CARACO PHARMACEUTICAL LABORATORIES LTD
Form 10-Q
April 30, 2004

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

{X} QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

for the quarterly period ended March 31, 2004

{ } TRANSITION REPORT PURSUANT TO SECTION 13
OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
for the transition period from _____ to _____

Commission File No. 0-24676

CARACO PHARMACEUTICAL LABORATORIES, LTD.
(Exact name of registrant as specified in its charter)

MICHIGAN	
38-2505723	
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

1150 ELIJAH MCCOY DRIVE, DETROIT, MICHIGAN	48202
(Address of principal executive offices)	(Zip Code)

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

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

Yes {X} No { }

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes {X} No { }

As of April 26, 2004, registrant had 24,577,828 shares of common stock issued and outstanding.

CARACO PHARMACEUTICAL LABORATORIES LTD.
UNAUDITED BALANCE SHEETS

	BALANCES AS AT	
	MARCH 31, 2004	DECE

	$	
ASSETS		
Current assets		
Cash and cash equivalents	4,244,815	4,
Accounts receivable, net	2,760,338	4,
Inventories	12,646,575	9,
Prepaid expenses and deposits	593,208	
Total current assets	20,244,936	18,
Property, plant and equipment - at cost		
Land	197,305	
Building and improvements	8,428,092	7,
Equipment	7,632,179	6,
Furniture and fixtures	489,252	
Total	16,746,828	15,
Less: accumulated depreciation	6,152,854	5,
Net property, plant & equipment	10,593,974	9,
Total assets	30,838,910	28,
LIABILITIES AND STOCKHOLDERS' EQUITY / (DEFICIT)		
Current liabilities		
Accounts payable	6,813,286	5,
Accrued expenses	1,942,704	4,
Current portion of bank loans payable	9,250,000	8,
EDC debt classified as current	1,214,906	1,
Accrued interest	31,005	
Total current liabilities	19,251,901	20,
Long term liabilities		
EDC debt	4,752,810	5,
Bank loans payable	3,125,000	8,
Total long term liabilities	7,877,810	13,
Total liabilities	27,129,711	33,
Stockholders' equity / (deficit)		
Common stock, no par value, authorized 50,000,000 shares; issued and outstanding shares - 24,577,828 shares	41,442,311	41,
Convertible Series B Preferred Stock, no par value, authorized 5,000,000 shares; issued and outstanding - 1,632,000 and -0- shares	10,931,530	
Additional paid in capital	2,718,735	2,
Accumulated deficit	(51,383,377)	(49,
Total stockholders' equity / (deficit)	3,709,199	(4,
Total liabilities and stockholders' equity / (deficit)	30,838,910	28,

See accompanying notes

CARACO PHARMACEUTICAL LABORATORIES, LTD.
UNAUDITED STATEMENTS OF OPERATIONS

	THREE MONTHS ENDED MARCH 31, 2004	2003
	$	$
Net sales	13,561,088	8,721,600
Cost of goods sold	5,390,702	4,225,949
Gross profit	8,170,386	4,495,651
Selling, general and administrative expenses	1,282,355	949,784
R&D cost	1,133,331	899,931
R&D cost - Affiliate	7,828,160	0
Operating (loss) / income	(2,073,459)	2,645,936
Other Expense		
Interest expense	(181,542)	(442,252)
Interest income	2,015	1,065
Other income	10,067	0
Net other expense	(169,460)	(441,187)
Net (loss) / income	(2,242,920)	2,204,749
Net (loss) / income per common share		
Basic	(0.09)	0.09
Diluted	(0.09)	0.09

See accompanying notes

CARACO PHARMACEUTICAL LABORATORIES, LTD.
UNAUDITED STATEMENTS OF CASH FLOWS

	THREE MONTHS ENDED MARCH 31, 2004	2003

	$	$
Cash flows from operating activities		
Net (loss) / income	(2,242,920)	2,204,749
Adjustments to reconcile net income / (loss) to net cash provided by /(used in) operating activities		
Depreciation	189,074	141,737
Preferred shares issued for R&D Cost - affiliate	7,828,160	0
Changes in operating assets and liabilities which provided / (used) cash:		
Accounts receivable	1,778,135	(5,109,668)
Inventories	(3,035,765)	33,422
Prepaid expenses and deposits	(31,178)	(120,049)
Accounts payable	1,587,310	1,132,418
Accrued expenses and interest	159,863	267,000
Net cash provided by / (used) in operating activities	6,232,679	(1,450,391)
Cash flows from investing activities		
Purchases of property, plant and equipment	(1,276,372)	(248,000)
Cash flows from financing activities		
Proceeds from long-term debt	0	1,600,000
Net bank loans paid	(4,500,000)	0
Payments of EDC debt	(417,774)	(248,421)
Net Loans (repaid to) / received from shareholders	0	150,000
Net cash (used in) / provided by financing activities	(4,917,774)	1,501,579
Net increase / (decrease) in cash and cash equivalents	38,533	(196,812)
Cash and cash equivalents, beginning of period	4,206,282	534,228
Cash and cash equivalents, end of period	4,244,815	337,416

