

CARACO PHARMACEUTICAL LABORATORIES LTD

Form 10-Q

July 27, 2006

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

for the quarterly period ended June 30, 2006

☐ 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 48202

(Address of principal executive offices)

(Zip Code)

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-Q

TELEPHONE: (313) 871-8400

Registrant's telephone number, including area code

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

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ☐ Accelerated Filer ☒ Non-Accelerated Filer ☐

Indicate by check mark whether the registrant is a shell company ((as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

As of July 24, 2006 the registrant had 26,427,594 shares of common stock issued and outstanding.

CARACO PHARMACEUTICAL LABORATORIES LTD.
(A subsidiary of Sun Pharmaceutical Industries Limited)
BALANCE SHEETS

JUNE 30, 2006	MARCH 31, 2006
UNAUDITED	AUDITED

ASSETS

Current assets

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-Q

	JUNE 30, 2006	MARCH 31, 2006
Cash and cash equivalents	\$ 17,376,066	\$ 11,924,245
Accounts receivable, net	22,810,271	20,859,099
Inventories	28,587,724	26,965,690
Prepaid expenses and deposits	1,694,750	2,532,561
Total current assets	70,468,811	62,281,595
Property, plant and equipment		
Land	197,305	197,305
Building and improvements	10,998,467	10,790,703
Equipment	13,088,969	12,040,688
Furniture and fixtures	792,088	681,705
Total	25,076,829	23,710,401
Less: accumulated depreciation	9,186,972	8,749,997
Net property, plant & equipment	15,889,857	14,960,404
Total assets	\$ 86,358,668	\$ 77,241,999
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 3,069,280	\$ 3,696,265
Accounts payable, Sun Pharma	14,729,663	14,678,085
Accrued expenses	2,811,871	2,489,398
Total liabilities (all current)	20,610,814	20,863,748
Stockholders' equity		
Series B convertible preferred stock, no par value; issued and outstanding 11,424,000 shares (June 30, 2006) 10,880,000 shares (March 31, 2006)	77,134,970	72,755,770
Common stock, no par value; authorized 30,000,000 shares, issued and outstanding 26,427,594 shares (June 30, 2006) 26,421,994 shares (March 31, 2006)	44,993,077	44,988,597
Additional paid in capital	2,718,735	2,718,735
Accumulated deficit	(59,098,928)	(64,084,851)
Total stockholders' equity	65,747,854	56,378,251
Total liabilities and stockholders' equity	\$ 86,358,668	\$ 77,241,999

See accompanying notes

CARACO PHARMACEUTICAL LABORATORIES, LTD.

(A subsidiary of Sun Pharmaceutical Industries Limited)

STATEMENTS OF OPERATIONS

	Quarter ended June 30,	
	2006	2005
	UNAUDITED	UNAUDITED
Net sales	\$ 24,751,146	\$ 17,612,531
Cost of goods sold	11,743,174	9,450,818
Gross profit	13,007,971	8,161,713
Selling, general and administrative expenses	2,116,440	1,704,633
Research and development costs - affiliate	4,379,200	3,242,240
Research and development costs - other	1,697,160	1,629,907
Operating income	4,815,172	1,584,933
Other income		
Interest income	130,920	27,143
Other income	39,832	4,170
Other income	170,752	31,313
Net income	\$ 4,985,924	\$ 1,616,246
Net income per common share		
Basic	0.19	0.06
Diluted	0.13	0.05

See accompanying notes

CARACO PHARMACEUTICAL LABORATORIES, LTD.

(A subsidiary of Sun Pharmaceutical Industries Limited)

STATEMENTS OF CASH FLOWS

	Quarter ended June 30,	
	2006	2005
	UNAUDITED	UNAUDITED
Cash flows from operating activities		
Net income	\$ 4,985,924	\$ 1,616,246
Adjustments to reconcile net income to net cash flow from operating activities		
Depreciation	436,974	306,626
Capital stock issued or to be issued to affiliate in exchange for product formula	4,379,200	3,242,240
Changes in operating assets and liabilities which provided (used) cash:		
Accounts receivable	(1,951,173)	(5,721,668)
Inventories	(1,622,033)	323,290
Prepaid expenses and deposits	837,811	633,088
Accounts payable	(575,409)	(1,056,103)
Accrued expenses	322,475	(114,740)
Net cash provided by (used in) operating activities	6,813,769	(771,021)
Cash flows from investing activities		
Purchases of property, plant and equipment	(1,366,428)	(252,494)
Net cash used in investing activities	(1,366,428)	(252,494)
Cash flows from financing activities		
Proceeds from exercise of stock options	4,480	15,680
Net cash provided by financing activities	4,480	15,680
Net increase (decrease) in cash and cash equivalents	5,451,821	(1,007,835)
Cash and cash equivalents, beginning of period	11,924,245	6,627,425
Cash and cash equivalents, end of period	\$ 17,376,066	\$ 5,619,590

See accompanying notes

CARACO PHARMACEUTICAL LABORATORIES, LTD.
(A subsidiary of Sun Pharmaceutical Industries Limited)
STATEMENT OF STOCKHOLDERS' EQUITY

	PREFERRED STOCK		COMMON STOCK		ADDITIONAL	ACCUMULATED	TOTAL
	SHARES	AMOUNT	SHARES	AMOUNT	PAID IN	DEFICIT	STOCKHOLDERS
					CAPITAL		EQUITY
Balances at April 1, 2006	10,880,000	\$ 72,755,770	26,421,994	\$ 44,988,597	\$ 2,718,735	\$ (64,084,852)	\$ 56,378,250
Issuances of preferred stock to affiliate in exchange for product technology transfers	544,000	4,379,200					\$ 4,379,200
Common stock options exercised			5,600	4,480			4,480
Net Income						4,985,924	4,985,924
Balances at June 30, 2006	11,424,000	\$ 77,134,970	26,427,594	\$ 44,993,077	\$ 2,718,735	\$ (59,098,928)	\$ 65,747,854

See accompanying notes

CARACO PHARMACEUTICAL LABORATORIES, LTD.

FORM 10-Q

NOTES TO UNAUDITED FINANCIAL STATEMENTS

1. BASIS OF PRESENTATION

The balance sheet as of March 31, 2006 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 Annual Report on Form 10-K as of and for the year ended March 31, 2006 of Caraco Pharmaceutical Laboratories, Ltd. (Caraco, the Company, or the Corporation and which is also referred to as we, us, or our).

