

CARACO PHARMACEUTICAL LABORATORIES LTD  
Form 10-Q  
October 25, 2007

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

FORM 10-Q

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

for the quarterly period ended September 30, 2007

- TRANSITION REPORT PURSUANT TO SECTION 13  
OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
for the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 0-24676

CARACO PHARMACEUTICAL LABORATORIES, LTD.  
(Exact name of registrant as specified in its charter)

MICHIGAN	38-2505723
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

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

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

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

Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition "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 October 23, 2007 the registrant had 29,822,094 shares of common stock issued and outstanding.



**CARACO PHARMACEUTICAL LABORATORIES LTD.**

(A subsidiary of Sun Pharmaceutical Industries Limited)

**BALANCE SHEETS**

	SEPTEMBER 30, 2007	MARCH 31, 2007
	UNAUDITED	AUDITED
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 33,170,366	\$ 33,897,622
Accounts receivable, net	43,876,747	26,125,146
Inventories	35,608,569	31,943,297
Prepaid expenses and deposits	6,152,494	3,473,340
Net deferred tax assets	522,443	
<b>Total current assets</b>	<b>119,330,619</b>	<b>95,439,405</b>
<b>Property, plant and equipment</b>		
Land	975,311	975,311
Buildings and improvements	12,717,436	12,448,221
Equipment	16,980,008	15,292,499
Furniture and fixtures	1,036,899	992,013
<b>Total</b>	<b>31,709,654</b>	<b>29,708,044</b>
Less accumulated depreciation	11,757,167	10,678,157
<b>Net property, plant and equipment</b>	<b>19,952,487</b>	<b>19,029,887</b>
Deferred income taxes	8,609,300	
<b>Total assets</b>	<b>\$ 147,892,406</b>	<b>\$ 114,469,292</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable, trade	\$ 4,989,463	\$ 3,350,024
Accounts payable, Sun Pharma	17,952,648	12,143,157
Accrued expenses	2,296,839	3,782,702
Income taxes payable	8,249,070	
<b>Total liabilities (all current)</b>	<b>33,488,020</b>	<b>19,275,883</b>
<b>Stockholders equity</b>		
Series B convertible preferred stock, no par value; issued and outstanding 9,792,000 shares (September 30, 2007) 10,880,000 shares (March 31, 2007)	68,674,560	73,585,520
Common stock, no par value; authorized 50,000,000 shares, issued and outstanding 29,820,094 shares (September 30, 2007) 28,102,394 shares (March 31, 2007)	66,815,317	55,970,097
Additional paid in capital	3,005,108	2,864,522

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

Accumulated deficit	(24,090,599)	(37,226,730)
<b>Total stockholders equity</b>	<b>114,404,386</b>	<b>95,193,409</b>
<b>Total liabilities and stockholders equity</b>	<b>\$ 147,892,406</b>	<b>\$ 114,469,292</b>

See accompanying notes

**CARACO PHARMACEUTICAL LABORATORIES, LTD.**

(A subsidiary of Sun Pharmaceutical Industries Limited)

**STATEMENTS OF INCOME**

	Six Months ended September 30,		Quarter ended September 30,	
	2007	2006	2007	2006
	UNAUDITED	UNAUDITED	UNAUDITED	UNAUDITED
<b>Net sales</b>	<b>\$ 76,754,883</b>	<b>\$ 53,031,116</b>	<b>\$ 41,354,567</b>	<b>\$ 28,279,969</b>
Cost of goods sold	42,871,307	25,788,987	23,338,768	14,045,813
<b>Gross profit</b>	<b>33,883,576</b>	<b>27,242,129</b>	<b>18,015,799</b>	<b>14,234,156</b>
Selling, general and administrative expenses	6,436,725	4,502,861	3,034,058	2,386,421
Research and development costs - affiliate	5,440,000	11,761,280	5,440,000	7,382,080
Research and development costs - other	8,389,210	4,043,476	5,103,723	2,346,316
<b>Operating income</b>	<b>13,617,641</b>	<b>6,934,512</b>	<b>4,438,018</b>	<b>2,119,339</b>
<b>Other income</b>				
Interest expense		(28,194)		(28,194)
Interest income	886,455	350,247	419,162	219,327
Other income		39,889		58
<b>Other income</b>	<b>886,455</b>	<b>361,942</b>	<b>419,162</b>	<b>191,191</b>
<b>Net income before income taxes</b>	<b>14,504,096</b>	<b>7,296,454</b>	<b>4,857,180</b>	<b>2,310,530</b>
Income taxes	1,367,966		236,265	
<b>Net income</b>	<b>\$ 13,136,130</b>	<b>\$ 7,296,454</b>	<b>\$ 4,620,915</b>	<b>\$ 2,310,530</b>
<b>Net income per common share</b>				
Basic	0.46	0.28	0.16	0.09
Diluted	0.34	0.19	0.12	0.06

