

CARACO PHARMACEUTICAL LABORATORIES LTD
Form 10-Q
October 21, 2004

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

FORM 10-Q

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

for the quarterly period ended September 30, 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
(State or other jurisdiction of
incorporation or organization)

38-2505723
(IRS Employer
Identification No.)

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

48202
(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 No

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

Yes No

As of October 18, registrant had 24,600,628 shares of common stock issued and outstanding.

CARACO PHARMACEUTICAL LABORATORIES LTD.
BALANCE SHEETS

BALANCES AS
SEPTEMBER 30,
2004

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	----- UNAUDITED
ASSETS	
CURRENT ASSETS	
Cash and cash equivalents	\$ 1,859,273
Accounts receivable, net	1,723,408
Inventories	14,697,759
Prepaid expenses and deposits	1,268,746

TOTAL CURRENT ASSETS	19,549,186

PROPERTY, PLANT AND EQUIPMENT - AT COST	
Land	197,305
Building and improvements	9,186,316
Equipment	8,528,690
Furniture and fixtures	551,864

Total	18,464,175
Less: accumulated depreciation	6,579,697

NET PROPERTY, PLANT & EQUIPMENT	11,884,478

TOTAL ASSETS	\$ 31,433,664
	=====
LIABILITIES AND STOCKHOLDERS' EQUITY / (DEFICIT)	
CURRENT LIABILITIES	
Accounts payable	\$ 1,714,920
Accounts payable - Sun Pharma	4,620,036
Accrued expenses	1,427,875
Current portion of bank loans payable	7,000,000
Current portion of EDC debt	0

TOTAL CURRENT LIABILITIES	14,762,831

LONG-TERM LIABILITIES	
EDC debt	0
Bank loans payable	0

TOTAL LONG-TERM LIABILITIES	0

TOTAL LIABILITIES	14,762,831

STOCKHOLDERS' EQUITY / (DEFICIT)	
Common stock, no par value, authorized 50,000,000 shares; issued and outstanding shares - 24,600,628 and 24,577,828 shares	41,464,227
Convertible Series B Preferred Stock, no par value, authorized 5,000,000 shares; issued and outstanding - 3,264,000 and -0- shares	21,282,490
Additional paid in capital	2,718,735
Accumulated deficit	(48,794,619)

TOTAL STOCKHOLDERS' EQUITY / (DEFICIT)	16,670,833

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY / (DEFICIT)	\$ 31,433,664

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See accompanying notes

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CARACO PHARMACEUTICAL LABORATORIES, LTD.
UNAUDITED STATEMENTS OF NET INCOME

	NINE MONTHS ENDED SEPTEMBER 30,		
	2004	2003	
	-----	-----	-----
NET SALES	\$ 43,659,631	\$ 32,905,662	\$ 1
Cost of goods sold	17,157,588	13,112,198	
	-----	-----	-----
Gross profit	26,502,043	19,793,464	
	-----	-----	-----
Selling, general and administrative expenses	3,576,514	5,689,566	
R&D cost	4,037,282	2,018,029	
R&D cost - affiliate (Note 7)	18,179,120	0	
	-----	-----	-----
Operating income	709,127	12,085,869	
	-----	-----	-----
Other income / (expense)			
Interest expense	(398,672)	(1,041,382)	
Interest income	34,767	24,790	
Other income / (expense)	617	0	
	-----	-----	-----
Net other expense	(363,288)	(1,016,592)	
	-----	-----	-----
NET INCOME	\$ 345,839	\$ 11,069,277	\$
	=====	=====	=====
NET INCOME PER COMMON SHARE			
Basic	0.01	0.46	
Diluted	0.01	0.44	

See accompanying notes

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CARACO PHARMACEUTICAL LABORATORIES, LTD.
UNAUDITED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) FOR THE
NINE MONTHS ENDED SEPTEMBER 30, 2004

