

CARACO PHARMACEUTICAL LABORATORIES LTD

Form 10-Q

October 25, 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 September 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	38-2505723
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

1150 ELIJAH MCCOY DRIVE, DETROIT, MICHIGAN	48202
(Address of principal executive offices)	(Zip Code)

TELEPHONE: (313) 871-8400  
Registrant's telephone number, including area code

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

Yes ☒ No ☐

Indicate by check mark whether the registrant is 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 <input type="checkbox"/>	Accelerated Filer <input checked="" type="checkbox"/>	Non-Accelerated Filer <input type="checkbox"/>
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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 October 17, 2006 the registrant had 26,442,794 shares of common stock issued and outstanding.

**CARACO PHARMACEUTICAL LABORATORIES LTD.**

(A subsidiary of Sun Pharmaceutical Industries Limited)

**BALANCE SHEETS**

	SEPTEMBER 30, 2006	MARCH 31, 2006
	UNAUDITED	AUDITED
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 21,748,113	\$ 11,924,245
Accounts receivable, net	24,101,199	20,859,099
Inventories	31,191,999	26,965,690
Prepaid expenses and deposits	2,052,905	2,532,561
<b>Total current assets</b>	<b>79,094,216</b>	<b>62,281,595</b>
<b>Property, plant and equipment</b>		
Land	651,443	197,305
Building and improvements	12,281,452	10,790,703
Equipment	14,406,022	12,040,688
Furniture and fixtures	874,734	681,705
<b>Total</b>	<b>28,213,651</b>	<b>23,710,401</b>
Less: accumulated depreciation	9,665,208	8,749,997
<b>Net property, plant &amp; equipment</b>	<b>18,548,443</b>	<b>14,960,404</b>
<b>Total assets</b>	<b>\$ 97,642,659</b>	<b>\$ 77,241,999</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 3,789,476	\$ 3,696,265
Accounts payable, Sun Pharma	15,937,746	14,678,085
Accrued expenses	2,462,812	2,489,398
<b>Total liabilities (all current)</b>	<b>22,190,034</b>	<b>20,863,748</b>
<b>Stockholders equity</b>		
Series B convertible preferred stock, no par value; issued and outstanding 12,512,000 shares (September 30, 2006) 10,880,000 shares (March 31, 2006)	84,517,050	72,755,770
Common stock, no par value; authorized 30,000,000 shares, issued and outstanding 26,442,794 shares (September 30, 2006) 26,421,994 shares (March 31, 2006)	45,005,237	44,988,597
Additional paid in capital	2,718,735	2,718,735
Accumulated deficit	(56,788,397)	(64,084,851)
<b>Total stockholders equity</b>	<b>75,452,625</b>	<b>56,378,251</b>

	SEPTEMBER 30, 2006	MARCH 31, 2006
	<u></u>	<u></u>
<b>Total liabilities and stockholders equity</b>	<b>\$ 97,642,659</b>	<b>\$ 77,241,999</b>
	<u></u>	<u></u>

See accompanying notes

**CARACO PHARMACEUTICAL LABORATORIES, LTD.**

(A subsidiary of Sun Pharmaceutical Industries Limited)

**STATEMENTS OF OPERATIONS**

	Six Months ended September 30,		Quarter ended September 30,	
	2006	2005	2006	2005
	UNAUDITED	UNAUDITED	UNAUDITED	UNAUDITED
<b>Net sales</b>	<b>\$ 53,031,116</b>	<b>\$ 37,408,932</b>	<b>\$ 28,279,969</b>	<b>\$ 19,796,402</b>
Cost of goods sold	25,788,987	19,532,259	14,045,813	10,081,440
<b>Gross profit</b>	<b>27,242,129</b>	<b>17,876,673</b>	<b>14,234,156</b>	<b>9,714,962</b>
Selling, general and administrative expenses	4,502,861	3,567,885	2,386,421	1,863,252
Research and development costs - affiliate	11,761,280	13,910,080	7,382,080	10,667,840
Research and development costs - other	4,043,476	3,664,387	2,346,317	2,034,480
<b>Operating income (loss)</b>	<b>6,934,512</b>	<b>(3,265,678)</b>	<b>2,119,339</b>	<b>(4,850,610)</b>
<b>Other income</b>				
Interest expense	(28,194)		(28,194)	
Interest income	350,247	53,310	219,327	26,166
Other income	39,889	8,998	58	4,828
<b>Other income</b>	<b>361,943</b>	<b>62,308</b>	<b>191,191</b>	<b>30,994</b>
<b>Net income (loss)</b>	<b>\$ 7,296,454</b>	<b>\$ (3,203,370)</b>	<b>\$ 2,310,530</b>	<b>\$ (4,819,616)</b>
<b>Net income (loss) per common share</b>				
Basic	0.28	(0.12)	0.09	(0.18)
Diluted	0.19	(0.12)	0.06	(0.18)