See accompanying notes

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

	Six Month ended September 30,	
	2007	2006
	UNAUDITED	UNAUDITED
<b>Cash flows from operating activities</b>		
Net income	\$ 13,136,130	\$ 7,296,454
Adjustments to reconcile net income to net cash flow from operating activities		
Depreciation	1,079,010	915,211
Capital stock issued or to be issued to affiliate in exchange for product formula	5,440,000	11,761,280
Stock option expense	140,586	
Stock grant expense	357,750	
Common stock issued to former officer & director for settlement	115,950	
Net deferred income taxes	(9,131,743)	
Changes in operating assets and liabilities which (used) / provided cash:		
Accounts receivable	(17,751,601)	(3,242,100)
Inventories	(3,665,272)	(4,226,308)
Prepaid expenses and deposits	(2,679,154)	479,656
Accounts payable	7,448,930	1,352,871
Accrued expenses	(1,485,863)	(26,586)
Income taxes payable	8,249,070	
<b>Net cash provided by operating activities</b>	<b>1,253,793</b>	<b>14,310,478</b>
<b>Cash flows from investing activities</b>		
Purchases of property, plant and equipment	(2,001,609)	(4,503,250)
<b>Net cash used in investing activities</b>	<b>(2,001,609)</b>	<b>(4,503,250)</b>
<b>Cash flows from financing activities</b>		
Proceeds from loans payable to financial institutions		5,000,000.00
Repayments of loans payable to financial institutions		(5,000,000.00)
Proceeds from exercise of stock options	20,560	16,640
<b>Net cash provided by financing activities</b>	<b>20,560</b>	<b>16,640</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>	<b>(727,256)</b>	<b>9,823,868</b>
Cash and cash equivalents, beginning of period	33,897,622	11,924,245
<b>Cash and cash equivalents, end of period</b>	<b>\$ 33,170,366</b>	<b>\$ 21,748,113</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 PAID IN CAPITAL</u>	<u>ACCUMULATED DEFICIT</u>	<u>TOTAL STOCKHOLDERS EQUITY</u>
	<u>SHARES</u>	<u>AMOUNT</u>	<u>SHARES</u>	<u>AMOUNT</u>			
Balances at April 1, 2007	10,880,000	\$ 73,585,520	28,102,394	\$ 55,970,097	\$ 2,864,522	\$ (37,226,730)	\$ 95,193,409
Issuances of preferred stock to affiliate in exchange for product technology transfers	544,000	5,440,000					5,440,000
Conversion of preferred stock into common stock	(1,632,000)	(10,350,960)	1,632,000	10,350,960			
Common stock options exercised			25,700	20,560			20,560
Common stock issued to former director & officer			15,000	115,950			115,950
Stock options expensed					140,586		140,586
Stock grants			45,000	357,750			357,750
Net Income						13,136,131	13,136,131
Balances at September 30, 2007	9,792,000	\$ 68,674,560	29,820,094	\$ 66,815,317	\$ 3,005,108	\$ (24,090,599)	\$ 114,404,386

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, 2007 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, 2007 of Caraco Pharmaceutical Laboratories, Ltd. (Caraco, the Company, or the Corporation and which is also referred to as we, us, or our).

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

**2. ORGANIZATION AND NATURE OF BUSINESS**

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

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

Our present product portfolio includes 42 prescription products in 89 strengths in various package sizes. These include both Caraco manufactured products as well as products we distribute for Sun Pharmaceutical Industries Limited (Sun Pharma). The products are intended to treat a variety of disorders including but not limited to 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. Sun Pharma owns approximately 68% of the outstanding shares of the Company (approximately 76% 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 second quarter and first six months of our current fiscal year ( fiscal 2008 ), we recorded net sales of \$41.4 million and \$76.8 million, respectively, compared to \$28.3 million and \$53.0 million during the corresponding periods of fiscal 2007. We incurred \$10.5 million and \$13.8 million, respectively, in R&D expense during the second quarter and first six months of fiscal 2008, as compared to \$9.7 million and \$15.8 million during the corresponding periods of fiscal 2007. This included \$5.4 million in both the second quarter and first six months of fiscal 2007 in non-cash R&D expense, as compared to \$7.4 million and \$11.8 million during the corresponding periods of fiscal 2007. We generated cash from operations of \$1.3 million during the first six months of fiscal 2008, as compared to \$14.3 million during the corresponding period of fiscal 2007. We earned a net pre-tax income of \$4.9 million and \$14.5 million during the second quarter and first six months of fiscal 2008, as compared to a net pre-tax income of \$2.3 million and \$7.3 million during the corresponding periods of fiscal 2007. During the second quarter and first six months of fiscal 2008, we provided a net income tax provision of \$0.2 million and \$1.4 million, respectively. There was no such provision for the corresponding periods of fiscal 2007. We earned net income of \$4.6 million and \$13.1 million during the second quarter and first six months of fiscal 2008, as compared to net income of \$2.3 million and \$7.3 million during the corresponding periods of fiscal 2007. At September 30, 2007, we had stockholders' equity of \$114.4 million, as compared to stockholders' equity of \$95.2 million at March 31, 2007. See Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Pursuant to our products agreement with Sun Pharma Global, Inc. ( Sun Global ), a wholly-owned subsidiary of Sun Pharma, we have selected, through September 30, 2007, all products out of the 25 products to be transferred to us by Sun Global. Of these, 24 products passed their bio-equivalency studies as of September 30, 2007. 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 Abbreviated New Drug Applications ( ANDAs ) relating to one product with the FDA during the first six months of fiscal 2008. We have received FDA approval for eight ANDAs relating to seven products and FDA tentative approval for four ANDAs during fiscal 2008. This brings our total number of ANDAs pending approval by the FDA to 25 (including four tentative approvals) relating to 17 products.

