CARACO PHARMACEUTICAL LABORATORIES LTD
Form 10-Q
January 26, 2006

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

FORM 10-Q

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

for the quarterly period ended December 31, 2005

o 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 x No o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes x No o

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

Yes o No x

As of January 20, 2006 the registrant had 26,421,394 shares of common stock issued and outstanding.

**CARACO PHARMACEUTICAL LABORATORIES LTD.**

**BALANCE SHEETS**

| | DECEMBER 31, 2005 | MARCH 31, 2005 |
|---|---|---|
| **ASSETS** | | |
| **Current assets** | | |
| Cash and cash equivalents | $ 8,865,440 | $ 6,627,425 |
| Accounts receivable, net | 19,518,008 | 6,736,778 |
| Inventories | 21,338,531 | 18,467,693 |
| Prepaid expenses and deposits | 3,005,040 | 1,105,618 |
| **Total current assets** | 52,727,019 | 32,937,514 |
| **Property, plant and equipment** | | |
| Land | 197,305 | 197,305 |
| Building and improvements | 9,816,175 | 9,605,888 |
| Equipment | 11,798,108 | 9,701,979 |
| Furniture and fixtures | 667,284 | 589,329 |
| Total | 22,478,872 | 20,094,501 |
| Less: accumulated depreciation | 8,281,353 | 7,197,422 |
| **Net property, plant & equipment** | 14,197,519 | 12,897,079 |
| **Total assets** | **66,924,538** | **45,834,593** |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| **Current liabilities** | | |
| Accounts payable | 2,178,571 | 2,577,669 |
| Accounts payable, Sun Pharma | 13,819,750 | 9,639,890 |
| Accrued expenses | 2,048,711 | 1,931,442 |
| **Total current liabilities** | 18,047,033 | 14,149,001 |
| **Total liabilities** | **18,047,033** | **14,149,001** |
| **Stockholders equity** | | |
| Common stock, no par value, authorized 30,000,000 shares; issued and outstanding shares - 26,396,394 and 26,360,294 shares | 44,956,867 | 44,927,987 |
| Convertible Series B Preferred Stock, no par value, authorized 15,000,000 shares; issued and outstanding - 9,248,000 and 5,984,000 shares | 58,747,770 | 37,700,410 |
| Additional paid in capital | 2,718,735 | 2,718,735 |
| Accumulated deficit | (57,545,867) | (53,661,540) |
| **Total stockholders equity** | 48,877,505 | 31,685,592 |

| | | |
|---|---|---|
| **Total liabilities and stockholders equity** | **66,924,538** | **45,834,593** |

See accompanying notes

**CARACO PHARMACEUTICAL LABORATORIES, LTD.**
**STATEMENTS OF INCOME**

| | NINE MONTHS ENDED DECEMBER 31, | | THREE MONTHS ENDED DECEMBER 31, | |
|---|---|---|---|---|
| | **2005** | **2004** | **2005** | **2004** |
| **Net sales** | 58,087,910 | 46,779,221 | 20,678,978 | 16,680,678 |
| Cost of goods sold | 29,861,857 | 19,050,867 | 10,329,598 | 7,283,981 |
| **Gross profit** | 28,226,053 | 27,728,354 | 10,349,380 | 9,396,697 |
| Selling, general and administrative expenses | 5,701,231 | 3,994,400 | 2,133,346 | 1,700,241 |
| Research and development costs - affiliate (Note 7) | 21,047,360 | 16,568,880 | 7,137,280 | 6,217,920 |
| Research and development costs - other | 5,512,554 | 4,920,003 | 1,848,167 | 2,016,052 |
| **Operating income** | (4,035,092) | 2,245,071 | (769,413) | (537,514) |
| **Other income (expense)** | | | | |
| Interest expense | 0 | (225,788) | 0 | (8,658) |
| Interest income | 108,130 | 38,301 | 54,820 | 5,549 |
| Other income (expense) | 42,635 | (14,031) | 33,637 | (4,582) |
| **Other expense - net** | 150,765 | (201,518) | 88,457 | (7,691) |
| **Net income** | **(3,884,327)** | **2,043,553** | **(680,956)** | **(545,205)** |
| **Net income per common share** | | | | |
| Basic | (0.15) | 0.08 | (0.03) | (0.02) |
| Diluted | (0.15) | 0.07 | (0.03) | (0.02) |

