CARACO PHARMACEUTICAL LABORATORIES LTD
Form 10QSB
November 05, 2003

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

FORM 10-QSB

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

for the quarterly period ended September 30, 2003

[ ] TRANSITION REPORT PURSUANT TO SECTION 13
OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
for the transaction period from _____ to _____

Commission File No. 0-24676

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

MICHIGAN	38-2505723
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
1150 ELIJAH MCCOY DRIVE, DETROIT, MICHIGAN (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 [ ]

As of October 30, 2003, registrant had 24,564,828 shares of common stock issued and outstanding.

Transitional Small Business Disclosure Format (check one):

Yes [ ] No [X]

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CARACO PHARMACEUTICAL LABORATORIES LTD.
UNAUDITED BALANCE SHEET

	30-Sep-03	30-Dec-02
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 2,851,831	$ 534,228
Accounts receivable, net	6,409,638	5,484,135
Inventories	7,483,310	5,615,962
Prepaid expenses and deposits	1,476,282	471,314
Total current assets	18,221,061	12,105,639
PROPERTY, PLANT AND EQUIPMENT - AT COST		
Land	197,305	197,305
Building and improvements	7,614,122	7,346,797
Equipment	6,390,585	5,458,314
Furniture and fixtures	349,114	232,112
Total	14,551,126	13,234,528
Less: accumulated depreciation	5,910,620	5,487,018
Net property, plant & equipment	8,640,506	7,747,510
Total assets	$ 26,861,567	$ 19,853,149
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES		
Accounts payable - Sun	2,667,579	2,024,028
Accounts payable	667,143	1,958,809
Accrued expenses	1,760,223	1,391,623
Current portion of notes payable to stockholders	-	5,850,000
Current portion of bank loans payable	8,750,000	625,000
EDC debt classified as current	1,214,753	1,004,000
Preferred stock dividends payable, current	-	350,380
Accrued interest	128,820	549,082
Total current liabilities	15,188,518	13,752,892
LONG-TERM LIABILITIES		
Notes payable to principal stockholder - Sun	2,850,000	3,850,000
EDC debt	5,478,143	6,598,547
Bank loans payable	8,750,000	15,275,000
Total long-term liabilities	17,078,143	25,723,547
Total liabilities	32,266,661	39,476,439
STOCKHOLDERS' DEFICIT		
Common stock, no par value, authorized 30,000,000 shares; issued and outstanding shares - 24,518,428 shares	41,498,569	40,449,508
Additional paid in capital	2,378,735	282,858
Subscription in advance for stock option exercise	11,500	7,520

Preferred stock dividends	(350,380)	(350,380)
Accumulated deficit	(48,943,518)	(60,012,796)
Total stockholders' deficit	(5,405,094)	(19,623,290)
Total liabilities and stockholders' deficit	$ 26,861,567	$ 19,853,149

See accompanying notes

CARACO PHARMACEUTICAL LABORATORIES, LTD.
UNAUDITED STATEMENTS OF OPERATIONS

	NINE MONTHS ENDED 30th September		THREE MONTHS END 30th September	
	2003	2002	2003	2
Net sales	32,905,662	14,828,849	12,294,125	5,8
Cost of goods sold	13,112,198	7,448,809	4,458,785	3,0
Gross profit	19,793,464	7,380,040	7,835,340	2,8
Selling, general and administrative expenses	5,689,566	2,648,202	2,599,745	8
R&D cost	2,018,029	2,541,449	491,310	9
R&D cost - Affiliate (see note 7 on R&D expense)	-	2,790,720	-	
Operating income / (loss)	12,085,869	(600,331)	4,744,285	1,0
Interest				
Interest expense	(1,041,381)	(1,130,898)	(223,660)	(3
Interest income	24,790	10,798	17,747	
Net interest expense	(1,016,591)	(1,120,100)	(205,914)	(3
Net income / (loss)	11,069,277	(1,720,431)	4,538,371	7
Net income / (loss) per common share				
Basic	0.46	(0.08)	0.19	
Diluted	0.44	(0.08)	0.18	

