

CARACO PHARMACEUTICAL LABORATORIES LTD  
Form 10-Q  
January 26, 2007

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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 December 31, 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  
(Address of principal executive offices)

48202  
(Zip Code)

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

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

Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition 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 January 24, 2007 the registrant had 26,444,794 shares of common stock issued and outstanding.



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

|   | DECEMBER 31,<br>2006  | MARCH 31,<br>2006    |
|---|-----------------------|----------------------|
|   | UNAUDITED             | AUDITED              |
| <b>ASSETS</b>   |                       |                      |
| <b>Current assets</b>   |                       |                      |
| Cash and cash equivalents   | \$ 25,993,824         | \$ 11,924,245        |
| Accounts receivable, net  | 26,268,125            | 20,859,099           |
| Inventories   | 32,339,294            | 26,965,690           |
| Prepaid expenses and deposits   | 2,694,783             | 2,532,561            |
| <b>Total current assets</b>   | <b>87,296,026</b>     | <b>62,281,595</b>    |
| <b>Property, plant and equipment</b>  |                       |                      |
| Land  | 975,311               | 197,305              |
| Building and improvements   | 12,409,577            | 10,790,703           |
| Equipment   | 14,996,807            | 12,040,688           |
| Furniture and fixtures  | 969,446               | 681,705              |
| <b>Total</b>  | <b>29,351,141</b>     | <b>23,710,401</b>    |
| Less: accumulated depreciation  | 10,150,115            | 8,749,997            |
| <b>Net property, plant &amp; equipment</b>  | <b>19,201,026</b>     | <b>14,960,404</b>    |
| <b>Total assets</b>   | <b>\$ 106,497,052</b> | <b>\$ 77,241,999</b> |
| <b>LIABILITIES AND STOCKHOLDERS EQUITY</b>  |                       |                      |
| <b>Current liabilities</b>  |                       |                      |
| Accounts payable  | \$ 3,228,984          | \$ 3,696,265         |
| Accounts payable, Sun Pharma  | 14,599,345            | 14,678,085           |
| Accrued expenses  | 3,155,026             | 2,489,398            |
| <b>Total liabilities (all current)</b>  | <b>20,983,355</b>     | <b>20,863,748</b>    |
| <b>Stockholders equity</b>  |                       |                      |
| Series B convertible preferred stock, no par value; issued and outstanding<br>12,512,000 shares (December 31, 2006) 10,880,000 shares (March 31, 2006)          | 84,517,050            | 72,755,770           |
| Common stock, no par value; authorized 50,000,000 shares, issued and<br>outstanding 26,444,794 shares (December 31, 2006) 26,421,994 shares (March<br>31, 2006) | 45,006,837            | 44,988,597           |
| Additional paid in capital  | 2,718,735             | 2,718,735            |
| Accumulated deficit   | (46,728,925)          | (64,084,851)         |
| <b>Total stockholders equity</b>  | <b>85,513,697</b>     | <b>56,378,251</b>    |

|  |                       |                      |
|--|-----------------------|----------------------|
| <b>Total liabilities and stockholders equity</b> | <b>\$ 106,497,052</b> | <b>\$ 77,241,999</b> |
|--|-----------------------|----------------------|

See accompanying notes

**CARACO PHARMACEUTICAL LABORATORIES, LTD.**  
(A subsidiary of Sun Pharmaceutical Industries Limited)  
**STATEMENTS OF OPERATIONS**