See accompanying notes

**CARACO PHARMACEUTICAL LABORATORIES, LTD.**

(A subsidiary of Sun Pharmaceutical Industries Limited)

**STATEMENTS OF CASH FLOWS**

	<b>Six Months ended September 30,</b>	
	<b>2006</b>	<b>2005</b>
	<b>UNAUDITED</b>	<b>UNAUDITED</b>
<b>Cash flows from operating activities</b>		
Net income (loss)	\$ 7,296,454	\$ (3,203,370)
Adjustments to reconcile net income to net cash flow from operating activities		
Depreciation	915,211	641,002
Capital stock issued or to be issued to affiliate in exchange for product formula	11,761,280	13,910,080
Changes in operating assets and liabilities which provided (used) cash:		
Accounts receivable	(3,242,100)	(14,268,436)
Inventories	(4,226,308)	748,585
Prepaid expenses and deposits	479,656	(181,442)
Accounts payable	1,352,871	(423,492)
Accrued expenses and interest	(26,586)	68,997
<b>Net cash provided by (used in) operating activities</b>	<b>14,310,478</b>	<b>(2,708,076)</b>
<b>Cash flows from investing activities</b>		
Purchases of property, plant and equipment	(4,503,250)	(1,353,976)
<b>Net cash used in investing activities</b>	<b>(4,503,250)</b>	<b>(1,353,976)</b>
<b>Cash flows from financing activities</b>		
Proceeds from loans payable to financial institutions	5,000,000	
Repayments of loans payable to financial institutions	(5,000,000)	
Proceeds from exercise of stock options	16,640	26,480
<b>Net cash provided by financing activities</b>	<b>16,640</b>	<b>26,480</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>9,823,868</b>	<b>(4,035,570)</b>
Cash and cash equivalents, beginning of period	11,924,245	6,627,425
<b>Cash and cash equivalents, end of period</b>	<b>\$ 21,748,113</b>	<b>\$ 2,591,855</b>

See accompanying notes

**CARACO PHARMACEUTICAL LABORATORIES, LTD.**

(A subsidiary of Sun Pharmaceutical Industries Limited)

**STATEMENT OF STOCKHOLDERS' EQUITY**

	<b>PREFERRED STOCK</b>		<b>COMMON STOCK</b>		<b>ADDITIONAL PAID IN CAPITAL</b>	<b>ACCUMULATED DEFICIT</b>	<b>TOTAL STOCKHOLDERS EQUITY</b>
	<b>SHARES</b>	<b>AMOUNT</b>	<b>SHARES</b>	<b>AMOUNT</b>			
Balances at April 1, 2006	10,880,000	\$ 72,755,770	26,421,994	\$ 44,988,597	\$ 2,718,735	\$ (64,084,851)	\$ 56,378,250
Issuances of preferred stock to affiliate in exchange for product technology transfers	1,632,000	11,761,280					11,761,280
Common stock options exercised			20,800	16,640			16,640
Net Income						7,296,454	7,296,454
Balances at September 30, 2006	12,512,000	\$ 84,517,050	26,442,794	\$ 45,005,237	\$ 2,718,735	\$ (56,788,397)	\$ 75,452,624