The accounting policies followed by the Corporation with respect to the unaudited interim financial statements are consistent with those stated in the Corporation's Annual Report on Form 10-K.

2. ORGANIZATION AND NATURE OF BUSINESS

Caraco is a corporation organized under Michigan law in 1984, engaged in the business of developing, manufacturing, marketing and distributing generic and private-label pharmaceuticals to the nation's largest wholesalers, distributors, warehousing and non- warehousing chain drugstores and managed care providers, throughout the U.S.

A generic pharmaceutical is the chemical and therapeutic equivalent of a brand-name drug as to which the patent and/or market exclusivity has expired. Generic pharmaceuticals are well accepted for substitution of brand pharmaceuticals (which substitution is regulated by individual state regulations) as they sell at a discount to the branded product's price and have been determined to be their equivalent in quality and bioavailability.

Our present product portfolio includes 23 prescription products in 47 strengths in various 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 Sun Pharmaceutical Industries Limited, a specialty pharmaceutical corporation organized under the laws of India (Sun Pharma). Since August 1997, 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

During the first quarter of our new fiscal year (fiscal 2007), we recorded net sales of \$24.8 million compared to \$17.6 million during the corresponding period of fiscal 2006. We incurred \$6.1 million in R&D expense during the first quarter of fiscal 2007 as compared to \$4.9 million during the corresponding period of fiscal 2006. This included \$4.4 million in first quarter of fiscal 2007 in non-cash R&D expense as compared to \$3.2 million during the corresponding period of fiscal 2006. We generated cash from operations of \$6.8 million during the first quarter of fiscal 2007 as compared to utilization of \$0.8 million during the corresponding period of fiscal 2006. We earned net income of \$5.0 million during the first quarter of fiscal 2007 as compared to net income of \$1.6 million during the corresponding period of fiscal 2006. At June 30, 2006, we had stockholders' equity of \$65.7 million as compared to stockholders' equity of \$36.6 million at June 30, 2005. See Item 2.

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-Q

Management's Discussion and Analysis of Financial Condition and Results of Operations.

Pursuant to our products agreement with Sun Pharma Global, Inc. ("Sun Global"), a wholly-owned subsidiary of Sun Pharma, we have selected, through June 30, 2006, all products out of the 25 products to be transferred to us by Sun Global. Of these, 21 products passed their bio-equivalency studies as of June 30, 2006, and one product since then. Sun Global earned 544,000 preferred shares for each product. See "Sun Pharmaceutical Industries Limited" and Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations "Future Outlook."

We filed two ANDAs with the FDA during the first quarter of fiscal 2007. We have subsequently received approvals for two ANDAs, one on July 11, 2006 and the other on July 19, 2006. This brings our total number of ANDAs pending approval by the FDA to 14 products.

On July 10, 2006, Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S (collectively, "Forest") filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Corporation's filing of an ANDA seeking approval to market its generic version of Forest's Lexapro® (escitalopram oxalate) drug product infringed Forest's Patent No. Re. 34,712, which is set to expire on September 13, 2011. Forest seeks an order from the court which, among other things, directs the FDA not to approve Caraco's ANDA any earlier than the claimed expiration date. The ANDA filed by Caraco contained a Paragraph IV Certification challenging the Forest patent. The Corporation believes that the Forest patent is invalid and/or will not be infringed by Caraco's manufacture, use or sale of the product, and the Corporation intends to vigorously defend this action. Prior to this action, Forest has filed two lawsuits with other manufacturers who sought to market a generic version of Lexapro®. Forest settled the lawsuit with Alphapharm Pty. Ltd. in October 2005, granting Alphapharm the exclusive right to distribute generic versions of Lexapro® for five years. Alphapharm's launch date is dependent on a number of factors but is set to be no later than two weeks before the claimed expiration of the Forest patent on September 13, 2011. On July 13, 2006, Forest obtained an order from the United States District Court for the District of Delaware, holding that IVAX Pharmaceuticals, Inc. and CIPLA Ltd.'s proposed generic version of Lexapro® infringed the Forest patent and that the asserted claims of the Forest patent are valid and enforceable.

An ANDA was filed, during the Transition Period (January - March 2005), for a generic version of Novo Nordisk A/D and Novo Nordisk, Inc.'s Prandin®, challenging its patent under a Paragraph IV Certification. We believe we are the first company to file such a Paragraph IV certification and therefore there is a potential to be granted 180 days of exclusivity upon successful resolution of patent litigation recently initiated by Novo Nordisk and approval of the ANDA by the FDA. See 12. Litigation below.

7

The FDA completed an inspection of the Company's facility in June 2006. Observations were provided on FDA Form 483. The Company is responding accordingly. The Company believes that the observations are not material and we remain substantially cGMP compliant. We have since received approval from the FDA for two products previously submitted.

Caraco initiated a market withdrawal at the wholesale level of Midrin® capsules. This withdrawal was classified as a class III recall in which the product is not likely to cause adverse health consequences. The recall for one of the previous lots already withdrawn was extended in July to the retail level (Class II) due to the potential for some of the bottles to contain foreign tablets. This lot represents 1023 bottles of which 717 bottles have been received by the Company, inspected and no foreign tablets were found. Neither action is expected to have any material financial impact on the Company. Appropriate corrective measures have been implemented.

4. RECENT ACCOUNTING PRONOUNCEMENTS

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-Q

In July 2005, the *Financial Accounting Standards Board* (FASB) published an Exposure Draft of a proposed Interpretation, *Accounting for Uncertain Tax Positions*. The Exposure Draft seeks to reduce the significant diversity in practice associated with recognition and measurement in the accounting for income taxes. It would apply to all tax positions accounted for in accordance with *Statement of Financial Accounting Standards* (SFAS) 109, *Accounting for Income Taxes*. The Exposure Draft requires that a tax position meet a probable recognition threshold for the benefit of the uncertain tax position to be recognized in the financial statements. This threshold is to be met assuming that the tax authorities will examine the uncertain tax position. The Exposure Draft contains guidance with respect to the measurement of the benefit that is recognized for an uncertain tax position, when that benefit should be derecognized, and other matters. This proposed Interpretation would clarify the accounting for uncertain tax positions in accordance with SFAS 109. This Interpretation, once approved, is expected to be effective as of the end of the fiscal year ending after December 15, 2005. The Corporation does not expect that the exposure draft will have a significant impact on its operating results.

