CARACO PHARMACEUTICAL LABORATORIES LTD
Form 10-Q
July 20, 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 June 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 {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 July 16, 2004, registrant had 24,587,228 shares of common stock issued and outstanding.

CARACO PHARMACEUTICAL LABORATORIES LTD.
BALANCE SHEETS

	BALANCES AS AT	
	JUNE 30, 2004	DECEMBER 3 2003
	UNAUDITED	AUDITED
ASSETS		

CURRENT ASSETS		
Cash and cash equivalents	$ 1,587,268	$ 4,206,2
Accounts receivable, net	6,028,565	4,538,4
Inventories	13,105,154	9,610,8
Prepaid expenses and deposits	407,658	562,0
TOTAL CURRENT ASSETS	21,128,646	18,917,5
PROPERTY, PLANT AND EQUIPMENT - AT COST		
Land	197,305	197,3
Building and improvements	8,887,170	7,917,9
Equipment	8,380,795	6,991,0
Furniture and fixtures	515,004	364,1
Total	17,980,274	15,470,4
Less: accumulated depreciation	6,377,530	5,963,7
NET PROPERTY, PLANT & EQUIPMENT	11,602,744	9,506,6
TOTAL ASSETS	$ 32,731,390	$ 28,424,2
LIABILITIES AND STOCKHOLDERS' EQUITY / (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable	$ 1,880,211	$ 1,386,1
Accounts payable - Sun Pharma	5,257,279	3,839,8
Accrued expenses	1,313,992	4,917,2
Current portion of bank loans payable	11,250,000	8,750,0
Current portion of EDC debt	0	1,115,2
TOTAL CURRENT LIABILITIES	19,701,482	20,008,4
LONG-TERM LIABILITIES		
EDC debt	0	5,270,2
Bank loans payable	3,125,000	8,125,0
TOTAL LONG-TERM LIABILITIES	3,125,000	13,395,2
TOTAL LIABILITIES	22,826,482	33,403,6
STOCKHOLDERS' EQUITY / (DEFICIT)		
Common stock, no par value, authorized 50,000,000 shares; issued and outstanding shares - 24,582,828 and 24,577,828 shares	41,447,907	41,442,3
Convertible Series B Preferred Stock, no par value, authorized 5,000,000 shares; issued and outstanding - 2,176,000 and -0- shares	15,594,970	
Additional paid in capital	2,718,735	2,718,7
Accumulated deficit	(49,856,704)	(49,140,4
TOTAL STOCKHOLDERS' EQUITY / (DEFICIT)	9,904,908	(4,979,4
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY / (DEFICIT)	$ 32,731,390	$ 28,424,2

See accompanying notes

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CARACO PHARMACEUTICAL LABORATORIES, LTD.
UNAUDITED STATEMENTS OF OPERATIONS

	SIX MONTHS ENDED JUNE 30,	THREE MONTHS ENDED JUNE 30,

	2004	2003	2004	2003
NET SALES	$28,360,953	$20,611,537	$14,799,865	$11,889,93
Cost of goods sold	11,111,175	8,653,413	5,720,474	4,427,46
Gross profit	17,249,777	11,958,124	9,079,391	7,462,47
Selling, general and administrative expenses	2,693,078	3,089,820	1,410,723	2,140,03
R&D cost	2,493,830	1,526,719	1,360,500	626,78
R&D cost - affiliate (Note 7)	12,491,600	0	4,663,440	
Operating (loss) / income	(428,731)	7,341,585	1,644,729	4,695,64
Other (expense)/income				
Interest expense	(317,175)	(817,722)	(135,633)	(375,47
Interest income	16,625	7,043	14,610	5,97
Other income	13,035	0	2,968	
Net other expense	(287,515)	(810,679)	(118,055)	(369,49
NET (LOSS) / INCOME	$ (716,246)	$ 6,530,906	$ 1,526,674	$ 4,326,15
NET (LOSS) / INCOME PER COMMON SHARE				
Basic	(0.03)	0.27	0.06	0.1
Diluted	(0.03)	0.26	0.05	0.1

See accompanying notes

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

	PREFERRED STOCK		COMMON STOCK		ADDITION PAID I CAPITA
	SHARES	AMOUNT	SHARES	AMOUNT	
BALANCES AT JANUARY 1, 2004	-	-	24,577,828	$41,442,311	$ 2,718
Issuances of common stock upon exercise of stock options			5,000	5,596	
Issuances of preferred stock to affiliate in exchange for product technology transfers	2,176,000	15,594,970			
Net loss					
BALANCES AT JUNE 30, 2004	2,176,000	$15,594,970	24,582,828	$41,447,907	$ 2,718