See accompanying notes

CARACO PHARMACEUTICAL LABORATORIES, LTD.
UNAUDITED STATEMENTS OF CASH FLOWS

	Nine Months ended September 30, 2003	2002
Cash flows from operating activities:		
Net income / (loss)	$ 11,069,277	$ (1,720,431)
Adjustments to reconcile net income / (loss) to net cash provided by / used in operating activities		
Depreciation	422,179	348,571
Common shares issued in lieu of cash for compensation	262,450	34,500
Common shares to be issued for R&D Cost - Affiliate	-	2,790,720
Variable compensation expense for stock options granted and extended to director	1,833,612	-
Changes in operating assets and liabilities which provided / (used) cash:		
Accounts receivable	(925,503)	(1,975,558)
Inventories	(1,867,348)	(1,872,650)
Prepaid expenses and deposits	(1,004,969)	(177,559)
Accounts payable	(648,115)	662,893
Accrued expenses and Interest	210,663	(81,033)
Net cash provided by / (used) in operating activities	9,352,247	(1,990,549)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(1,315,204)	(1,273,055)
Cash flows from financing activities:		
Proceeds from long-term debt	1,600,000	900,000
Proceeds from sale of shares in private placement	-	1,692,000
Advance for stock option exercise	11,500	7,520
Net short term repayments	-	(75,000)
Proceeds from exercise of stock options	779,091	-
Payment of preferred stock dividends	(350,380)	-
Payments of EDC debt	(909,651)	(554,000)
Net Loans (repaid to) / received from shareholders	(6,850,000)	1,400,000
Net cash (used in) / provided by financing activities	(5,719,440)	3,370,520
Net increase in cash and cash equivalents	2,317,603	106,916
Cash and cash equivalents, beginning of period	534,228	241,110

Cash and cash equivalents, end of period	$ 2,851,831	$ 348,026

See accompanying notes

CARACO PHARMACEUTICAL LABORATORIES, LTD.
UNAUDITED STATEMENTS OF SHAREHOLDERS' DEFICIT FOR THE
NINE MONTHS ENDED SEPTEMBER 30, 2003

	PREFERRED STOCK SHARES	PREFERRED STOCK AMOUNT	COMMON STOCK SHARES	COMMON STOCK AMOUNT	ADDITIONAL PAID IN CAPITAL	PREF ST DIVI
Balance at January 1, 2003	-	-	23,762,532	$40,457,028	$ 282,858	$(35
Issuances of common stock to directors as compensation in lieu of cash			31,000	262,450		
Subscriptions in advance				11,500		
Issuances of common stock upon exercise of stock options			724,896	779,091	2,095,877	
Net Profit						
Balance at September 30, 2003	-	-	24,518,428	$41,510,069	$2,378,735	$(35

See accompanying notes

CARACO PHARMACEUTICAL LABORATORIES, LTD.

NOTES TO FINANCIAL STATEMENTS (UNAUDITED)

1. BASIS OF PRESENTATION

The balance sheet as of September 30, 2003 and the related statements of operations, stockholders' deficit and cash flows for the three months and the nine months ended September 30, 2003 and 2002 are unaudited. In the opinion of management, all adjustments necessary for a fair presentation of such financial statements have been included. Such adjustments consisted only of normal recurring items. Interim results are not necessarily indicative of results for the full year.

The financial statements as of September 30, 2003 and for the three months and nine months ended September 30, 2003 and 2002 should be read in conjunction with the financial statements and notes thereto included in the Corporation's Annual Report on Form 10-KSB for the year ended December 31, 2002.

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

2. ORGANIZATION AND NATURE OF BUSINESS

Caraco Pharmaceutical Laboratories, Ltd. ("Caraco" or "the Corporation" which is also referred to as we, us or our), is 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 for their equivalence in quality and bioavailability.

Our present product portfolio includes 17 products in 30 strengths in 70 package sizes. We are currently marketing 16 of the products in 28 strengths and 62 package sizes. The products are intended to treat a variety of disorders including the following: hypertension, arthritis, epilepsy, diabetes and pain management.

To date, we have submitted 14 Abbreviated New Drug Applications (ANDAs) to the Food and Drug Administration ("FDA"). Of these, we have received approvals for 12 ANDAs, one each of which was received during the first quarter and the third quarter; we have 2 ANDAs pending approval. We also have 5 Drug Efficacy Study Implementations (DESI) products.