Supplemental disclosure of cash flows information:

During the quarter ended March 31, 2004, 544,000 shares of preferred stock were issued to Sun Global in satisfaction of the related liability for one product transfer that had been accrued at December 31, 2003 in the amount of $3,103,370.

See accompanying notes

CARACO PHARMACEUTICAL LABORATORIES, LTD.
UNAUDITED STATEMENTS OF STOCKHOLDERS' EQUITY FOR THE
THREE MONTHS ENDED MARCH 31, 2004

	PREFERRED STOCK	COMMON STOCK	ADDITIONAL PAID IN	AC

	SHARES	AMOUNT	SHARES	AMOUNT	CAPITAL	
		$		$		
Balances at January 1, 2004	0	0	24,577,828	41,442,311	2,718,735	(4
Issuances of preferred stock to affiliate in exchange for product technology transfers	1,632,000	10,931,530				
Net loss						(
Balances at March 31, 2004	1,632,000	10,931,530	24,577,828	41,442,311	2,718,735	(5

See accompanying notes

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CARACO PHARMACEUTICAL LABORATORIES, LTD.

NOTES TO FINANCIAL STATEMENTS (UNAUDITED)

1. BASIS OF PRESENTATION

The balance sheets as of March 31, 2004 and December 31, 2003 and the related statements of operations and cash flows for the three months March 31, 2004 and 2003 and shareholders' equity for the three months ended March 31, 2004 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, 2004 and December 31, 2003 and for the three months ended March 31, 2004 and 2003 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, 2003.

The accounting policies followed by the Corporation with respect to the unaudited interim financial statements are consistent with those stated in the 2003 Caraco Pharmaceutical Laboratories, Ltd., Annual Report on Form 10-KSB.

2. ORGANIZATION AND NATURE OF BUSINESS

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

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 at their equivalence in quality and bioavailability.

Our present product portfolio includes 18 products in 35 strengths in 82 package sizes. We are currently marketing 16 of the products in 28 strengths and 62

package sizes. The products are intended to treat a variety of disorders including the following: hypertension, arthritis, epilepsy, diabetes, depression and pain management.

A significant source of our funding has been from private placement offerings and loans. Since August 1997, Sun Pharmaceutical Industries Limited, a specialty pharmaceutical corporation organized under the laws of India ("Sun Pharma"), has contributed equity capital and has advanced us loans. In addition, among other things, Sun Pharma has acted as a guarantor on loans to Caraco, has supplied us with raw materials for certain of our products, helped us obtain machinery and equipment to enhance our production capacities at competitive prices and transferred certain generic products to us. (See "Current Status of the Corporation" and "Sun Pharmaceutical Industries, Limited" below.)

3. CURRENT STATUS OF THE CORPORATION

Net sales for the period ended March 31, 2004 were $13.6 million as compared to $8.8 million for the corresponding period of 2003. We incurred an operating loss of $2.1 million during the period ended March 31, 2004 as compared to earning operating income of $2.6 million for the corresponding period of 2003. After interest costs, we incurred a net loss of $2.2 million during the period ended March 31, 2004 as compared to earning net income of $2.2 million for the corresponding period of 2003. Net cash generated

from operating activities was $6.2 million for the period ended March 31, 2004 as compared to net cash used in operating activities of $1.5 million for the corresponding period in 2003. At March 31, 2004, for the first time since inception, we had a positive stockholders' equity of $3.7 million, as compared to a stockholders' deficit of $5 million at December 31, 2003. (See "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.")

Pursuant to our products agreement with Sun Pharma Global, Inc. ("Sun Global"), a wholly-owned subsidiary of Sun Pharma, we have selected, through the first quarter of 2004, seven products out of the 25 products to be transferred to us by Sun Global. Of these, one product passed its bio-equivalency studies in the fourth quarter of 2003 and two products passed bio-equivalency studies during the first quarter of 2004. Under the products agreement, Sun Global has earned 544,000 preferred shares for each such product. (See "Sun Pharmaceutical Industries Limited" and "Item 2. - Future Outlook.")