PREFERRED STOCK	COMMON STOCK	ADDITIONAL PAID IN
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	SHARES	AMOUNT	SHARES	AMOUNT	CAPITAL
	-----	-----	-----	-----	-----
BALANCES AT JANUARY 1, 2004	-	-	24,577,828	\$41,442,311	\$ 2,718,735
Issuances of common stock upon exercise of stock options			22,800	21,916	
Issuances of preferred stock to affiliate in exchange for product technology transfers	3,264,000	21,282,490			
Net income					
BALANCES AT SEPTEMBER 30, 2004	3,264,000	\$21,282,490	24,600,628	\$41,464,227	\$ 2,718,735
	=====	=====	=====	=====	=====

See accompanying notes

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CARACO PHARMACEUTICAL LABORATORIES, LTD.
UNAUDITED STATEMENTS OF CASH FLOWS

	NINE MONTHS ENDED SEPTEMBER 30	
	2004	2003
	-----	-----
CASH FLOWS FROM OPERATING ACTIVITIES		
Net (loss) / income	\$ 345,839	\$ 11,069,277
Adjustments to reconcile net (loss) / income to net cash provided by operating activities		
Depreciation	615,915	422,180
Common shares issued in lieu of cash for compensation	0	262,450
Variable compensation expense for stock options	0	1,833,612
Preferred shares issued to affiliate for R&D cost	18,179,120	0
Changes in operating assets and liabilities which provided / (used) cash:		
Accounts receivable	2,815,065	(925,503)
Inventories	(5,086,949)	(1,867,348)
Prepaid expenses and deposits	(706,714)	(1,004,969)
Accounts payable	1,108,980	(648,115)
Accrued expenses	(385,971)	210,663
Net cash provided by operating activities	16,885,285	9,352,247
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(2,993,720)	(1,315,204)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from bank loans	10,000,000	1,600,000
Net bank loans paid	(19,875,000)	0

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Proceeds from exercise of stock options	21,916	790,591
Payment of preferred stock dividends	0	(350,380)
Payments of EDC debt	(6,385,490)	(909,651)
Net loans repaid to stockholders	0	(6,850,000)
	-----	-----
Net cash used in financing activities	(16,238,574)	(5,719,440)
	-----	-----
NET (DECREASE) / INCREASE IN CASH AND CASH EQUIVALENTS	(2,347,009)	2,317,603
Cash and cash equivalents, beginning of period	4,206,282	534,228
	-----	-----
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 1,859,273	\$ 2,851,831
	=====	=====

SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:

During the nine months ended September 30, 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

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CARACO PHARMACEUTICAL LABORATORIES, LTD. NOTES TO FINANCIAL STATEMENTS (UNAUDITED)

1. BASIS OF PRESENTATION

The balance sheet as of December 31, 2003 is audited. All other financial statements contained herein 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 contained herein 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.

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Our present product portfolio includes 18 products in 35 strengths in 82 package sizes. We are currently marketing 17 of the products in 33 strengths and 78 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 a substantial portion of raw materials for 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.)

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3. CURRENT STATUS OF THE CORPORATION

Net sales for the three months and nine months ended September 30, 2004 were \$15.3 million and \$43.7 million, respectively, as compared to \$12.3 million and \$32.9 million, respectively, for the corresponding periods of 2003. We have earned an operating income of \$1.1 million and \$0.7 million, respectively, for the three months and nine months ended September 30, 2004 as compared to operating income of \$4.7 million and \$12.1 million, respectively, for the corresponding periods of 2003. After interest expense, we have earned net income of \$1.1 million and \$0.3 million, respectively, for the three months and nine months ended September 30, 2004 as compared to net income of \$4.5 million and \$11.1 million, respectively, for the corresponding periods of 2003. Net cash generated from operating activities was \$16.9 million for the nine months ended September 30, 2004 as compared to \$9.4 million for the corresponding period in 2003. At September 30, 2004, stockholders' equity increased to \$16.7 million as compared to a stockholders' deficit of \$5.0 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, during the second quarter of 2004, eight additional products over and above the seven products selected in the first quarter of 2004. This makes a selection of a total of 15 products out of the 25 products to be transferred to us by Sun Global. Of these, six products have passed bio-equivalency studies, including five products during the nine months ended September 30, 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" below.)