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 26 prescription products in 55 strengths in various package sizes. The products are intended to treat a variety of disorders including the following: hypertension, arthritis, epilepsy, diabetes, antipsychotic, 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 second quarter and six months of our new fiscal year ( fiscal 2007 ), we recorded net sales of \$28.3 million and \$53.0, million respectively, compared to \$19.8 million and \$37.4 million during the corresponding periods of fiscal 2006. We incurred \$9.7 million and \$15.8 million in R&D expense during the second quarter and six months of fiscal 2007, as compared to \$12.7 million and \$17.6 million during the corresponding periods of fiscal 2006. This included \$7.4 million and \$11.8 million in the second quarter and six months of fiscal 2007, respectively, in non-cash R&D expense as compared to \$10.7 million and \$13.9 million during the corresponding periods of fiscal 2006. We generated cash from operations of \$14.3 million during the six months of fiscal 2007 as compared to utilization of \$2.7 million during the corresponding period of fiscal 2006. We earned net income of \$2.3 million and \$7.3 million during the second quarter and six months of fiscal 2007, as compared to net losses of \$4.8 million and \$3.2 million during the corresponding periods of fiscal 2006. At September 30, 2006, we had stockholders equity of \$75.5 million as compared to stockholders equity of \$56.4 million at March 31, 2006. See Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

Pursuant to our products agreement with Sun Pharma Global, Inc. ( Sun Global ), a wholly-owned subsidiary of Sun Pharma, we have selected, through September 30, 2006, all products out of the 25 products to be transferred to us by Sun Global. Of these, 23 products passed their bio-equivalency studies as of September 30, 2006. 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 three ANDAs with the FDA during the second quarter of fiscal 2007. We have received approvals for three ANDAs during the second quarter of fiscal 2007. This brings our total number of ANDAs pending approval by the FDA to 17 products (including two tentative approvals).

The FDA completed an inspection of the Company s facility in June 2006. Observations were provided on FDA Form 483. The Company has responded accordingly. The Company believes that the observations are not material and we remain substantially cGMP compliant. As noted above, we have since received approval from the FDA for three 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 2006 to the retail level (Class II) due to the potential for some of the bottles to contain foreign tablets. This lot represents 1,023 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**

In July 2006, the FASB issued FASB Interpretation No. 48 ( FIN 48 ), Accounting for Uncertainty in Income Taxes. FIN 48 prescribes detailed guidance for the financial statement recognition, measurement and disclosure of uncertain tax positions recognized in an enterprise s financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes. Tax positions must meet a more-likely-than-not recognition threshold at the effective date to be recognized upon the adoption of FIN 48 and in subsequent periods. FIN 48 will be effective for fiscal years beginning after December 15, 2006 and the provisions of FIN 48 will be applied to all tax positions upon initial adoption of the Interpretation. The cumulative effect of applying the provisions of this Interpretation will be reported as



an adjustment to the opening balance of retained earnings for that fiscal year. We are currently evaluating the impact of FIN 48 on our financial statements.

On September 13, 2006, the SEC issued Staff Accounting Bulletin (SAB) No. 108 on quantifying financial statement misstatements. In summary, SAB 108 states that registrants should use **both** a balance sheet (iron curtain) approach and an income statement (rollover) approach when quantifying and evaluating the materiality of a misstatement, and contains guidance on correcting errors under the dual approach.

In addition, SAB 108 provides transition guidance for correcting errors existing in prior years. If prior-year errors that had been previously considered immaterial (based on the appropriate use of the registrant's prior approach) now are considered material based on the approach in this SAB, the registrant need not restate prior period financial statements. SAB 108 is effective for Caraco's annual financial statements covering our fiscal year ending March 31, 2007, with earlier application encouraged for any interim period of our current fiscal year and filed after September 13, 2006.

While the Company is considering the effects of implementing its provisions, management does not presently believe that SAB 108 will have a material impact on Caraco's financial position or results of operations.

#### 5. **COMPUTATION OF EARNINGS PER SHARE**

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

The basic and diluted weighted average number of common shares outstanding for the second quarter of fiscal 2007 were 26,429,040 and 39,106,236, respectively, and were 26,429,040 and 38,463,119, respectively, for the six months of fiscal 2007. Correspondingly, the basic and diluted weighted average number of common shares outstanding for the second quarter and six months of fiscal 2006 ended September 30, 2005 were 26,377,065.