During the first quarter of 2004, we filed ANDAs for two of the three above-mentioned products with the FDA. We expect to file the third product during the second quarter.

During the first quarter of 2004, we received approval from the FDA for an additional strength for one product in our portfolio. In April 2004, we received approval of one product from the FDA. This brings the total number of ANDAs pending approval by the FDA to three. (See "Organization and Nature of Business" above).

During the first quarter of 2004, we appointed three new independent directors to comply with the requirements of the Sarbanes-Oxley Act of 2002 and the regulations of the American Stock Exchange. The new independent directors replace the three independent directors who resigned in late 2003. The new independent directors are William C. Brooks, Timothy Manney and Georges Ugeux.

During the first quarter of 2004, Sun Pharma acquired 3,452,291 additional shares of common stock and 1,329,066 stock options from two former directors and a significant shareholder; thereby increasing its beneficial ownership from

approximately 48% to 63%.

During the first quarter of 2004, the Company repaid the entire balance of a $4.4 million loan from ICICI Bank Limited. In April 2004, the Company repaid the entire balance of the $6.0 million loan from the Economic Development Corporation of the City of Detroit (the "EDC"). The payoffs were funded from internal cash flow and by utilizing part of a new $10.0 credit line arranged with Citibank, N.A.

4. RECENT ACCOUNTING PRONOUNCEMENTS

In April 2003 the FASB issued Statement of Financial Accounting Standards (SFAS) No. 149, which amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments imbedded in other contracts and for hedging activities under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." SFAS No. 149 clarifies under what circumstances a contract with an initial net investment meets the characteristic of a derivative discussed in paragraph 6 (b) of SFAS No. 133, clarifies when a derivative contains a financing component, amends a definition to conform to language used in FASB interpretation No. 45, and amends certain other existing pronouncements. SFAS No. 149 is effective for contracts entered into or modified after June 30, 2003. The subject matter of SFAS No. 149 is not currently applicable to the Corporation; accordingly, it is not expected that the provisions of SFAS No. 149 will have a material impact on the financial position, results of operations or cash flows of the Corporation.

In May 2003 the FASB issued SAFS No. 150, which establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both debt and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise was effective for the beginning of the first interim period beginning after June 15, 2003. It is to be implemented by cumulative effect of a change in accounting principle for financial instruments created before the issuance date of SFAS No. 150 and still existing at the beginning of the interim period of adoption. The subject matter of SFAS No. 150 is not currently applicable to the Corporation; accordingly, it is not expected that provisions of statement No. 150 will have a material impact on the financial position, results of operations or cash flows of the Corporation.

5. COMPUTATION OF (LOSS) / EARNINGS PER SHARE

(Loss) / Earnings 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 potential dilution of all common stock equivalents.

The basic and diluted weighted average numbers of common shares outstanding for the three months ended March 31, 2004 were 24,577,828. The basic and diluted weighted average numbers of common shares outstanding for the three months ending March 31, 2003 were 23,762,532 and 25,061,469.

6. MORTGAGE NOTE WITH EDC

Our manufacturing facility and executive offices were constructed in 1991 and financed by $9.1 million loan pursuant to a Development and Loan Agreement dated August 10, 1990 (the "Agreement") from the EDC. The loan was collateralized by a first mortgage, effectively, on all of the Corporation's property and equipment purchased pursuant to the Agreement.

On March 1, 1994, the EDC Agreement was amended to extend the maturity date to July 1, 2002. On August 5, 1997, we restructured the loan from the EDC. We became in default of the restructured loan; however, from February 1999 to April 2003 we made $100,000 monthly payments to the EDC while we were negotiating another restructuring of the loan.

On April 23, 2003, the loan was again restructured, effective as of January 1, 2003. The loan was extended for six years, with interest rates starting at 2.75% and increasing to 5.16% p.a. (current year's effective rate of interest being 3.36% p.a.). Under the extension, the EDC retained a first mortgage on our property, and a first lien on our furniture, fixtures, equipment, ANDAs and intellectual property. The EDC removed its first lien on our accounts receivable and inventory. In addition to other covenants, we agreed that we would not redeem any of our outstanding shares, pay any dividends with respect to our outstanding common stock or preferred shares or merge or consolidate with any other corporation or other entity without the prior written consent of the EDC. However, the EDC eliminated the prior restriction on capital investment in excess of $2 million by permitting us, so long as we were 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 were not reduced below the balance as of December 31, 2002 and the proceeds of any such sales were retained by us. As of March 31, 2004, the obligations of the Corporation to the EDC were classified on the accompanying balance sheet in accordance with the terms of the restructured loan. At March 31, 2004, the loan from the EDC had been reduced to $6.0 million.