See accompanying notes

**CARACO PHARMACEUTICAL LABORATORIES, LTD.**
**STATEMENTS OF CASH FLOWS**

| | NINE MONTHS ENDED DECEMBER 31, | |
|---|---|---|
| | **2005** | **2004** |
| **Cash flows from operating activities** | | |
| Net (loss) income | (3,884,327) | 2,043,553 |
| Adjustments to reconcile net (loss) / income to net cash flow from operating activities | | |
| Depreciation | 1,101,942 | 743,345 |
| Capital stock issued or to be issued to affiliate in exchange for product formula | 21,047,360 | 16,568,880 |
| Changes in operating assets and liabilities which provided (used) cash: | | |
| Accounts receivable | (13,024,424) | (1,842,529) |
| Inventories | (2,870,838) | (4,487,236) |
| Prepaid expenses and deposits | (1,899,421) | (70,603) |
| Accounts payable | 4,023,955 | 3,103,479 |
| Accrued expenses & interest | 117,269 | (263,060) |
| **Net cash flow from operating activities** | 4,611,513 | 15,795,829 |
| **Cash flows from investing activities** | | |
| Purchases of property, plant and equipment | (2,399,978) | (2,695,404) |
| **Net cash used in investing activities** | (2,399,978) | (2,695,404) |
| **Cash flows from financing activities** | | |
| Proceeds from loans payable to financial institutions | 0 | 10,000,000 |
| Repayments of loans payable to financial institutions | 0 | (22,375,000) |
| Proceeds from exercise of stock options | 26,480 | 3,453,946 |
| Repayments of EDC loan | 0 | (5,967,716) |
| **Net cash flow (used) in financing activities** | 26,480 | (14,888,770) |
| **Net increase in cash and cash equivalents** | **2,238,015** | **(1,788,345)** |
| Cash and cash equivalents, beginning of period | 6,627,425 | 4,244,815 |
| **Cash and cash equivalents, end of period** | **8,865,440** | **2,456,470** |

See accompanying notes

**CARACO PHARMACEUTICAL LABORATORIES, LTD.**
**STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)**

| | PREFERRED STOCK | | COMMON STOCK | |
|---|---|---|---|---|
| | SHARES | AMOUNT | SHARES | AMOUNT |
| Balances at April 1, 2005 | 5,984,000 | 37,700,410 | 26,360,294 | 44,927,987 |
| Issuances of preferred stock to affiliate in exchange for product technology transfers | 3,264,000 | 21,047,360 | | |
| Common stock options exercised | | | 36,100 | 26,480 |
| Net income | | | | |
| Balances at December 31, 2005 | 9,248,000 | 58,747,770 | 26,396,394 | 44,954,467 |

| | ADDITIONAL PAID IN CAPITAL | ACCUMULATED DEFICIT | TOTAL STOCKHOLDERS EQUITY (DEFICIT) |
|---|---|---|---|
| Balances at April 1, 2005 | 2,718,735 | (53,661,540) | 31,685,592 |
| Issuances of preferred stock to affiliate in exchange for product technology transfers | | | 21,047,360 |
| Common stock options exercised | | | 26,480 |
| Net income | | (3,884,327) | (3,884,327) |
| Balances at December 31, 2005 | 2,718,735 | (57,545,867) | 48,875,105 |

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, 2005 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 Transition Report ( Transition Report ) on Form 10-K/T for the period January 1, 2005 to March 31, 2005 (the Transition Period ) and the Annual Report on Form 10-K as of and for the year ended December 31, 2004 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 Transition Report on Form 10-K/T.

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 19 prescription products in 43 strengths in 98 package sizes. The products are intended to treat a variety of disorders including the following: hypertension, arthritis, epilepsy, diabetes, depression and pain management.

