

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10QSB

CARACO PHARMACEUTICAL LABORATORIES LTD

Form 10QSB

May 15, 2003

U.S. SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 10-QSB  
QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE  
QUARTERLY PERIOD ENDED March 31, 2003

Commission File No. 0-24676  
CARACO PHARMACEUTICAL LABORATORIES, LTD.  
(Exact name of registrant as specified in its charter)

MICHIGAN  
(State or other jurisdiction of  
incorporation or organization)

38-2505723  
(IRS Employer  
Identification No.)

1150 ELIJAH MC COY DRIVE, DETROIT, MICHIGAN  
(Address of principal executive offices)

48202  
(Zip Code)

Registrant's telephone number, including area code  
(313) 871-8400

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

Yes  No

Common Stock outstanding at May 13, 2003-- 23,807,820

CARACO PHARMACEUTICAL LABORATORIES LTD.  
UNAUDITED BALANCE SHEETS

PARTICULARS	March 31, 2003
-----	
ASSETS	
Current assets	
Cash and cash equivalents	\$ 337,415
Accounts receivable, net	10,593,803
Inventories	5,582,540
Prepaid expenses and deposits	591,362
	-----
Total current assets	17,105,121
Property, plant and equipment - at cost	
Land	197,305
Building and improvements	7,439,897

## Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10QSB

Equipment	5,569,738
Furniture and fixtures	275,504
	-----
Total	13,482,444
Less: accumulated depreciation	5,628,755
	-----
Net property, plant & equipment	7,853,688
	-----
	-----
Total assets	\$ 24,958,810
	=====
LIABILITIES AND STOCKHOLDERS' DEFICIT	
Current liabilities	
Accounts payable	\$ 5,115,255
Accrued expenses	1,583,892
Current portion of notes payable to stockholders	6,000,000
Current portion of loan payable to financial institutions	4,375,000
Short term borrowings	--
EDC debt classified as current	1,215,835
Preferred stock dividends payable	350,380
Accrued interest	676,415
	-----
Total current liabilities	19,316,777
	-----
Long-term liabilities	
Notes payable to principal stockholders	3,850,000
Preferred stock dividends payable	--
EDC debt classified as long term	6,085,575
Loans payable	13,125,000
	-----
Total long-term liabilities	23,060,575
	-----
	-----
Total liabilities	42,377,352
	-----
Stockholders' deficit	
Preferred stock, no par value, authorized 5,000,000 shares; issued and outstanding 0 & 285,714 Series A shares	--
Common stock, no par value, authorized 30,000,000 shares; issued and 23,762,532 outstanding shares	40,457,028
Additional Paid in Capital	282,858
Preferred stock dividends	(350,380)
Accumulated deficit	(57,808,047)
	-----
Total stockholders' deficit	(17,418,541)
	-----
	-----
Total liabilities and stockholders' deficit	\$ 24,958,810
	=====

See accompanying notes

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10QSB

CARACO PHARMACEUTICAL LABORATORIES LIMITED  
 UNAUDITED STATEMENTS OF OPERATIONS

PARTICULARS	THREE MONTHS ENDED 31-MARCH	
	2003	2002
	\$	\$
Net Sales	8,721,600	3,301,959
Cost of goods sold	4,225,949	1,847,547
Gross profit	4,495,651	1,454,412
Selling, general & administrative expenses	949,784	754,655
R&D cost	899,931	850,873
Operating income / (loss)	2,645,936	(151,116)
Interest		
Interest expense	(442,252)	(369,067)
Interest income	1,065	940
Net interest expense	(441,187)	(368,127)
Net income / (loss)	2,204,749	(519,243)
Net income / (loss) per basic and diluted common share	0.09	(0.03)

See accompanying notes

3

CARACO PHARMACEUTICAL LABORATORIES, LTD.  
 UNAUDITED STATEMENTS OF CASH FLOWS

PARTICULARS

Cash flows from operating activities:  
 Net income / (loss)  
 Adjustments to reconcile net loss to  
 net cash used in operating activities