In May 2005, the FASB issued SFAS 154, *Accounting Changes and Error Corrections*, which replaces APB Opinion No. 20, *Accounting Changes*, and supersedes FASB Statement No. 3, *Reporting Accounting Changes in Interim Financial Statements* an amendment of APB Opinion No. 28. SFAS 154 requires retrospective application to prior periods financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. When it is impracticable to determine the period-specific effects of an accounting change on one or more individual prior periods presented, SFAS 154 requires that the new accounting principle be applied to the balances of assets and liabilities as of the beginning of the earliest period for which retrospective application is practicable and that a corresponding adjustment be made to the opening balance of retained earnings for that period rather than being reported in an income statement. When it is impracticable to determine the cumulative effect of applying a change in accounting principle to all prior periods, SFAS 154 requires that the new accounting principle be applied as if it were adopted prospectively from the earliest date practicable. SFAS 154 shall be effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The Corporation does not expect that the provisions of the SFAS 154 will have a significant impact on its operating results.

The FASB has proposed amending SFAS 128, *Earnings per Share*, to make it consistent with International Accounting Standard 33, *Earnings per Share*, and make earning per share, or EPS,

8

computations comparable on a global basis. Under the proposed amendment, the year-to-date EPS computation would be performed independently from the quarterly computations. Additionally, for all contracts that may be settled in either cash or shares of stock, companies must assume that settlement will occur by the issuance of shares for purposes of computing diluted EPS, even if they intend to settle by paying cash or have a history of cash-only settlements, regardless of who controls the means of settlement. Lastly, under the proposed amendment, shares that will be issued upon conversion of a mandatory convertible security must be included in the weighted-average number of shares outstanding used in computing basic EPS from the date that conversion becomes mandatory, using the if-converted method, regardless of whether the result is anti-dilutive. The proposed amended standard was expected to be issued during the first quarter of 2005. However, the FASB has not yet finalized the revised effective date of the proposed amendment or its transition provisions. Retrospective application in all periods presented would be required and could require the restatement of previously reported EPS. The Corporation does not expect that the provisions of the amended SFAS 128 will have a significant impact on its operating results.

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.

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-Q

The basic and diluted weighted average numbers of common shares outstanding for the first quarter of fiscal 2007 ended June 30, 2006 were 26,422,321 and 38,185,021 respectively. Correspondingly, the basic and diluted weighted average numbers of common shares outstanding for the first quarter of fiscal 2006 ended June 30, 2005 were 26,362,773 and 33,272,376, respectively.

6 **SUN PHARMACEUTICAL INDUSTRIES LIMITED**

Pursuant to a stock purchase agreement, Sun Pharma made an initial investment of \$7.5 million for the purchase of 5.3 million common shares of Caraco in 1997.

Sun Pharma and its affiliates have loaned the Corporation approximately \$10.0 million since August 1997. As of December 31, 2003, all such loans had been repaid. Sun Pharma has also assisted the Corporation, by acting as guarantor, in obtaining line of credit loans from ICICI Bank Limited, The Bank of Nova Scotia and Citibank FSB in the amounts of \$5.0 million, \$12.5 million and \$10.0 million, respectively, all of which have been repaid and terminated as of December 31, 2004.

In August 1997, Caraco entered into an agreement, whereby Sun Pharma was required to transfer the technology formula for 25 generic pharmaceutical products over a five-year period through August 2003 in exchange for 544,000 shares of Caraco common stock for each technology transfer of an ANDA product (when bio-equivalency studies were successfully completed) and 181,333 shares for each technology transfer of a DESI (Drug Efficacy Study Implementation) product. The products provided to the Corporation from Sun Pharma were selected by mutual agreement. Under such agreement, Caraco conducted, at its own expense, all tests including bio-equivalency studies. Pursuant to such agreement through 2002, Sun Pharma delivered the technology formula for 13 products. This agreement expired on November 21, 2002, and the Corporation entered into a new technology transfer agreement with Sun Global an affiliate of Sun Pharma.

9

Under the agreement, which was approved by the Corporation's independent directors, Sun Global agreed to provide the formulations for 25 new generic drugs over a five-year period. Caraco's rights to the products are limited to the United States and its territories or possessions, including Puerto Rico. Sun Global retains rights to the products in all other territories. The products are selected by mutual agreement. Under this agreement, Caraco conducts at its own expense all tests, including bio-equivalency studies. The Corporation also markets the products consistent with its customary practices and provides marketing personnel. In return for the technology transfer, Sun Global receives 544,000 shares of Series B Preferred Stock for each generic drug transferred when such drug has passed its bio-equivalency studies. The preferred shares are non-voting, do not receive dividends and are convertible into common shares after three years (or immediately upon a change in control) on a one-to-one basis. The preferred shares have a liquidation preference equal to the value attributed to them on the dates on which they were earned. While such preferred shares are outstanding, we cannot, without the consent of the holders of a majority of the outstanding shares of the preferred stock, amend or repeal our articles of incorporation or bylaws if such action would adversely affect the rights of the preferred stock. In addition, without such consent, we cannot authorize the issuance of any capital stock having any preference or priority superior to the preferred stock.

The products agreement was amended by the Independent Committee, comprised of the three independent directors, in the first quarter of 2004 to eliminate the provision requiring that the Independent Committee concur in the selection of each product, and provides instead that each product satisfy certain objective criteria developed by management and approved by the Independent Committee. Pursuant to such objective criteria, all 25 of the products under this agreement have been selected, 21 of which passed bio-equivalency studies through June 30, 2006 and

one since then. See Item - 2. Management's Discussion and Analysis of Financial Conditions and Results of Operations Future Outlook .

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

Sun Pharma and its subsidiaries supply the Corporation with certain raw materials and formulations, assist in acquiring machinery and equipment to enhance production capacities, and provide qualified technical professionals who work as Caraco employees. Also, four of the nine directors of Caraco are, or were, affiliated with Sun Pharma. Further, Sun Pharma and its affiliates may use Caraco as a contract manufacturer and/or distributor of their products. In December 2004, Caraco entered into an agreement for two such products.