A significant source of our funding has been from Sun Pharmaceutical Industries Limited, a specialty pharmaceutical corporation organized under the laws of India ( Sun Pharma ). Since August 1997, Sun Pharma has contributed equity capital and has advanced us loans. In addition, among other things, Sun Pharma has acted as a guarantor on loans to Caraco, has supplied us

with a substantial portion of raw materials for our products, helped us obtain machinery and equipment to enhance our production capacities at competitive prices and transferred certain generic products to us. (See Current Status of the Corporation and Sun Pharmaceutical Industries Limited below.)

3. **CURRENT STATUS OF THE CORPORATION**

During the three and nine months ended December 31, 2005, of our new fiscal year ( fiscal 2006 ), we recorded net sales of $20.7 million and $58.1 million, respectively, compared to $16.7 million and $46.8 million during the corresponding periods of 2004. We incurred $9.0 million and $26.6 million in R&D expense during the three and nine months ended December 31, 2005 compared to $8.2 million and $21.5 million during the corresponding periods of 2004. This included $7.1 million and $21.0 million in non-cash R&D expense compared to $6.2 million and $16.6 million during the relevant periods. We generated cash from operations of $4.6 million during the nine months ended December 31, 2005 compared to $15.8 million during the corresponding period. This cash was used primarily to augment working capital. We incurred net loss of $0.7 million and $3.9 million during the three and nine months ended December 31, 2005 compared to a net loss of $0.5 million and net income of $2.0 million during the corresponding periods of 2004. At December 31, 2005, we had stockholders equity of $48.9 million as compared to stockholders equity of $25.8 million at December 31, 2004. 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, 2005, all products out of the 25 products to be transferred to us by Sun Global. Of these, 17 products passed their bio-equivalency studies as of December 31, 2005, and one product since then. Sun Global earned 544,000 preferred shares for each product. See Sun Pharmaceutical Industries Limited and Item 2 Management s Discussion and Analysis of Financial Condition and Results of Operations. Future Outlook.

We filed two ANDAs with the FDA during the third quarter of fiscal 2006. We received approvals for two ANDAs during the third quarter of fiscal 2006. We also received a tentative approval for one strength of one of the products submitted for approval. This brings our total number of ANDAs pending approval by the FDA to thirteen products.

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

The FDA commenced an inspection of the Company s facility during the Transition Period. The FDA completed its inspection in May 2005 and issued observations on FDA Form 483. The Company has responded to the Form 483, and has since received approvals from the FDA for various products previously submitted.

4. **RECENT ACCOUNTING PRONOUNCEMENTS**

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

In December 2004, the FASB issued SFAS 123(R), Share-Based Payments, which replaces FASB Statement No. 123, Accounting for Stock-Based Compensation, and supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees. SFAS 123(R) will require all share-based payments to employees, including grants of employee stock options, to be recognized in the statement of operations based on their fair values. SFAS 123(R) offers alternative methods for determining the fair value. In April 2005, the SEC issued a new rule that allows companies to implement Statement No. 123(R) at the beginning of the next fiscal year, instead of the next reporting period, that begins after June 15, 2005. As a result, we will implement SFAS 123(R) in the reporting period starting April 1, 2006. We expect that SFAS 123(R) will not have a significant impact on our financial statements. At the present time, we have not yet determined which valuation method we will use.

The FASB has proposed amending SFAS 128, Earnings per Share, to make it consistent with International Accounting Standard 33, Earnings per Share, and make earning per share, or EPS, computations comparable on a global basis. Under the proposed amendment, the year-to-date EPS computation would be performed independently from the quarterly computations. Additionally, for all contracts that may be settled in either cash or shares of stock, companies must assume that settlement will occur by the issuance of shares for purposes of computing diluted EPS, even if they intend to settle by paying cash or have a history of cash-only settlements, regardless of who controls the means of settlement. Lastly, under the proposed amendment, shares that will be issued upon conversion of a mandatory convertible security must be included in the weighted-average number of shares outstanding used in computing basic EPS from the date that conversion becomes mandatory, using the if-converted method, regardless of whether the result is anti-dilutive. The proposed amended standard was expected to be issued

during the first quarter of 2005. However, the FASB has not yet finalized the revised effective date of the proposed amendment or its transition provisions. Retrospective application in all periods presented would be required, and could require the restatement of previously reported EPS. We do not expect the provisions of the amended SFAS 128 will have a significant impact on our results of operations.