In April 2004, the Company repaid the entire balance of the $6.0 million loan from EDC (effective rate of interest of 3.36%). This was funded by utilizing part of a new $10.0 credit line arranged with Citibank, N.A. (effective rate of interest of 2.25%). Accordingly, the EDC liens on our intellectual property and capital assets, and other restrictions have been removed.

7. 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.

Sun Pharma and its affiliates had loaned us, since August 1997, approximately $10.0 million at interest rates ranging from of 8.0% to 10% per annum, payable quarterly. Prior to December 31, 2003, we repaid all of such loans.

Sun Pharma had also assisted us, by acting as guarantor, in obtaining line of credit loans from ICICI Bank Limited and The Bank of Nova Scotia in the amounts of $5.0 million and $12.5 million, respectively. As of March 31, 2004, we have repaid all of such loan to ICICI Bank Limited and made a scheduled installment payment of $3.1 million to The Bank of Nova Scotia.

In August 1997, we entered into an agreement with Sun Pharma for the transfer of technology for 25 generic pharmaceutical products over a period of five years through August 2002 in exchange for 544,000 shares of our common stock for each ANDA product (when bio-equivalency studies were successfully completed) and 181,333 shares for each DESI product. The products provided to us by Sun Pharma were selected by mutual agreement. Under such agreement, we conducted, at our expense, all tests including bio-equivalency studies. Pursuant to such agreement, Sun Pharma delivered to us the technology for 13 products. This agreement has expired and, as noted immediately below, we have entered into a new agreement with Sun Global.

In November 2002, we entered into a new products agreement with Sun Global for the transfer of the technology for 25 generic products over a period of 5 years. Under such agreement, we conduct, at our expense, all tests including bio-equivalency studies. Sun Global receives 544,000 shares of a new class of preferred stock (convertible into common stock after three years) for each ANDA product transferred upon the ANDA successfully passing the bio-equivalency studies. The preferred shares are non-voting and do not receive dividends.

The products agreement with Sun Global was amended by the Independent Committee in the first quarter of 2004 to eliminate the provision requiring that the Independent Committee concur in the selection of each product, and provide instead, that each product satisfy certain objective criteria developed by management and approved by the Independent Committee. Pursuant to such objective criteria, we selected seven products during the first quarter of 2004 that we had been working on during 2003, but had not been formally selected under the products agreement prior to its amendment. One of the seven products passed its bio-equivalency studies in December 2003 and two products passed their respective bio-equivalency studies in the first quarter of 2004. Sun Global has thereby earned 544,000 preferred shares for each product.

Sun Pharma has established Research and Development Centers in Mumbai and Baroda, India where the development work for products is performed.

Sun Pharma supplies us with certain raw materials and formulations. In addition, Sun Pharma assists us in acquiring machinery and equipment to enhance our production capacities.

Sun has also provided us with qualified technical professionals, many of whom are currently working at the facility.

During the first quarter of 2004, Sun Pharma acquired 3,452,291 additional shares of common stock and 1,329,066 stock options from two former directors and a significant shareholder, thereby increasing its beneficial ownership from approximately 48% to 63%.

8. TERM LOAN FROM ICICI BANK

The Corporation had obtained a term loan of $5 million from ICICI Bank Limited with the guarantee of Sun Pharma. This term loan had been used to finance research and development activities, upgrade facilities, repay loans and meet working capital requirements. Interest payments, based on Libor + 140 basis points (effective rate at the time of repayment (see below) was 2.40%), were due quarterly, with quarterly principal payments scheduled to be made from December 2003 through September 2005.

During the quarter, we have repaid the entire loan due to ICICI Bank Limited out of funds generated from operations.

9. TERM LOAN FROM THE BANK OF NOVA SCOTIA

The Corporation had obtained term loans of $12.5 million from The Bank of Nova Scotia with the guarantee of Sun Pharma. This term loan had been used to finance research and development activities, upgrade facilities, repay other loans and meet working capital requirements. Interest payments, based on an average of Libor + 175 basis points (current effective rate is 2.75%), are due quarterly, with semi-annual principal payments scheduled to be made from February 2004 through September 2005. The first installment due during the quarter in the amount of $3.1 million was repaid to The Bank of Nova Scotia out of funds generated from operations. That portion of the loan, which is due within one year from March 31, 2004, approximately $6.3 million, has been classified as

current on the accompanying balance sheet.

