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CARACO PHARMACEUTICAL LABORATORIES LTD  
Form 10QSB  
August 08, 2003

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

FORM 10-QSB

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

for the quarterly period ended June 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  
(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

As of August 7, 2003, registrant had 24,382,353 shares of common stock issued and outstanding.

Transitional Small Business Disclosure Format (check one):

Yes  No

CARACO PHARMACEUTICAL LABORATORIES LTD.  
UNAUDITED BALANCE SHEET

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PARTICULARS

June 30, 20

ASSETS	
Current assets	
Cash and cash equivalents	\$ 4,24
Accounts receivable, net	9,39
Inventories	5,24
Prepaid expenses and deposits	91
	-----
Total current assets	19,79
	-----
Property, plant and equipment - at cost	
Land	19
Building and improvements	7,49
Equipment	5,96
Furniture and fixtures	29
	-----
Total	13,94
Less: accumulated depreciation	5,80
	-----
Net property, plant & equipment	8,14
	-----
	-----
Total assets	\$27,94
	=====
LIABILITIES AND STOCKHOLDERS' DEFICIT	
Current liabilities	
Accounts Payable - Sun	2,46
Accounts payable	1,59
Accrued expenses	2,25
Current portion of notes payable to stockholders	5,61
Current portion of bank loans payable	4,37
EDC debt classified as current	1,21
Preferred stock dividends payable, current	
Accrued interest	42
	-----
Total current liabilities	17,93
	-----
Long-term liabilities	
Notes payable to principal stockholders	3,85
EDC debt	5,78
Bank loans payable	13,12
	-----
Total long-term liabilities	22,76
	-----
	-----
Total liabilities	40,69
	-----
Stockholders' deficit	
Common stock, no par value, authorized 30,000,000 shares; issued and outstanding 24,142,995 shares	40,79
Additional paid in capital	28
Preferred stock dividends	(35)

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Accumulated deficit	(53,48
Total stockholders' deficit	(12,75
Total liabilities and stockholders' deficit	\$27,94

See accompanying notes

2

CARACO PHARMACEUTICAL LABORATORIES, LTD.  
UNAUDITED STATEMENTS OF OPERATIONS

PARTICULARS	SIX MONTHS ENDED 30-JUN	
	2003	2002
Net Sales	\$20,611,537	\$ 8,929,408
Cost of goods sold	8,653,413	4,413,468
Gross profit	11,958,124	4,515,940
Selling, general & administrative expenses	3,089,820	1,839,689
R&D cost	1,526,719	1,571,502
R&D cost - Affiliate	-	2,790,720
Operating income / (loss)	7,341,585	(1,685,971)
Interest		
Interest expense	(817,722)	(745,982)
Interest income	7,043	2,420
Net interest expense	(810,680)	(743,562)
Net income / (loss)	\$ 6,530,906	\$ (2,429,533)
Net income / (loss) per common share		
Basic	0.27	(0.11)
Diluted	0.26	(0.11)

See accompanying notes

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3

CARACO PHARMACEUTICAL LABORATORIES, LTD.  
UNAUDITED STATEMENTS OF CASH FLOWS

PARTICULARS	Six Months ended 2003
-----	
Cash flows from operating activities:	
Net income / (loss)	\$6,530,906
Adjustments to reconcile net income / (loss) to net cash provided by / (used in) operating activities	
Depreciation	316,261
Common shares issued in lieu of cash for compensation	32,450
Common shares to be issued for R&D Cost - Affiliate	-
Variable compensation expense for stock options granted & extended to director	851,800
Changes in operating assets and liabilities which provided (used) cash:	
Accounts receivable	(3,914,949)
Inventories	375,536
Prepaid expenses and deposits	(441,715)
Accounts payable	68,467
Accrued expenses and Interest	(106,615)
	-----
Net cash provided by / used in operating activities	3,712,143
	-----
Cash flows from investing activities:	
	-----
Purchases of property, plant and equipment	(712,947)
	-----
Cash flows from financing activities:	
Proceeds from long-term debt	1,600,000
Proceeds from sale of shares in private placement	-
Advance for Stock Option Exercise	-
Net short term repayments	-
Proceeds from exercise of stock options	305,403
Payment of preferred stock dividends	(350,380)
Payments of EDC debt	(604,350)
Net Loans received from / (repaid to) Shareholders	(240,000)
	-----
Net cash provided from financing activities	710,673
	-----
Net (decrease) in cash and cash equivalents	3,709,867
Cash and cash equivalents, beginning of period	534,228
	-----
Cash and cash equivalents, end of period	\$4,244,094
	=====