|  | Nine Months ended December 31, |                       | Three Months ended December 31, |                      |
|--|--------------------------------|-----------------------|---------------------------------|----------------------|
|  | 2006                           | 2005                  | 2006                            | 2005                 |
|  | UNAUDITED                      | UNAUDITED             | UNAUDITED                       | UNAUDITED            |
| <b>Net sales</b>                             | <b>\$ 84,288,303</b>           | <b>\$ 58,087,910</b>  | <b>\$ 31,257,187</b>            | <b>\$ 20,678,978</b> |
| Cost of goods sold                           | 41,915,021                     | 29,861,857            | 16,126,034                      | 10,329,598           |
| <b>Gross profit</b>                          | <b>42,373,282</b>              | <b>28,226,053</b>     | <b>15,131,153</b>               | <b>10,349,380</b>    |
| Selling, general and administrative expenses | 7,105,896                      | 5,701,231             | 2,603,035                       | 2,133,346            |
| Research and development costs - affiliate   | 11,761,280                     | 21,047,360            |                                 | 7,137,280            |
| Research and development costs - other       | 6,778,204                      | 5,512,554             | 2,734,727                       | 1,848,167            |
| <b>Operating income (loss)</b>               | <b>16,727,902</b>              | <b>(4,035,092)</b>    | <b>9,793,391</b>                | <b>(769,413)</b>     |
| <b>Other income</b>                          |                                |                       |                                 |                      |
| Interest expense                             | (28,194)                       |                       |                                 |                      |
| Interest income                              | 616,321                        | 108,130               | 266,074                         | 54,820               |
| Other income                                 | 39,897                         | 42,635                | 6                               | 33,637               |
| <b>Other income</b>                          | <b>628,024</b>                 | <b>150,765</b>        | <b>266,080</b>                  | <b>88,457</b>        |
| <b>Net income (loss)</b>                     | <b>\$ 17,355,926</b>           | <b>\$ (3,884,327)</b> | <b>\$ 10,059,471</b>            | <b>\$ (680,956)</b>  |
| <b>Net income (loss) per common share</b>    |                                |                       |                                 |                      |
| Basic  | 0.66                           | (0.15)                | 0.38                            | (0.03)               |
| Diluted                                      | 0.45                           | (0.15)                | 0.26                            | (0.03)               |
| See accompanying notes                       |                                |                       |                                 |                      |

**CARACO PHARMACEUTICAL LABORATORIES, LTD.**  
(A subsidiary of Sun Pharmaceutical Industries Limited)  
**STATEMENTS OF CASH FLOWS**

|   | Nine Months ended December 31, |                     |
|---|--------------------------------|---------------------|
|   | 2006                           | 2005                |
|   | UNAUDITED                      | UNAUDITED           |
| <b>Cash flows from operating activities</b>                                       |                                |                     |
| Net income (loss)   | \$ 17,355,926                  | \$ (3,884,327)      |
| Adjustments to reconcile net income to net cash flow from operating activities    |                                |                     |
| Depreciation  | 1,400,118                      | 1,083,931           |
| Capital stock issued or to be issued to affiliate in exchange for product formula | 11,761,280                     | 21,047,360          |
| Changes in operating assets and liabilities which (ued) / provided cash:          |                                |                     |
| Accounts receivable   | (5,409,026)                    | (12,781,230)        |
| Inventories   | (5,373,604)                    | (2,870,838)         |
| Prepaid expenses and deposits   | (162,222)                      | (1,899,421)         |
| Accounts payable  | (546,023)                      | 3,780,761           |
| Accrued expenses and interest   | 665,631                        | 117,269             |
| <b>Net cash provided by operating activities</b>                                  | <b>19,692,080</b>              | <b>4,593,506</b>    |
| <b>Cash flows from investing activities</b>                                       |                                |                     |
| Purchases of property, plant and equipment  | (5,640,740)                    | (2,384,371)         |
| <b>Net cash used in investing activities</b>                                      | <b>(5,640,740)</b>             | <b>(2,384,371)</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   | 18,240                         | 28,880              |
| <b>Net cash provided by financing activities</b>                                  | <b>18,240</b>                  | <b>28,880</b>       |
| <b>Net increase in cash and cash equivalents</b>                                  | <b>14,069,580</b>              | <b>2,238,015</b>    |
| Cash and cash equivalents, beginning of period                                    | 11,924,245                     | 6,627,425           |
| <b>Cash and cash equivalents, end of period</b>                                   | <b>\$ 25,993,824</b>           | <b>\$ 8,865,440</b> |

See accompanying notes

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

|  | <u>PREFERRED STOCK</u> |               | <u>COMMON STOCK</u> |               | <u>ADDITIONAL<br/>PAID IN<br/>CAPITAL</u> | <u>ACCUMULATED<br/>DEFICIT</u> | <u>TOTAL<br/>STOCKHOLDERS<br/>EQUITY</u> |
|--|------------------------|---------------|---------------------|---------------|---|--------------------------------|--|
|  | <u>SHARES</u>          | <u>AMOUNT</u> | <u>SHARES</u>       | <u>AMOUNT</u> |   |                                |  |
| Balances at<br>April 1, 2006   | 10,880,000             | \$ 72,755,770 | 26,421,994          | \$ 44,988,597 | \$ 2,718,735                              | \$ (64,084,851)                | \$ 56,378,251                            |
| Issuances of<br>preferred stock<br>to affiliate in<br>exchange for<br>product<br>technology<br>transfers | 1,632,000              | 11,761,280    |                     |               |   |                                | 11,761,280                               |
| Common stock<br>options<br>exercised   |                        |               | 22,800              | 18,240        |   |                                | 18,240                                   |
| Net Income   |                        |               |                     |               |   | 17,355,926                     | 17,355,926                               |
| Balances at<br>December 31,<br>2006  | 12,512,000             | \$ 84,517,050 | 26,444,794          | \$ 45,006,837 | \$ 2,718,735                              | \$ (46,728,925)                | \$ 85,513,697                            |