10. LINE OF CREDIT FROM CITIBANK N.A.

The Corporation has obtained a new $10.0 million line of credit from Citibank, N.A. with a secured irrevocable and unconditional standby letter of credit provided by Sun Pharma. The line of credit shall be used to finance working capital requirements, higher cost debt redemption and for financing capital expenditures. Interest payments are due monthly. The line of credit is revolving and for 1 year. Outstanding balances on the line of credit may be repaid at any time. The rate of interest is Libor + 125 basis points (current effective rate being 2.25%). That portion of the loan, which is due within one year from March 31, 2004, has been classified as current on the accompanying balance sheet.

11. COMMON STOCK ISSUANCES

No common stock was issued during the quarters ended March 31, 2004 and 2003, respectively.

12. PREFERRED STOCK ISSUANCES

We issued 1,632,000 shares of preferred stock to Sun Global during the first quarter of 2004 in connection with 1 product transfer during the last quarter of 2003 and 2 product transfers during the first quarter of 2004. No shares of preferred stock were issued to Sun Global during the corresponding period in 2003.

13. SALES AND CUSTOMERS

Certain of our customers purchase our products through designated wholesale customers, which act as intermediary distribution channels for our products. For example, the Veterans Administration, which has entered into the sales contract discussed below, selected Amerisource Bergen as its designated wholesaler.

Shipments to one wholesale customer accounted for approximately 63% and 76% of net sales during the three months ended March 31, 2004 and March 31, 2003, respectively. Balances due from this wholesaler represented approximately 64% of accounts receivable at March 31, 2004 and 78% of accounts receivables at March 31, 2003. No other single customer represented more than 10% of our net sales during the past two years.

14. LITIGATION

As previously disclosed, on February 12, 2003, C. Arnold Curry filed a complaint in the Wayne County Circuit Court alleging breach of a written employment agreement. Mr. Curry is seeking 175,000 shares of

our common stock (35,000 shares for each of the first five ANDAs approved by the FDA). We, and plaintiff, have each filed a motion for summary judgment. No trial date has been scheduled. We intend to vigorously defend ourselves against these claims, which we believe have no merit.

As previously disclosed, we were named as one of two defendants and as one of several defendants in two separate product liability suits, involving Miraphen, which contains phenylopropanolame (PPA), one in federal court in Pennsylvania and another in state court in New Jersey, respectively. These lawsuits sought 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 plaintiff in the federal lawsuit stipulated to a dismissal of the lawsuit and the case was formally dismissed by the federal

court in December 2003. It is our understanding that a stipulation of dismissal as to Caraco was entered by the state court on April 8, 2004. At this time, we have not, however, received a copy of the formal order.

We are involved in certain legal proceedings from time to time incidental to our normal business activities. While the outcome of any such proceedings cannot be accurately predicted, we do not believe the ultimate resolution of any existing matters should have a material adverse effect on our financial position or results of operations.

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

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 and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in the Company's 2003 annual report on Form 10-KSB and the unaudited interim financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

OVERVIEW

We have generated cash from operations of $6.2 million during the first quarter of 2004 compared to using cash in operations of $1.5 million during the first quarter of 2003. This cash was available and used primarily to pay off Company debt. While we did incur a net loss of $2.2 million during the first quarter of 2004 compared to net income of $2.2 million during the first quarter of 2003, the loss was primarily due to non-cash research and development expenses of $7.8 million in the first quarter of 2004 relating to 2 products passing their bio-equivalency studies during such period compared to no non-cash research and development expenses during the first quarter of 2003, as no product passed bio-equivalency studies during this period.

FDA COMPLIANCE AND PRODUCT APPROVALS

During November 2002, the FDA conducted an inspection of our facility and found us to be substantially in compliance with cGMP regulations. While the FDA did issue us an FDA 483 list of observations, we do not believe they are material and we have taken appropriate remedial actions.

We have submitted 17 ANDAs to the FDA for approval since August 1997, including 2 filed during the first quarter of 2004. Of these, 14 have been approved and three are pending approval. We expect to file the product, which passed bio-equivalency studies at the end of March 2004, during the the second quarter of 2004.