A significant source of our funding has been from private placement offerings and loans. Sun Pharmaceutical Industries, Limited, a specialty pharmaceutical corporation organized under the laws of India ("Sun Pharma"), which owns approximately 48% of our outstanding shares has contributed equity capital and has advanced us loans and has assisted us in obtaining line of credit loans by acting as guarantor. Also, pursuant to a products agreement with us, Sun Pharma has transferred certain products to us. (See "Current Status of the Corporation" and "Sun Pharmaceutical Industries, Limited." below.)

3. CURRENT STATUS OF THE CORPORATION

We have been achieving sales necessary to support our operations since the second quarter of 2002. Net sales for the three months and nine months ended September 30, 2003 were $12.3 million and $32.9 million, respectively, as compared to $5.9 million and $14.8 million, respectively, for the same periods of 2002. We have earned a gross profit of $7.8 million and $19.8 million, respectively, during the three months and nine months ended September 30, 2003 as compared to $2.9 million and $7.4 million during the same periods in 2002. We

earned operating income of $4.7 million and $12.1 million, respectively, during the three months and nine months ended September 30, 2003 as compared to operating income of $1.1 million and an operating loss of $0.6 million, respectively, during the same

periods in 2002. After interest costs, we have earned net income of $4.5 million and $11.1 million, respectively, during the three months and nine months ended September 30, 2003 as compared to a net income of $0.7 million and a net loss of $1.7 million, respectively, during the same periods of 2002. At September 30, 2003, we had a stockholders' deficit of $5.4 million as compared to a deficit of $19.6 million at December 30, 2002. See "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations."

4. RECENT ACCOUNTING PRONOUNCEMENTS

In January 2003, the Financial Accounting Standards Board (FASB) issued Financial Interpretation No. (FIN) 46 "Consolidation of Variable Interest Entities." This standard clarifies the application of Accounting Research Bulletin No. 51, "Consolidated Financial Statements," and addresses consolidation by business enterprises of variable interest entities, more commonly known as "Special Purpose Entities" or "SPE'S." FIN 46 requires existing unconsolidated variable interest entities' interests to be consolidated by their primary beneficiaries if the entities do not effectively disperse risk among the parties involved. FIN 46 also enhances the disclosure requirements related to variable interest entities. The interpretation is effective with respect to interests in variable interest entities created after January 31, 2003. For interests in variable interest entities created before February 1, 2003, the interpretation applies to the first interim or annual reporting period beginning after June 15, 2003. The subject matter of FIN 46 is not currently applicable to the Corporation; accordingly, it is not expected that the provisions of FIN 46 will have a material impact on financial position, results of operations or cash flows of the Corporation.

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 / (LOSS) PER SHARE

Earnings / (Loss) per share is computed using the weighted average number of common shares outstanding during each period and considers a dual presentation and reconciliation of "basic" and "diluted" per share amounts. Diluted reflects the potential dilution of all common stock equivalents.

The basic and diluted weighted average numbers of common shares outstanding for the nine months ended September 30, 2003 were 23,997,673 and 25,317,464, respectively. The basic and diluted weighted average numbers of common shares outstanding for the nine months ending September 30, 2002 were both 21,593,243.

6. MORTGAGE NOTE WITH EDC

Our manufacturing facility and executive offices were constructed in 1990 and financed by $9.1 million loan pursuant to a Development and Loan Agreement dated August 10, 1990 (the "Agreement") from the Economic Development Corporation of the City of Detroit (the "EDC").

At September 30, 2003, the loan from the EDC has been reduced to $6.7 million. The loan was collateralized by a first mortgage, effectively, on all of the Corporation's property and equipment purchased pursuant to the Agreement. The loan was restructured on April 23, 2003, but with the revised terms effective as of January 1, 2003. The loan has been extended for six years, with interest rates starting at 2.75% p.a. and increasing to 5.16% p.a. Under the extension, the EDC retains a first mortgage on our property, and a first lien on our furniture, fixtures equipment and intellectual property. The EDC has removed its first lien on our accounts receivable and inventory. Further, the EDC has eliminated the prior restriction on capital investment in excess of $2 million by permitting us to purchase new capital assets and sell the existing capital assets, as long as we are not in default of any of our obligations. Further, we have to ensure that as a result of such transactions, the book value of our assets is not reduced below the balance as of December 31, 2002 and the Corporation retains the proceeds of any such sales. The obligations of the Corporation to the EDC have been appropriately classified on the accompanying balance sheet in accordance with the terms of the restructured loan.