In July 2005, the FASB published an Exposure Draft of a proposed Interpretation, Accounting for Uncertain Tax Positions. The Exposure Draft seeks to reduce the significant diversity in practice associated with recognition and measurement in the accounting for income taxes. It would apply to all tax positions accounted for in accordance with SFAS 109, Accounting for Income Taxes. The Exposure Draft requires that a tax position meet a probable recognition threshold for the benefit of the uncertain tax position to be recognized in the financial statements. This threshold is to be met assuming that the tax authorities will examine the uncertain tax position. The Exposure Draft contains guidance with respect to the measurement of the benefit that is recognized for an uncertain tax position, when that benefit should be derecognized, and other matters. This proposed Interpretation would clarify the accounting for uncertain tax positions in accordance with SFAS 109. This Interpretation, once approved, is expected to be effective as of the end of the first fiscal year ending after December 15, 2005. We are currently evaluating the impact this proposed Interpretation would have on our 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 weighted average number of common shares outstanding for the three and nine months ended December 31, 2005 was 26,383,457. Correspondingly, the basic and diluted weighted average numbers of common shares outstanding for the three and nine months ended December 31, 2004 were 24,734,282 and 29,239,634, respectively.

6. **SUN PHARMACEUTICAL INDUSTRIES LIMITED**

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

Sun Pharma and its affiliates had loaned us approximately $10 million since August 1997. As of December 31, 2003, we have repaid all of such loans. Sun Pharma has also assisted us, 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. As of December 31, 2004, we have repaid all of such loans and the related credit lines are closed.

In August 1997, we entered into an agreement, whereby Sun Pharma was required to transfer to us the technology formula for 25 generic pharmaceutical products over a period of five years

through August 2003. We exchanged 544,000 shares of our 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 product. The products provided to us from Sun Pharma were selected by mutual agreement. Under such agreement, we conducted, at our expense, all tests including bio-equivalency studies. Pursuant to such agreement, Sun Pharma delivered to us the technology for 13 products. This agreement expired and, as noted below, we have entered into a new agreement,with Sun Global.

On November 21, 2002, we entered into a products agreement with Sun Global. Under the agreement, which was approved by our Independent Committee (comprised of independent directors), Sun Global has agreed to provide us with 25 new generic drugs over a five-year period. Our 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 such agreement, we conduct, at our expense, all tests including bio-equivalency studies. We are also obligated to market the products consistent with our customary practices and to provide marketing personnel. In return for the technology transfer, Sun Global receives 544,000 shares of a newly created 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 in the quarter ended March 31, 2004 to eliminate the provision requiring that the Independent Committee concur in the selection of each product, and to provide instead, that each product satisfy certain objective criteria developed by management and approved by the Independent Committee. Pursuant to the products agreement, we have selected all the 25 products, seventeen of which passed bio-equivalency studies as of December 31, 2005, and one product since then. See Management s Discussion and Analysis of Financial Condition 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 us with certain raw materials and formulations. In addition, Sun Pharma assists us in acquiring machinery and equipment to enhance our production capacities. We acquire machinery and equipment from Sun Pharma which is sold to us at its cost.

Sun Pharma also assists us by sending qualified technical professionals who work as Caraco employees.

Sun Pharma and its affiliates are using Caraco as a contract manufacturer and/or distributor for two of its products pursuant to agreements entered into in December 2004 and January 2005.

During the Transition Period, SPARC Bioresearch Private Limited ( SPARC ), an affiliate of Sun Pharma, performed certain analytical studies required as part of the bio-equivalency process for two products. The Corporation incurred approximately $172,000 of costs during this period for the studies performed by SPARC. No similar studies were performed by SPARC during the three and nine months ended December 31, 2005 or the corresponding periods of 2004.

As of December 31, 2005, Sun and its affiliates beneficially own 63.9% of the outstanding shares of Caraco (73.3% including the convertible Series B Preferred Stock).