#### 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.

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, 23 of which passed bio-equivalency studies through September 30, 2006. 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.

## **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.

For the second quarter and six months 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 September 30, 2006 total unrecognized compensation cost related to stock options granted was \$255,000. 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 July 11, 2006 to the CEO of the Corporation, which will vest in the amount of 1/3<sup>rd</sup> every anniversary thereafter. In addition, the Company granted options to purchase 1,500 shares of common stock to each of the two independent directors on July 20, 2006, which will vest in the amount of 1/3<sup>rd</sup> every anniversary thereafter. Stock options to purchase 18,000 shares were granted to various employees during the six months of fiscal 2007, which will vest in the amount of 1/3<sup>rd</sup> every anniversary thereafter.

#### 8. COMMON STOCK ISSUANCES

We issued 20,800 shares and 33,100 shares of common stock to our employees upon exercise of their stock options during the six months of fiscal 2007 and fiscal 2006, respectively.

#### 9. PREFERRED STOCK ISSUANCES

We issued 1,632,000 shares and 2,176,000 shares of preferred stock to Sun Global during the six months of fiscal 2007 and fiscal 2006 respectively.

#### 10. SALES AND CUSTOMERS

Our Company effectively executed its operating plan during the six months 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 six months of fiscal 2007 these wholesale accounts equate to 53% of our net sales, yet the actual sales are for various customers with underlying direct contracts with our Company.

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 last of which was exercised in this quarter. 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 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 5.33% and 7.25%, respectively at September 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 September 30, 2006. There are no outstanding borrowings under this Credit Agreement as at September 30, 2006.

#### 12. **LITIGATION**

As previously disclosed, 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.

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 sought an order from the district court which, among other things, directed 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 asserted that the Ortho-McNeil patent is invalid and/or will not be infringed by Caraco 's manufacture, use or sale of the product. Since filing this action, Ortho-McNeil has entered into a license agreement with another manufacturer which has launched its product generically while another manufacturer has launched its approved generic at risk. On October 8, 2005, arguments were heard in the United States District Court for 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 Caraco 's generic product. Ortho-McNeil has filed an appeal of the finding of non-infringement by the district court and that appeal is currently pending before the United States Court of Appeals for the Federal Circuit. Additionally, the United States Patent and Trademark Office has approved Ortho-McNeil 's request for a reissue patent. Although the district court has determined that Caraco does not infringe Ortho-McNeil 's original patent, on July 31, 2006, Ortho-McNeil filed a lawsuit against Caraco in the United States District Court for the District of New Jersey, alleging that Caraco 's generic version of Ultracet® brand tramadol/acetaminophen drug product infringes its Reissue Patent Number RE39221. On September 26, 2006, Caraco filed an Answer denying, among other things, that its generic product infringes any valid claims of Ortho-McNeil 's reissue patent. The Corporation believes that, like its original patent, Ortho-McNeil 's reissue patent is invalid and/or is not infringed by Caraco 's manufacture, use or sale of the product, and the Corporation intends to vigorously defend this action. There is no assurance, however, that the corporation will prevail in this action. If the Company does not prevail it could have a material adverse effect on our financial condition or results of operations.

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 awarded to 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:

	(Amount in Dollars)	
	September 30, 2006	March 31, 2006
Raw materials	\$ 10,569,225	\$ 9,735,502
Goods in transit	4,944,862	5,974,600
Work in process	3,699,171	3,283,911
Finished goods	11,978,741	7,971,677
Total	\$ 31,191,999	\$ 26,965,690

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

October 12, 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 September 30, 2006 and the related statements of operations for the three and six months ended September 30, 2006 and 2005, the statement of stockholders' equity for the six months ended September 30, 2006, and the statements of cash flows for the six months ended September 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.

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

The following discussion and analysis provides information that management believes is relevant to an understanding of the Corporation's results of operations and financial condition. The discussion should be read in conjunction with the financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included in the Company's 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. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

**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 estimate chargebacks at the point of sale for our wholesale customers.



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

1. 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 for current quarter as compared to previous quarter and compared to last six month period.
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.

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. 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.