While management has a basis to reasonably believe that Sun Pharma's substantial investment in Caraco provides Sun Pharma with sufficient economic incentive to continue to assist Caraco in developing its business, and Sun Pharma has expressed its intent to continue to support Caraco's operations in the near term, as it has done in the past, there can be no assurance that such support will, in fact, continue.

In addition to its substantial relationship with and dependence on Sun Pharma as described above, the Corporation is subject to certain risks associated with companies in the generic pharmaceutical industry. Profitable operations are dependent on the Corporation's ability to market its products at reasonable profit margins. In addition to maintaining profitable operations, the ongoing success of the Corporation will depend, in part, on its continuing ability to attract and retain key employees, obtain timely approvals of its ANDAs, and develop new products (see Operations , below).

10

7. ACCOUNTING FOR STOCK BASED COMPENSATION

On April 1, 2006, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123 (Revised 2004), *Share-Based Payment* (Statement No. 123 (R)), which requires employee share-based compensation to be accounted for under the fair value method and requires the use of an option pricing model for estimating the fair value of stock options at the date of grant. Previously, the Company accounted for stock options under the intrinsic value method prescribed by Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, and provided the required pro forma disclosures prescribed by SFAS No. 123, *Accounting for Stock-Based Compensation*, (Statement No. 123), as amended. Since the exercise price of options equaled the market price of the stock on the date of grant, the stock options had no intrinsic value and, therefore, no expense was recognized for stock options by the Company prior to the beginning of fiscal 2007.

The Company elected to adopt Statement No. 123(R) using the modified prospective method, which requires compensation expense to be recorded for all unvested share-based awards beginning in the first quarter of adoption. Accordingly, prior period information presented in this Report on Form 10-Q has not been restated to reflect the fair value method of expensing stock options.

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-Q

For the first quarter of fiscal 2007, the Company has not recognized any expense related to share-based compensation, as it is immaterial to the financial statements. As of June 30, 2006 total unrecognized compensation cost related to stock options granted was \$157,000. The unrecognized stock option compensation cost is expected to be recognized over a period of approximately 3 to 5 years.

The Company estimates the fair value of stock options granted using the Black-Scholes option-pricing model, which requires the Company to estimate the expected term of the stock option grants and expected future stock price volatility over the term. The term represents the expected period of time the company believes the options will be outstanding based on historical information. Estimates of expected future stock price volatility are based on the historical volatility of the Company's common stock. The Company calculates the historical volatility as the standard deviation of the differences in the natural logarithms of the weekly stock closing price, adjusted for dividends and stock splits.

Options to purchase 40,000 shares of common stock were granted on May 2, 2005 to the CEO of the Corporation, which will vest in the amount of 1/3rd every anniversary thereafter. The Company also granted 45,000 shares of common stock on May 2, 2005 to the CEO of the Corporation, which will vest in the amount of 1/3rd every anniversary date thereafter. In addition, the Company granted options to purchase 3,000 shares of common stock to each of the new independent directors upon the date of their appointment. No options or stock grants were granted during the first quarter of fiscal 2007 ended June 30, 2006.

8. COMMON STOCK ISSUANCES

We issued 5,600 shares and 19,200 shares of common stock to our employees upon exercise of their stock options during the first quarter of fiscal 2007 and first quarter of fiscal 2006, respectively.

11

9. PREFERRED STOCK ISSUANCES

We issued 544,000 shares of preferred stock to Sun Global during both of the first quarters of fiscal 2007 and fiscal 2006.

10. SALES AND CUSTOMERS

Our Company effectively executed its operating plan during the first quarter of fiscal 2007. The organization continues to be strengthened to meet the demands of a competitive US generic pharmaceutical market, while providing additional support for our future growth and reducing costs where possible.

As is typical in the US retail sector, many of our customers are serviced through their designated wholesalers such as Amerisource-Bergen Corporation, McKesson Corporation and/or Cardinal Health, which provide a service to supplement our direct relationship with our customers or act as an intermediary to service the customers directly in lieu of direct shipments from our Company. Collectively, for the first quarter of fiscal 2007 ended June 30, 2006, these wholesale accounts equate to 79% of our gross sales, yet the actual sales are for various customers with underlying direct contracts with our Company. No other single customer represents more than 10% of our gross sales during the relevant periods.

Certain of the Corporation's customers purchase its products through designated wholesalers, who act as an intermediary distribution channel for the Corporation's products. One such customer, the Veterans Administration, an agency of the United States Government, entered into a sales contract with the Corporation effective August 5, 2002 to purchase a minimum of \$13,000,000 of product per year over a one year base contract period that ended June 30, 2003. The contract has four one-year option periods, the first three of which were exercised. The agreement may be terminated by the purchaser without cause and in such case, Caraco would only be entitled to a percentage of the contract price, plus reasonable

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-Q

charges that have resulted from the termination. The agreement further provides for certain penalty provisions if the Corporation is unable to meet its sales commitment.

11. LINE OF CREDIT

On November 17, 2005, the Corporation entered into a one-year, \$10 million Credit Agreement with JP Morgan Chase Bank, N.A. Under the Credit Agreement, the lender may make loans and issue letters of credit to the Corporation for the Corporation's working capital needs and general corporate purposes. Letters of credit, if issued, expire one year from their date of issuance, but no later than November 17, 2007.

Borrowings are secured by the Corporation's receivables and inventory. Interest is payable based on a LIBOR Rate or an alternate base rate (determined by reference to the prime rate or the federal funds effective rate), as selected by the Corporation. The rate of interest is LIBOR plus 75 basis points or the bank's prime rate minus 100 basis points (effective rates of 6.08% and 8.0%, respectively at June 30, 2006.) The Credit Agreement requires that certain financial covenants be met on a quarterly basis. The Corporation is in compliance with these financial covenants at June 30, 2006. There are no borrowings under this Credit Agreement as at June 30, 2006.