### 4. RECENT ACCOUNTING PRONOUNCEMENTS

In July 2006, the Financial Accounting Standards Board ( FASB ) issued Interpretation No. 48 Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109 ( FIN 48 ). FIN 48 clarified the accounting for uncertain income taxes recognized in an entity's financial statements in accordance with FASB Statement 109, Accounting for Income Taxes and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under FIN 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods,

disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company adopted the provisions of FASB Interpretation No. 48 on April 1, 2007. The Company recognized no increase in the liability for unrecognized tax benefits as a result of the adoption of FIN 48.

In September 2006, the FASB issued SFAS No. 157 Fair Value Measurements . This Statement replaces multiple existing definitions of fair value with a single definition, establishes a consistent framework for measuring fair value, and expands financial statement disclosures regarding fair value measurements. This Statement applies only to fair value measurements that are already required or permitted by other accounting standards and does not require any new fair value measurements. SFAS No. 157 is effective for fiscal years beginning subsequent to November 15, 2007. The Corporation will be required to adopt SFAS No. 157 for the first quarter of Fiscal 2009.

In February 2007, the FASB issued Statement No. 159, The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of FASB Statement No. 115 ( SFAS 159 ). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. SFAS 159 does not affect any existing accounting literature that requires certain assets and liabilities to be carried at fair value. SFAS 159 is effective for fiscal years beginning after November 15, 2007. Management currently does not expect adoption of SFAS 159 will have a material effect on the Corporation s financial position or results of operations. The Corporation plans to adopt SFAS 159 for the first quarter of fiscal 2009.

## 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 second quarter of fiscal 2008 were 28,739,315 and 38,640,844, respectively, and were 28,739,315 and 38,483,864, respectively, for the first six months of fiscal 2008. Correspondingly, the basic and diluted weighted average numbers of common shares outstanding for the second quarter of fiscal 2007 were 26,429,040 and 39,106,236, respectively, and were 26,429,040 and 38,463,119, respectively, for the first six months of fiscal 2007.

## 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, we entered into an agreement, whereby Sun Pharma was required to transfer to us the technology formula for 25 mutually agreed upon generic pharmaceutical products over a period of five years through August 2003. We exchanged 544,000 shares of our common stock for each such

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 Program-DESI) product. DESI products are Pharmaceutical products marketed prior to 1962 that required only a demonstration of safety. With the passage of the Drug Amendments of 1962, this changed and the law required drug products also show efficacy. Under the terms of this agreement, we conducted, at our expense, all tests including bio-equivalency studies. Sun Pharma delivered 13 out of a possible 25 products to us under this agreement.

On November 21, 2002, we entered into a new products agreement with Sun Global. Under the agreement, which was approved by our independent directors, Sun Global agreed to provide us with 25 new mutually agreed upon 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. Under this 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. Sun Global receives 544,000 shares of Series B Preferred Stock for each generic drug transferred, after 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 an Independent Committee, comprised of 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, 24 of which passed bio-equivalency studies through September 30, 2007. See Item - 2. Management's Discussion and Analysis of Financial Conditions and Results of Operations - Future Outlook .

During the first quarter of 2004, Sun Pharma acquired 3,452,291 additional shares of common stock and 1,679,066 stock options from two former directors and a significant shareholder. Sun exercised these stock options during the fourth quarter of 2004.

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 from time to time 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.

In fiscal 2007, the Company entered into a three-year marketing agreement with Sun Pharma, which was reviewed and approved by the Independent Committee. Under the agreement, the Company purchases selected product formulations offered from Sun Pharma and markets and distributes the same as part of our current product offerings in the U.S., its territories and possessions, including Puerto Rico.

The net sales from products selected under this agreement were \$5.8 million and \$11.9 million during the second quarter and first six months of fiscal 2008, respectively.

On March 31, 2007, Sun Global converted 1,632,000 shares of Series B Preferred Stock into 1,632,000 shares of Common Stock. Further on May 23, 2007 and on August 28, 2007, Sun Global converted 544,000 shares and 1,088,000 shares, respectively, of Series B Preferred Stock into 544,000 shares and 1,088,000 shares of Common Stock.