7. **ACCOUNTING FOR STOCK BASED COMPENSATION**

The Corporation follows only the disclosure aspects of Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation* . Management believes that the fair value and pro-forma disclosures, required by SFAS No. 123, are not material to the financial statements. The Corporation continues to apply Accounting Principles Board (APB) Opinion No. 25 in accounting for its plans and, accordingly, no compensation cost has generally been recognized in the financial statements for its outstanding stock options. Options to purchase 40,000 shares of common stock were granted on May 2, 2005 to the CEO of the Corporation, which will vest in the amount of 1/3$^{rd}$ every anniversary thereafter. The Company also granted 45,000 shares of common stock on May 2, 2005 to the CEO of the Corporation, which will vest in the amount of 1/3$^{rd}$ every anniversary date thereafter. In addition, the Company granted options to purchase 3,000 shares of common stock to each of the new independent directors upon the date of their appointment. No other options or stock grants were granted during the nine months ended December 31, 2005 or 2004.

8. **COMMON STOCK ISSUANCES**

We issued 36,100 and 77,800 shares of common stock to our employees upon exercise of their stock options during the nine months ended December 31, 2005 and 2004, respectively. During the nine months ended December 31, 2004, we issued 1,679,066 shares of common stock to Sun Pharma against exercise of stock options, which, Sun Pharma had acquired from two former directors during the first quarter of 2004.

9. **PREFERRED STOCK ISSUANCES**

We issued 3,264,000 shares and 2,720,000 shares of preferred stock to Sun Global during the nine month periods ended December 31, 2005 and 2004, respectively.

10. **SALES AND CUSTOMERS**

Our Company effectively addressed its challenges during the first nine months of fiscal 2006. The organization continues to be strengthened to meet the demands of the US generic market, while supporting our expected growth.

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 nine months ended December 30, 2005, these wholesale accounts equate to 76% of our gross sales, yet the actual sales are for various customers with underlying direct contracts with our Company. No other single customer represents more than 10% of our gross sales during the relevant periods.

In 2002 we entered into a sales contract with the Veterans Administration, an agency of the U.S. government. The Veterans Administration has designated McKesson Corporation as its wholesaler. Our agreement which commenced June 21, 2002 was for one year with four 1 year option periods and is for one product, Metformin Hydrochloride. The first three option periods were exercised. The agreement may be terminated by the purchaser without cause and in such case, we would only be entitled to a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges that have resulted from the termination. The agreement provides that certain penalties would be incurred if we are unable to meet our sales commitment.

11. **LINE OF CREDIT**

On November 17, 2005, the Company 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 Company for the Company 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. As of December 31, 2005, no amounts have been drawn down under the Credit Agreement. Borrowings are secured by the Company s receivables, inventory and all proceeds therefrom. Borrowings may be prepaid at any time by the Company. Interest is payable based on LIBOR or an alternate base rate (determined by reference to the prime rate or the federal funds effective rate), as selected by the Company. The rate of interest is LIBOR plus 75 basis points or Prime rate minus 100 basis points.

12. **LITIGATION**

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 Company s filling 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. We believe that the Novo Nordisk patent is invalid and / or will not be infringed by Caraco s manufacture, use or sale of the product, and we intend to vigorously defend this action in order to capitalize on potential 180 days of marketing exclusivity available for this product.

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 Company s filing of an ANDA seeking approval to market its generic version of Ortho-McNeil s

Ultracet® drug product infringed Ortho-McNeil s patent, which expires on September 6, 2011. Ortho-McNeil seeks an order from the Court which, among other things, directs the FDA not to approve Caraco s ANDA any earlier than the claimed expiration date. The ANDA filed by Caraco contained a Paragraph IV Certification challenging the Ortho-McNeil patent. We believe that the Ortho-McNeil patent is invalid and/or will not be infringed by Caraco s manufacture, use or sale of the product, and we intend to vigorously defend this action. Since this action, Ortho-McNeil has entered into a license agreement with another manufacturer and has launched its product generically while another manufacturer has launched its approved generic at risk. On October 8, 2005, arguments were heard in the US District Court in the Eastern District of Michigan, on our motion for summary judgment on the issue of non- infringement. On October 19, 2005 our motion for summary judgment was granted in our favor. On December 19, 2005, the FDA approved the manufacture, use and sale of the product. Ortho-McNeil has filed an appeal of the finding of non-infringement by the Eastern District of Michigan. Additionally, the United States Patent and Trademark Office has allowed Ortho-McNeil s request for a reissue patent that, when issued, Ortho-McNeil contends will be infringed by Caraco s now-marketed product. We believe that, like its original patent, Ortho-McNeil s reissue patent will be invalid and unenforceable.