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. and Puerto Rico.

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 27 prescription products in 58 strengths in various package sizes. The products are intended to treat a variety of disorders including, but not limited to, 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. Sun Pharma owns approximately 64% of the outstanding shares of the Company (approximately 75% including the convertible Series B Preferred Stock). See Current Status of the Corporation and Sun Pharmaceutical Industries Limited below.



### 3. CURRENT STATUS OF THE CORPORATION

During the third quarter and nine months of our current fiscal year ( fiscal 2007 ), we recorded net sales of \$31.3 million and \$84.3 million, respectively, compared to \$20.7 million and \$58.1 million during the corresponding periods of fiscal 2006. We incurred \$2.7 million and \$18.5 million in R&D expense during the third quarter and nine months of fiscal 2007, as compared to \$9.0 million and \$26.6 million during the corresponding periods of fiscal 2006. This included \$11.8 million in the nine month period of fiscal 2007, in non-cash R&D expense as compared to \$21.0 million during the corresponding period of fiscal 2006. There have been no non cash R&D expenses in the third quarter of fiscal 2007 as compared to \$7.1 million included in the corresponding period of fiscal 2006. We generated cash from operations of \$19.7 million during the nine months of fiscal 2007, as compared to \$4.6 million during the corresponding period of fiscal 2006. We earned net income of \$10.1 million and \$17.4 million during the third quarter and nine months of fiscal 2007, as compared to net losses of \$0.7 million and \$3.9 million during the corresponding periods of fiscal 2006. At December 31, 2006, we had stockholders equity of \$85.5 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 December 31, 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 December 31, 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 two new ANDAs with the FDA during the third quarter of fiscal 2007. This brings our total number of ANDAs pending approval by the FDA to 19 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 submitted a response to the observations to the FDA. The Company believes that we remain substantially cGMP compliant.

Caraco initiated a wholesale level recall of Midrin® capsules in July 2006. This withdrawal was classified as a class III recall in which the product is not likely to cause adverse health consequences. This recall is considered completed by Caraco and closed by the FDA.

### 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 numbers of common shares outstanding for the third quarter of fiscal 2007 was 26,434,238 and 39,119,085, respectively, and were 26,434,238 and 38,756,119, respectively, for the nine months of fiscal 2007. Correspondingly, the basic and diluted weighted average number of common shares outstanding for the third quarter and nine months of fiscal 2006 ended December 31, 2005 were 26,383,457.

#### **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 December 31, 2006. See Item - 2. Management's Discussion and Analysis of Financial Conditions and Results of Operations - Future Outlook .

The Company has entered into a three-year marketing agreement with Sun Pharma, which was reviewed and approved by the Board's Independent Committee. Under the agreement, the Company will purchase selected products offered from Sun and will market and distribute the same as part of our product offerings. The revenue and distribution margin resulting from this agreement will be provided separately from the manufacturing margin in an effort to provide clarity on the core manufacturing revenue and profit margins of the Company.

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 a vested interest in continuing 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 third quarter and nine months of fiscal 2007, the Company has recognized expense amounting to \$110,665 related to share-based compensation. As of December 31, 2006 total unrecognized compensation cost related to stock options granted was \$269,522. 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 22,000 shares were granted to various employees during the nine 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 22,800 shares and 36,100 shares of common stock to our employees upon exercise of their stock options during the nine months of fiscal 2007 and fiscal 2006, respectively.

#### **9. PREFERRED STOCK ISSUANCES**

We issued 1,632,000 shares and 3,264,000 shares of preferred stock to Sun Global during the nine months of fiscal 2007 and fiscal 2006, respectively.