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

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

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

## 7. ACCOUNTING FOR STOCK BASED COMPENSATION

The Company follows the provisions of 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. 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.

For the second quarter and first six months of fiscal 2008, the Company has recognized expense amounting to \$69,104 and \$140,586, respectively, related to share-based compensation. As of September 30, 2007, total unrecognized compensation cost related to stock options granted was \$536,420. The unrecognized stock option compensation cost is expected to be recognized over a period of approximately three to five years.

Stock options to purchase 40,000 shares of common stock were granted on August 9, 2007 to the CEO of the Corporation. In addition, the Company granted options to purchase 1,500 shares of common stock to each of two independent directors upon the anniversary date of their appointment. Stock options to purchase 3,000 shares were granted to a new employee during the first six months of fiscal 2008. All options vest in the amount of 1/3<sup>rd</sup> on every anniversary following the date of grant.

**8. COMMON STOCK ISSUANCES**

We issued 25,700 shares and 20,800 shares of common stock to our employees upon exercise of their stock options during the first six months of fiscal 2008 and first six months of fiscal 2007, respectively.

During the first six months of fiscal 2008, Sun Global converted 1,632,000 shares of Series B Preferred Stock into 1,632,000 shares of Common Stock. See Part II Other Information: Item 2. Unregistered Sales of Equity Securities and Use of Proceeds below.

During the first six months of fiscal 2008, 15,000 shares of common stock were issued to a former officer and director. See Part II Other Information: Item 2. Unregistered Sales of Equity Securities and Use of Proceeds below.

During the first six months of fiscal 2008, 45,000 shares of common stock were issued to the CEO of the Corporation in accordance with the terms of his Employment agreement with the Corporation. 15,000 shares of this allotment will vest in the next fiscal year.

**9. PREFERRED STOCK ISSUANCES**

We issued 544,000 shares and 1,632,000 shares of preferred stock to Sun Global during the first six months of fiscal 2008 and fiscal 2007, respectively. See Part II Other Information: Item 2. Unregistered Sales of Equity Securities and Use of Proceeds below.

**10. SALES AND CUSTOMERS**

Our Company effectively executed its operating plan during the second quarter and first six months of fiscal 2008. 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, Cardinal Health and/or McKesson Corporation, which provide a service to supplement our direct relationship with our customers, or act as an intermediary to service the customers directly in lieu of direct shipments from our Company. Collectively, for the first six months of fiscal 2008, these wholesale accounts equate to 60% of our net sales, as compared to 53% of our net sales for the first six months of fiscal 2007. 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. No other single customer represented more than 10% of our net sales during the relevant periods.

Certain of the Corporation's customers purchase their 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 million of product per year over a one year base contract period that ended June 30, 2003. The contract had four one-year option periods, the last of which was exercised in August 2006. Though the contract expired in August 2007, we continue to do business with the Veterans Administration for this product and others.

11. **LINE OF CREDIT**

The Corporation has a one-year, \$10 million Credit Agreement with JP Morgan Chase Bank, N.A., which expires November 30, 2007. Under the Credit Agreement, the lender may make loans and issue letters of credit to the Corporation for the Corporation's working capital needs and general corporate purposes. Letters of credit, if issued, expire one year from their date of issuance, but no later than November 17, 2007. Borrowings are secured by the Corporation's receivables and inventory. Interest is payable based on a LIBOR Rate or an alternate base rate (determined by reference to the prime rate or the federal funds effective rate), as selected by the Corporation. The rate of interest is LIBOR plus 75 basis points or the bank's prime rate minus 100 basis points (effective rates of 5.98% and 6.75%, respectively at September 30, 2007.) The Credit Agreement requires that certain financial covenants be met on a quarterly basis. The Corporation is in compliance with these financial covenants at September 30, 2007. There are no borrowings under this Credit Agreement as at September 30, 2007.

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.

As previously disclosed, 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 the Company 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 or the Company's manufacture, use or sale of the product. Sun believes it is first to file a Paragraph IV certification for this drug product and both Sun and the Company 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 Company'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 the Company's ANDA any earlier than the claimed expiration date. The ANDA filed by the Company contains a Paragraph IV certification challenging the Novo Nordisk patent. The Company believes that this Novo Nordisk patent is invalid and/or will not be infringed by the Company's manufacture, use or sale of the product. The Company 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 Company'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 the Company's ANDA any earlier than the claimed expiration date. The ANDA filed by the Company contained Paragraph IV Certifications challenging Forest's Patent Nos. Re. 34,712 ( 712 patent ) and 6,916,941 ( 941 patent ). The Company believes that the 712 patent and 941 patent are invalid and/or will not be infringed by the Company's manufacture, use or sale of the product. Forest's suit alleges only that Caraco infringes the 712 patent, which the Company intends to vigorously defend.

Prior to this action, Forest had filed two lawsuits on the 712 patent 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 712 patent.