During the nine months ended September 30, 2004, we filed three ANDAs with the FDA of the six above-mentioned products. This brings the total number of ANDAs pending approval by the FDA to four. We anticipate that a majority of the three pending ANDAs will be filed shortly.

One of the filed ANDAs is for a generic version of Ortho-McNeil Pharmaceutical Inc.'s Ultracet(R), challenging its patent under a commonly known procedure as a paragraph IV certification. We believe that we were the third company to file a paragraph IV certification for the drug product and we do not expect to get 180 days exclusivity. Ortho-McNeil Pharmaceutical Inc. has instituted patent litigation against Caraco. (See "Litigation" below.)

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During the nine months ended September 30, 2004, we received approvals for an additional strength of one product in our portfolio and one new product from the FDA. (See "Organization and Nature of Business" above).

During the nine months ended September 30, 2004, the Company repaid the entire balance of \$4.4 million due to ICICI Bank Limited and the \$6.4 million mortgage loan due to the Economic Development Corporation of the City of Detroit (the "EDC"), and repaid \$12.5 million due to the Bank of Nova Scotia. These payoffs were funded from internal cash flow and

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by utilizing a \$10.0 million credit line arranged with Citibank, N.A. Of this \$10.0 million, the Company has repaid \$3.0 million during the third quarter of 2004. This leaves a total outstanding balance of \$7.0 million payable to Citibank at September 30, 2004.

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." 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 SFAS No. 150, which establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both debt and equity. 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 EARNINGS PER SHARE

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 and nine months ended September 30, 2004 were 24,583,220 and 29,318,828, respectively. The basic and diluted weighted average numbers of common shares outstanding for the three and nine months ended September 30, 2003 were 23,977,673 and 25,317,464, respectively.

6. MORTGAGE NOTE WITH EDC

On April 13, 2004, the Company repaid the entire \$6.1 million loan balance due to the EDC (effective rate of interest of 3.36%). This was funded by utilizing part of the \$10.0 credit line arranged with Citibank, N.A. (effective rate of interest of 2.25%). Accordingly, all liens and other restrictions previously imposed on the Company by the EDC 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

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common shares.

Sun Pharma had 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

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million, respectively. As of September 30, 2004, we have repaid all of such loans. Sun Pharma also assisted us by acting as a guarantor of the Citibank credit line (see Note 9 below).

In November 2002, we entered into a 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 Series B 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 new 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 provides 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. Subsequently, during the second quarter, we have selected eight additional products, making a total of 15 products. Of these, six products have passed bio-equivalency studies, including five products during the nine months ended September 30, 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 a substantial portion of our raw materials and certain formulations. In addition, Sun Pharma assists us in acquiring machinery and equipment to enhance our production capacities.

Sun Pharma has also provided us with qualified technical professionals, many of whom are currently working at our 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 stockholder, thereby increasing its beneficial ownership from approximately 48% to 63%. Based on the current number of shares of common stock and options outstanding and if the 3,264,000 shares of Series B preferred stock were converted to common stock, Sun Pharma's beneficial ownership would increase to approximately 68%. The Series B preferred stock is convertible after three years from the date of issuance or following a person (other than Sun Pharma and its affiliates) acquiring control of the Corporation.

8. TERM LOANS FROM ICICI BANK AND THE BANK OF NOVA SCOTIA

During the nine months ended September 30, 2004, we have repaid the entire loan due to ICICI Bank Limited out of funds generated from operations.

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Also, during the nine months ended September 30, 2004, we have prepaid the entire loan due to Bank of Nova Scotia partly out of funds generated from operations and the balance from a line of credit from Citibank N.A (see note 9 below).