See accompanying notes

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

	PREFERRED SHARES	STOCK AMOUNT	COMMON SHARES	STOCK AMOUNT	ADDITIONAL PAID IN CAPITAL	PRE S DIV
Balance at January 1, 2003	-	-	\$23,762,532	\$40,457,028	\$282,858	\$(3
Issuances of common stock to directors as compensation in lieu of cash			11,000	32,450		
Issuances of common stock upon exercise of stock options			369,463	305,403		
Net Profit						
Balance at June 30, 2003	-	-	\$24,142,995	\$40,794,881	\$282,858	\$(3

See accompanying notes

CARACO PHARMACEUTICAL LABORATORIES, LTD.

NOTES TO FINANCIAL STATEMENTS (UNAUDITED)

1. BASIS OF PRESENTATION

The balance sheet as of June 30, 2003 and the related statements of operations, stockholders' deficit and cash flows for the three months and the six months ended June 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 June 30, 2003 and for the three months and six months ended June 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.

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

### 2. ORGANIZATION AND NATURE OF BUSINESS

Caraco Pharmaceutical Laboratories, Ltd. ("Caraco" or "the Corporation" which is also referred to as we, us or our), 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 29 strengths in 64 package sizes. We are currently marketing all 17 products. The products are intended to treat a variety of disorders including the following: hypertension, arthritis, seizures, epilepsy, diabetes and pain management.

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

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

6

### 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 six months ended June 30, 2003 were \$11.9 million and \$20.6 million, respectively, as compared to \$5.6 million and \$8.9 million, respectively, for the same periods of 2002. We have earned a gross profit of \$7.5 million and \$12.0 million, respectively, during

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the three months and six months ended June 30, 2003 as compared to \$3.1 million and \$4.5 during the same periods in 2002. We earned an operating profit of \$4.7 million and \$7.3 million, respectively, during the three months and six months ended June 30, 2003 as compared to incurring operating losses of \$1.5 million and \$1.7 million, respectively, during the same periods in 2002. After interest costs, we have earned net income of \$4.3 million and \$6.5 million, respectively, during the three months and six months ended June 30, 2003 as compared to a net losses of \$1.9 million and \$2.4 million, respectively, during the same periods of 2002. At June 30, 2003, we had a stockholders' deficit of \$12.75 million as compared to a deficit of \$21.85 million at June 30, 2002. We have continued to be dependent on the support of Sun Pharma; however, Sun Pharma is not legally obligated to fund our operations. Sun Pharma is also subject to the prevailing regulatory process in India and Sun Pharma may be constrained from fully pursuing its business interests outside of India. We believe, however, that our financial reliance on Sun Pharma has decreased because of the increased revenues and higher cash flows from internal operations since the second quarter of 2002. See "Sun Pharmaceutical Industries, Ltd." and "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations." We received one ANDA approval during the first quarter of 2003. See "Caraco's Products and Product Strategy" below. We have 3 products pending approval with the FDA.

#### 4. COMPUTATION OF 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 six months ended June 30, 2003 were 23,830,923 and 24,909,282, respectively. The basic and diluted weighted average numbers of common shares outstanding for the six months ending June 30, 2002 were 21,470,033 and 22,773,764 respectively.

#### 5. MORTGAGE NOTE WITH EDC

Debt at June 30, 2003 includes \$7.0 million payable to the Economic Development Corporation of the City of Detroit ("EDC") related to funds advanced to the Corporation pursuant to a Development and Loan Agreement (the "Agreement") dated August 10, 1990 as amended. The note was collateralized by a first mortgage, effectively, on all of the Corporation's property and equipment purchased pursuant to the Agreement. The loan was restructured on April 23, 2003, 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% and increasing to 5.16%. Under the extension, the EDC retains a first mortgage on our property, and a first lien on our furniture, fixtures equipment and intellectual property. The EDC has removed its first lien on our accounts receivable and inventory. Further, the EDC has eliminated the prior restriction on capital investment in excess of \$2 million by permitting us, so long as we are not in default of any of our obligations, to purchase new capital assets and sell the existing capital assets so long as a result of such transactions, the book value of our assets is not reduced below the balance as of December 31, 2002 and the proceeds of any such sales are retained by the Corporation. The obligations of the Corporation to the EDC have been classified on the accompanying balance sheet in accordance with the terms of the restructured loan.