Forest proceeded in its action against IVAX and CIPLA and 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 712 patent and that the asserted claims of the 712 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 Federal Circuit held an oral argument on the case on May 9, 2007, but a decision has not yet issued.

On August 23, 2006, Forest filed a motion to transfer its action against the Company to the United States District Court for the District of Delaware, where Forest had litigated its case with Ivax. On November 15, 2006, the Court denied the motion and, accordingly, the litigation will proceed in the Eastern District of Michigan. In February of 2007, the Eastern District of Michigan court granted Forest's motion to stay the proceeding until June 20, 2007 but allowed the parties to exchange documents related to the case. On June 18, 2007, Forest filed a Motion to Extend the Stay Pending Appeal of the Federal Circuit's ruling on Forest v. Ivax. That motion is currently pending.

On February 20, 2007, Caraco brought a declaratory judgment action in the Eastern District of Michigan court against Forest seeking a declaration that its generic version of Lexapro® will not infringe the related 941 patent. On April 13, 2007, Forest granted Caraco a covenant not to sue on the 941 patent, and the court, in May 2007, dismissed the case for lack of a controversy. Caraco filed a notice of appeal of that dismissal on June 8, 2007, and that appeal is currently pending in the U.S. Court of Appeals for the Federal Circuit. On September 5, 2007, in a related case involving one of the same patents that Forest asserted against Caraco, the Federal Circuit recently affirmed a finding of patent validity.

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 Company's filing of an ANDA seeking approval to market its generic version of Ortho-McNeil's Ultracet® brand tramadol/acetaminophen drug product infringed Ortho-McNeil's patent, which expires on September 6, 2011. Ortho-McNeil sought an order from the district court which, among other things, directed the FDA not to approve the Company's ANDA any earlier than the claimed expiration date.





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

The provision for income taxes is different from that which would be obtained by applying the statutory federal income tax rate to income before income taxes. The items causing the difference for the six months ended September 30, 2007, are as follows:

Provision for income taxes at federal statutory rate	\$ 4,934,752
Change in valuation allowance	(2,862,422)
Other	(704,364)
	<u>                    </u>
Income taxes	\$ 1,367,966
	<u>                    </u>

Deferred taxes consist of the following:

	<u>September 30, 2007</u>	<u>March 31, 2007</u>
Deferred tax assets:		
Net operating loss carryforwards	\$ 1,162,263	\$ 6,354,984
Intangibles	27,199,567	398,886
Other	522,443	1,343,139
	<u>                    </u>	<u>                    </u>
Total deferred tax assets	\$ 28,884,273	\$ 8,097,009
	<u>                    </u>	<u>                    </u>
Deferred tax liabilities:		
Intangibles	\$ 15,012,217	
Depreciation	640,313	\$ 595,528
	<u>                    </u>	<u>                    </u>
Total deferred tax liabilities	\$ 15,652,530	\$ 595,528
	<u>                    </u>	<u>                    </u>
Net deferred tax assets before valuation allowance	\$ 13,231,743	\$ 7,501,481
Valuation allowance	4,100,000	6,962,422
	<u>                    </u>	<u>                    </u>
Net deferred tax assets	\$ 9,131,743	\$ 539,059
	<u>                    </u>	<u>                    </u>

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

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

We have reviewed the balance sheet of Caraco Pharmaceutical Laboratories, Ltd. as of September 30, 2007 and the related statements of income for the three and six months ended September 30, 2007 and 2006, the statement of stockholders' equity for the six months ended September 30, 2007, and the statements of cash flows for the six months ended September 30, 2007 and 2006. 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, 2007, (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 14, 2007, we expressed an unqualified opinion on those financial statements.

/s/ Rehmann Robson

Grand Rapids, Michigan  
October 23, 2007

**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 2007 Annual Report on Form 10-K as of and for the year ended March 31, 2007 (the Annual Report) and the unaudited interim financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

**Critical Accounting Policies and Estimates**

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

**Revenue Recognition**

Revenue from product sales, net of estimated provisions, is recognized when there is persuasive evidence that an arrangement exists, shipment of the goods has occurred, the selling price is fixed or determinable, and collectibility is reasonably probable. Our customers consist primarily of large pharmaceutical wholesalers who sell directly into the retail channel, 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 time of sale for our wholesale customers. We are currently unable to specifically determine whether the amounts allowed in specific prior periods for chargeback reserves have been over or understated. Wholesaler

customers who submit chargebacks to the Company do not reference a specific invoice that the chargeback is related to when the chargeback is submitted to the Company. Thus, we cannot determine the specific period to which the wholesaler's chargeback relates.

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 actual chargeback reports from our primary wholesaler customers.
2. Volume of all products sold to wholesaler customers and the average chargeback rates for the current quarter as compared to the previous quarter and compared to the last six month period.
3. The sales trends and future estimated prices of our products, wholesale acquisition cost (WAC), the contract prices with the retailers, chain stores, managed care organizations (end-users), and our wholesaler customer's contract prices.
4. We utilize remaining inventories on hand at our primary wholesaler customers at the end of the period in the calculation of our estimates.