9. LINE OF CREDIT FROM CITIBANK N.A.

The Corporation has obtained a \$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 is being 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%). As of September 30, 2004, we have an outstanding balance of \$7.0 million from Citibank, which has been classified as current on the accompanying September 30, 2004 balance sheet.

10. COMMON STOCK ISSUANCES

We issued 22,800 and 724,896 shares of common stock to our employees upon exercise of their stock options during the nine months ended September 30, 2004 and 2003, respectively. No common stock was issued to the directors as compensation for attendance at board and committee meetings during the nine months ended September 30, 2004 as compared to 31,000 shares issued during the corresponding period of 2003.

11. PREFERRED STOCK ISSUANCES

We issued 3,264,000 shares of preferred stock to Sun Global during the nine months ended September 30, 2004, of which 544,000 were earned in 2003. No shares of preferred stock were issued to Sun Global during the corresponding period in 2003.

12. 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, has selected McKesson as its designated wholesaler.

Shipments to two wholesale customers accounted for approximately 72% and 77% of gross sales during the nine months ended September 30, 2004 and September 30, 2003, respectively. Balances due from these wholesalers represented approximately 61% of gross accounts receivable at September 30, 2004 and 66% of gross accounts receivables at December 31, 2003. No other single customer represented more than 10% of our gross sales during the past two years.

13. LITIGATION

On September 22, 2004, Ortho-McNeil Pharmaceutical, Inc. ("Ortho-McNeil") filed a complaint in the United States District Court for the Eastern District of Michigan alleging that

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the Company's filing of an ANDA seeking approval to market its generic version of Ortho-McNeil's Ultracet(R) drug product infringed Ortho-McNeil's patent, which Ortho-McNeil claims expires on September 6, 2011. Ortho-McNeil seeks an order from the Court which, among other things, directs the FDA not to approve Caraco's ANDA any earlier than the claimed expiration date. As noted above under "Current Status of the Corporation," the ANDA contained a paragraph IV certification challenging the Ortho-McNeil patent. We believe that the Ortho-McNeil patent is invalid and/or will not be infringed by Caraco's manufacture, use or sale of the product, and we intend to vigorously defend this action.

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 disposition. A hearing on the motions has been set for November 2004. No trial date has been scheduled. We intend to vigorously defend ourselves against this claim, which we believe has no merit.

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 would have a material adverse effect on our financial position or results of operations.

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INDEPENDENT ACCOUNTANTS' REVIEW REPORT

Stockholders and Board of Directors
Caraco Pharmaceutical Laboratories, Ltd.
Detroit, Michigan

We have reviewed the balance sheet of Caraco Pharmaceutical Laboratories, Ltd. as of September 30, 2004 and the related statements of net income, stockholders' equity (deficit) and cash flows for the three-month and nine-month periods ended September 30, 2004 and September 30, 2003. These financial statements are the responsibility of the Company's management.

We conducted our reviews in accordance with standards established by the American Institute of Certified Public Accountants. A review of interim financial information consists principally of applying analytical procedures to financial data and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with auditing standards generally accepted in the United States of America, the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

Based on our reviews, we are not aware of any material modifications that should be made to the accompanying financial statements in order for them to be in conformity with accounting principles generally accepted in the United States of America.

We have previously audited, in accordance with auditing standards generally accepted in the United States of America, the balance sheet of Caraco Pharmaceutical Laboratories, Ltd. as of December 31, 2003, and the related statements of operations, stockholders' deficit and cash flows for the year then ended (not presented herein), and in our report dated February 23, 2004, we

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expressed an unqualified opinion on those financial statements.

REHMANN ROBSON

Troy, Michigan
October 18, 2004

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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 \$16.9 million for the nine months ended September 30, 2004 as compared to \$9.4 million for the corresponding period of 2003. This \$16.9 million is the net cash generated after \$5.1 million utilized in increase of inventories. This cash was available and used primarily to pay off Company debt and to fund our capital expenditures. We earned net income of \$0.3 million during the nine months ended September 30, 2004 compared to net income of \$11.1 million during the corresponding period of 2003. The lower net income was primarily due to non-cash research and development expense (R&D) of \$18.2 million for the nine months ended September 30, 2004 compared to no similar expense during the corresponding period of 2003. This non-cash R&D expense related to 5 products passing their bio-equivalency studies during the nine months ended September 30, 2004 as compared to none during the corresponding period of 2003.