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 have loaned us approximately $10.0 million. Prior to June 30, 2003, we have repaid $0.5 million of these loans. Between June 30, 2003 and September 30, 2003, we have repaid an additional $6.6 million of these loans, leaving, as of September 30, 2003, a loan balance of approximately $2.9 million payable to Sun Pharma by August 2006 at an interest rate of 8.0% p.a. payable quarterly.

Sun Pharma has 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. Such lines are fully utilized as of September 30, 2003.

In August 1997, we entered into an agreement, whereby Sun Pharma was required to transfer to us the technology formula for 25 generic pharmaceutical products over a period of five years through August 2002. We exchanged 544,000 shares of our common stock for each technology transfer of an ANDA product (when a bio-equivalency study was successfully completed) and 181,333 shares for each technology transfer of a DESI product. The products provided to us from 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 below, we have entered into a new agreement with an affiliate of Sun Pharma.

In November 2002, we entered into a new products agreement with Sun Pharma Global, Inc., an affiliate of Sun Pharma ("Sun Global"), for the transfer of the technology formula 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 study. Shares issued to Sun Global in exchange for the product transfers are valued at market and are included as non-cash research and development expenses. Depending on the number of products transferred and the fair value of the preferred shares attributable thereto, the preferred shares earned by Sun Global could cause our non-cash research and development expenses to increase to an amount which would significantly decrease profit or create a loss. Preferred shares are be earned by Sun Global for the product transfers even if the product is not successfully produced and marketed.

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

Sun Pharma supplies us with certain raw materials and machinery and equipment to increase our production and productivity.

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

8. TERM LOAN FROM ICICI BANK

The Corporation had obtained a term loan of $5 million from ICICI Bank of India with the guarantee of Sun Pharma. This term loan has been used to finance research and development activities, upgrade facilities, repay loans and meet working capital requirements. Interest payments are due quarterly, with quarterly principal payments scheduled to be made from December 2003 through September 2005. That portion of the loan which is due within one year from September 30, 2003, $2,500,000, has been classified as current on the accompanying balance sheet.

9. TERM LOAN FROM 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 has been used to finance research and development activities, upgrade facilities, repay other loans and meet working capital requirements. Interest payments are due quarterly, with semi-annual principal payments scheduled to be made from February 2004 through September 2005. That portion of the loan which is due within one year from September 30, 2003, $6,250,000, has been classified as current on the accompanying balance sheet.

10. COMMON STOCK ISSUANCES

We issued 31,000 shares of common stock to the directors as compensation for attendance at board and committee meetings held during 2002 and 2003. We have also issued to our officers, employees and certain ex-employees, 724,896 shares of common stock upon exercise of their stock options during the second and third quarters of 2003.

11. SALES AND CUSTOMERS

A major portion of our business with our customers is facilitated by the use of wholesalers like AmeriSource-Bergen, Cardinal Health, etc., who have large warehousing facilities to store products of multiple companies. We have independent contracts with our end customers, who procure our goods from the wholesalers. The role of the wholesalers is solely to act as an intermediary in the supply chain. Therefore, even though the sales are initially recorded as made to the wholesaler, the end user is a secondary customer. It is the end customer who decides the wholesaler through whom it would like to procure our products.

Invoicing of such shipments to one such wholesaler, namely AmeriSource Bergen, accounted for approximately 72% and 65% of net sales during the nine months ended September 30, 2003 and year-end 2002, respectively. Balances due from this wholesaler represented approximately 78% of accounts receivable at September 30, 2003 and 80% of accounts receivables at December 31, 2002.

12. LITIGATION

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 intend to vigorously defend ourselves against these claims, which we believe have no merit.

We have been named as one of two defendants and as one of several defendants in two separate product liability suits, involving Miraphen, which contains phenylpropanalomine (PPA), one in federal court in Pennsylvania and

another in state court in New Jersey, respectively. These lawsuits seek damages generally for personal injury as well as punitive damages under a variety of liability theories including strict products liability, breach of warranty and negligence. The Federal lawsuit does not set forth a specific dollar amount of damages requested; the state lawsuit seeks damages of $20 million. We are only in the initial stages of discovery. Our products liability insurer has informed us that we are not covered by insurance because the policy does not apply to any

claim relating to any product containing PPA. Although the ultimate outcome of these cases and the potential effect on us cannot be determined, we believe we have substantial defenses to the claims and we will vigorously defend the lawsuits.