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 materially over or under estimate the amount that will ultimately be charged back to us by our wholesale 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 customer's 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 twelve 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 collected.

#### *Gross Sales and Related Reserves*

Our gross sales for the second quarter and first six months of fiscal 2008 were \$108.6 million and \$192.1 million, respectively, as compared to \$73.9 million and \$138.2 million for the corresponding periods of fiscal 2007. Chargebacks, returns, discounts and other customary customer deductions and other sales costs constituted approximately 62% and 60% for the second quarter and first six months of fiscal 2008, as compared to 62% for both of the corresponding periods of fiscal 2007. Net sales for the second quarter and first six months of fiscal 2008 were \$41.4 million and \$76.8 million, respectively, as compared to \$28.3 million and \$53.0 million for the corresponding periods of fiscal 2007. The primary cause of the decrease in the sales allowances by almost 2% between the six month periods is the impact of change in wholesale acquisition (WAC) price during the period on certain products and also some change in the mix of customers and products we sell.

The following is a roll forward of the provisions for chargebacks, shelf stock adjustments, returns and allowances and estimated doubtful account allowances during fiscal 2007 and the first six months of fiscal 2008.

(\$ in Thousands)

	<b>Balances at beginning of period</b>	<b>Allowances charged to Gross Sales</b>		<b>Credits taken by customers</b>	<b>Balance at the end of period</b>
		<b>Current Period</b>	<b>Prior Period</b>		
For all of fiscal 2007					
Chargebacks & shelf stock adjustments	\$ 11,467	\$ 190,586	-0-	\$ 169,415	\$ 32,638
Returns and other allowances	1,500	9,000	-0-	6,748	3,752
Doubtful Accounts	100	-0-	-0-	-0-	100
For first six months of fiscal 2008					
Chargebacks & shelf stock adjustments	\$ 32,638	\$ 110,385	-0-	\$ 119,513	\$ 23,510
Returns and other allowances	3,752	4,939	-0-	4,947	3,744
Doubtful Accounts	100	-0-	-0-	-0-	100

**Income Taxes**

As part of the process of preparing our financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. We account for income taxes by the liability method. Under this method, deferred income taxes are recognized for tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end, based on enacted laws and statutory tax rates applicable for the differences that are expected to affect taxable income. In assessing the ability to realize deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. We have net deferred tax assets of \$13.2 million and \$7.5 million at September 30, 2007 and March 31, 2007, respectively. Valuation allowances are provided when 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 recorded a net federal tax provision of \$0.2 million and \$1.4 million

during the second quarter and first six months of fiscal 2008, respectively. No such provision was recorded for the corresponding period of fiscal 2007. We have provided a valuation allowance of \$4.1 million as of September 30, 2007, as compared to a valuation allowance of \$7.0 million as of March 31, 2007. Based upon the level of projected future taxable incomes over the periods in which these deferred assets are deductible, the Company is unable to conclude that it is more likely than not that it will realize the benefit of some of these temporary differences. As of September 30, 2007, we had federal net operating loss carryforwards ( NOLs ) of approximately \$3.4 million, which are restricted by limitations of Internal Revenue Code Section 382, available to reduce taxable income and will expire between 2008 and 2012. The decrease in the NOLs from March 31, 2007 to September 30, 2007 is due to a Company elected change in the first quarter of fiscal 2008 in the amortization of certain intangibles (primarily technology transfer costs) for income tax purposes only and the utilization of a portion of the available NOLs to offset estimated fiscal 2008 taxable income. As a result of this election, NOLs of approximately \$15 million were converted for tax purposes into an intangible asset that results in future tax amortization. The elected change results in no material impact on previously reported operating results. In addition, as a result of the election, the estimated current tax liability for the year ended March 31, 2007 increased, and a deferred tax asset is recognized for financial reporting purposes.

The Company adopted FASB Interpretation 48, Accounting for Uncertainty in Income Taxes ( FIN 48 ), at the beginning of fiscal 2008. The Company has determined that no adjustments for unrecognized tax benefits are necessary as a result of the adoption of FIN 48.

The Company is subject to U.S. federal income tax as well as income tax in multiple state jurisdictions. The Company has not been a subject of an IRS examination. The Company's federal statute of limitations has expired for years prior to 2003.