QUARTER ENDED MARCH 31, 2004 COMPARED WITH QUARTER ENDED MARCH 31, 2003

NET SALES.

Net sales for the three months ended March 31, 2004 and 2003 were $13.6 million and $8.7 million, respectively, and reflects an increase of 56%. The increase is due to the higher production and marketing of most of our products. In addition, with our larger base of products, we have been able to attract both new customers and larger orders. As of March 31, 2004, we manufacture and market all except one of the approved products. Sales of two products accounted for 70% of our net sales during the three months ended March 31, 2004 as compared to 84% during the three months ended March 31, 2003, respectively.

GROSS PROFIT.

We earned a gross profit of $8.2 million during the three months ended March 31, 2004 as compared to a gross profit of $4.5 million during the corresponding period in 2003, reflecting an increase of 82%. The improvement was primarily due to higher sales volumes and better-cost absorption of operational overheads.

As a result of increased sales, the gross profit as a percentage of net sales has also improved for the three months ended March 31, 2004 as compared to the corresponding period of 2003. The percentage for the three months ended March 31, 2004 was 60% as compared to 52% for the corresponding period in 2003. The increase was the result of:

- Reduction in the material costs.
- Changes in product mix to higher profit margin products.
- Better cost absorption of manufacturing costs.
- Further improved efficiency in the overall manufacturing process associated with higher utilization of plant capacity.
- Utilization of newly installed larger and faster equipment to achieve economies of scale.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES.

Selling, general and administrative expenses for the three months ended March 31, 2004 and 2003, respectively, were $1.3 million and $0.9 million. This represents an increase of 35%. Selling, general and administrative expenses, as a percentage of net sales, during the three months ended March 31, 2004 have marginally improved to 9.5% compared to 10.9% during the same period of 2003.

The increase of $0.4 million for the three months ended March 31, 2004 was primarily due to additional professional costs ($0.05 million) in connection with the ongoing litigation against the Company, higher product liability and other insurance costs ($0.16 million) and other costs related to sales and marketing.

RESEARCH AND DEVELOPMENT EXPENSES.

Cash research and development expenses during the period ended March 31, 2004 were $1.1 million as compared to $0.9 million during the corresponding period of 2003. The reason for the higher cash research and development expenses was higher expenditures for bio-study costs during the first quarter of 2004 compared to none during the corresponding period of 2003.

Non-cash research and development expenses of $7.8 million (technology transfer costs) have been recorded during the period ended March 31, 2004 for 1,088,000 shares of preferred stock earned by Sun Global for 2 products transfers during the three months ended March 31, 2004. There were no non-cash research and development expenses during the corresponding period of 2003.

INTEREST EXPENSE.

Interest expense on loans was $0.2 million and $0.4 million for the three months ended March 31, 2004 and 2003, respectively. The reduction in interest expense is primarily due to our repaying the loan of $10 million to Sun Pharma and its affiliates, the loan of $4.4 million to ICICI Bank Limited and our first installment of $3.1 million to The Bank of Nova Scotia during 2003 and 2004.

RESULTS OF OPERATIONS.

We incurred a net loss of $2.2 million for the three months ended March 31, 2004 as compared to earning net income of $2.2 million for the same period of 2003. The significantly reduced results of operations in the current three-month period of 2004 is primarily due to non-cash research and development expenses of $7.9 million compared to no such expenses in the corresponding period of 2003.

LIQUIDITY AND CAPITAL RESOURCES.

During the period ended March 31, 2004, we generated cash of $6.2 million as compared to using cash in operations of $1.5 million during the same period of 2003. The higher cash generation was due to higher sales and improved cost absorptions in our operations.

In addition to repaying the entire debt of $4.4 million to ICICI Bank Limited and making a scheduled payment of $3.1 million to The Bank of Nova Scotia, operations have generated sufficient cash to fund our capital expenditures of $1.3 million during the three months ended March 31, 2004. In contrast, we had to borrow $1.6 million from The Bank of Nova Scotia to fund our operations and also finance our capital expenditure of $0.25 million during the corresponding period in 2003.

At March 31, 2004, the Corporation had positive working capital of $1.0 million compared to a negative working capital of $1.1 million at December 31, 2003. The positive working capital position is primarily due to reduction of debt and current liabilities during 2004. As of December 31, 2003, the negative working capital was mainly due to the classification of $2.5 million loan payable to the ICICI Bank Limited and $6.25 million loan payable to The Bank of Nova Scotia as current, since these loans were due to mature in within one year from March 31, 2003.