#### 6. SUN PHARMACEUTICAL INDUSTRIES LIMITED

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

Further, Sun Pharma has made loans to us, the details of which as of June 30, 2003, are summarized below:

8% Promissory note payable to Sun Pharma, principal balance payable in full in October 2003, with interest payable quarterly.	\$5,300,000
8% Promissory note payable to Sun Pharma, principal balance payable in full in August 2006, with interest payable quarterly.	3,850,000
8% promissory note payable to Sun Pharma Global, Inc., a wholly owned subsidiary of Sun Pharma ("Sun Global"), payable by October 2003 with interest payable quarterly.	200,000
8% short term loan to Sun Pharma, payable upon demand	110,000
	-----
Notes payable to Sun Pharma and Sun Global	\$9,460,000
	=====

Since June 30, 2003, we have paid off \$5.6 million of the above loans to Sun Pharma and its affiliates, and the only loan pending to be paid to Sun is the \$3.85 million loan shown above.

In August 1997, we entered into an agreement, whereby Sun Pharma was required to transfer to us the technology formula for 25 generic pharmaceutical products over a period of five years through August 2002. The agreement has expired. We exchanged 544,000 shares of our common stock for each technology transfer of an ANDA product (when a bio-equivalency study was successfully completed) and 181,333 shares for each technology transfer of a DESI (Drug Efficacy Study Implementation) product. The products provided to us from Sun Pharma were selected by mutual agreement. Under such agreement, we conducted, at our expense, all tests including bioequivalency studies. As of June 30, 2003, Sun Pharma delivered to us the technology for 13 products. A total of 5,802,666 shares were issued to Sun Pharma and its affiliates in exchange for the technology transfer under the old and now expired agreement.

We entered into a new product agreement with Sun Global for the transfer of the technology formula for 25 generic products over a period of 5 years in November 2002 replacing the previous product agreement with Sun Pharma. Under such agreement, we conduct, at our expense, all tests including bioequivalency 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 bioequivalency study. Our shares issued to Sun Global in exchange for the transfer of the products are valued at market and are included in research and development expenses. Depending on the number of products transferred and the fair value of the shares attributable thereto, the issuance of preferred stock to Sun Global could cause our research and development expenses to increase to an amount which would significantly decrease profit or create a loss. Preferred shares are be earned



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by Sun Global even if the product is not successfully produced and marketed.

Sun Pharma has assisted us, by acting as guarantor, in obtaining line of credit loans from ICICI Bank Limited and The Bank of Nova Scotia in the amount of \$5.0 million and \$12.5 million, respectively. Such lines have been fully utilized.

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 also the machinery and equipment to increase productivity and production. During the six months ended June 30, 2003, we purchased \$3.9 million in raw materials and \$0.16 million in machinery from Sun. During the year ended December 31, 2002, we purchased \$2.4 million in raw materials and \$0.3 million in machinery and equipment from Sun Pharma. Such purchases have been made at competitive prices and at better payment terms. Sun is an primary supplier of a significant portion of our raw materials, but is not the sole

8

supplier for such raw materials. Sun has also provided us with qualified technical professionals. Twenty-one of our technical professional employees were former Sun Pharma employees.