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10QSB

Depreciation  
 Common Shares issued in lieu of cash for compensation

Changes in operating assets and liabilities which provided (used) cash:			
Accounts receivable			
Inventories			
Prepaid expenses and deposits			
Accounts payable			
Accrued expenses and Interest			
Net cash used in operating activities			-----
Cash flows from investing activities:			-----
Purchases of property, plant and equipment			-----
Cash flows from financing activities:			-----
Proceeds from long-term debt			
Proceeds from Sale of Shares in Private Placement			
Payments of EDC debt			
Net Loans received from Shareholders			
Net cash provided from financing activities			-----
Net (decrease) in cash and cash equivalents			-----
Cash and cash equivalents, beginning of period			-----
Cash and cash equivalents, end of period			=====

See accompanying notes

4

CARACO PHARMACEUTICAL LABORATORIES, LTD.  
 UNAUDITED STATEMENT OF SHAREHOLDERS' DEFICIT FOR THE  
 THREE MONTHS ENDED MARCH 31, 2003

	PREFERRED STOCK SHARES	STOCK AMOUNT	COMMON S SHARES	
Balance at January 1, 2003	-	-	23,762,532	
Net loss				
Balance at March 31, 2003	-	\$ -	23,762,532	\$

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10QSB

	ADDITIONAL PAID IN CAPITAL	PREFERRED STOCK DIVIDENDS	ACCUMULATED DEFICIT	
Balance at January 1, 2003	282,858	(350,380)	(60,012,796)	\$ (
Net loss			2,204,749	
Balance at March 31, 2003	\$ 282,858	\$ (350,380)	\$ (57,808,047)	\$ (

See accompanying notes

5

CARACO PHARMACEUTICAL LABORATORIES LTD.

NOTES TO FINANCIAL STATEMENTS (UNAUDITED)

1. BASIS OF PRESENTATION

The balance sheet as of March 31, 2003 and the related statements of operations, stockholders' deficit and cash flows for the three months ended March 31, 2003 and 2002 are unaudited. In the opinion of management, all adjustments necessary for a fair presentation of such financial statements have been included. Such adjustments consisted only of normal recurring items. Interim results are not necessarily indicative of results for the full year.

The financial statements as of March 31, 2003 and for the three months ended March 31, 2003 and 2002 should be read in conjunction with the financial statements and notes thereto included in the Corporation's Annual Report on Form 10-KSB for the year ended December 31, 2002.

The accounting policies followed by the Corporation with respect to the unaudited interim financial statements are consistent with those stated in the 2002 Caraco Pharmaceutical Laboratories, Ltd., Annual Report on Form 10-KSB.

The accompanying financial statements have been prepared assuming that the Corporation will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Realization of a major portion of the assets is dependent upon the Corporation's ability to meet its future financing requirements and the success of future operations.

2. ORGANIZATION AND NATURE OF BUSINESS

Caraco Pharmaceutical Laboratories, Ltd. ("Caraco" or "the Corporation" which is also referred to as we, us or our), engaged in the business of developing, manufacturing and marketing generic drugs for the ethical (prescription) and over-the-counter (non-prescription or "OTC") markets.

## Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10QSB

A generic drug is a pharmaceutical product, which is the chemical and therapeutic equivalent of a brand-name drug as to which the patent and/or market exclusivity has expired. Generics are well accepted for substitution of brand products as they sell at a discount to the branded product's price and for their equivalence in quality and bioavailability.

Our present product portfolio includes 13 products in 22 strengths in 46 package sizes. We are currently marketing all 13 products. The products are intended to treat a variety of disorders including the following: hypertension, arthritis, seizures, epilepsy, diabetes and pain management. We have recently started shipments of 1 additional product in 2 strengths and 4 pack sizes. This brings our formulary of products to 14 products in 24 strengths and 50 pack sizes.

To date, we have submitted 14 ANDAs to the Food and Drug Administration ("FDA"). Of these, we have received approvals for 11 ANDAs, one of which was received during the first quarter; we have 3 ANDAs pending approval. We also have 5 DESI products.

A significant source of our funding has been from private placement offerings and loans. Sun Pharmaceutical Industries, Limited, a specialty pharmaceutical corporation organized under the laws of India ("Sun Pharma"), which owns 49% of our outstanding shares has contributed equity capital and has advanced us loans. Also, pursuant to a products agreement with us, Sun Pharma has transferred certain products to us. (See "Current Status of the Corporation" and "Sun Pharmaceutical Industries, Ltd." below.) Our manufacturing facility and executive offices were constructed pursuant to a \$9.1 million loan from the Economic Development Corporation of the City of Detroit (the "EDC"). (See "Current Status of the Corporation" and "Mortgage Note" below.)