#### *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.

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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.

## *Gross Sales and Related Reserves*

Our gross sales for the second quarter and six months of fiscal 2007 were \$73.9 million and \$138.2 million, as compared to \$46.1 million and \$89.3 million for the corresponding periods of fiscal 2006. Chargebacks, returns, discounts and other customary customer deductions and other sales costs constituted approximately 62% for each of the second quarter and six months of fiscal 2007, compared to 57% and 58% for the corresponding periods of fiscal 2006. Net sales for the second quarter and six months of fiscal 2007 were \$28.3 million and \$53.0 million respectively, as compared to \$19.8 million and \$37.4 million respectively for the corresponding periods of fiscal 2006. The primary cause of increase in the sales allowances by almost 4% between the periods is the impact of price erosion for the products we sell and the corresponding impact of such price erosion 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 six months of fiscal 2007.

(\$ in Thousands)					
<b>Fiscal 2006</b>	<b>Roll forward allowances at beginning of fiscal 2006</b>	<b>Allowances charged to Gross Sales for fiscal 2006</b>	<b>Credits taken by customers during fiscal 2006</b>	<b>Balance at the end of fiscal 2006</b>	
		<b>Current Period</b>	<b>Prior Period</b>		
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
<b>For Six Months of fiscal 2007</b>	<b>Roll forward allowances at beginning of fiscal 2007</b>	<b>Allowances charged to Gross Sales for six months of fiscal 2007</b>	<b>Credits taken by customers during six months of fiscal 2007</b>	<b>Balance at the end of September 30, 2006</b>	
		<b>Current Period</b>	<b>Prior Period</b>		
Chargebacks & shelf stock adjustments	\$ 11,467	\$ 80,570	\$ -0-	\$ 75,980	\$ 16,057
Returns and other allowances	1,500	4,615	-0-	3,498	2,637

Doubtful Accounts	100	-0-	-0-	-0-	100
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## **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 second quarter and six months 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 September 30, 2006 and March 31, 2006. At September 30, 2006, we had federal net operating loss carry forwards of approximately \$51.5 million available to reduce future 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.

## **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 second quarter of fiscal 2007 represents 22 quarters of successive sales revenue growth. During the second quarter and six months of fiscal 2007, we recorded net sales of \$28.3 million and \$53.0 million compared to \$19.8 million and \$37.4 million during the corresponding periods of fiscal 2006. This represents an improvement of 43% and 42% respectively. We incurred \$9.7 million and \$15.8 million in R&D expense during the second quarter and six months of fiscal 2007 compared to \$12.7 million and \$17.6 million during the corresponding periods of fiscal 2006. This reduction included \$7.4 million and \$11.8 million in second quarter and six months of fiscal 2007 respectively, in non-cash R&D expense as compared to \$10.7 million and \$13.9 million during the corresponding periods of fiscal 2006. We generated cash from operations of \$14.3 million during the six months of fiscal 2007 as compared to utilization of \$2.7 million during the corresponding period of fiscal 2006. The \$17.0 million dollar improvement is primarily due to our sales increase of \$15.6 million for the six month period. We earned net income of \$2.3 million and \$7.3 million during the second quarter and six months of fiscal 2007, as compared to net loss of \$4.8 million and \$3.2 million during the corresponding periods of fiscal 2006. At September 30, 2006, we had stockholders equity of \$75.5 million as compared to stockholders equity of \$56.4 million at March 31, 2006.

## 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 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 three products previously submitted. We continue to focus on improving the amount of support in both quality assurance and quality control in order to continually improve our performance in quality. This support is derived from the improvement of systems, training on risk management and cGMP, while adding the appropriate level of personnel to support our growth. During the first six months of fiscal 2007 and in addition to our own internal audits we have consulted with outside companies to audit both our laboratory and manufacturing areas of our company in order to improve and or maintain our systems of operation. These audits were based on a historical look back and offered improvements based on Caraco's future requirements. In the first six months of fiscal 2007 we added 25 persons in the quality assurance (QA) and quality control, (QC). There is an ongoing effort to add qualified people in these areas as well as manufacturing to support our ongoing compliance.