	TOTAL STOCKHOLDERS' (DEFICIT) / EQUITY

BALANCES AT JANUARY 1, 2004	$ (4,979,412)
Issuances of common stock upon exercise of stock options	5,596
Issuances of preferred stock to affiliate in exchange for product technology transfers	15,594,970
Net loss	(716,246)
BALANCES AT JUNE 30, 2004	$ 9,904,908

See accompanying notes

CARACO PHARMACEUTICAL LABORATORIES, LTD.
UNAUDITED STATEMENTS OF CASH FLOWS

	SIX MONTHS ENDED JUNE 30,	
	2004	2003
CASH FLOWS FROM OPERATING ACTIVITIES		
Net (loss) / income	$ (716,246)	$ 6,530,906
Adjustments to reconcile net (loss) / income to net cash provided by operating activities		
Depreciation	413,749	316,261
Common shares issued in lieu of cash for compensation	0	32,450
Variable compensation expense for stock options	0	851,800
Preferred shares issued to affiliate for R&D cost	12,491,600	0
Changes in operating assets and liabilities which provided / (used) cash:		
Accounts receivable	(1,490,092)	(3,914,949)
Inventories	(3,494,344)	375,536
Prepaid expenses and deposits	154,372	(441,715)
Accounts payable	1,911,514	68,467
Accrued expenses	(499,854)	(106,615)
Net cash provided by operating activities	8,770,699	3,712,141
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(2,509,819)	(712,947)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from bank loans	6,000,000	1,600,000
Net bank loans paid	(8,500,000)	0
Proceeds from exercise of stock options	5,596	305,403
Payment of preferred stock dividends	0	(350,380)
Payments of EDC debt	(6,385,490)	(604,350)
Net loans repaid to stockholders	0	(240,000)
Net cash (used in) / provided by financing activities	(8,879,894)	710,673
NET (DECREASE) / INCREASE IN CASH AND CASH EQUIVALENTS	(2,619,014)	3,709,867
Cash and cash equivalents, beginning of period	4,206,282	534,228

CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 1,587,268	$ 4,244,095

SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:
During the six months ended June 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.

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.)

3. CURRENT STATUS OF THE CORPORATION

Net sales for the three months and six months ended June 30, 2004 were $14.8 million and $28.4 million, respectively, as compared to $11.9 million and $20.6 million, respectively, for the corresponding periods of 2003. We have earned an operating income of $1.6 million and incurred an operating loss of $0.4 million, respectively, for the three months and six months ended June 30, 2004 as compared to operating income of $4.7 million and $7.3 million, respectively, for the corresponding periods of 2003. After interest expense, we have earned net income of $1.5 million and incurred a net loss of $0.7 million, respectively, for the three months and six months ended June 30, 2004 as compared to net income of $4.3 million and $6.5 million, respectively, for the corresponding periods of 2003. Net cash generated from operating activities was $8.8 million for the six months ended June 30, 2004 as compared to $3.7 million for the corresponding period in 2003. At June 30, 2004, stockholders' equity increased to $9.9 million, as compared to $3.7 million as of

March 31, 2004 and 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, four products have passed bio-equivalency studies, including three products during the six months ended June 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 six months ended June 30, 2004, we filed ANDAs with the FDA for three of the four above-mentioned products. This brings the total number of ANDAs pending approval by the FDA to four.

During the six months ended June 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 six months ended June 30, 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 six months ended June 30, 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 (See `Sun Pharmaceutical Industries Limited' below).

During the six months ended June 30, 2004, the Company repaid the entire $4.4 million loan balance due to ICICI Bank Limited and the $6.4 million mortgage loan balance due to the Economic Development Corporation of the City of Detroit (the "EDC"). The payoffs were funded from internal cash flow and by utilizing $6.0 million of a new $10.0 million credit line arranged with Citibank, N.A. Of this $6.0 million, the Company has repaid $1.0 million during the second quarter of 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." 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 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 six months ended June 30, 2004 were 24,578,333. The basic and diluted weighted average numbers of common shares outstanding for the three months ended June 30, 2004 were 24,578,333 and 28,259,327, respectively. The basic and diluted weighted average numbers of common shares outstanding for the three and six months ended June 30, 2003 were 23,830,923 and 24,909,282, respectively.