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 is seeking 175,000 shares of our common stock (35,000 shares for each of the first five ANDAs approved by the FDA). We and the plaintiff each filed a motion for summary disposition. Both parties motions were denied, and the parties have submitted the matter to binding arbitration. We intend to vigorously defend ourselves against these claims, which we believe have no merit.

From time to time, we are also involved in other legal proceedings incidental to our normal business activities, and while the outcome of any such proceedings cannot be accurately predicted, we do not believe the ultimate resolution of any existing matters would have a material adverse effect on our financial position or results of operations.

13. **INVENTORIES**

Inventories consist of the following amounts at December 31:

| | 2005 | 2004 |
|---|---|---|
| Raw materials | $ 7,225,576 | 5,030,430 |
| Goods in transit | 4,236,576 | 2,901,626 |
| Work in process | 2,250,595 | 2,993,587 |
| Finished goods | 7,625,783 | 6,208,168 |
| Total | $ 21,338,531 | 17,133,811 |

**REVIEW REPORT OF INDEPENDENT REGISTERED**

**PUBLIC ACCOUNTING FIRM**

January 18, 2006

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

We have reviewed the balance sheet of Caraco Pharmaceutical Laboratories, Ltd. as of December 31, 2005 and the related statements of operations for the three and nine months ended December 31, 2005 and 2004, the statements of cash flows for the nine months ended December 31, 2005 and 2004, and the statements of stockholders equity for the nine months ended December 31, 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, 2005, and the related statements of operations, stockholders equity, and cash flows for the three-month period then ended (not presented herein), and in our report dated June 7, 2005, 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 2004 Annual Report on Form 10-K as of and for the year ended December 31, 2004 (the Annual Report ), the Company s Transition Report as of and for the three months ended March 31, 2005, and the unaudited interim financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

**OVERVIEW**

The first three quarters of fiscal 2006 ended December 31, 2005 represent 19 quarters of successive sales revenue growth. During the three and nine months ended December 31, 2005, of our new fiscal year ( fiscal 2006 ), we recorded net sales of $20.7 million and $58.1 million, respectively, compared to $16.7 million and $46.8 million during the corresponding periods of 2004. We incurred $9.0 million and $26.6 million in R&D expense during the three and nine months ended December 31, 2005 compared to $8.2 million and $21.5 million during the corresponding periods of 2004. This included $7.1 million and $21.0 million in non-cash R&D expense compared to $6.2 million and $16.6 million during the relevant periods. We generated cash from operations of $4.6 million during the nine months ended December 31, 2005 compared to $15.8 million during the corresponding period. This cash was used primarily to augment working capital. We incurred net loss of $0.7 million and $3.9 million during the three and nine months ended December 31, 2005 compared to net loss of $0.5 million and net income of $2.0 million during the corresponding periods of 2004. At December 31, 2005, we had stockholders equity of $48.9 million as compared to stockholders equity of $25.8 million at December 31, 2004.

**FDA COMPLIANCE**

The FDA commenced an inspection of the Company s facility during the Transition Period. The FDA completed its inspection in May 2005 and issued observations on Form 483. We believe that we responded appropriately and have since received product approval of Clozapine 50mg, a tentative approval of Zolpidem (a generic version of Ambien®), approval of Carbamazepine 100, 200, 300 and 400 mg tablets and approval of Tramadol Hydrochloride with Acetaminophen tablets (the generic version of Ultracet®). We also received a tentative approval of one strength of Carvedilol (a generic version of Coreg®).

**CRITICAL ACCOUNTING POLICIES**

Our significant accounting policies are described in Note 1 to our financial statements included in our Annual Report and in Note 1 to our financial statements included in our Transition Report

filed with the Securities and Exchange Commission. 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. As stated previously, these are discussed in more detail in Note 1 to our Annual Report and in Note 1 to our Transition Report. We have reviewed and determined that these policies remain our critical accounting policies for the first three fiscal quarters of 2006. We did not make any changes in these policies during this period.