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

FORWARD LOOKING STATEMENTS

This report, other than the historical financial and business information, may contain forward-looking statements. Those statements include statements regarding the intent, belief, and current expectation of the Corporation. The statements are not guarantees of future performance and are subject to risks and uncertainties that cannot be predicted or quantified. Consequently, actual results could differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include: (i) that the information is of a preliminary nature and may be subject to further adjustment; (ii) not obtaining FDA approval for new products or delays in receiving FDA approvals; (iii) governmental restrictions on the sale of certain products; (iv) dependence on key personnel; (v) development by competitors of new or superior products or cheaper products or new technology for the production of products or the entry into the market of new competitors; (vi) market and customer acceptance and demand for new pharmaceutical products, (vii) availability of raw materials, (viii) timing and success of product development and launch (ix) integrity and reliability of the Corporation's data; (x) conflicts of interests between Sun Pharma and its affiliates and the Corporation, which are all engaged in the same business, in among other things, determining which products to transfer to us and which to keep for themselves, how much to charge us for active raw materials, equipment and/or production machinery, when and how their loans to us shall be repaid, whether to continue to perform formulation and analytical research for us at its Mumbai facility, whether and how much it shall fund our operations, and which employees, if any, it determines to transfer to us; and (xi) other risks identified in this report and identified from time to time in the Corporation reports and registration statements filed with the Securities and Exchange Commission.

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

THREE MONTHS AND NINE MONTHS ENDED SEPTEMBER 30, 2003 COMPARED WITH THREE MONTHS AND NINE MONTHS ENDED SEPTEMBER 30, 2002

NET SALES. Net sales for the three months and nine months ended September 30, 2003 were $12,294,125 and $32,905,662, respectively, as compared to $5,899,441 and $14,828,849, respectively, for the same periods of 2002 and reflect increases of almost 108% and 122%, respectively. The increases are due to the higher production and marketing of most of our products. Sales of Metformin Hydrochloride and Metoprolol Tartrate accounted for 78% of our net sales for the three and nine months ended September 30, 2003.

GROSS PROFIT. We earned gross profits of $7,835,340 and $19,793,464, respectively, during the three months and nine months ended September 30, 2003 as compared to gross profits of $2,864,101 and $7,380,040, respectively, during the corresponding periods in 2002. The improvement was primarily due to higher sales volumes with improved margins due to change in sales mix to more profitable products such as Metroprolol Tartrate, Metformin Hydrochloride, Tramadol Hydrochloride and Oxaprozin; acquiring raw materials at more

competitive prices; reduction in manufacturing costs due to increased batch sizes; improved efficiency in the overall manufacturing process associated with higher utilization of plant capacity; utilization of $1.6 million and $1.3 million equipment installed during the year ended December 31, 2002 and during the nine months ended September 30, 2003, respectively; and enhanced ability to absorb operational overheads due to higher sales.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES. Selling, general and administrative expenses for the three months and nine months ended September 30, 2003 were $2,599,745 and $5,689,566, respectively, as compared to $808,863 and $2,648,202, respectively, for the same periods in 2002. This represents increases of 221% and 114% for the two periods, respectively. Selling, general and administrative expenses have marginally increased to 21% and 17% of net sales during the three months and nine months ended September 30, 2003 from 14% and 18% of net sales during the same periods in 2002.

The increase of $3.0 million for the nine-month period was due to additional professional costs ($0.5 million) primarily in connection with the ongoing litigation against the Company (See note 12 of the notes to the financial statements), and recording of variable compensation expense on stock options granted and extended to a director ($1.8 million) and other costs related to sales and marketing.

RESEARCH AND DEVELOPMENT EXPENSES. Cash research and development expenses of $491,310 and $2,018,029, respectively, for the three months and nine months ended September 30, 2003 were lower by 50% and 21%, respectively, when compared with $969,947 and $2,541,449, respectively, incurred during the corresponding periods of 2002. The major reason for the lower cash research and development expenses was that there were no expenditures for bio-study costs during the second and third quarters of 2003.