#### **10. SALES AND CUSTOMERS**

Our Company effectively executed its operating plan during the nine 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 indirect relationships with our customers or act as an intermediary to service the customers directly in lieu of direct shipments from our Company. Collectively, for the nine months of fiscal 2007 these wholesale accounts equate to 57% of our net sales. These net sales include sales for various customers of ours that have underlying direct contracts with our Company that are facilitated through our wholesale customers.

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 \$13.0 million 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 August 2006. 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. On November 16, 2006, this agreement was renewed through November 30, 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 6.1% and 7.25%, respectively at December 31, 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 December 31, 2006. There are no outstanding borrowings under this Credit Agreement as of December 31, 2006.

#### 12. LITIGATION

While it is not possible to determine with any degree of certainty the ultimate outcome of the following legal proceedings, the Company believes that it has meritorious defenses with respect to the claims asserted against it and intends to vigorously defend its position. An adverse outcome in any of these proceedings could have a material adverse effect on the Company's financial position and results of operations.

On September 29, 2006, Schering Corporation ( Schering ) filed a complaint in the United States District Court for the District of New Jersey. A nearly identical complaint was filed on October 5, 2006, in the Eastern District of Michigan. Both complaints allege, inter alia, that Sun Pharmaceutical Industries, Ltd. ( Sun ) filing of ANDA 78-359 - seeking approval to market its generic version of Schering's Clarinex® drug product - infringed Schering's U.S. Patent No. 6,100,274 ( the 274 patent ), which expires July 7, 2019. Schering further alleges that Caraco Pharmaceutical Laboratories, Ltd. ( Caraco ) either directly infringed the 274 patent by aiding in the filing of Sun's ANDA, or will induce others to infringe by marketing and/or selling Sun's generic version of Clarinex® upon receiving FDA approval. Schering's complaint seeks an order from the Court which, among other things, directs the FDA not to approve Sun's ANDA any earlier than the claimed expiration date. The ANDA filed by Sun

contains a Paragraph IV certification challenging the 274 patent. Sun believes that the 274 patent is invalid, unenforceable and/or will not be infringed by Sun's or Caraco's manufacture, use or sale of the product and both Sun and Caraco intend 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 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 U.S. Patent No. 6,677,358. 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 this Novo Nordisk patent is invalid and/or will not be infringed by Caraco's manufacture, use or sale of the product. The Corporation believes that it is the first to file an ANDA with a paragraph IV certification for this drug product and it intends to defend this action vigorously to capitalize on the potential for obtaining 180 days exclusivity available for this product.

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 (extended to March 14, 2012 based upon a six month pediatric exclusivity). 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.

On August 23, 2006, Forest filed a motion to transfer its action against the Corporation to the United States District Court for the District of Delaware, where a similar action by Forest was pending. (This action is described below.) On November 15, 2006 the Court denied the motion and, accordingly, the litigation will proceed in the Eastern District of Michigan. The Court has since entered a scheduling order setting forth a basic timeline for the case.

Prior to this action, Forest had filed two lawsuits against other manufacturers who sought to market a generic version of Lexapro®, one against Alphapharm Pty. Ltd. (Alphapharm) and the other against IVAX Pharmaceuticals, Inc. (IVAX) and CIPLA Ltd. (CIPLA). Forest settled the lawsuit with Alphapharm 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.

Forest proceeded in its action against IVAX and CIPLA. On July 13, 2006, Forest obtained an order from the United States District Court for the District of Delaware, holding that IVAX and CIPLA's proposed generic version of Lexapro® infringed the Forest patent and that the asserted claims of the Forest patent were valid and enforceable. On November 6, 2006, IVAX and CIPLA filed a notice to appeal the decision to the United States Court of Appeals for the Federal Circuit. The appeal is currently pending.

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



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

January 19, 2007

Stockholders and Board of Directors  
Caraco Pharmaceutical Laboratories, Ltd.  
Detroit, Michigan

We have reviewed the balance sheet of Caraco Pharmaceutical Laboratories, Ltd. as of December 31, 2006 and the related statements of operations for the three and nine months ended December 31, 2006 and 2005, the statement of stockholders' equity for the nine months ended December 31, 2006, and the statements of cash flows for the nine months ended December 31, 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, chain drug stores, distributors, and managed care customers. 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 retroactive credits given to our wholesale customers that represent the difference between the lower price they sell (contractual price) to retail, chain stores, and managed care organizations and what we charge the wholesaler. 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 the previous quarter and compared to the 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. 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 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, what 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 on 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.