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 18 ANDAs to the FDA for approval since August 1997, including three filed during the nine months ended September 30, 2004. Of these, 14 have been approved and four are pending approval.

THREE MONTHS AND NINE MONTHS ENDED SEPTEMBER 30, 2004 COMPARED WITH THREE MONTHS AND NINE MONTHS ENDED SEPTEMBER 30, 2003

NET SALES

Net sales for the three months and nine months ended September 30, 2004 were \$15.3 million and \$43.7 million, respectively, as compared to \$12.3 million and \$32.9 million, respectively for the corresponding periods of 2003, reflecting increases of 24% and 33%, respectively. The increases are 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 September 30, 2004, we manufacture and market all except

one of the approved products. Sales of three products accounted for 81% of our net sales during the nine months ended September 30, 2004 as compared to 82% during the nine months ended September 30, 2003.

GROSS PROFIT

We earned a gross profit of \$9.3 million and \$26.5 million during the three months and nine months ended September 30, 2004, respectively, as compared to a gross profit of \$7.8 million and \$19.8 million during the corresponding periods in 2003, reflecting increases of 19% and 34%, respectively. The improvement was primarily due to higher sales volumes, better-cost absorption of operational overheads, and cost reductions.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

Selling, general and administrative expenses for the three months and nine months ended September 30, 2004 were \$0.9 million and \$3.6 million, respectively, as compared to \$2.6 million and \$5.7 million, respectively, for the same periods in 2003. This represents decreases of 65% and 37%, respectively. Selling, general and administrative expenses, as a percentage of net sales, during the nine months ended September 30, 2004 have decreased to 8% compared to 17% during the corresponding period of 2003. The decrease in selling, general and administrative expenses was primarily due to the absence of variable compensation expense during the three and nine months ended September 30, 2004.

RESEARCH AND DEVELOPMENT EXPENSES

Cash research and development expenses during the three months and nine months ended September 30, 2004 were \$1.5 million and \$4.0 million, respectively, as compared to \$0.5 million and \$2.0 million, respectively, during the corresponding periods of 2003. The reason for the higher cash research and development expenses was higher expenditures for bio-study costs during the relevant periods of 2004 compared to none during the corresponding periods of 2003.

Non-cash research and development expenses of \$5.7 million and \$18.2 million (technology transfer costs) have been recorded for the three and nine months ended September 30, 2004 for two and five product transfers, respectively. There were no non-cash research and development expenses during the corresponding periods of 2003.

OPERATING INCOME

We earned operating income of \$1.1 million and \$0.7 million during the three months and nine months ended September 30, 2004 as compared to operating income of \$4.7 million and \$12.1 million during the corresponding periods in 2003. The decreases were primarily due to higher non-cash research and development expense of \$5.7 million and \$18.2 million, respectively, in 2004 as compared to no similar expense during the corresponding periods in 2003.

INTEREST EXPENSE

Interest expense on loans was \$0.1 million and \$0.4 million, respectively, for the three months and nine months ended September 30, 2004 compared to \$0.2 million and \$1.0 million, respectively, for the corresponding periods of 2003.

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The reduction in interest expense is primarily due to our repaying the loan of \$10 million to Sun Pharma and its affiliates during 2003, the loans of \$4.4 million to ICICI Bank Limited, \$6.4 million to the EDC and \$12.5 million to The Bank of Nova Scotia during 2004.

RESULTS OF OPERATIONS

We earned net income of \$1.1 million and \$0.3 million, respectively for the three months and nine months ended September 30, 2004 as compared to earning net income of \$4.6 million and \$11.1 million for the corresponding periods of 2003.