No non-cash R&D charges have been recorded for the three month and nine months ended September 30, 2003 because no products have been transferred by Sun Global with respect to the products agreement and, accordingly, no preferred shares have been earned. We recorded expenditures of $2,790,720 for the nine months ended September 30, 2002 for non-cash R&D charges relating to common shares earned by Sun Pharma for 2 product transfers.

DEPRECIATION EXPENSE. We incurred depreciation expense of $422,179 for the nine months ended September 30, 2003 as compared to $348,571 during the corresponding period of 2002. Depreciation has increased due to additional investment into capital assets of $1.6 million during 2002 and additional capital investments of $1.3 million during the first nine months of 2003.

INTEREST EXPENSE. Interest expense was $223,660 and $1,041,381 for the three and nine months ended September 30, 2003, respectively, as compared to $384,917 and $1,130,898, respectively, for the same periods of 2002, which was incurred in connection with our mortgage obligation to the EDC, interest on notes payable to Sun Pharma and Sun Global as well as on term loans granted to us by ICICI Bank and the Bank of Nova Scotia, and guaranteed by Sun Pharma. The reduction in interest expense, which was partially offset by an additional borrowing of $1.6 million from bank of Nova Scotia during the first quarter of 2003, is primarily due to our repaying $6.6 million of our debt to Sun Pharma during the third quarter of 2003.

RESULTS OF OPERATIONS. We earned net income of $4,538,371 and $11,069,277, respectively, for the three and nine months ended September 30, 2003 as compared to net income of $708,651 and a net loss of $1,720,431, respectively, for the same periods of 2002, reflecting improvement of almost 540% and 743%, respectively. The significantly improved results of operations in the current three-month and nine-month periods as compared to the corresponding periods of 2002 are primarily due to significantly higher sales volumes, improved cost absorption due to increased sales, improved product mix, obtaining more competitive prices for raw materials and having no non-cash research and development expenses.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2003, the Corporation had positive working capital of $3.0 million compared with a negative working capital of $1.6 million at December 31, 2002. The positive working capital position is primarily due to our profitable operations during 2003. As of December 31, 2002, the negative working capital was mainly due to the classification of the $5.9 million loan payable to Sun Pharma and its affiliates as current since these loans were due to mature in October 2003.

To enable the Corporation to fund the development of its facility in 1990, the Corporation borrowed $9.1 million from the EDC. The EDC loan was restructured effective as of January 1, 2003. As of September 30, 2003, $6.7 million is

outstanding. To enable the Corporation to fund its research and development activities and working capital needs, Sun Pharma has (i) loaned the Corporation a total of approximately $10.0 million, of which approximately $2.9 is outstanding as of September 30, 2003; and (ii) become a security guarantor for a credit lines of $5 million from ICICI Bank of India and $12.5 million from Bank of Nova Scotia. As of September 30, 2003, the Corporation has received $5 million from ICICI Bank of India and $12.5 million from Bank of Nova Scotia through these credit facilities

FDA

We underwent FDA inspections in November 2002 and we were found to be in substantial compliance with cGMPs. Although we did receive an FDA 483, we do not believe the observations are material and we have taken appropriate remedial actions. During each of the first and third quarters of 2003, we received approval for one of the then pending ANDAs. We now have 2 ANDAs pending approval.

FUTURE OUTLOOK

We have experienced difficult times in the past. With our having been found to be in substantial compliance by the FDA with respect to cGMPs during the second quarter of 2001 and the fourth quarter of 2002, and also with the approvals of 12 ANDAs during 2001, 2002 and 2003, management believes that our future outlook is brighter. Revenues have been constantly improving and consequently, so have operating income, net income and cash flows. The Corporation expects revenues to improve during the rest of 2003. The Corporation has raised its 2003 revenue estimate to $45 million. Also, management is focused on cost controls and consumption controls. Management's plans for improving profitability, cash flow and operations for the remainder of 2003 and for 2004 are set forth below. We also expect Sun Pharma to continue to support us, as it has in the past.