Sun Pharma beneficially owns approximately 49% of the currently outstanding shares of Caraco. Five of the eight members of the Board of Directors of Caraco are affiliated with Sun Pharma. The Chief Executive Officer and Chief Financial Officer of Caraco are affiliated with Sun Pharma. As a result, Sun Pharma is subject to a number of conflicts of interest. Sun Pharma is engaged in the same business as Caraco, and there may be conflicts in determining which products will be transferred to Caraco by Sun Pharma's wholly-owned subsidiary, Sun Global, pursuant to its products agreement and which to keep, and how much to charge for active raw materials, equipment and/or production machinery it sells or leases to Caraco. At this time, we are substantially dependent on Sun Pharma and its affiliates for the development of new products. We only have a small in-house development center. We are not prohibited, however, from expanding our in-house development center or from contracting with third parties for technology transfers. We are also considering manufacturing on a contract basis certain products of which the technology and ownership would belong to Sun Pharma. There may also be conflicts in determining when and how its loans to Caraco shall be repaid, whether to continue to perform its formulation and analytical research at its Mumbai facility on behalf of Caraco, and whether and how much it shall fund Caraco's operations and which Sun Pharma employees, if any, it determines to transfer to Caraco. Although Caraco and Sun Pharma attempt, to the extent possible, to avoid conflicts by causing Caraco directors who are affiliated with Sun Pharma to abstain from voting on matters in which Sun Pharma is an interested party, and requiring all business relationships to be on terms no less favorable than with unaffiliated parties, such requirements will not necessarily deter Sun Pharma from taking actions it believes are in Sun Pharma's best interests but which may be detrimental to Caraco. This could include keeping products with a greater potential for itself. It could also include situations in which, although other shareholders believe it would be advantageous for Caraco to take certain actions, for example, a merger or sale of significant assets, Sun Pharma would not agree and would block it. Caraco believes, that with respect to most matters, Sun Pharma's substantial investment in Caraco will provide it with an economic incentive to assist Caraco and to

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favor arrangements, which are beneficial to both Sun Pharma and Caraco.

### 7. 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 June 30, 2003, has been classified as current.

### 8. 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 June 30, 2003, has been classified as current.

### 9. COMMON STOCK ISSUANCES

We issued 11,000 shares of common stock during the second quarter of 2003 to the directors as compensation for attendance at board and committee meetings held during 2002. We have also issued to our officers and employees, 368,263 shares of common stock upon their exercise of their stock options during the second quarter of 2003.

### 10. SALES & CUSTOMERS

Shipments to one wholesale customer, namely Amerisource Bergen, accounted for approximately 72% and 65% of sales during the six months ended June 30 2003 and the year ended December 31, 2002, respectively. Balances due from this customer represented approximately 80% of accounts receivable at June 30, 2003 and December 31, 2002. Certain of our customers, such as

9

Amerisource Bergen, act as the intermediary in the distribution channel for our products. Therefore, even though the sales are initially recorded as made to the wholesaler, the end user would be a secondary customer. For example, the Veterans Administration procures our products from Amerisource Bergen.

### 11. 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 phenylpropanolame (PPA), one in federal court in Pennsylvania and another in state court in New Jersey, respectively. These lawsuits seek damages generally for personal injury as well as punitive damages under a variety of liability theories including strict products liability, breach of warranty and negligence. The Federal lawsuit does not set forth a specific dollar amount of damages requested; the state lawsuit seeks damages of \$20 million. We are only in the

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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; and (x) other risks identified in this report and identified from time to time in the Corporation reports and registration statements filed with the Securities and Exchange Commission.

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

#### THREE MONTHS AND SIX MONTHS ENDED JUNE 30, 2003 COMPARED WITH THREE MONTHS AND SIX MONTHS ENDED JUNE 30, 2002

NET SALES. Net sales for the three months and six months ended June 30, 2003 were \$11,889,937 and \$20,611,537, respectively, as compared to \$5,627,449 and \$8,929,408, respectively for the same periods of 2002 reflecting increases of almost 131% and 111%, respectively. The increases are due to the higher production and marketing of most of our products following the achievement of substantial compliance with cGMPs. Sales of Metformin Hydrochloride, Tramadol Hydrochloride and Metoprolol Tartrate accounted for 86% of our net sales for the three and

10

six months ended June 30, 2003. Sales of Metformin Hydrochloride primarily increased because of our contract with the Veterans Administration as well as the sales to other customers; however, the sales of Metformin Hydrochloride to such agency have been made at lower sales prices. (See "Gross Profit" below).