**Three and Nine Months Ended December 31, 2005 Compared to Three and Nine Months Ended December 31, 2004**

**Net Sales**. Net sales for the relevant periods were $20.7 and $58.1 million, respectively, compared to $16.7 million and $46.8 million, reflecting an increase of 24% for each of the relevant periods. The increase is due to the higher production and increased marketing of our products to new and existing customers and in part due to the recent launch of Tramadol Hydrochloride with Acetaminophen, which represented approximately $0.8 million in net sales in the last 10 days of the period. Currently, we manufacture and market all except two of the approved products. Sales of three products accounted for approximately 69% and 74% of net sales for the relevant nine-month periods of 2005 and 2004, respectively. Sales of these three products accounted for approximately 79% and 84% of net sales for the relevant three-month periods of 2005 and 2004, respectively.

**Gross Profit**. We earned gross profit of $10.3 million and $28.2 million during the relevant periods as compared to gross profit of $9.4 million and $27.7 million during the relevant corresponding periods, reflecting increases of 10% and 2% for the relevant periods. The increase in gross profit for the relevant periods is primarily due to higher sales, an improved balance in the mix of customers or the class of trade and product selection being sold offset in part by price erosion during the quarter.

The gross profit margins for the relevant periods declined to 50% and 49% as compared to 56% and 59%. The decrease was primarily the result of increased competition, both domestic and foreign, resulting in erosion of prices and profit margins. The 50% profit margin reflects a 1 percent improvement over the second quarter 2006 profit margin, primarily due to mix of products being sold during the quarter.

**Selling, General and Administrative Expenses**. Selling, general and administrative expenses during the relevant periods were $2.1 million and $5.7 million compared to $1.7 million and $4.0

million, representing increases of 24% and 43%. The selling, general and administrative expenses continue to remain at approximately 10% of net sales for the relevant periods.

The increase in SG&A for the nine months ended December 31, 2005 has been due to an increase in regulatory costs for compliance with SEC regulations, including Sarbanes-Oxley requirements ($0.3 million), primarily additions to management and associated compensation ($0.5 million), higher taxes on income and property ($0.2 million) and higher SG&A expenses associated with higher sales volumes as well as a one time charge ($0.3 million) in the current three and nine month periods associated with our decision to forego an acquisition of real property in favor of alternate expansion opportunities.

**Research and Development Expenses**. Total R&D expenses for the relevant periods were $9.0 and $26.6 million compared to $8.2 million and $21.5 million. Actual cash research and development expenses were $1.8 million and $5.5 million compared to $2.0 million and $4.9 million during the relevant periods. We incurred non-cash research and development expenses (technology transfer cost) of $7.1 million and $21.0 million for 2 and 6 product transfers during the relevant periods of 2005, as compared to $6.2 million and $16.6 million for 2 and 5 product transfers during the corresponding periods of 2004. Each product transfer earns 544,000 shares of preferred stock. The cash R&D expenses during the nine months ended December 2005 were slightly higher compared to those during the corresponding 2004 period due to increased R&D activity.

**Interest Expense**. We did not incur any interest cost during the relevant periods of 2005. Interest expense on loans from the Economic Development Corporation of the City of Detroit (the EDC ), ICICI Bank, the Bank of Nova Scotia and Citibank amounted to $0.2 million during the nine month period ended December 31, 2004. The decrease in the amount of interest is due to paying off the entire loans due to the EDC, ICICI Bank, the Bank of Nova Scotia and CitiBank during 2004.

**Results of Operations**. We incurred a net loss of $0.7 million and $3.9 million during the relevant periods. We incurred a net loss of $0.5 million and earned net income of $2.0 million during the corresponding periods of 2004.

**Liquidity and Capital Resources**

We generated cash from operations of $4.6 million for the nine months ended December 31, 2005 as compared to generating cash of $4.8 million from operations during the Transition Period ended March 31, 2005 (January 1 to March 31, 2005). Accounts receivable increased by $12.8 million during the relevant period of Fiscal 2006 as compared to $6.7 million in accounts receivable at the end of March 31, 2005. The increase in accounts receivable is relative to the increase in sales and associated terms offered to our customers and has a direct correlation to the timing of chargebacks received. This current period s positive cash flow is more consistent with historical trends.