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 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 a new $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 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 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 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. Subsequently, during the second quarter, we have selected eight additional products, making a total of 15 products. Of these, four products have passed bio-equivalency studies, including three products during the six months ended June 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 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 stockholder, thereby increasing its beneficial ownership from approximately 48% to 63%. Based on the current number of shares of common stock and options outstanding, if the 2,176,000 shares of Series B preferred stock were converted to common stock, Sun Pharma's beneficial ownership would increase to approximately 67%. The Series B preferred stock is convertible three years from its date of issuance or following a person (other than Sun Pharma and its affiliates) acquiring control of the Corporation.

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 six months ended June 30, 2004, 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 six months ended June 30, 2004 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 June 30, 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%). As of June 30, 2004 we have borrowed $5.0 million from Citibank, which is due within one year from June 30, 2004, and has been classified as current on the accompanying balance sheet.

11. COMMON STOCK ISSUANCES

We issued 5,000 and 368,263 shares of common stock to our employees upon exercise of their stock options during the second quarter of 2004 and 2003, respectively. No common stock was issued to the directors as compensation for attendance at board and committee meetings during the second quarter of 2004 as compared to 11,000 shares issued during the second quarter of 2003.

12. PREFERRED STOCK ISSUANCES

We issued 2,176,000 shares of preferred stock to Sun Global during the six months ended June 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.

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 two wholesale customers accounted for approximately 76% and 77% of sales during the six months ended June 30, 2004 and June 30, 2003, respectively. Balances due from these wholesalers represented approximately 85% of gross accounts receivable at June 30, 2004 and 66% of gross accounts receivables at December 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 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.

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 phenylpropanolamine (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. Also, the plaintiff in the state lawsuit stipulated to a dismissal of the lawsuit and the case was formally dismissed by the state court on April 8, 2004.

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.

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 June 30, 2004 and the related statements of operations, stockholders' equity and cash flows for the three-month and six-month periods ended June 30, 2004 and June 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 expressed an unqualified opinion on those financial statements.

REHMANN ROBSON

Troy, Michigan
July 14, 2004

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 $8.8 million for the six months ended June 30, 2004 as compared to $3.7 million for the corresponding period of 2003. This $8.8 million is the net cash generated after $1.5 million utilized in increase of accounts receivable and $3.5 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 incurred a net loss of $0.7 million during the six months ended June 30, 2004 compared to earning net income $6.5 million during the corresponding period of 2003. The loss was primarily due to non-cash research and development expense (R&D) of $12.5 million for the six months ended June 30, 2004 compared to no similar expense during the corresponding period of 2003. This non-cash R&D expense related to 3 products passing their bio-equivalency studies during the six months ended June 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 3 filed during the six months ended June 30, 2004. Of these, 14 have been approved and four are pending approval.

THREE MONTHS AND SIX MONTHS ENDED JUNE 30, 2004 COMPARED WITH THREE MONTHS AND SIX MONTHS ENDED JUNE 30, 2003

NET SALES.

Net sales for the three months and six months ended June 30, 2004 were $14.8 million and $28.4 million, respectively, as compared to $11.9 million and $20.6 million, respectively for the corresponding periods of 2003, reflecting increases of 24% and 38%, 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 June 30, 2004, we manufacture and market all except one of the approved products. Sales of three products accounted for 89% of our net sales during the six months ended June 30, 2004 as compared to 86% during the six months ended June 30, 2003.

GROSS PROFIT.

We earned a gross profit of $9.1 million and $17.3 million during the three months and six months ended June 30, 2004, respectively, as compared to a gross profit of $7.5 million and $12.0 million during the corresponding periods in 2003, reflecting increases of 21% and 44%, respectively. The improvement was primarily due to higher sales volumes and better-cost absorption of operational overheads.

The gross profit as a percentage of net sales has also improved for the six months ended June 30, 2004 as compared to the corresponding period of 2003. The percentage for the six months ended June 30, 2004 was 61% as compared to 58% for the corresponding period in 2003. The increase was the result of:

- Reduction in 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 and six months ended June 30, 2004 were $1.4 million and $2.7 million, respectively, as compared to $2.1 million and $3.1 million, respectively, for the same periods in 2003. This represents decreases of 33% and 11%, respectively. Selling, general and administrative expenses, as a percentage of net sales, during the six months ended June 30, 2004 have decreased to 9.5% compared to 15% 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 six months ended June 30, 2004.