GROSS PROFIT. We earned gross profits of \$7,462,473 and \$11,958,124,

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respectively, during the three months and six months ended June 30, 2003 as compared to gross profits of \$3,061,528 and \$4,515,940, 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 Metoprolol Tartrate, Metformin Hydrochloride; Tramadol Hydrochloride and Oxaprozin; acquiring raw materials at more competitive prices; reduction in manufacturing costs due to increased batch sizes; improved efficiency in the overall manufacturing process associated with higher utilization of plant capacity; utilization of equipment installed during the year ended December 31, 2002 of \$1.6 million and during the six months ended June 30, 2003 of \$0.7 million; 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 six months ended June 30, 2003 were \$2,140,036 and \$3,089,820, respectively, as compared to \$1,084,584 and \$1,839,689, respectively, for the same periods in 2002. The overall increases are 97% and 67% for the two periods. Selling, general and administrative expenses have effectively decreased down to 18% and 15% of net sales during the three months and six months ended June 30, 2003 from almost 19% and 21% of net sales during the same periods in 2002.

The actual increases of \$1.25 million and \$1.06 million, respectively for the two periods were due to additional professional costs (\$0.28 million) primarily in connection with the ongoing litigation against the Company (see Note 11 above), and recording of variable compensation expense on stock options granted and extended to a director (\$0.85 million) and costs associated with development of improved services and quality measures to customers.

RESEARCH AND DEVELOPMENT EXPENSES. Cash research and development expenses of \$626,788 and \$1,526,719, respectively, for the three months and six months ended June 30, 2003 were lower by 3% and 13% when compared with \$720,630 and \$1,571,502, respectively, incurred during the corresponding period 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 quarter of 2003.

No non-cash R&D charge has been recorded for the three month and six months ended June 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 three months and six months ended June 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 \$316,261 for the first six months ended June 30, 2003 as compared to \$227,776 incurred in 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 \$0.7 million during the first six months of 2003.

INTEREST EXPENSE. Interest expense, 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, was \$375,470 and \$817,722 for the three and six months ended June 30, 2003, respectively as compared to \$376,915 and \$745,982, respectively, for the same periods of 2002, respectively. The increase in the amount of interest is due to the increase in borrowing levels. During the six months ended June 30, 2003, we utilized \$1.6 million of the remaining draw from Bank of Nova Scotia and borrowed \$0.61 from Sun Pharma (demand loans) to finance increased working capital. \$0.5 million of the demand loans borrowed from Sun Pharma during the first quarter of 2003 was repaid during the second quarter of 2003.

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RESULTS OF OPERATIONS. We earned net income of \$4,326,158 and \$6,530,906, respectively, for the three and six months ended June 30, 2003 as compared to net losses of \$1,909,840 and \$2,429,533, respectively, for the same periods of 2002, reflecting improvement of almost 327% and 369%, respectively, for the comparable periods of 2003 and 2002. The significantly improved results of operations in the current three-month and six-month periods as compared to the previous respective periods are primarily due to significantly higher sales volumes, improved cost

11

absorption due to increased sales, improved product mix, obtaining more competitive prices for raw materials and having no non-cash research and development expenses.

A number of uncertainties exist that may influence the Corporation's future operating results, including general economic conditions, changes in conditions affecting the pharmaceutical industry primarily related to generic drug competition, obtaining additional financing, government restrictions on sale of certain products, obtaining new FDA approvals, development by competitors of new or superior products or new technology for production of products, the entry into the market of new competitors, and the cost of non-cash research and development expenses with respect to preferred shares to be earned by Sun Global (valued at the market price when earned) for products anticipated to be transferred under the products agreement.

### LIQUIDITY AND CAPITAL RESOURCES

For the first time since inception, at June 30, 2003, the Corporation had positive working capital of \$1,861,384 compared with a negative working capital of \$1,647,253 at December 31, 2002. The positive working capital position has primarily been on account of our recently profitable operations and the cash recovery of our receivables improving during the course of the second quarter. The negative working capital positions as of December 31, 2002 and 2001 respectively were mainly due to the classification of the \$5.85 million loan payable to Sun Pharma and its affiliates as current as it becomes due in October 2003.

To enable the Corporation to fund its research and development activities, repay certain term loans and fund working capital needs, Sun Pharma has become a security guarantor for credit lines of \$5 million from ICICI Bank of India and \$12.5 million from Bank of Nova Scotia. As of June 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. Further, the Corporation has received an additional short-term loan of \$0.5 million during the first quarter of 2003 and \$0.1 million during the beginning of the second quarter of 2003 from Sun Pharma to help the Corporation finance its increased working capital requirements. The short term loan of \$0.5 million from Sun Pharma has been repaid during the second quarter. The cash generated out of the operations has generally been sufficient to fund the operations of the Corporation as well as repay a portion of the restructured EDC debt.

