competitors that challenge our patents, obtain patents that may have an adverse effect on our ability to conduct business or are able to circumvent our patents. Further, we may not have the necessary financial resources to enforce our patents.

To protect our trade secrets and proprietary technologies and processes, we rely, in part, on confidentiality agreements with our employees, consultants and advisors. These agreements may not provide adequate protection for our trade secrets and other proprietary information in the event of any unauthorized use or disclosure, or if others lawfully develop the information.

Third Parties May Claim That Our Technologies, Or The Products In Which They Are Used, Infringe On Their Rights And We May Incur Significant Costs Resolving These Claims.

Third parties may claim that the manufacture, use or the sale of our drug delivery technologies infringe on their patent rights. If such claims are asserted, we may have to seek licenses, defend infringement actions or challenge the validity of those patents in court. If we cannot obtain required licenses, are found liable for infringement or are not able to have these patents declared invalid, we may be liable for significant monetary damages, encounter significant delays in bringing products to market or be precluded from participating in the manufacture, use or sale of products or methods of drug delivery covered by the patents of others. We may not have identified, or be able to identify in the future, U.S. and foreign patents that pose a risk of potential infringement claims.

We enter into collaborative agreements with pharmaceutical companies to apply our drug delivery technologies to drugs developed by others. Ultimately, we receive license revenues and product development fees, as well as revenues from, and royalties on, the sale of products incorporating our technology. The drugs to which our drug delivery technologies are applied are generally the property of the pharmaceutical companies. Those drugs may be the subject of patents or patent applications and other forms of protection owned by the pharmaceutical companies or third parties. If those patents or other forms of protection expire, are challenged or become ineffective, sales of the drugs by the collaborating pharmaceutical company may be restricted or may cease.

Because We Have A Limited Operating History, Potential Investors In Our Stock May Have Difficulty Evaluating Our Prospects.

We recorded the first commercial sales of products using our fast dissolve technologies in early 1997. Accordingly, we have only a limited operating history, which may make it difficult for you and other potential investors to evaluate our prospects. The difficulty investors may have in evaluating our prospects may cause volatile fluctuations, including decreases, in the market price of our common stock as investors react to information about our prospects. Since 1997, we have generated revenues from product development fees and licensing arrangements, sales of products using our fast dissolve technologies and royalties. We are currently making the transition from research and product development operations with limited production to commercial operations with expanding production capabilities in addition to research and product development activities. Our business and prospects, therefore, must be evaluated in light of the risks and uncertainties of a company with a limited operating history and, in particular, one in the pharmaceutical industry.

If We Are Not Profitable In The Future, The Value Of Our Stock May Fall.

Although we were profitable for the year ended December 31, 2001, and the quarter ended March 31, 2002, we have accumulated aggregate net losses from inception of approximately $23.6 million. If we are unable to sustain profitable operations in future periods, the market price of

our stock may fall. The costs for research and product development of our drug delivery technologies and general and administrative expenses have been the principal causes of our losses. Our ability to achieve sustained profitable operations depends on a number of factors, many of which are beyond our direct control. These factors include:

- the demand for our products;
- our ability to manufacture our products efficiently and with the required quality;
- our ability to increase our manufacturing capacity;
- the level of product and price competition;
- our ability to develop additional commercial applications for our products;
- our ability to control our costs; and
- general economic conditions.

We May Require Additional Financing, Which May Not Be Available On Favorable Terms Or At All And Which May Result In Dilution Of The Equity Interest Of An Investor.

We may require additional financing to fund the development and possible acquisition of new drug delivery technologies and to increase our production capacity beyond what is currently anticipated. If we cannot obtain financing when needed, or obtain it on favorable terms, we may be required to curtail our plans to develop and possibly to acquire new drug delivery technologies or limit the expansion of our manufacturing capacity. We believe our cash and cash equivalents, and expected revenues from operations will be sufficient to meet our anticipated capital requirements for the foreseeable future. However, we may elect to pursue additional financing at any time to more aggressively pursue development of new drug delivery technologies and expand manufacturing capacity beyond that currently planned.