## Second Quarter and Six Months Fiscal 2007 Compared to Second Quarter and Six Months Fiscal 2006

**Net Sales.** Net sales for the second quarter and six months of fiscal 2007 were \$28.3 million and \$53.0 million, respectively, compared to \$19.8 million and \$37.4 million for the corresponding periods of fiscal 2006, reflecting an increase of 43% and 42%, respectively. 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 launches of new product approvals. Currently, we manufacture and market all except two of the approved products. Sales of four products accounted for approximately 74% and 73% of net sales for the second quarter and six months of fiscal 2007 as compared to sales of three products accounting for approximately 72% and 77% of net sales during corresponding periods of fiscal 2006.

**Gross Profit.** We earned gross profit of \$14.2 million and \$27.2 million during the second quarter and six months of fiscal 2007 as compared to gross profit of \$9.7 million and \$17.9 million during the corresponding periods of fiscal 2006, reflecting an increase of 46% and 52% respectively. The increases in gross profits were primarily due to higher sales and an improved balance in the mix of customers or the class of trade and product selection being sold partially offset by price erosion.

The gross profit margin for the second quarter and six months of fiscal 2007 increased to 50% and 51% from 49% and 48% during the corresponding periods 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. We have incurred an additional charge of \$0.3 million in write-offs for product that had become short dated which we donated during the second quarter of 2007. This write-off and overall sales mix resulted in a reduction in margin for the second quarter, although the first six month period margin of fiscal 2007 remained improved, by 3% as compared to the respective period of fiscal 2006.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses during the second quarter and six months of fiscal 2007 were \$2.4 million and \$4.5 million, respectively, compared to \$1.9 million and \$3.6 million during the corresponding periods of fiscal 2006, representing an increase of 26% and 25% in the respective periods. The selling, general and administrative expenses, as a percentage of net sales, have declined to 8% for the six months of fiscal 2007, as compared to 10% for the corresponding period of fiscal 2006. The selling, general and administrative expenses percentage improved to 8% for second quarter fiscal 2007 as compared to 9% for first quarter fiscal 2007.

**Research and Development Expenses.** Total R&D expenses for the second quarter and six months of fiscal 2007 were \$9.7 million and \$15.8 million, respectively, as compared to \$12.7 million and \$17.6 million during the corresponding periods of fiscal 2006. Actual cash research and development expenses were \$2.3 million and \$4.0 million respectively during the second quarter and six months of fiscal 2007, compared to \$2.0 million and \$3.7 million during the corresponding periods of fiscal 2006. We incurred non-cash research and development expenses (technology transfer cost) of \$7.4 million and \$11.8 million for two and three product transfers during the second quarter and six months of fiscal 2007 respectively, as compared to \$10.7 million and \$13.9 million for three and four product transfers during the corresponding periods of fiscal 2006. Each product transfer earns 544,000 shares of preferred stock. The cash R&D expenses during the second quarter and six months of fiscal 2007 were slightly higher compared to those during the corresponding periods of fiscal 2006 due to increased internal R&D activity and initial milestone payments paid to a third party for initiating technology transfer of two products (see Future Outlook ). We filed three products with the FDA during the second quarter of fiscal 2007.

**Results of Operations.** We earned net income of \$2.3 million and \$7.3 million in the second quarter and six months of fiscal 2007 as compared to net losses of \$4.8 million and \$3.2 million during the corresponding periods of fiscal 2006.

#### **Liquidity and Capital Resources**

We generated cash from operations of \$14.3 million during the six months of fiscal 2007 as compared to utilization of cash of \$2.7 million from operations during the corresponding period of fiscal 2006. During the second quarter fiscal 2007 Caraco acquired a facility that currently houses our bottling operation for \$1.7 million. This 33,369 sq. ft. facility was owned and operated by our third party packager who has packaged our portfolio of products during the last several years. It is our intention to hire certain employees of such third party packager that have contributed to our growth and manage the trained staff of the bottling operation internally. We expect a transition of six months or less in order to assume the packaging services. We envision this facility acquisition and the subsequent transition will improve

overall costs in packaging, increase our vision in production and planning while improving throughput on a long term basis. Accounts receivable increased by \$3.2 million to \$24.1 million during the six months of fiscal 2007 as compared to \$20.9 million at the end of fiscal 2006. Our accounts receivable increase is primarily commensurate with the increase in sales. Our day's sales outstanding, (DSO), for the second quarter of fiscal 2007 improved to 78 days from 84 days for the first quarter of 2007.