### **Inventory**

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



## OVERVIEW

The second quarter of fiscal 2008, ended September 30, 2007, represents 26 quarters of successive sales revenue growth. During the second quarter and first six months of fiscal 2008, we recorded net sales of \$41.4 million and \$76.8 million, respectively, as compared to \$28.3 million and \$53 million during the corresponding periods of fiscal 2007. We incurred \$10.5 million and \$13.8 million in R&D expense during the second quarter and first six months of fiscal 2008, respectively, as compared to \$9.7 million and \$15.8 million during the corresponding periods of fiscal 2007. These include \$5.4 million for second quarter and first six months of fiscal 2008 in non-cash R&D expenses, as compared to \$7.4 million and \$11.8 million, respectively, for the corresponding periods of fiscal 2007. The non-cash R&D expenses consist of technology transfer costs associated with Sun Global earning 544,000 preferred shares for each product transferred that has passed its bio-equivalency study, as per the terms of the technology transfer agreement. All 25 products have been selected and 24 of them have already passed their bio-equivalency studies. We generated cash from operations of \$1.3 million during the six months of fiscal 2008, as compared to \$14.3 million during the corresponding period of fiscal 2007. The lower cash results were primarily due to higher inventories to support higher sales, higher accounts receivable due to timing of sales in the period and associated chargebacks, customer mix with longer terms combined with significant growth over the previous quarter's sales, and higher prepaids and deposits. We earned a net pre-tax income of \$4.9 million and \$14.5 million during the second quarter and first six months of fiscal 2008, respectively, as compared to a net pre-tax income of \$2.3 and \$7.3 million during the corresponding periods of fiscal 2007. This was primarily due to lower non-cash R&D expenses for the period. During the second quarter and first six months of fiscal 2008, we provided a net income tax provision of \$0.2 million and \$1.4 million respectively. There was no such provision for the corresponding periods of fiscal 2007. During the second quarter and first six months of fiscal 2008, we earned a net income of \$4.6 million and \$13.1 million, respectively, as compared to a net income of \$2.3 million and \$7.3 million during the corresponding periods of fiscal 2007. At September 30, 2007, we had stockholders' equity of \$114.4 million as compared to stockholders' equity of \$95.2 million at March 31, 2007.

## FDA COMPLIANCE

The FDA completed an inspection in August 2007, which was a follow-up to its earlier observations provided to the Company when it completed an inspection of the premises in June 2006, and the subsequent responses given by the Company. The FDA provided an observation on FDA Form 483. The Company has responded accordingly, and we believe that we remain substantially cGMP compliant. We continue to focus on improving the amount of support in both quality assurance and quality control in order to continually improve our performance and outcome in quality. This support is derived from the improvement of systems, training on risk management, continual improvement on our corrective and preventative actions, (CAPA) and cGMPs, while adding the appropriate level of personnel and equipment to support our growth. During 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 will continue and increase in fiscal 2008. These audits are based on a historical look back and offer improvements based on the Company's future requirements. It also includes follow up on the recommendations made by the FDA both from their inspections and areas they advise the industry on regularly throughout the year.

We remain extremely pro-active in regards to growing our business appropriately. During fiscal 2007, the analytical staff was more than doubled, and is currently at approximately 65 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.

#### **Second Quarter and First Six Months Fiscal 2008 Compared to Second Quarter and First Six Months Fiscal 2007**

**Net Sales.** Net sales for the second quarter and first six months of fiscal 2008 were \$41.4 million and \$76.8 million, respectively, as compared to \$28.3 million and \$53.0 million for the corresponding periods of fiscal 2007, reflecting an increase of 46% and 45%, respectively. The increase is mainly due to newer products, consisting of both Caraco and of Sun Pharma ANDAs launched in the market, and increased market share of current products to new and existing customers. Currently, we manufacture and market all except two of the approved products. The sales mix amongst various products is more diversified now as sales of four products accounted for approximately 56% and 53% of net sales for the second quarter and first six months of fiscal 2008, respectively, as compared to sales of four products accounting for approximately 74% and 73% of net sales during corresponding periods of fiscal 2007.

**Gross Profit.** We earned gross profit of \$18.0 million and \$33.9 million during the second quarter and first six months of fiscal 2008, respectively, as compared to gross profit of \$14.2 million and \$27.2 million during the corresponding periods of fiscal 2007, reflecting an increase of 27% and 25%, respectively. The increase in gross profit was primarily due to higher sales, partially offset by the change in sales mix and the weight of distributed products versus manufactured products and price erosion.

The gross profit margin for both the second quarter and first six months of fiscal 2008 decreased to 44% weighted with both distribution and manufactured margin products, as compared to 50% and 51% with only manufactured margin products during the corresponding periods of fiscal 2007. The decrease was primarily due to increased sales of distributed products and the weight of the associated lower margins versus the manufactured products margin which had an impact on the overall margin. Net sales for distributed products were \$6.4million and \$13.4 million for second quarter and first six months of fiscal 2008, respectively. The gross profit margin on distributed products sold was 17% and 20% for the respective periods. The net sales for manufactured products were \$34.9 million and \$63.3 million for the second quarter and first six months of fiscal 2008, respectively. The gross profit margin for manufactured products was 48% and 49% for the respective periods, as compared to 50% for fiscal 2007. We believe the manufactured margins remain fairly stable considering various factors such as changes in product sales mix, the balance of product sold to the various class of trade and continued price erosion and we expect that distribution margins will normalize in the mid teens as a percentage. We can not determine the mix of distributed product sales versus manufactured product sales in any given future period as it depends on our ability to gain market share on each product and is relative to when the FDA approves any given

product in either category of product and the revenue potential of that product once it has been approved.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses during the second quarter and first six months of fiscal 2008 were \$3.0 million and \$6.4 million, respectively, as compared to \$2.4 million and \$4.5 million during the corresponding periods of fiscal 2007, representing an increase of 25% and 42% in respective periods. The increase was mainly due to higher marketing and administrative increases relative to the increase in sales. Selling, general and administrative expenses, as a percentage of net sales were 8%, for the first six months of fiscal 2008, consistent with 8% for the corresponding period of fiscal 2007.