Other factors that will affect future capital requirements and may require us to seek additional financing include:

- the level of expenditures necessary to develop and, or, acquire new products or technologies;
- the progress of our research and product development programs;
- the need to construct a larger than currently anticipated manufacturing facility, or additional manufacturing facilities, to meet demand for our products;
- the results of our collaborative efforts with current and potential pharmaceutical company partners; and
- the timing of, and amounts received from, future product sales, product development fees and licensing revenue and royalties.

Demand For Some Of Our Products Is Seasonal, And Our Sales And Profits May Suffer During Periods When Demand Is Light.

Certain non-prescription products that we manufacture for our pharmaceutical company partners treat seasonal ailments such as colds, coughs and allergies. Our pharmaceutical company partners may choose to not market those products in off-seasons and our sales and profits may decline in those periods as a result. For full-year 2001 and for the first three months of 2002, operating revenues from Novartis, which included revenues related to Triaminic, a seasonal cold, cough and allergy product, represented 33% and 17%, respectively, of our total operating revenues for such periods. We may not be successful in developing a mix of products to reduce these seasonal variations.

If The Marketing Claims Asserted About Our Products Are Not Approved, Our Revenues May Be Limited.

Once a drug product incorporating our technologies is approved by the FDA, the Division of Drug Marketing, Advertising and Communication, the FDA' s marketing surveillance department within the Center for Drug Evaluation and Research, must approve marketing claims asserted about it by our pharmaceutical company partners. If our pharmaceutical company partners fail to obtain from the Division of Drug Marketing acceptable marketing claims for a product incorporating our drug technology, our revenues from that product may be limited. Marketing claims are the basis for a product' s labeling, advertising and promotion. The claims our pharmaceutical company partners are asserting about our drug delivery technology, or the drug product itself, may not be approved by the Division of Drug Marketing.

We May Face Product Liability Claims Related To Participation In Clinical Trials Or The Use Or Misuse Of Our Products.

The testing, manufacturing and marketing of products using our drug delivery technologies may expose us to potential product liability and other claims resulting from their use. If any such claims against us are successful, we may be required to make significant compensation payments. Any indemnification that we have obtained, or may obtain, from contract research organizations or pharmaceutical companies conducting human clinical trials on our behalf may not protect us from product liability claims or from the costs of related litigation. Similarly, any indemnification we have obtained, or may obtain, from pharmaceutical companies with which we are developing our drug delivery technologies may not protect us from product liability claims from the consumers of those products or from the costs of related litigation. If we are subject to a product liability claim, our product liability insurance may not reimburse us, or be sufficient to reimburse us, for any expenses or losses we may suffer. A successful product liability claim against us, if not covered by, or if in excess of, our product liability insurance, may require us to make significant compensation payments, which would be reflected as expenses on our statement of operations and reduce our earnings.

Anti-Takeover Provisions Of Our Corporate Charter Documents, Delaware Law And Our Stockholders' Rights Plan May Affect The Price Of Our Common Stock.

Our corporate charter documents, Delaware law and our stockholders' rights plan include provisions that may discourage or prevent parties from attempting to acquire us. These provisions may have the effect of depriving our stockholders of the opportunity to sell their stock at a price in excess of prevailing market prices in an acquisition of us by another company. Our board of directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the rights, preferences and privileges of those shares without any further vote or action by our stockholders. The rights of holders of our common stock may be adversely affected by the rights of the holders of any preferred stock that may be issued in the future. Additional provisions of our certificate of incorporation and bylaws could have the effect of making it more difficult for a third party to acquire a majority of our outstanding voting common stock. These include provisions that limit the ability of stockholders to call special meetings or remove a director for cause.

We are subject to the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a "business combination" with

an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. For purposes of Section 203, a "business combination" includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and an "interested stockholder" is a person who, either alone or together with affiliates and associates, owns (or within the past three years, did own) 15% or more of the corporation' s voting stock.

We also have a stockholders' rights plan, commonly referred to as a poison pill, which makes it difficult, if not impossible, for a person to acquire control of us without the consent of our board of directors.

Our Stock Price Has Been Volatile And May Continue To Be Volatile.