12. LITIGATION

On July 10, 2006, Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S (collectively, Forest) filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Corporation's filing of an ANDA seeking approval to market its generic

12

version of Forest's Lexapro® (escitalopram oxalate) drug product infringed Forest's Patent No. Re. 34,712, which is set to expire on September 13, 2011. Forest seeks an order from the court which, among other things, directs the FDA not to approve Caraco's ANDA any earlier than the claimed expiration date. The ANDA filed by Caraco contained a Paragraph IV Certification challenging the Forest patent. The Corporation believes that the Forest patent is invalid and/or will not be infringed by Caraco's manufacture, use or sale of the product, and the Corporation intends to vigorously defend this action. Prior to this action, Forest has filed two lawsuits with other manufacturers who sought to market a generic version of Lexapro®. Forest settled the lawsuit with Alphapharm Pty. Ltd. in October 2005, granting Alphapharm the exclusive right to distribute generic versions of Lexapro® for five years. Alphapharm's launch date is dependent on a number of factors but is set to be no later than two weeks before the claimed expiration of the Forest patent on September 13, 2011. On July 13, 2006, Forest obtained an order from the United States District Court for the District of Delaware, holding that IVAX Pharmaceuticals, Inc. and CIPLA Ltd.'s proposed generic version of Lexapro® infringed the Forest patent and that the asserted claims of the Forest patent are valid and enforceable.

As previously disclosed, on June 9, 2005, Novo Nordisk A/S and Novo Nordisk, Inc. (Novo Nordisk) filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Corporation's filing of an ANDA seeking approval to market its generic version of Novo Nordisk's Prandin® drug product infringed Novo Nordisk's patent, which expires June 12, 2018. Novo Nordisk seeks an order from the Court which, among other things, directs the FDA not to approve Caraco's ANDA any earlier than the claimed expiration date. The ANDA filed by Caraco contains a Paragraph IV certification challenging the Novo Nordisk patent. The Corporation believes that the Novo Nordisk patent is invalid and/or will not be infringed by Caraco's manufacture, use or sale of the product, and the Corporation intends to vigorously defend this action in order to capitalize on the potential 180 days of marketing exclusivity available for this product.

As previously disclosed, on September 22, 2004, Ortho-McNeil Pharmaceutical, Inc. (Ortho-McNeil) filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Corporation's filing of an ANDA seeking approval to market its generic version of Ortho-McNeil's Ultracet® brand tramadol/acetaminophen drug product infringed Ortho-McNeil's patent, which expires on September 6, 2011. Ortho-McNeil seeks an order from the Court which, among other things, directs the FDA not to approve Caraco's ANDA any earlier than the claimed expiration date. The ANDA filed by Caraco contained a Paragraph IV Certification challenging the Ortho-McNeil patent. The corporation believes that the Ortho-McNeil patent is invalid and/or will not be infringed by Caraco's manufacture, use or sale of the product, and

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-Q

the corporation intends to vigorously defend this action. Since this action, Ortho-McNeil has entered into a license agreement with another manufacturer who has launched its product generically while another manufacturer has launched its approved generic at risk. On October 8, 2005, arguments were heard in the US District Court in the Eastern District of Michigan, on the Corporation's motion for summary judgment on the issue of non-infringement. On October 19, 2005 the motion for summary judgment was granted in the Corporation's favor. On December 19, 2005, the FDA approved the manufacture, use and sale of the product. Ortho-McNeil has filed an appeal of the finding of non-infringement by the Eastern District of Michigan. Additionally, the United States Patent and Trademark Office has approved Ortho-McNeil's request for a reissue patent which will be in effect August 2006. Although the district court determined that we do not infringe the original patent, it is possible Ortho-McNeil could contend that its reissue patent will be infringed by Caraco's now-marketed product. The Corporation believes that, like its original patent, Ortho-McNeil's reissue patent will be invalid and unenforceable.

13

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. Dr. Curry sought 175,000 shares of the Corporation's common stock (35,000 shares for each of the first five ANDAs approved by the FDA). The corporation and the plaintiff each filed a motion for summary disposition. Both parties' motions were denied, and the parties submitted the matter to binding arbitration. In connection with the submission to arbitration, the parties agreed that Mr. Curry would receive a minimum of 15,000 shares of common stock. On April 20, 2006, the arbitrator entered a determination of no cause of action against Mr. Curry and in favor of the Corporation, thus capping the Corporation's liability to Mr. Curry at 15,000 shares. The Corporation has recorded an expense of approximately \$116,000 related to the 15,000 shares earned by Mr. Curry.

The Corporation is involved in certain legal proceedings from time to time incidental to normal business activities. While the outcome of any such proceedings cannot be accurately predicted, the Corporation does not believe the ultimate resolution of any existing matters would have a material adverse effect on its financial position or results of operations.

13. INVENTORIES

Inventories consist of the following amounts:

	June 30, 2006	March 31, 2006
Raw materials	\$ 9,776,451	\$ 9,735,502
Goods in transit	4,873,398	5,974,600
Work in process	3,927,249	3,283,911
Finished goods	10,010,626	7,971,677
Total	\$ 28,587,724	\$ 26,965,690

**REVIEW REPORT OF INDEPENDENT REGISTERED
PUBLIC ACCOUNTING FIRM**

July 18, 2006

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, 2006 and the related statements of operations, stockholders' equity, and cash flows for the three months ended June 30, 2006 and 2005. These financial statements are the responsibility of the Company's management.

We conducted our reviews in accordance with standards of the Public Company Accounting Oversight Board (United States). A review of interim financial information consists principally of applying analytical procedures and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with the standards of the Public Company Accounting Oversight Board (United States), 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 standards of the Public Company Accounting Oversight Board (United States), the balance sheet of Caraco Pharmaceutical Laboratories, Ltd. as of March 31, 2006, (presented herein) and the related statements of operations, stockholders' equity, and cash flows for the year then ended (not presented herein), and in our report dated May 7, 2006, we expressed an unqualified opinion on those financial statements.

5750 New King Street o Suite 200 o Troy, MI 48098 o 248.952.5000 o Fax 248.952.5750 o www.rehmann.com

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 2006 Annual Report on Form 10-K as of and for the year ended March 31, 2006 (the Annual Report) and the unaudited interim financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

Critical Accounting Policies and Estimates

Our significant accounting policies are described in Note 1 to our financial statements included in our Annual Report. Certain of our accounting policies are particularly important to the portrayal of our financial position and results of operations and require management's subjective judgments. As a result, these judgments are subject to an inherent degree of uncertainty. In applying these policies, management makes estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates. Significant estimates include, but are not limited to, provisions for estimated customer returns, discounts, rebates and other price adjustments, including customer chargebacks, valuation allowances for deferred tax assets, and valuation of overhead components in inventory. Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. There have neither been material changes to our critical accounting policies for the periods presented nor any material quantitative revisions to our critical accounting estimates for the periods presented.