As noted, the Corporation has repaid the entire loan of $4.4 million due to ICICI Bank Limited and made a scheduled principal repayment of $3.1 million to The Bank of Nova Scotia. As at March 31, 2004, $9.4 million of The Bank of Nova Scotia loan is outstanding.

The Corporation has obtained a $10.0 million line of credit from Citibank, N.A., with a secured irrevocable and unconditional standing letter of credit provided by Sun Pharma. Subsequent to the end of the first quarter, $6.0 million of the line of credit was used to pay off the EDC. It is anticipated that the balance of the line of credit shall be used to finance working capital requirements, higher cost debt redemption and for financing capital expenditures.

FUTURE OUTLOOK

We have experienced difficult times in the past. However, because we have been substantially compliant with cGMPs since 2001, have received approvals of twelve ANDAs during the last three years, have expanded and upgraded our facilities and have expanded our customer base, management feels that our future outlook is brighter.

Management expects an increase in sales and improvement in cash flow during 2004. The pricing pressures, which resulted in lower gross margins in the fourth quarter of 2003, are expected to continue in

2004 due to increased competition. However, we still expect to meet our previously stated guidance of 20-25% revenue growth during 2004.

As disclosed, under the products agreement dated November 21, 2002, between Sun Global and the Company, Sun Global has agreed to transfer the technology for 25 products to the Company over a five year period in exchange for 544,000 preferred shares (which are convertible on a one-to-one basis into common shares) per product. Since the date of the products agreement, seven products have been selected for development by the Company and three of these products have passed their respective bio-equivalency studies (one in 2003 and two in the first quarter of 2004). If some or all of the remaining four products pass their bio-equivalency studies in 2004, the fair value of the preferred shares earned by Sun Global in exchange for such products could cause our non-cash research and development expenses to increase to an amount which would significantly decrease profit or create a loss, as it has during the first quarter of 2004, in which two products passed bio-equivalency studies.

While the development of new products will increase our non-cash R&D expense and will impact EPS, the cash will be available, among other things, to repay loans and reduce interest burden, meet increased working capital requirements and finance capital investments. This in turn will strengthen our balance sheet and build value for our shareholders.

The Company will continue to aggressively move forward on the development of the products ("Products") presented and to be presented for consideration by Sun Global pursuant to the products agreement. We believe that receiving products from Sun Global, provides us with a partner who has a proven track record; one that already has provided us with quality products. Moreover, Sun Pharma's increased beneficial ownership in us, to approximately 63% of our outstanding shares, should, we believe, provide it with the incentive to continue to help us succeed. Sun Pharma has already provided us with millions of dollars in capital, loans, and guarantees of loans, and with personnel, raw materials and equipment, which have significantly helped us to date.

Management's plans for the remainder of 2004 include:

- Continued focus on FDA compliance.
- Continued research and development activities.
- Continued expenditures for capital investment including equipment and expansion of capacity.
- Increased market share for certain existing products and recently introduced new products and enhanced customer reach and satisfaction.
- Prompt introduction of new approved products to the market.
- Achieving further operational efficiencies by attaining economies of scale and cost reduction per unit.
- Increasing the number of products, as well as anticipated volume increases for existing products, which, in turn, will improve manufacturing capacity utilization.
- Considering alternative ways of increasing cash flow including developing, manufacturing and marketing ANDAs owned by Sun Pharma.
- Locating and utilizing facilities of contract-manufacturers to enhance production and therefore sales.
- Further reducing debt, if adequately supported by positive cash flows.

FORWARD LOOKING STATEMENTS

This report, other than the historical financial and business information, may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act. Without limitation, the words "believes," "plans," "expects," and similar expressions are intended to identify forward-looking statements. Those statements include statements

regarding our intent, belief, and current expectation. These 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 including, but not limited to: (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 in a timely manner, at competitive prices, and in required quantities; (viii) timing and success of product development and launch; (ix) integrity and reliability of the Company's data; (x) lack of success in attaining full compliance with regard to regulatory and cGMP compliance; (xi) experiencing difficulty in managing our recent rapid growth and anticipated future growth; (xii) dependence on limited customer base; (xiii) occasional credits to certain customers reflecting price reductions on products previously sold to them and still available as shelf-stock; (xiv) possibility of an incorrect estimate of charge-backs and the impact of such an incorrect estimate on net sales, gross profit and net income; (xv) dependence on few products generating majority of sales; (xvi) product liability claims for which the Company may be inadequately insured; (xvii) subjectivity in judgment of management in applying certain significant accounting policies derived based on historical experience, terms of contracts, our observations of trends of industry, information received from our customers and other sources, to estimate revenues, accounts receivable allowances including chargebacks, rebates, income taxes, values of assets and inventories etc and (xviii) other risks identified in this report and identified from time to time in our reports and registration statements filed with the Securities and Exchange Commission. These forward-looking statements represent our judgment as of the date of this report. We disclaim, however, any intent or obligation to update our forward-looking statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We do not use any derivative financial instruments. All of our direct sales are in the United States and denominated in U.S. dollars. Our exposure to market risk for a change in interest rates relates primarily to our debt instruments. Our debt instruments, at March 31, 2004, are subject to variable interest rates, which float based upon a spread over LIBOR. Management does not believe that any risk inherent in these instruments is likely to have a material effect on our financial statements.