The trading price of our common stock has been, and is likely to continue to be, highly volatile. The market value of your investment in our common stock may fall sharply at any time due to this volatility. In the year ended December 31, 2001, the closing sale price for our common stock ranged from $30.05 to $85.75. For the three months ended March 31, 2002, the closing sale price for our common stock ranged from $19.60 to $35.45. The market prices for securities of drug delivery, biotechnology and pharmaceutical companies historically have been highly volatile. Factors that could adversely affect our stock price include:

- fluctuations in our operating results;
- announcements of technological collaborations, innovations or new products by us or our competitors;
- governmental regulations;
- developments in patent or other proprietary rights owned by us or others;
- public concern as to the safety of drugs developed by us or others;
- the results of pre-clinical testing and clinical studies or trials by us or our competitors;
- litigation;
- decisions by our pharmaceutical company partners relating to the products incorporating our technologies;
- actions by the FDA in connection with submissions related to the products incorporating our technologies; and
- general market conditions.

Our Operating Results May Fluctuate, Causing Our Stock Price To Fall.

Fluctuations in our operating results may lead to fluctuations, including declines, in our stock price. Our operating results may fluctuate from quarter to quarter and from year to year depending on:

- demand by consumers for the products we produce;
- new product introductions;
- the seasonal nature of the products we produce to treat seasonal ailments;
- pharmaceutical company ordering patterns;

our production schedules;

the number of new collaborative agreements that we enter into;

the number and timing of product development milestones that we achieve under collaborative agreements;

the level of our development activity conducted for, and at the direction of, pharmaceutical companies under collaborative agreements; and

the level of our spending on new drug delivery technology development and technology acquisition, and internal product development.

Item 3. Quantitative and Qualitative Disclosures about Market Risks

The Company is subject to interest rate and foreign currency risks. Our investments in fixed-rate debt securities, which are classified as available-for-sale at March 31, 2002, have remaining maturities ranging from 3 to 36 months and thus are exposed to the risk of fluctuating interest rates. Available-for-sale securities had a market value of $133.5 million at March 31, 2002, and represented 67% of total assets. The primary objective of our investment activities is to preserve capital. We have not used derivative financial instruments in our investment portfolio.

We performed a sensitivity analysis assuming a hypothetical 10% adverse movement in interest rates applicable to fixed rate investments maturing during the next twelve months that are subject to reinvestment risk. As of March 31, 2002, the analysis indicated that these hypothetical market movements would not have a material effect on our financial position, results of operations or cash flow.

PART II – OTHER INFORMATION

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

Exhibit	Description of Document	Method of Filing
3.1	Fifth Restated Certificate of Incorporation of CIMA, as amended.	(1)
3.2	Third Restated Bylaws of CIMA.	(2)
4.1	Form of Certificate for Common Stock.	(3)
4.2	Amended and Restated Rights Agreement dated June 26, 2001, between CIMA and Wells Fargo Bank Minnesota, N.A. as Rights Agent.	(4)

(1) Filed as an exhibit to CIMA' s Registration Statement on Form S-8, filed June 13, 2001, File No. 333-62954, and incorporated herein by reference.

(2) Filed as an exhibit to CIMA' s Quarterly Report on Form 10-Q for the quarter ended June 30, 1999, File No. 0-24424, and incorporated herein by reference.

(3) Filed as an exhibit to CIMA' s Registration Statement on Form S-1, File No. 33-80194, and incorporated herein by reference.

(4) Incorporated by reference to Exhibit 1 to CIMA' s Amendment No. 1 to Registration Statement on Form 8-A/A, filed July 18, 2001, File No. 0-24424.

(b) Reports on Form 8-K

On March 27, 2002, we filed a report on Form 8-K dated March 18, 2002, which reported under Item 5, the announcement by Dr. John M. Siebert, President, Chief Executive Officer and Director of the Company, of his plans to retire from the Company.

SIGNATURE

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

CIMA LABS INC.
Registrant

Date May 10, 2002

By /s/ David A. Feste
David A. Feste
Chief Financial Officer
(principal financial and accounting officer, duly authorized to sign on behalf of the registrant)