### 3. CURRENT STATUS OF THE CORPORATION

For the first time since inception, during the last three quarters of 2002 and the first quarter of 2003, we achieved sales necessary to support our operations. Net sales for the three months ended March 31, 2003 were \$8.7 million as compared to \$3.3 million for the three months ended March 31, 2002. We have earned an operating gross profit of \$4,495,651 for the three months ended March 31, 2003 as compared to \$1,454,412 during the same period in 2002. We earned an operating profit income of \$2,645,936 during the period of March 31, 2003 as compared to incurring operating losses of \$151,116 during the same period in 2002. After interest costs, we have earned a net profit income of \$2,204,749 for the three months ended March 31, 2003 as compared to a net loss of \$519,243 for the three months ended March 31, 2002. At March 31, 2003, we had a stockholders' deficit of \$17,481,541 as compared to a deficit of \$22,812,242 at March 31, 2002. We have continued to be dependent on the support of Sun Pharma, however, but the financial support is reduced due to the increased revenues and higher cash flows from internal operations since the second quarter of 2002. See "Sun Pharmaceutical Industries, Ltd." and "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations." We received one ANDA approval during the first quarter of 2003. See "Caraco's Products and Product Strategy" below. We have 3 products pending approval with the FDA.

### 4. COMPUTATION OF LOSS PER SHARE

Loss per share is computed using the weighted average number of common shares outstanding during each period and considers a dual presentation and reconciliation of "basic" and "diluted" per share amounts. Diluted reflects the

## Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10QSB

potential dilution of all common stock equivalents.

The basic and diluted weighted average number of common shares outstanding for the period ended March 31, 2003 were 23,762,532 and 25,061,469, respectively. The basic and diluted weighted average number of common shares outstanding for the period ending March 31, 2002 21,242,874 respectively.

### 5. MORTGAGE NOTE

#### EDC Loan

Debt at March 31, 2003 includes approximately \$7.3 million payable to the Economic Development Corporation of the City of Detroit ("EDC") related to funds advanced to the Corporation pursuant to a Development and Loan Agreement (the "Agreement") dated August 10, 1990 as amended. The note was collateralized by a first mortgage, effectively, on all of the Corporation's property and equipment purchased pursuant to the Agreement. The loan was restructured on April 23, 2003, but is effective as of January 1, 2003. The loan has been extended for six years, with interest rates starting at 2.75% and increasing to 5.16%. Under the extension, the EDC retains a first mortgage on our property, and a first lien on our furniture, fixtures equipment and intellectual property. The EDC has removed its first lien on our accounts receivable and inventory. Further, the EDC has eliminated the prior restriction on capital investment in excess of \$2 million by permitting us, so long as we are not in default of any of our obligations, to purchase new capital and sell the existing capital equipment so long as a result of such transactions, the book value of our assets is not reduced below the balance as of December 31, 2002 and the proceeds of any such sales are retained by the Company. The obligations of the Corporation to the EDC have been classified in accordance with the terms of the restructured loan.

### 6. SUN PHARMACEUTICAL INDUSTRIES LIMITED

Pursuant to a stock purchase agreement, Sun Pharma had, as of December 31, 1998, remitted a total of \$7.5 million to us for the purchase of 5.3 million common shares.

Further, Sun Pharma has made loans to us, the details of which as of March 31, 2003, are given below:

2

8% Promissory note payable to Sun Pharma, principal balance payable in full in October 2003, with interest payable semi-annually.	\$5,300,000
8% Promissory note payable to Sun Pharma, principal balance payable in full in August 2006, with interest payable quarterly.	\$3,850,000
8% promissory note payable to Sun Pharma Global, Inc., a wholly owned subsidiary of Sun Pharma ("Sun Global"), payable by October 2003 with interest payable semi-annually.	\$ 200,000
8% short term loan to Sun Pharma, payable upon demand	\$ 500,000 -----

## Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10QSB

Notes payable to principal stockholders \$9,850,000  
=====

Notes payable to Sun Pharma and Sun Pharma Global, Inc. are subordinated to the EDC loan. Furthermore, the Sun Pharma and Sun Global loans due to mature in October of 2003 are classified as current.