Revenue Recognition

Revenue from product sales, net of estimated provisions, is recognized when there is persuasive evidence that an arrangement exists, shipment of the goods has occurred, the selling price is fixed or determinable, and collectibility is reasonably probable. Our customers consist primarily of large pharmaceutical wholesalers who sell directly into the retail channel. Provisions for sales discounts, and estimates for chargebacks, rebates, and product returns are established as a reduction of product sales revenue at the time revenues are recognized, based on historical experience and current market trends adjusted to reflect known changes in the factors that impact these reserves. These revenue reductions are reflected as a direct reduction to accounts receivable through an allowance.

Chargebacks

Chargebacks represent our most significant provision against gross accounts receivable and related reduction to gross revenue. Chargebacks are credits given to our wholesale customers for the price difference on our product they sell (at a contractual price) to retail, chain stores, and managed care organizations at prices lower than we sell to our wholesale customer. We record an estimate at the end of the reporting period to the wholesaler of the amount to be charged back to us, over and above those already received by us. Such estimated amounts, in addition to certain other deductions, are deducted from our gross sales to determine our net revenues. We have recorded provisions for chargebacks based

upon various factors, including current contract prices, historical trends, and our future expectations. The amount of actual chargebacks claimed could be either higher or lower than the amounts we accrued. Changes in our estimates, if any, would be recorded in the income statement in the period of the change.

16

If we over or under estimate the amount that will ultimately be charged back to us by our wholesaler customers, there could be a material impact on our financial statements.

We consider the following factors in the determination of the estimates of chargebacks.

1. We consider the historical data of chargebacks as a percentage of sales, as well as the various chargeback reports that we receive from the customers.
2. Volume of product sold to wholesalers and the average chargeback rates, on a quarterly and annualized basis are applied to current period and annual product sales to make a realistic accrual.
3. The sales trends for future estimated prices, wholesale acquisition cost (WAC), the contract prices with the retailers, chain stores and managed care organizations (end-users). Our prices with the wholesalers and end users are contracted prices.

Shelf Stock Adjustments

Shelf stock adjustments are credits issued to our customers to reflect decreases in the selling prices of our product. These credits are customary in the industry and are intended to reduce the customers' inventory cost to better reflect current market prices. The determination to grant a shelf stock adjustment to a customer following a price decrease is at our discretion.

Factors considered when recording a reserve for a shelf stock adjustments include estimated launch dates of competing products based on market intelligence, estimated decline in market price of our product based on historical experience and input from customers and levels of inventory held by customers at the date of the adjustments as provided by them.

Product returns and other allowances

In the pharmaceutical industry, customers are normally granted the right to return product for credit if the product has not been used prior to its expiration date. Our return policy typically allows product returns for products within a 12-month window from six months prior to the expiration date and up to six months after the expiration date. We estimate the level of sale, which will ultimately be returned pursuant to our return policy, and record a related reserve at the time of sale. These amounts are deducted from our gross sales to determine our net revenues. Our estimates take into consideration historical returns of our products and our future expectations. We periodically review the reserves established for returns and adjust them based on actual experience, if necessary. The primary factors we consider in estimating our potential product returns include shelf life of expiration date of each product and historical levels of expired product returns. In case we become aware of any returns due to product related issues, such information from the customers, is used to estimate an additional reserve. The amount of actual product return could be either higher or lower than the amounts we accrued. Changes in our estimates, if any, would be recorded in the income statement in the period of the change. If we over or under estimate the quantity of product which will ultimately be returned, there may be a material impact to our financial statements.

Discounts (trade and prompt payment discounts) are accrued at the end of every reporting period based on the gross sales made to the customers during the period and based on their terms of trade. We review the contracts between the customer and us as well as the historical data and percentages to estimate the discount accrual.

Customer rebates are estimated at every period end, based on direct or indirect purchases. If the purchases are direct, the rebates are recognized when products are purchased and a periodic credit is given. For indirect purchases, the rebates are recognized based on the terms with such customer. Medicaid Rebates are estimated based on the historical data we receive from the public sector benefit providers, which is based on the final dispensing of our product by a pharmacy to a benefit plan participant.

Doubtful Accounts

Doubtful accounts are estimated based on the data available from external sources, including information on financial condition of customers. Also, a regular review of past due receivables is done on a quarterly basis to identify and make provision for such receivables not expected to be recovered.

Our gross sales for the first quarter of fiscal 2007 ended June 2006 were \$64.3 million, as compared to \$43.2 million for the corresponding period of fiscal 2006. Chargebacks, returns, discounts and other customary customer deductions and other sales costs constituted approximately 61% for the first quarter of fiscal 2007 ended June 2006 compared to 59% for the corresponding period of fiscal 2006. Net sales for the first quarter of fiscal 2007 ended June 2006 were \$24.8 million, as compared to \$17.6 million for the corresponding period of fiscal 2006. The primary cause of increase in the sales allowances by almost 2% between the periods is the impact of price erosions for the products we sell and the corresponding impact of such price erosions on chargebacks

The following is a roll forward of the provisions for chargebacks, shelf stock adjustments, returns and allowances and estimated doubtful account allowances during fiscal 2006 and the first quarter of fiscal 2007.

(\$ in Thousands)

	Balances at beginning of period	Allowances charged to Gross Sales Current Period	Prior Period	Credits taken by customers	Balance at the end of period
For fiscal 2006					
Chargebacks & shelf stock adjustments	\$19,810	\$ 111,525	-0-	\$119,868	\$11,467
Returns and other allowances	1,120	7,471	-0-	7,091	1,500
Doubtful Accounts	100	-0-	-0-	-0-	100

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-Q

	Balances at beginning of period	Allowances charged to Gross Sales		Credits taken by customers	Balance at the end of period
For first quarter fiscal 2007					
Chargebacks & shelf stock adjustments	\$11,467	\$36,662	-0-	\$32,654	\$15,475
Returns and other allowances	1,500	2,400	-0-	1,277	2,623
Doubtful Accounts	100	-0-	-0-	-0-	100

Income Taxes

As part of the process of preparing our financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. We account for income taxes by the liability method. Under this method, deferred income taxes are recognized for tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end, based on enacted laws and statutory tax rates applicable for the differences that are expected to affect taxable income. Valuation allowances are provided if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. We have not recorded any federal tax provision or benefit for the first quarter of fiscal 2007, and fiscal 2006. We have provided a valuation allowance for the full amount of our net deferred tax assets since realization of any future benefit from deductible temporary differences and net operating loss carry forwards cannot be sufficiently assured at June 30, 2006 and March 31, 2006. At June 30, 2006, we had federal net operating loss carryforwards of approximately \$53.8 million available to reduce future

19

taxable income, which will expire between 2007 and 2017. Under the provisions of the Internal Revenue Code, certain substantial changes in our ownership may result in a limitation on the amount of net operating loss carry forwards which can be used in future years. We believe that ownership changes to date will not limit future utilization of net operating loss carryforwards.