We generated cash from operations of $4.6 million as compared to $15.8 million from operations during the relevant nine-month periods. In addition to augmenting working capital, the balance at the beginning of the relevant periods and cash generated from operations were used to finance our capital expenditures of $2.4 million and $2.7 million.

During the nine months ended December 31, 2004, we repaid the entire balance of $6.0 million due to the EDC, $9.4 million to The Bank of Nova Scotia and $10 million to Citibank, FSB. These payoffs were funded from internal cash flow and by utilizing a $10.0 million credit line arranged with Citibank, FSB.

At December 31, 2005 we had working capital of $34.7 million compared to working capital of $13.2 million at December 31, 2004. We had working capital of $18.8 million at March 31, 2005. The increased working capital in fiscal 2006 is primarily due to increased accounts receivable balances resulting from higher sales volumes. Additionally we have available the $10 million line of credit recently obtained through JPMorgan Chase Bank, N.A. which would allow us flexibility in expansion efforts to increase our capacity over the next few years.

**Future Outlook**

We continue to be optimistic about our future outlook. We believe we are substantially compliant with cGMPs. We have received two ANDA approvals and one tentative approval during the most recent quarter both in the last month of the quarter. Currently, we have 13 products pending approval at the FDA. We continue to expand and upgrade our facilities and improve our customer base. Our efforts combined with Sun Global in developing new products have also picked up momentum and this should permit us to grow at a reasonable level. We now have four products, Metformin, Metoprolol, Tramadol and Salsalate whose market share is ranked third or higher against the same products of our generic competitors. Based on current trends we believe it necessary to increase our previous guidance from 15-20% growth to 25-30% growth for fiscal 2006 compared to calendar 2004.

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

As disclosed, under the products agreement dated November 21, 2002 between Sun Global and the Company, Sun Global has agreed to transfer the technology for 25 products to the Company over a five year period in exchange for 544,000 preferred shares (which are convertible on a one-to-one basis into common shares) per product. Since the date of the products agreement, the Company has selected all 25 products for development and eighteen of these products have passed their respective bio-equivalency studies (one in December 2003, seven in 2004, three during the Transition Period, one during the first quarter of fiscal 2006, three during the second quarter of fiscal 2006, two during the third quarter of fiscal 2006 and one since then). If some or all of the remaining products pass their bio-equivalency studies in fiscal 2006, the fair value of the preferred shares earned by Sun Global in exchange for such products could cause our non-cash research and development expenses to increase to an amount which would significantly decrease profit or create a loss.

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

The Company will continue to aggressively move forward with the development of new products. We believe that receiving products from Sun provides us with a partner with a proven track record; one that already has provided us with quality products. Moreover, Sun Pharma s increased beneficial ownership in us to approximately 63.9% (approximately 73.3% including the convertible Series B Preferred Stock), should, we believe, provide it with the incentive to continue to help us succeed. Sun Pharma has previously provided us with capital, loans, guarantees of loans, personnel, raw materials and equipment, which have significantly helped us to date.

Management s plans for the remainder of fiscal 2006 include:

(a) Continued focus and improvement on FDA compliance.

(b) Increased pace of research and development activities, with a view to maximize ANDA filings.

(c) Continue to invest in equipment and facilities to expand capacity to meet requirements of projected growth in near term.

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

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

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

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

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

(i) Locating and acquiring facilities to enhance production and therefore sales.

(j) 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 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. 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 2006 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**

| | |
|---|---|
| 10.26 | Credit Agreement dated as of November 17, 2005 between Caraco and JP Morgan Chase Bank, N.A. |
| 10.27 | Security Agreement dated as of November 17, 2005 between Caraco and JP Morgan Chase Bank, N.A. |
| 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: January 20, 2006

By: /s/ Daniel H. Movens

Daniel H. Movens
Chief Executive Officer

Date: January 20, 2006

By: /s/ Jitendra N. Doshi

Jitendra N. Doshi
Chief Financial Officer

EXHIBIT INDEX

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