In August 1997, we entered into an agreement, whereby Sun Pharma was required to transfer to us the technology formula for 25 generic pharmaceutical products over a period of five years through August 2002. The agreement has expired. We exchanged 544,000 shares of our common stock for each technology transfer of an ANDA product (when a bio-equivalency study was successfully completed) and 181,333 shares for each technology transfer of a DESI (Drug Efficacy Study Implementation) product. The products provided to us from Sun Pharma were selected by mutual agreement. As of March 31, 2003, Sun Pharma delivered to us the technology for 13 products. A total of 5,802,666 shares were issued to Sun Pharma and its affiliates in exchange for the technology transfer under the old and now expired agreement.

We entered into a new product agreement with Sun Global for the transfer of the technology formula for 25 generic products over a period of 5 years in November 2002 replacing the previous product agreement with Sun Pharma. Sun Global receives 544,000 shares of preferred stock (convertible into common stock after three years) for each ANDA product transferred. The value of the shares issued to Sun Global for the transfer of the products shall be included in research and development expenses. Depending on the number of products transferred and the market value of the shares attributable thereto, the issuance of preferred stock to Sun Global could cause our research and development expenses to increase to an amount which would significantly decrease profit or create a loss. Preferred shares can be earned by Sun Global even if the product is not successfully produced and marketed.

In connection with the technology transfer, Sun Pharma has established a Research and Development Center in Mumbai with a staff of 30 persons, including PhDs, pharmacy graduates, analytical chemists and regulatory professionals. Sun Pharma primarily performs formulation and analytical development for us at this laboratory.

Sun Pharma supplies us with certain raw materials and also the machinery and equipment to increase productivity and production. Sun has also provided us with qualified technical professionals. Twenty-one of our technical professional employees were former Sun Pharma employees.

### 7. TERM LOAN FROM ICICI BANK

The Corporation had obtained a term loan of \$5 million from ICICI Bank of India with the support of Sun Pharma. This term loan has been used to finance research and development activities, upgrade facilities, repay loans and meet working capital requirements. The Corporation, as of March 31, 2003, has received proceeds in the amount of \$5 million with interest payments due quarterly. Quarterly principal payments are scheduled, to be made from December 2003 through September 2005. A portion of the loan which is due within one year from March 31, 2003 has been classified as current.

### 8. TERM LOAN FROM BANK OF NOVA SCOTIA



## Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10QSB

The Corporation had obtained term loans of \$12.5 million from the Bank of Nova Scotia with the support of Sun Pharma. This term loan has been used to finance research and development activities, upgrade facilities, repay other loans and meet working capital requirements. As of March 31, 2003, payments of interest are due quarterly. Semi-annual principal payments are scheduled to be made from February 2004 through September 2005. A portion of the loan which is due within one year from March 31, 2003 has been classified as current.

### 9. COMMON STOCK ISSUANCES

We have not issued any shares of common stock during the first quarter of 2003. During the first quarter ended March 31, 2002, the Corporation issued 15,000 shares of common stock to the directors as compensation for attendance at board and committee meetings held during 2001. In addition, during the first quarter of 2002, 250,000 shares of common stock were issued by the Corporation for cash of \$650,000 pursuant to a private placement to accredited investors.

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

### FORWARD LOOKING STATEMENTS

This report, other than the historical financial and business information, may contain forward-looking statements. Those statements include statements regarding the intent, belief, and current expectation of the Corporation. The statements are not guarantees of future performance and are subject to risks and uncertainties that cannot be predicted or quantified. Consequently, actual results could differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include: (i) that the information is of a preliminary nature and may be subject to further adjustment; (ii) not obtaining FDA approval for new products or delays in receiving FDA approvals; (iii) governmental restrictions on the sale of certain products; (iv) dependence on key personnel; (v) development by competitors of new or superior products or cheaper products or new technology for the production of products or the entry into the market of new competitors; (vi) market and customer acceptance and demand for new pharmaceutical products, (vii) availability of raw materials, (viii) timing and success of product development and launch (ix) integrity and reliability of the Corporation's data; and (x) other risks identified in this report and identified from time to time in the Corporation reports and registration statements filed with the Securities and Exchange Commission.

The following discussion and analysis provides information that management believes is relevant to an understanding of the Corporation's results of operations and financial condition. The discussion should be read in conjunction with the financial statements and notes thereto.