ITEM 4. CONTROLS AND PROCEDURES

a. The term "disclosure controls and procedures" is defined in Rules 13a-15(e) and 15d-15(e) 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, who is also our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report (the "Evaluation Date"), and has concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective in providing him 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 changes in the Corporation's internal controls over financial reporting that occurred during registrant's last fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Corporation's internal control over financial reporting.

PART II -- OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

As previously disclosed, on February 12, 2003, C. Arnold Curry filed a complaint in the Wayne County Circuit Court alleging breach of a written employment agreement. Mr. Curry is seeking 175,000 shares of our common stock (35,000 shares for each of the first five ANDAs approved by the FDA). We, and plaintiff, have each filed a motion for summary judgment. No trial date has been scheduled. We intend to vigorously defend ourselves against these claims, which we believe have no merit.

As previously disclosed, we were named as one of two defendants and as one of several defendants in two separate product liability suits, involving Miraphen, which contains phenylopropanolame (PPA), one in federal court in Pennsylvania and another in state court in New Jersey, respectively. These lawsuits sought 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 plaintiff in the federal lawsuit stipulated to a dismissal of the lawsuit and the case was formally dismissed by the federal court in December 2003. It is our understanding that a stipulation of dismissal as to Caraco was entered by the state court on April 8, 2004. At this time, we have not, however, received a copy of the formal order.

We are involved in certain legal proceedings from time to time incidental to our normal business activities. While the outcome of any such proceedings cannot be accurately predicted, we do not believe the ultimate resolution of any existing matters should have a material adverse effect on our financial position or results of operations.

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

During the quarter ended March 31, 2004, registrant issued 1,632,000 preferred shares to Sun Global in exchange for the transfer of 3 products pursuant to our products agreement with Sun Global. Such preferred shares were issued to Sun Global pursuant to exemptions from registration under Section 4(2), Section 4(6) and Regulation D under the Securities Act of 1933.

Pursuant to various stock and option purchase agreements between Sun Pharma and three shareholders and their affiliates, Sun Pharma acquired in January and February, 2004, 3,452,291 shares of common stock and rights to acquire options for 1,679,066 shares of common stock. The shares were acquired for $9.00 per share and the rights to the options were acquired for $9.00 less the exercise

price of each option.

ITEM 5. OTHER INFORMATION

Under SEC regulations, the Company ceased being a small business issuer in February 2004 when Sun Pharma became the beneficial owner of more than a majority of the Company's outstanding shares. At such time, the Company became a controlled company under Amex regulations. As a controlled company, the Company is not required to have independent directors comprise a majority of the board of directors and is not required to have (i) director nominations made or recommended by a nominating committee comprised solely of independent directors or by a majority of the independent directors; or (ii) compensation

of the CEO and all other officers determined or recommended by a compensation committee comprised solely of independent directors or by a majority of the independent directors.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

3.09 Amendment to Amended and Restated Bylaws dated January 16, 2004.

10.28 Line of credit loan with Citibank, N.A.

10.29 Master Note - Citibank.

10.30 Negative Pledge Agreement - Citibank

31.1 Certification of Chief Executive Officer and Chief Financial Officer.

32.1 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.

On February 19, 2004, the Corporation filed a Form 8-K disclosing in Item 1 thereof, the acquisition by Sun Pharma of stock and options of Caraco in private purchases.

On March 3, 2004, the Corporation filed a Form 8-K disclosing in Item 12 thereof its results of operations for the year ended December 31, 2003.

SIGNATURE

In accordance with 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/ Jitendra N. Doshi

Jitendra N. Doshi
Chief Executive Officer
and Chief Financial Officer

Dated: April 30, 2004

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32.1 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.