*Gross Sales and Related Reserves*

Our gross sales for the third quarter and nine months of fiscal 2007 were \$87.9 million and \$226.1 million, as compared to \$52.2 million and \$141.5 million for the corresponding periods of fiscal 2006. Chargebacks, returns, discounts and other customary customer deductions and other sales costs constituted approximately 64% for the third quarter and 63% for the nine months of fiscal 2007, compared to 60% and 59% for the corresponding periods of fiscal 2006. Net sales for the third quarter and nine months of fiscal 2007 were \$31.3 million and \$84.3 million respectively, as compared to \$20.7 million and \$58.1 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 nine months of fiscal 2007.

(\$ in Thousands)

| Fiscal 2006                           | Roll forward allowances at beginning of fiscal 2006 | Allowances charged to Gross Sales for fiscal 2006 |              | Credits taken by customers during fiscal 2006 | Balance at the end of fiscal 2006 |
|---------------------------------------|---|---|--------------|---|-----------------------------------|
|                                       |   | Current Period                                    | Prior Period |   |                                   |
| 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                               |

| For nine months of fiscal 2007        | Roll forward allowances at beginning of fiscal 2007 | Allowances charged to Gross Sales for nine months of fiscal 2007 |              | Credits taken by customers during nine months of fiscal 2007 | Balance at the end of December 31, 2006 |
|---------------------------------------|---|--|--------------|--|---|
|                                       |   | Current Period   | Prior Period |  |   |
| Chargebacks & shelf stock adjustments | \$ 11,467   | \$ 134,915   | \$ -0-       | \$ 122,185   | \$ 24,197                               |
| Returns and other allowances          | 1,500   | 6,864  | -0-          | 5,359  | 3,005                                   |
| Doubtful Accounts                     | 100   | -0-  | -0-          | -0-  | 100                                     |
| <b>Income Taxes</b>                   |   |  |              |  |   |

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 third quarter and nine 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 December 31, 2006 and March 31, 2006. At December 31, 2006, we had federal net operating loss carry forwards of approximately \$41.4 million available to reduce future taxable income, which will expire between 2007 and 2017. Based on our tax analysis we believe that there are sufficient net operating losses available, to fully offset any regular taxable income for fiscal 2007. We are in the process of having a formal study completed regarding our limitations on the utilization of our net operating losses. Such study is expected to be completed prior to the end of Fiscal 2007. This study, along with other information will be used to continue to evaluate the realization and utilization of our net operating losses in future periods. Currently, 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 third quarter of fiscal 2007 represents 23 successive quarters of sales revenue growth. During the third quarter and nine months of fiscal 2007, we recorded net sales of \$31.3 million and \$84.3 million compared to \$20.7 million and \$58.1 million during the corresponding periods of fiscal 2006. This represents an improvement of 51% and 45%, respectively. We incurred \$2.7 million and \$18.5 million in R&D expense during the third quarter and nine months of fiscal 2007 compared to \$9.0 million and \$26.6 million during the corresponding periods of fiscal 2006. This reduction included \$11.8 million for the nine month period of fiscal 2007 in non-cash R&D expense as compared to \$21.0 million during the corresponding period of fiscal 2006. There were no non-cash R&D expenses in the third quarter of fiscal 2007 as compared to \$7.1 million included in the corresponding period of fiscal 2006. We generated cash from operations of \$19.7 million during the nine months of fiscal 2007 as compared to \$4.6 million during the corresponding period of fiscal 2006. The \$15.1 million dollar improvement is primarily due to our sales increase of \$26.2 million for the nine month period. We earned net income of \$10.1 million and \$17.4 million during the third quarter and nine months of fiscal 2007, as compared to net losses of \$0.7 million and \$3.9 million during the corresponding periods of fiscal 2006. At December 31, 2006, we had stockholders' equity of \$85.5 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 submitted a response to the observations to the FDA. The Company believes that 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 nine months of fiscal 2007, in addition to our own internal audits we have retained 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.

We remain extremely pro-active in regards to growing our business appropriately. Since April 2006, the analytical staff has been increased from 32 to approximately 55 employees, thereby enabling the laboratory to better cope with a significantly increased workload with improved timeliness, higher quality, and increased cGMP compliance. Several members of the lab staff attend supplemental professional training courses and conferences, which increases the laboratory's technical and cGMP

proficiency. The lab facility has also undergone major upgrades, including a significant increase in working space to improve analyst efficiency and safety. Additional lab instruments and equipment have been purchased which will enable increased compliance with cGMP requirements, cut future costs by enabling in-house rather than contract analyses, and speed sample testing. Significant resources have also been spent to improve overall lab operations. Such expenditures demonstrate to the regulators, clients and shareholders that upper management is continually committed to adding quality individuals to the work force, providing the resources necessary to upgrade lab equipment and improve the effectiveness of lab operations and cGMP compliance.