RESEARCH AND DEVELOPMENT EXPENSES.

Cash research and development expenses during the three months and six months ended June, 2004 were $1.4 million and $2.5 million, respectively, as compared to $0.6 million and $1.5 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 $12.5 million (technology transfer costs) have been recorded for the six months ended June 30, 2004 for 1,632,000 shares of preferred stock earned by Sun Global for 3 products transfers during the six months ended June 30, 2004. There were no non-cash research and development expenses during the corresponding period of 2003.

OPERATING INCOME

We earned operating income of $1.6 million and incurred an operating loss of $0.4 million during the three months and six months ended June 30, 2004 as compared to operating income of $4.7 million and $7.3 million during the corresponding periods in 2003. The decreases were primarily due to higher non-cash research and development expense of $4.7 million and $12.5 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 $0.3 million, respectively, for the three months and six months ended June 30, 2004 compared to $0.4 million and $0.8 million, respectively, for the corresponding periods of 2003. 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, the total outstanding loan of $6.4 million to the EDC and $3.1 million to The Bank of Nova Scotia during 2003 and 2004.

RESULTS OF OPERATIONS.

We earned net income of $1.5 million and incurred a net loss of $0.7 million, respectively for the three months and six months ended June 30, 2004 as compared to earning net income of $4.3 million and $6.5 million for the corresponding periods of 2003.

The significantly reduced results of operations in the six months ended June 30, 2004 are primarily due to non-cash research and development expense of $12.5 million compared to no similar expense in the corresponding period of 2003.

LIQUIDITY AND CAPITAL RESOURCES.

During the six months ended June 30, 2004, we generated net cash from operations of $8.8 million as compared to $3.7 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 $8.8 million is the net cash generated after $1.5 million utilized in increase of accounts receivable and $3.5 million utilized in increase of inventories.

In addition to repaying the entire debt of $4.4 million to ICICI Bank Limited, repaying a portion of the EDC loan of $6.1 million on April 13, 2004 and making a scheduled payment of $3.1 million to The Bank of Nova Scotia, operations have generated cash sufficient to fund our capital expenditures of $2.5 million during the six months ended June 30, 2004. The capital expenditures were primarily for expanding manufacturing facilities and purchasing related equipment.

At June 30, 2004, the Corporation had positive working capital of $1.4 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 $8.8 million of debt obligations classified as current at December 31, 2003 and reductions in current liabilities from 2003 related primarily to technology transfer costs.

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 June 30, 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 standby letter of credit provided by Sun Pharma. We borrowed $6.0 million of the line of credit to pay off the EDC, and have repaid $1.0 million to Citibank. It is anticipated that the $5 million available 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 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 continued increases in sales and improvement in cash flows 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 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, fifteen products have been selected

for development by the Company and four of these products have passed their respective bio-equivalency studies (one in 2003 and three in the first six months of 2004). If some of the remaining eleven 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 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 stockholders.

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%, 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 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 June 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

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. 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.

During the quarter ended June 30, 2004, registrant issued 544,000 preferred shares to Sun Global in exchange for the transfer of 1 product 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 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 for $9.00 per share and the rights to the options were acquired for $9.00 less the exercise price of each option.

ITEM 4. SUBMISSIONS OF MATTERS TO A VOTE OF SECURITY HOLDERS

The Annual Meeting of the Shareholders of the Corporation was held on June 7, 2004 in Detroit, Michigan for the purpose of electing three directors for the three-year terms expiring in 2007 and upon the election and qualification of their successors.

NAME OF THE DIRECTOR	VOTES "FOR"	VOTES WITHHELD
William C. Brooks	23,432,399	137,680
Timothy S. Manney	23,432,399	137,680
Sudhir V. Valia	23,164,269	405,810

The names of the other directors and their remaining terms are as follows:

NAME OF DIRECTOR	TERM
Dilip S. Shanghvi	2006
Jitendra N. Doshi	2006

Sailesh T. Desai	2005
Georges Ugeux	2005

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

3.10 Amendment to Amended and Restated By-Laws dated May 31, 2004

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 April 30, 2004, the Corporation filed a Form 8-K disclosing in item 12 thereof its results of operations for the quarter ended March 31, 2004.

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: July 20, 2004

EXHIBIT INDEX

3.10 Amendment to Amended and Restated Bylaws dated May 31, 2004.

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.