The significantly lower net income in the three and nine months ended September 30, 2004 were primarily due to higher non-cash research and development expense of \$5.7 million and \$18.2 million compared to no similar expense in the corresponding periods of 2003.

LIQUIDITY AND CAPITAL RESOURCES

During the nine months ended September 30, 2004, we generated net cash from operations of \$16.9 million as compared to \$9.4 million during the corresponding period of 2003. The higher cash generation was primarily due to higher sales and improved cost absorptions in our operations. This \$16.9 million is the net cash generated after \$5.1 million utilized in increase of inventories.

In addition to helping repay the entire balances of \$4.4 million to ICICI Bank Limited, \$6.4 million to the EDC and \$12.5 million to The Bank of Nova Scotia, operations have generated cash sufficient to fund our capital expenditures of \$3.0 million during the nine months ended September 30, 2004. The capital expenditures were primarily for augmenting manufacturing facilities.

At September 30, 2004, we have an outstanding balance of \$7.0 million due to Citibank N.A.

At September 30, 2004, the Corporation had positive working capital of \$4.8 million compared to a negative working capital of \$1.1 million at December 31, 2003. The positive working capital position is primarily due to repayments of our debt obligations classified as current at December 31, 2003 and reductions in current liabilities from 2003 related primarily to technology transfer costs.

FUTURE OUTLOOK

We are substantially cGMP compliant since 2001, and have received approvals for twelve ANDAs during the last three years. We have expanded and upgraded our facilities and expanded our customer base.

Management expects the trend of continued increases in sales and improvement in cash flows during the remainder of 2004. Pricing pressures, due to increased competition, have continued during 2004 and are expected to continue in 2005, which may result in lower gross margins. Management has and will continue to work diligently to counter the pricing pressures through increased sales volumes, better-cost absorption of operational overheads, and cost reductions. We are optimistic to achieve the higher of our previously stated guidance of 20 to 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

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technology for 25 products to the Company over a five year period in exchange for 544,000 preferred shares (which are convertible after three years on a one-to-one basis into common shares) per product, upon the passing of bio-equivalency studies. Since the date of the products agreement, 15 products have been selected for development by the Company and six of these products have passed their respective bio-equivalency studies (one in 2003 and five in the first nine months of 2004). If some of the remaining nine 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.

While the development of new products will increase our non-cash R&D expense and will impact earnings per share, we anticipate that 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 stockholders.

The Company will continue to aggressively move forward on the development of the 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%, 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.
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- 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.

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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 include, but are 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; (xviii)

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litigation involving claims of patent infringement; and (xix) 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 September 30, 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

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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

The information in note 14 of Part I, Notes to Financial Statements, is incorporated herein by reference.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

During the quarter ended March 31, 2004, on March 31, 2004, registrant issued 1,632,000 Series B preferred shares to Sun Global in exchange for the transfer of three products pursuant to registrant's products agreement with Sun Global. Such preferred shares were issued

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to Sun Global pursuant to exemptions from registration under Section 4(2), Section 4(6) and Regulation D under the Securities Act of 1933.

During the quarter ended June 30, 2004, on May 21, 2004, registrant issued 544,000 Series B preferred shares to Sun Global in exchange for the transfer of one product pursuant to registrant's 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.

During the quarter ended September 30, 2004, on each of August 22, 2004 and August 27, 2004, registrant issued 544,000 Series B preferred shares to Sun Global in exchange for the transfer of one product pursuant to registrant's 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.

The above Series B preferred shares are convertible into common stock on a one-for-one basis after three years from the date of issuance or following a person (other than Sun Pharma and its affiliates) acquiring control of registrant.

Pursuant to various stock and option purchase agreements between Sun Pharma and three stockholders 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

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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

The information in Item 2 relating to the sale of the Series B preferred shares to Sun Global during the third quarter of 2004 is hereby incorporated by reference.

ITEM 6. EXHIBITS

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.

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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: October 20, 2004

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EXHIBIT INDEX

31.1 Certification of Chief Executive Officer and Chief Financial Officer.

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.

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