Inventory

We value inventories at the lower of cost or market. We determine the cost of raw materials, work in process and finished goods using the specific identification cost method. We analyze our inventory levels quarterly and write down inventory that has become obsolete and inventory that has a cost basis in excess of its expected net realizable value. Expired inventory is disposed of and the related costs are written off. Materials acquired for R&D on products yet to be launched are written off in the year of acquisition. The determination of whether or not inventory costs will be realizable requires estimates by management. A critical estimate in this determination is the estimate of the future expected inventory requirements, whereby we compare our internal sales forecasts to inventory on hand. Actual results may differ from those estimates and inventory write-offs may be required. We must also make estimates about the amount of manufacturing overhead to allocate to our finished goods and work in process inventories. Although the manufacturing process is generally similar for our products, we must make judgments as to the portion of costs to allocate to purchased product, work in process and finished goods, and such allocations can vary based upon the composition of these components and the fact that each product produced does not necessarily require the same amount of time or effort for the same production step. Accordingly, the assumptions we make can impact the value of reported inventories and cost of sales.

OVERVIEW

The first quarter of fiscal 2007 ended June 30, 2006 represents 21 quarters of successive sales revenue growth. During the first quarter of fiscal 2007 ended June 30, 2006, we recorded net sales of \$24.8 million compared to \$17.6 million during the corresponding period of fiscal 2006. We incurred \$6.1 million in R&D expense during the first quarter of fiscal 2007 ended June 30, 2006 compared to \$4.9 million during the

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-Q

corresponding period of fiscal 2006. This included \$4.4 million in non-cash R&D expense compared to \$3.2 million during the corresponding period. We generated cash from operations of \$6.8 million during the first quarter of fiscal 2007 ended June 30, 2006 compared to utilization of \$0.8 million during the corresponding period of fiscal 2006. We earned net income of \$5.0 million during the first quarter of fiscal 2007 ended June 30, 2006 compared to net income of \$1.6 million during the corresponding period of fiscal 2006. At June 30, 2006, we had stockholders equity of \$65.7 million as compared to stockholders equity of \$36.6 million at June 30, 2005.

FDA COMPLIANCE

The FDA completed an inspection of the Company's facility in June 2006. Observations were provided on FDA Form 483. The Company has responded appropriately. The Company believes that the observations are not material and we remain substantially cGMP compliant. We have since received approval from the FDA for two products previously submitted.

20

First Quarter Fiscal 2007 Compared to First Quarter Fiscal 2006

Net Sales. Net sales for the first quarter of fiscal 2007 was \$24.8 million compared to \$17.6 million for the corresponding period of fiscal 2006, reflecting an increase of 41%. The increase is due to the higher production and increased marketing of our products to new and existing customers and in part due to the recent launch of Tramadol Hydrochloride with Acetaminophen. Currently, we manufacture and market all except two of the approved products. Sales of four products accounted for approximately 73% of net sales for the first quarter of fiscal 2007 as compared to sales of three products accounting for approximately 82% of net sales during corresponding period of fiscal 2006.

Gross Profit. We earned gross profit of \$13.0 million during the first quarter of fiscal 2007 as compared to gross profit of \$8.2 million during the corresponding period of fiscal 2006, reflecting an increase of 58.5%. The increase in gross profit was primarily due to higher sales and an improved balance in the mix of customers or the class of trade and product selection being sold.

The gross profit margin for the first quarter of fiscal 2007 increased to 53% as compared to 46% during corresponding period of fiscal 2006. The increase was primarily the result of change in product mix and improved balance in the mix of customers or the class of trade. The 53% profit margin reflects a 2% improvement over the last quarter of fiscal 2006 profit margin, primarily due to mix of products being sold during the quarter partially offset by price erosion.

Selling, General and Administrative Expenses. Selling, general and administrative expenses during the first quarter of fiscal 2007 were \$2.1 million compared to \$1.7 million during the corresponding period of fiscal 2006, representing an increase of 24%. The selling, general and administrative expenses, as a percentage of net sales, has declined to 8.6% for the first quarter of fiscal 2007, as compared to 9.7% for the corresponding period of fiscal 2006.

Research and Development Expenses. Total R&D expenses for the first quarter of fiscal 2007 were \$6.1 million as compared to \$4.9 million during the corresponding period of fiscal 2006. Actual cash research and development expenses were \$1.7 million during the first quarter of fiscal 2007 compared to \$1.6 million during the corresponding period of fiscal 2006. We incurred non-cash research and development expenses (technology transfer cost) of \$4.4 million for one product transfer during the first quarter of fiscal 2007, as compared to \$3.2 million for one product transfer during the corresponding period of fiscal 2006. Each product transfer earns 544,000 shares of preferred stock. The cash R&D expenses during the first quarter of fiscal 2007 were slightly higher compared to those during the corresponding period of fiscal 2006 due to

increased R&D activity.

Results of Operations. We earned net income of \$5.0 million in the first quarter of fiscal 2007 as compared to net income of \$1.6 million during the corresponding period of fiscal 2006.

Liquidity and Capital Resources

We generated cash from operations of \$6.8 million during the first quarter of fiscal 2007 as compared to utilization of cash of \$0.8 million from operations during the corresponding period of fiscal 2006. Accounts receivable increased by \$1.9 million to \$22.8 million during the first quarter of fiscal 2007 as compared to \$20.9 million at the end of fiscal 2006.