### **Third Quarter and Nine Months Fiscal 2007 Compared to Third Quarter and Nine Months Fiscal 2006**

**Net Sales** Net sales for the third quarter and nine months of fiscal 2007 were \$31.3 million and \$84.3 million, respectively, compared to \$20.7 million and \$58.1 million for the corresponding periods of fiscal 2006, reflecting an increase of 51% and 45%, 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 of Caraco and of Sun Pharma. Currently, we manufacture and market all except two of the approved products. Sales of four products accounted for approximately 70% and 72% of net sales for the third quarter and nine months of fiscal 2007 as compared to sales of three products accounting for approximately 79% and 84% of net sales during corresponding periods of fiscal 2006. Net sales for the first nine months of fiscal 2007 surpassed the Company's entire annual sales of fiscal 2006.

**Gross Profit** We earned gross profit of \$15.1 million and \$42.4 million during the third quarter and nine months of fiscal 2007, as compared to gross profit of \$10.3 million and \$28.2 million during the corresponding periods of fiscal 2006, reflecting an increase of 47% and 50%, 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 third quarter and nine months of fiscal 2007 were 48% and 50%, as compared to 50% and 49% during the corresponding periods of fiscal 2006. The shift was primarily the result of change in product mix and the balance in the mix of customers or the class of trade. In the third quarter fiscal 2007, we have incurred an additional charge of \$0.4 million in write-offs for product that had become short dated, which we donated during the third quarter of 2007.

The write-off of product, inclusion of the new products being marketed and distributed pursuant to the Sun Pharma marketing agreement, and overall sales mix, resulted in a reduction in gross profit margin percentage for the third quarter, although the nine-month period gross profit margin percentage of fiscal 2007 improved by 1% compared to the respective period of fiscal 2006.

The net sales for distributed products was \$1.0 million for the period. The gross profit margin percentage on distributed products sold was 24%. The net sales for manufactured products was \$30.3 million for the period. The gross profit margin percentage for manufactured products was 49%.

**Selling, General and Administrative Expenses** Selling, general and administrative expenses during the third quarter and nine months of fiscal 2007 were \$2.6 million and \$7.1 million, respectively, compared to \$2.1 million and \$5.7 million during the corresponding periods of fiscal 2006, representing an increase of 24% and 25% in the respective periods. The selling, general and administrative expenses, as a percentage of net sales, have declined to 8% for the nine months of fiscal 2007, as compared to 10% for the corresponding period of fiscal 2006.

**Research and Development Expenses** Total R&D expenses for the third quarter and nine months of fiscal 2007 were \$2.7 million and \$18.5 million, respectively, as compared to \$9.0 million and \$26.6 million during the corresponding periods of fiscal 2006. Actual cash research and development expenses were \$2.7 million and \$6.8 million, respectively, during the third quarter and nine months of fiscal 2007, compared to \$1.8 million and \$5.5 million during the corresponding periods of fiscal 2006. We incurred non-cash research and development expenses (technology transfer cost) of \$11.8 million for three product transfers during the nine months of fiscal 2007 as compared to \$21.0 million for six product transfers during the corresponding period of fiscal 2006. There were no product transfers in the third quarter of fiscal 2007 as compared to two products being transferred in the corresponding period of fiscal 2006 at a non-cash cost of \$7.1 million. Each product transfer earned 544,000 shares of preferred stock. The cash R&D expenses during the third quarter and nine months of fiscal 2007 were higher compared to those during the corresponding periods of fiscal 2006 due to increased internal R&D activity and initial milestone payments paid to third parties for initiating technology transfer of three products (see Future Outlook ). We filed two products with the FDA during the third quarter of fiscal 2007.

**Results of Operations** We earned net income of \$10.1 million and \$17.4 million in the third quarter and nine months of fiscal 2007, as compared to net losses of \$0.7 million and \$3.9 million during the corresponding periods of fiscal 2006.