At September 30, 2006 we had working capital of \$56.9 million compared to working capital of \$41.4 million at March 31, 2006. The increase in working capital in fiscal 2007 is 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 credit obtained through JP Morgan Chase Bank, N.A. which allows 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 cGMP. We continue to invest in improved systems, training and personnel in quality assurance, quality control and manufacturing to improve our overall performance in quality.

We received three ANDA approvals from the FDA during the second quarter. Currently, we have 17 products pending approval at the FDA (including two tentative approvals). We continue to expand and upgrade our facilities, increase our staff by attracting talented individuals to our Company and improve our customer base. Our efforts, combined with Sun in developing new products have also picked up momentum and this should permit us to grow at the level of our guidance as provided below. We now have eight products, Metformin, Metoprolol, Tramadol, Salsalate and Tramadol with Acetaminophen, Clonazepam, Mirtazapine, Tizanidine, 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 a minimum of 25-30% growth in sales 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, and 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 23 of these products have passed their respective bio-equivalency studies. There are two products that remain in our development pipeline that pertain to this agreement. We expect that one of these products will pass its bio-equivalency study prior to the end of fiscal 2007 and the other will most likely be completed by the end of the 1<sup>st</sup> fiscal quarter of 2008

While the development of new products will increase our cash R&D expense and will impact EPS, we expect that we will continue to have the cash 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 75.4% 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. In addition to the Sun products agreement we have initiated alternate development strategies that will complement the Sun development pipeline by creating development opportunities with various parties both domestically and abroad. Accordingly, during the second quarter of fiscal 2007, Caraco has signed a definitive agreement with one such company for two products to be developed for Caraco ANDAs. This agreement has milestone payments to be paid in cash and profit sharing on future sales for a defined period, for performance of services rendered and offers additional opportunities for future development of other products. We anticipate other such agreements will be consummated and will allow us to eliminate any future gaps in our calendar of approvals we anticipate from the FDA. We also continue to fortify our own research and development team and increased the number of products we have in development internally.

Lastly, management is working towards closure on a formal agreement to market Sun ANDAs that are awaiting approval at the FDA. We anticipate that this agreement will be completed and approved during the next quarter of fiscal 2007. This agreement will solidify Sun's intention to have Caraco market its products in the US. This agreement will provide for an alternate stream of products that will complement our internal research and development, our outsourced development and our current technology agreement with Sun, providing four diverse paths of future development pipelines and potential revenue. The various paths mitigate the risk of each other, potentially allowing for an ongoing stream of approvals from the FDA.

Management's plans for the remainder of fiscal 2007 include:

Continued focus and improvement on FDA compliance.

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

Continue to invest in equipment and facilities to expand capacity to meet requirements of projected short term and long term growth while improving quality.

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 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 second 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 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

The Annual Meeting of Shareholders of the Corporation was held on September 11, 2006 in Dearborn, Michigan for the purpose of electing three directors for a three-year term expiring at the annual meeting in 2009 and upon the election and qualification of their successors.

<u>Name of the Director</u>	<u>Votes FOR</u>	<u>Votes Withheld</u>
Dilip S. Shanghvi	24,480,319	1,307,708
Jitendra N. Doshi	24,680,701	1,107,326
Dr. John D. Crissman	25,772,232	15,795

The names of the other directors and the expiration dates of their remaining terms (at the applicable annual meeting dates and upon the election and qualification of their successors) are as follows:

<u>Name of the Director</u>	<u>Term</u>
Timothy S. Manney	2007
Madhava Reddy	2007
Sudhir Valia	2007
Daniel H. Movens	2008
Sailesh T. Desai	2008
Georges Ugeux	2008

**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

**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: October 25, 2006

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

Date: October 25, 2006

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

EXHIBIT INDEX

31.1     Certificate of Chief Executive Officer

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.

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