### FDA

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

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then pending ANDAs. We now have 3 ANDAs pending approval.

### FUTURE OUTLOOK

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

The FDA 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. Net sales of Guaifenesin LA during the year ended December 31, 2002 and during the six months ended June 30, 2003 were \$1.65 million and \$1.00 million, respectively.

12

As disclosed, under the products agreement 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. In light of the current market price of our common shares, however, each product will be analyzed carefully and selected by the directors on the our Board's Independent Committee only if the cost of the transfer technology can be justified. At this time, no products have yet been selected and agreed to between Sun Global and the directors of the Independent Committee.

During the first and second quarters of 2003, the Corporation has generated substantial revenues as compared to the past. Capacity utilizations are improving and costs are being controlled. The Corporation expects revenues to improve during the rest of 2003. The Corporation has raised its 2003 revenue estimate to \$42 million.

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

- o Continued focus on FDA compliance.
- o Continued research and development activities.
- o Increased market share for certain existing products and recently introduced new products and enhanced customer reach and satisfaction.
- o Prompt introduction of new approved products to the market.

- o Striving to capture larger market share for existing products.
- o Achieving operational efficiencies by attaining economies of scale, cost reduction per unit, and obtaining additional cost reductions for active substances acquired from competitors and/or Sun Pharma.
- o Increase the width and depth of product portfolio to serve customers effectively.
- o Increase the number of products, as well as anticipated volume increases for existing products, which, in turn, will improve manufacturing capacity utilization.
- o Considering alternative ways of increasing cash flow including developing, manufacturing and marketing ANDAs owned by Sun Pharma.
- o Locating and utilizing facilities of contract-manufacturers to enhance production and therefore sales.
- o Possible raising of equity capital through additional number of registered shares, by Form SB-2, which was recently declared effective by the SEC.
- o Raising of additional lines of credit to support increasing working capital requirements.

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 and our Chief Financial Officer have evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by the report (the "Evaluation Date"), and have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective in providing them with material information

13

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-Q was being prepared that has materially affected, or is reasonably likely to materially affect, the Corporation's internal control over financial reporting.

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## PART II -- OTHER INFORMATION

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

The Annual Meeting of the Shareholders of the Corporation was held on June 3, 2003 in Detroit, Michigan for the purpose of electing three directors for three year terms expiring in 2006 and upon the election and qualification of their successors and for the purpose of approving the amendment to Amended and Restated Articles of Incorporation increasing the number of common shares to 50 million and of preferred shares to 15 million.

The results of the voting were as follows:

Name of Director	Votes for	Votes Against
Dilip S. Shanghvi	21,024,939	18,095
Jitendra N. Doshi	21,024,939	18,095
Jay F. Joliat	21,025,039	17,995

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

Name of Director	Term
Narendra N. Borkar	2004
Phyllis Harrison-Ross	2004
Sudhir Valia	2004
Sailesh T. Desai	2005
David A. Hagelstein	2005

The following are the results with respect to the amendment to Amended and Restated Articles of Incorporation increasing the number of common shares to 50 million and of preferred shares to 15 million:

For	Against	Abstained	Unvoted
16,642,823	130,632	22,200	4,122,789

### ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

#### (a) Exhibits

- 31.1 Certification of Chief Executive Officer
- 31.2 Certification of 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.



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On May 6, 2003, the Corporation filed a Form 8-K disclosing in Item 9 thereof and including as an exhibit the press release announcing its result of operations for the first quarter ended March 31, 2003.

### SIGNATURES

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

CARACO PHARMACEUTICAL LABORATORIES, LTD.

By: /s/ Narendra N. Borkar

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Narendra N. Borkar  
Chief Executive Officer

By: /s/ Jitendra N. Doshi

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Jitendra N. Doshi  
Chief Financial Officer

Dated: August 8, 2003

15

### EXHIBIT INDEX

- 31.1 Certification of Chief Executive Officer
- 31.2 Certification of 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.

16