### THREE MONTHS ENDED MARCH 31, 2003 COMPARED WITH THREE MONTHS ENDED MARCH 31, 2002

**NET SALES.** Net sales for the three months ended March 31, 2003 and 2002 were \$8,721,600 and \$3,301,959, respectively, reflecting an increase of almost 164%. The increase is due to the higher production and marketing of most of our products following the achievement of substantial compliance with cGMPs. Sales of Metformin Hydrochloride, Tramadol Hydrochloride and Metoprolol Tartrate accounted for 85% of our net sales for the quarter. Sales of Metformin Hydrochloride increased because of our contract with the Veterans Administration, however, the sales of Metformin Hydrochloride to such agency have been made at lower sales prices. (See "Gross Profit" below).

**GROSS PROFIT.** We earned a gross profit of \$4,495,651 during the three months ended March 31, 2003 as compared to a gross profit of \$1,454,412 during the

## Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10QSB

corresponding period in 2002. The improvement was

4

primarily due to higher sales volumes with improved margins due to change in sales mix to more profitable products such as Metoprolol Tartrate, Metformin Hydrochloride; Tramadol Hydrochloride and Oxaprozin; acquiring raw materials at more competitive prices; reduction in manufacturing costs due to increased batch sizes. Improved efficiency in the overall manufacturing process associated with higher utilization of plant capacity; utilization of equipment installed during the twelve months ended December 31, 2002 of \$1.6 million; and acquire raw materials at highly competitive prices in the current period, and ability to absorb operational overheads due to higher sales.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES. Selling, general and administrative expenses for the three months ended March 31, 2003 and March 31, 2002 were \$949,784 and \$754,655 respectively, representing an increase of 25%. Selling, general and administrative expenses have effectively decreased down to 10.8% of net sales during the three months ended March 31, 2003 from almost 22% of net sales during the same period in 2002.

The actual increase of approximately \$195,000 was due to additional professional costs (\$25,000) primarily in connection with the ongoing litigation against the Company, costs of introducing new products into the market (\$25,000), additional sales personnel (\$15,000), increases in the salaries of sales and administrative staff (\$25,000), recording of variable compensation expense on stock options granted and extended to a director (\$35,000) and costs associated with development of improved services and quality measures to customers.

RESEARCH AND DEVELOPMENT EXPENSES. Cash research and development expenses of \$899,931 for the three months ended March 31, 2003 were higher by 5% when compared with \$850,873 incurred during the corresponding period of 2002. The major reason for the additional cash research and development expenses was the costs for raw material of approximately \$80,000 for one of the projects currently undergoing efficacy studies and other filing costs.

DEPRECIATION EXPENSE. We incurred depreciation expense of \$138,770 for the first three months of March 2003 as compared to \$108,208 incurred in the corresponding period of 2002. Depreciation has increased due to additional investment into capital assets during 2002 of \$1.6 million.

INTEREST EXPENSE. Interest expense, which was incurred in connection with our mortgage obligation to the EDC, interest on notes payable to Sun Pharmaceutical and Sun Global as well as on term loans granted to us by ICICI Bank and the Bank of Nova Scotia, and guaranteed by Sun Pharmaceutical, was \$441,187 and \$368,127, for the three months ended March 31, 2003 and 2002, respectively. The increase in the amount of interest is due to the increase in borrowing levels. We have utilized the \$1.6 million of the remaining draws from Bank of Nova Scotia as well as having borrowed \$500,000 from Sun Pharma (a demand loan) to finance increased working capital.

RESULTS OF OPERATIONS. We earned net income of \$2,204,749 for the three months ended March 31, 2003 as compared to a net loss of \$519,243 for the same period of 2002, respectively, reflecting an improvement of almost 525%. The significantly improved results of operations in the current three-month period as compared to the previous respective period are primarily due to significantly higher sales volumes, improved cost absorption due to increased sales, improved product mix and obtaining more competitive prices for raw materials.

A number of uncertainties exist that may influence the Corporation's future

## Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10QSB

operating results, including general economic conditions, changes in conditions affecting the pharmaceutical industry primarily related to generic drug competition, obtaining additional financing, government restrictions on sale of certain products, obtaining new FDA approvals, development by competitors of new or superior products or new technology for production of products or the entry into the market of new competitors.