The FDA had directed the manufacturers and distributors of Guaifenesin LA, which, including us, consists of 66 companies, to cease manufacturing Guaifenesin LA by May 23, 2003 and to cease all sales after November 2003. The FDA has determined that Guaifenesin LA is a new drug, which requires a new drug application and approval before it may be manufactured and sold. We intend to comply with the FDA's directive. We do not intend to file a new drug application with the FDA with respect to Guaifenesin LA, however, we are seeking clarification from the FDA as to whether application to manufacture and sell Guaifenesin LA may be made other than through a new drug application. We have discontinued to market the product since the third quarter of 2003. Net sales of Guaifenesin LA during the year ended December 31, 2002 and during the nine months ended September 30, 2003 were $1.65 million and $1.38 million, respectively.

As disclosed, under the products agreement dated November 21, 2002, between Sun Global and us, Sun Global has agreed to transfer the technology for 25 products to us over a five year period in exchange for 544,000 preferred shares (which are convertible on a one-to-one basis into common shares) per product. Depending on the number of products transferred to us pursuant to the products agreement between Sun Global and us and the fair value of the preferred shares attributable thereto, the preferred shares earned by Sun Global could cause our non-cash research and development expenses to increase to an amount which would significantly decrease profit or create a loss. Since the date of the products agreement, however, no products have yet been selected and agreed upon by the Company, the Independent Committee of Directors of the Company and Sun Global. While they are engaged in discussions, the Company has decided to perform research and development for certain products ("Products") (currently six) presented for consideration by Sun Global pursuant to the products agreement. However, if the Company does not select and accept any such Products for itself for filing as ANDAs with the FDA, Sun Global will reimburse the Company for all of its research and development and other costs associated with such Product. Sun Global may then file the ANDA with the FDA in its name, and the Company and Sun Global may negotiate an agreement pursuant to which the Company will manufacture and market the Product. The consideration payable to the Company will be no less favorable than what unrelated third parties would receive.

Management's continued plans for the remainder of 2003 and 2004 include:

(a) Continued focus on FDA compliance.

(b) Continued research and development activities.

(c) Continued expenditures for capital investment including equipment and expansion of capacity.

(d) Increased market share for certain existing products and recently introduced new products and enhanced customer reach and satisfaction.

(e) Prompt introduction of new approved products to the market.

(f) Achieving further operational efficiencies by attaining economies of scale and cost reduction per unit.

(g) Increase the number of products, as well as anticipated volume increases for existing products, which, in turn, will improve manufacturing capacity utilization.

(h) Considering alternative ways of increasing cash flow including developing, manufacturing and marketing ANDAs owned by Sun Pharma.

(i) Locating and utilizing facilities of contract-manufacturers to enhance production and therefore sales.

(j) Possible raising of equity capital through the sale of common stock registered on Form SB-2.

(k) Raising of additional lines of credit to support increasing working capital requirements.

(l) Further reducing debt, if adequately supported by positive cash flows.

ITEM 3. 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 the 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 the period this Form 10-QSB was being prepared that has materially affected, or is reasonably likely to materially affect, the Corporation's internal control over financial reporting.

PART II -- OTHER INFORMATION

ITEM 2. CHANGES IN SECURITIES

During the nine months ended September 30, 2003, we issued 31,000 shares of our common stock to our non-employee directors for past attendance at board and committee meetings. The shares of common stock were issued pursuant to exemptions from registration under Section 4(2), 4(6) and Regulation D under the Securities Act of 1933.

ITEM 5. OTHER INFORMATION

Jitendra N. Doshi was promoted to the position of interim Chief Executive Officer of the Corporation, effective as of October 1, 2003, following the retirement of Narenda N. Borkar, the former Chief Executive Officer of the Corporation, on September 30, 2003. Mr. Doshi was the Chief Operating Officer (since June 2001) and is the Chief Financial Officer (since November 2002) of the Corporation.

On October 1, 2003, David A. Hagelstein resigned as a director of the Corporation.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) 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.

(b) Reports on Form 8-K.

On July 31, 2003, the Corporation filed a Form 8-K disclosing in Item 12 thereof and including as an exhibit the press release announcing its result of operations for the second quarter ended June 30, 2003.

SIGNATURE

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

CARACO PHARMACEUTICAL LABORATORIES, LTD.

By: /s/ Jitendra N. Doshi

Jitendra N. Doshi
Chief Executive Officer
and Chief Financial Officer

Dated: November 5, 2003

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.