At June 30, 2006 we had working capital of \$49.9 million compared to working capital of \$23.7 million at June 30, 2005. We had working capital of \$41.4 million at March 31, 2006. The increase in working capital in fiscal 2007 is primarily in cash and some increase in accounts receivable and inventory balances resulting from higher sales volumes. Additionally we have available the \$10.0 million line of

21

credit obtained through JP Morgan Chase Bank, N.A. which would allow us flexibility in expansion efforts to increase our capacity over the next few years.

Future Outlook

We believe the competitive environment we find ourselves in is conducive to our success. Due to our size and management structure, we believe that we are able to move swiftly and effectively. We are disciplined and have the ability to execute our plan. We believe we are substantially compliant with cGMPs. We have received one ANDA approval subsequent to the most recent quarter. Currently, we have 15 products pending approval at the FDA. We continue to expand and upgrade our facilities and improve our customer base. Our efforts, combined with Sun Global in developing new products have also picked up momentum and this should permit us to grow at a reasonable level. We now have five products, Metformin, Metoprolol, Tramadol, Salsalate and Tramadol with Acetaminophen whose market share is ranked third or higher against the same products of our generic competitors. Based on current trends, we believe we will achieve 25-30% growth for fiscal 2007 compared to fiscal 2006.

We are confident that, although gross profit margins may come down due to price erosion, our sales growth, product portfolio improvements and execution of our plans will offset any long-term impact. However, should the pricing pressures become more severe than anticipated; the result may be lower growth rates and gross margins. Management has and will continue to work diligently to counter the pricing pressures through increased sales volumes, expansion of our customer base, improved productivity, better-cost absorption of operational overheads, cost reductions and increased development plans.

As disclosed, under the products agreement dated November 21, 2002 between Sun Global and the Company, Sun Global has agreed to transfer the technology for 25 products to the Company over a five year period in exchange for 544,000 preferred shares (which are convertible on a one-to-one basis into common shares) per product. Since the date of the products agreement, the Company has selected all 25 products for development and twenty two of these products have passed their respective bio-equivalency studies..

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-Q

While the development of new products will increase our cash R&D expense and will impact EPS, we expect that cash will be available, among other things, to meet increased working capital requirements, fund potential Paragraph IV Certification litigation and finance further capital investments.

The Company will continue to aggressively move forward with the development of new products. We believe that receiving products from Sun provides us with a partner with a proven track record; one that already has provided us with quality products. Moreover, Sun Pharma's increased beneficial ownership in us to approximately 64% (approximately 75.2% including the convertible Series B Preferred Stock), should, we believe, provide it with the incentive to continue to help us succeed. Sun Pharma has previously provided us with capital, loans, guarantees of loans, personnel, raw materials and equipment, which have significantly helped us to date.

Management's plans for fiscal 2007 include:

- Continued focus and improvement on FDA compliance.

- Increased pace of research and development activities, with a view to maximize the number of ANDA filings.

- Continue to invest in equipment and facilities to expand capacity to meet requirements of

22

projected short term and long term growth.

- 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.

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

- Consider alternative ways of increasing cash, such as marketing ANDAs owned by Sun Pharma,

- Expand our relationships with financial institutions to fortify our credit position and borrowings as necessary.

- Research alternate product development sources and product licenses such as in licensing authorized generics from brand innovator companies and acquisitions of ANDAs from competitor manufacturers both domestically and abroad.

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 of 1934. Without limitation, the words "believes," "plans," "expects," and similar expressions are intended to identify forward-looking statements. Those statements include statements regarding our intent, belief, and current expectation. These statements are not guarantees of future performance and are subject to risks and uncertainties that cannot be predicted or quantified. Consequently, actual results could differ materially from those expressed or implied by such forward-looking statements.

Such risks and uncertainties include, but are not limited to: (i) that the information is of a preliminary nature and may be subject to further adjustment; (ii) not obtaining FDA approval for new products or delays in receiving FDA approvals; (iii) governmental restrictions on the sale of certain products; (iv) dependence on key personnel; (v) development by competitors of new or superior products or cheaper products or new technology for the production of products or the entry into the market of new competitors; (vi) market and customer acceptance and demand for new pharmaceutical products; (vii) availability of raw materials in a timely manner, at competitive prices, and in required quantities; (viii) timing and success of product development and launch; (ix) integrity and reliability of the Company's data; (x) lack of success in attaining full compliance with regard to regulatory and cGMP compliance; (xi) experiencing difficulty in managing our recent rapid growth and anticipated

future growth; (xii) dependence on limited customer base; (xiii) occasional credits to certain customers reflecting price reductions on products previously sold to them and still available as shelf-stock; (xiv) possibility of an incorrect estimate of charge-backs and the impact of such an incorrect estimate on net sales, gross profit and net income; (xv) dependence on few products generating majority of sales; (xvi) product liability claims for which the Company may be inadequately insured; (xvii) subjectivity in judgment of management in applying certain significant accounting policies derived based on historical experience, terms of contracts, our observations of trends of industry, information received from our customers and other sources, to estimate revenues, accounts receivable allowances including chargebacks, rebates, income taxes, values of assets and inventories; (xviii) litigation involving claims of patent infringement; (xix) litigation involving claims for royalties and/or options relating to a prior contract for one product and (xx) other risks identified in this report and identified from time to time in our reports and

23

registration statements filed with the Securities and Exchange Commission (see our Annual Report, Part I, Item 1A, for more detailed discussion of such risks). 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

The Company has no debt or other market risk securities or transactions in foreign exchange.

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 and our Chief Financial Officer have evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this 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 relating to the Company known to others within the Company which is required to be included in our periodic reports filed under the Exchange Act.

b. There has been no change in the Company's internal control over financial reporting that occurred during the first quarter of fiscal 2007 that materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II -- OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The information presented in Note 12 of Part I, Notes to Financial Statements, is incorporated herein by reference.

ITEM 6. 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.

24

SIGNATURES

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

CARACO PHARMACEUTICAL
LABORATORIES, LTD.

Date: July 26, 2006

By: /s/ Daniel H. Movens
Daniel H. Movens
Chief Executive Officer

Date: July 26, 2006

By: /s/ Jitendra N. Doshi
Jitendra N. Doshi
Chief Financial Officer

25

EXHIBIT INDEX

31.1 Certificate of Chief Executive Officer

SIGNATURES

24

31.2 Certificate of Chief Financial Officer

32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