5

### LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2003, the Corporation had negative working capital of \$2,211,655 compared with a negative working capital of \$4,693,663 at the corresponding period of 2002. The negative working capital positions as of March 31, 2003 and 2002, respectively, were mainly due to the classification of certain portions of the loans payable to Bank of Nova Scotia and ICICI Bank coming due within the next twelve months and \$5.5 million of the loans payable to Sun Pharma and Sun Global coming due in October 2003. In the first quarter of 2002, \$3,208,769 of the EDC debt was reclassified from accrued interest to principal.

To enable the Corporation to fund its research and development activities, repay certain term loans and fund working capital needs, Sun Pharma has become a security guarantor for a credit line of \$5 million from ICICI Bank of India and \$12.5 million from Bank of Nova Scotia. As of March 31, 2003, the Corporation has received \$5,000,000 from ICICI Bank of India and \$12,500,000 from Bank of Nova Scotia through these credit facilities. Further, the Corporation has received an additional short-term loan of \$500,000 during the first quarter of 2003 from Sun Pharma to help the Corporation finance its increased working capital requirements. The cash generated out of the operations has generally been sufficient to run the operations of the Corporation as well as repay a portion of the EDC debt.

### FDA

We underwent FDA inspections in November 2002 and we were found to be in substantial compliance with cGMPs. Although we did receive an FDA 483, we do not believe the observations are material and we have taken appropriate remedial actions. During the first quarter of 2003, we received approval for one of the then pending ANDAs. We now have 3 ANDAs pending approval.

### FUTURE OUTLOOK

We have experienced difficult times in the past. With our having been found to be in substantial compliance by the FDA with respect to cGMPs during the second quarter of 2001 and the fourth quarter of 2002, and also with the approvals of 11 ANDAs during 2001, 2002 and 2003, management feels that our future outlook is brighter. Revenues have been improving and consequently, so have operational profits, net income and cash flows. Also, management is focused on cost controls and consumption controls. Management's future plans for improving profitability, cash flow positions and operations include increased sales (see below) and infusion of additional funding through the issuance of equity. We also expect Sun Pharma to continue to support us, as it has in the past.

The FDA has directed the manufacturers and distributors of Guaifenesin LA which, including us, consists of 66 companies, to cease manufacturing Guaifenesin LA by May 23, 2003 and to cease all sales after November 2003. The FDA has determined that Guaifenesin LA is a new drug which requires a new drug application and approval before it may be manufactured and sold. We intend to comply with the FDA's directive. We do not intend to file a new drug application with the FDA with respect to Guaifenesin LA. Net sales of Guaifenesin LA during the year

## Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10QSB

ended December 31, 2002 and during the quarter ended March 31, 2003 were \$1.65 million and \$0.36 million, respectively.

Management believes that the new products agreement ("Products Agreement") with Sun Global, pursuant to which products are paid for in a newly created preferred stock and not in cash should benefit Caraco. As we have disclosed, under the Products Agreement, we conduct, at our expense, all tests, including bioequivalency studies. We believe that the new Products Agreement benefits us by, among other things, preserving our cash resources. By acquiring products for stock instead of cash or instead of for cash and for royalties, we should thereby have such cash available to support our operations. While the payment for products in stock would have the effect of reducing earnings or causing a loss because the stock will be valued on the respective dates on which it is earned and constitute a non-cash research and development expense, we believe that the advantages to us of preserving our cash for operations outweighs the non-cash effect on earnings.

6

During the first quarter of 2003, the Corporation has generated substantial revenues as compared to the past. Capacity utilizations are improving and costs are being controlled. The Corporation expects revenues to improve during the rest of 2003.

Management's plans for the remainder of 2003 include:

- o Continued focus on FDA compliance.
- o Continued research and development activities.
- o Increased market share for certain existing products and recently introduced new products and enhanced customer reach and satisfaction.
- o Prompt introduction of new approved products to the market.
- o Striving to capture larger market share for existing products.
- o Achieving operational efficiencies by attaining economies of scale, cost reduction per unit, and obtaining additional cost reductions for active substances acquired from competitors and/or Sun Pharma.
- o Increase the width and depth of product portfolio to serve customers effectively.
- o Increase the number of products, as well as anticipated volume increases for existing products, which, in turn, will improve manufacturing capacity utilization.
- o Considering alternative ways of increasing cash flow including developing, manufacturing and marketing ANDAs owned by Sun Pharma.
- o Locating and utilizing facilities of contract-manufacturers to enhance production and therefore sales.

# Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10QSB

## ITEM 3. CONTROLS AND PROCEDURES

- a. The term "disclosure controls and procedures" is defined in Rules 13a-14(c) and 15d-14(c) of the Securities Exchange Act of 1934 (the "Exchange Act"). These rules refer to the controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is recorded, processed, summarized and reported within required time periods. Our Chief Executive Officer and our Chief Financial Officer have evaluated the effectiveness of our disclosure controls and procedures as of a date within 90 days before the filing of this quarterly report (the "Evaluation Date"), and have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective in providing them with material information relating to the Corporation known to others within the Corporation which is required to be included in our periodic reports filed under the Exchange Act.
- b. There have been no significant changes in the Corporation's internal controls or in other factors which could significantly affect internal controls subsequent to the Evaluation Date.

7

## PART II -- OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

Except as previously disclosed in past reports, and for the following, we are not a party to any litigation, which, individually or in the aggregate, is believed to be material to our business:

As previously disclosed, we have been named as one of two defendants and as one of several defendants in two separate product liability suits, involving Miraphen which contains phenylpropanolame (PPA), one in federal court in Pennsylvania and another in state court in New Jersey, respectively. These lawsuits seek damages generally for personal injury as well as punitive damages under a variety of liability theories including strict products liability, breach of warranty and negligence. The federal lawsuit does not set forth a specific dollar amount of damages requested; the state lawsuit seeks damages of \$20 million. Our product liability insurer has recently informed us that we are not covered by insurance because the policy does not apply to any claim relating to any product containing PPA. Although the ultimate outcome of these cases and the potential effect on us cannot be determined, we have retained counsel and we believe we have substantial defenses to the claims and intend to vigorously defend the lawsuits.

### ITEM 2. CHANGES IN SECURITIES

None

## Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10QSB

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

We were in default on our loan from the EDC, however, we are not currently in default. The loan was restructured on April 23, 2003, but is effective as of January 1, 2003. The loan has been extended for six years, with interest rates starting at 2.75% and increasing to 5.16%. Under the extension, the EDC retains a first mortgage on our property, and a first lien on our furniture, fixtures equipment and intellectual property. The EDC has removed its first lien on our accounts receivable and inventory. Further, the EDC has eliminated the prior restriction on capital investment in excess of \$2 million by permitting us, so long as we are not in default of any of our obligations, to purchase new capital and sell the existing capital equipment so long as a result of such transactions, the book value of our assets is not reduced below the balance as of December 31, 2002 and the proceeds of any such sales are retained by the Company.

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

N.A.

### ITEM 5. OTHER INFORMATION

None.

### ITEM 6. EXHIBITS AND REPORTS ON FORM 10-QSB

#### (a) Exhibits

- 10.24 Third Note Modification Agreement
- 10.25 Third Mortgage Modification Agreement

8

- 99.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

#### (b) Reports on Form 8-K.

There were no Form 8-Ks filed during the first quarter of 2003.

9

SIGNATURES

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

CARACO PHARMACEUTICAL LABORATORIES, LTD.

By: /s/ Narendra N. Borkar

-----

Narendra N. Borkar  
Chief Executive Officer

By: /s/ Jitendra N. Doshi

-----

Jitendra N. Doshi  
Chief Financial Officer

Dated: May 15, 2003

CERTIFICATION

I, Narendra N. Borkar, the Chief Executive Officer of Caraco Pharmaceutical Laboratories Ltd. (the "registrant") certify that:

1. I have reviewed this quarterly report on Form 10-QSB of the registrant;
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 officer 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 is made known to us by others, 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 officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the board of directors (or persons fulfilling 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 officer 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.

May 15, 2003

/s/ Narendra N. Borkar  
-----  
Narendra N. Borkar  
Chief Executive Officer

CERTIFICATION

I, Jitendra N. Doshi, the Chief Financial Officer of Caraco Pharmaceutical Laboratories Ltd. (the "registrant") certify that:

- 1. I have reviewed this quarterly report on Form 10-QSB of the registrant;
- 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;



Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10QSB

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 officer 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 is made known to us by others, 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 officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the board of directors (or persons fulfilling 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 officer 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.

May 15, 2003

/s/ Jitendra N. Doshi

-----  
Jitendra N. Doshi  
Chief Financial Officer

EXHIBIT INDEX

- 10.24 Third Note Modification Agreement
- 10.25 Third Mortgage Modification Agreement
- 99.1 Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.