**Liquidity and Capital Resources** We generated cash from operations of \$19.7 million during the nine months of fiscal 2007, as compared to \$4.6 million during the corresponding period of fiscal 2006. During the second quarter of fiscal 2007, Caraco acquired a packaging facility for \$1.7 million. This 33,369 sq. ft. facility was previously owned and operated by a third party packager of our portfolio of products. We intend to hire certain key employees of this third party packager to manage and operate our packaging and bottling operation. We will continue the transition in the fourth quarter of fiscal 2007. We envision this acquisition will improve overall costs in packaging, bottling and increase our production. During the third quarter fiscal 2007, Caraco acquired six acres of land directly adjacent to its existing manufacturing facility for \$0.3 million. We are contemplating the construction of a 100,000 sq. ft. facility on this site.

Accounts receivable increased by \$5.4 million to \$26.3 million during the nine months of fiscal 2007, as compared to \$20.9 million at the end of fiscal 2006. The increase in accounts receivable is primarily commensurate with the increase in sales. Our day s sales outstanding, (DSO), for the third quarter of fiscal 2007 improved to 77 days from 78 days for the second quarter of 2007, and 84 days for the first quarter of 2007.

At December 31, 2006, we had working capital of \$66.3 million compared to working capital of \$41.4 million at March 31, 2006. The increase in working capital in fiscal 2007 is primarily due to an increase in cash from operations and an increase in accounts receivable and inventory balances resulting from higher sales volumes. Additionally, we have a \$10.0 million line of credit through JP Morgan Chase Bank, N.A., which allows us flexibility in our 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 aptitude 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.

Currently, we have 19 products pending approval at the FDA (including two tentative approvals). We continue to expand and upgrade our facilities, attract and hire talented individuals and expand our customer base. Our internal 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, Tramadol with Acetaminophen, Clonazepam, Mirtazapine and 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 30% growth in sales for fiscal 2007, compared to fiscal 2006.

Although gross profit margins may come down over time due to price erosion, we are confident that our sales growth, expanding product portfolio and successful execution of our business plan 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 previously disclosed, under the products agreement dated November 21, 2002 between Sun Global and the Company, Sun Global 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 do not expect any of these products will complete their bio-equivalency studies prior to the end of fiscal 2007. They will most likely be completed by the end of the first quarter of fiscal 2008.

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

The Company intends to aggressively move forward with the development of new products. We believe that Sun is a partner with a proven track record; and one that already has provided the Company with quality products. Moreover, Sun Pharma's increased beneficial ownership in the Company to approximately 64% (approximately 75% including the convertible Series B Preferred Stock), should, we believe, provide it with the vested interest to continue to help the Company succeed. Sun Pharma has previously provided the Company with capital, loans, guarantees of loans, personnel, raw materials and equipment, which have significantly helped the Company to date. In addition to the Sun products agreement, we have implemented additional development strategies with various third parties both domestically and abroad that will complement the Sun development pipeline.

In the second quarter of fiscal 2007, Caraco entered into a definitive agreement with a company to develop two additional Caraco ANDAs and provide additional opportunities for the future development of products. This agreement contains both milestone payments to be paid in cash and profit sharing based upon future sales for a defined period.

During the third quarter of fiscal 2007, Caraco entered into a definitive agreement with a third party for the development of a Caraco ANDA. This agreement contains milestone payments to be paid in cash, without any obligation to share profits in the future. Additionally, after the close of the third quarter fiscal 2007, the Company entered into a similar agreement with a third party in which it will share profits in the future.



This makes three definitive agreements signed with third party developers or formulators. We anticipate additional agreements will be entered into in order to eliminate any future gaps in our calendar of approvals that we anticipate from the FDA. We continue to fortify our own research and development team by adding formulators and increasing the number of products we have in development internally.

As previously mentioned, we have recently entered into a definitive agreement to market Sun ANDAs that are either approved or awaiting approval at the FDA. Accordingly, we have begun marketing a number of these products. 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 development, an increased product pipeline and potential revenue. These 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 and long-term growth while improving quality.

Increased market share for certain existing products and recently introduced products.

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.

Research possible development of brands for existing stream of products where such potential exists.

#### **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 third 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.

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**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: January 26, 2007

By: /s/ Daniel H. Movens

\_\_\_\_\_  
Daniel H. Movens  
Chief Executive Officer

Date: January 26, 2007

By: /s/ Jitendra N. Doshi

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Jitendra N. Doshi  
Chief Financial Officer  
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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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