**Research and Development Expenses.** Total R&D expenses for the second quarter and first six months of fiscal 2008 were \$10.5 million and \$13.8 million, respectively, as compared to \$9.7 million and \$15.8 million during the corresponding periods of fiscal 2007. Actual cash research and development expenses were \$5.1 million and \$8.4 million during the second quarter and first six months of fiscal 2008, respectively, as compared to \$2.3 million and \$4.0 million during the corresponding periods of fiscal 2007. We incurred non-cash research and development expenses (technology transfer cost) of \$5.4 million for one product transfer during the second quarter and first six months of fiscal 2008, as compared to \$7.4 million and \$11.8 million for two and three product transfers during the corresponding periods of fiscal 2007. Each product transfer earns 544,000 shares of preferred stock. The cash R&D expenses during the second quarter and first six months of fiscal 2008 were higher compared to those during the corresponding periods of fiscal 2007 due to increased R&D activity including milestone payments for outside development, increased patent related expenses and increases in other expenses in an effort to file more products with the FDA.

**Other Income.** We earned other income of \$0.4 million and \$0.9 million during the second quarter and first six months of fiscal 2008, respectively, as compared to \$0.2 million and \$0.4 million during corresponding periods of fiscal 2007, consisting of interest income which is reflective of an increase in average cash balances between the two periods.

**Net Income Tax Provisions.** We recorded a net income tax provision of \$0.2 million and \$1.4 million during the second quarter and first six months of fiscal 2008, respectively. There was no such provision recorded for the corresponding periods of fiscal 2007. As the Company has been profitable over the past few quarters, substantially all of the NOLs have been utilized and thus the Company is expected to pay income taxes on current profits. Also see discussion under **Income Taxes** above.

**Results of Operations.** We earned a net pre-tax income of \$4.9 million and \$14.5 million during the second quarter and first six months of fiscal 2008, respectively, as compared to a net pre-tax income of \$2.3 million and \$7.3 million during the corresponding periods of fiscal 2007. We earned net income of \$4.6 million and \$13.1 million in the second quarter and first six months of fiscal 2008, respectively, as compared to net income of \$2.3 million and \$7.3 million during the corresponding periods of fiscal 2007.

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

We generated cash from operations of \$1.3 million during the first six months of fiscal 2008 as compared to \$14.3 million during the corresponding period of fiscal 2007. Accounts receivable increased by \$17.8 million to \$43.9 million during the first six months of fiscal 2008, as compared to \$26.1 million at the end of fiscal 2007 due to higher net sales, higher sales to customers later in the period and change in sales mix to certain customers with longer credit terms

which primarily created an additional 13 days sales outstanding. The lower cash results were also due to higher prepaids due to a marked increase in a contractual deposit with a customer relative to the growth in business with that customer, and the additional investment in inventory. There has been cash outflow due to payment of federal income taxes of \$2.2 million as a result of a change in the Company's tax position. See discussion under "Income Taxes" above. Inventory level is equivalent to 79 days sales on hand as compared to 105 days for the relative period of fiscal 2007, and accounts receivable is 98 days sales outstanding (DSO) versus 78 days for the relative period of fiscal 2007.

At September 30, 2007, we had working capital of \$85.8 million, as compared to working capital of \$76.2 million at March 31, 2007. The increase in working capital in fiscal 2008 is due to an increase in accounts receivable and inventory balances resulting from higher sales volumes, and also an increase in prepaids due to an increase in contractual deposit with a customer, partially offset by higher current liabilities. Additionally, we have available the \$10.0 million line of credit obtained through JP Morgan Chase Bank, N.A. which would allow us flexibility in expansion efforts to increase our capacity over the next few years. The Company currently remains free of debt.

#### **Future Outlook**

We continue to 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 remain 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 25 ANDAs pending approval at the FDA (including four tentative approvals) relating to 17 products. We continue to expand and upgrade our facilities, attract and hire talented individuals and expand our customer base. Our internal efforts, combined with Sun Pharma 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 fifteen products, whose market share is ranked third or higher against the same products of our generic competitors where there are more than three competitors. Based on current trends, we believe we will achieve 30% growth in sales for fiscal 2008 compared to fiscal 2007. Additionally during second quarter of fiscal 2008 we gained FDA approval on five products and two tentative approvals and one tentative approval since then for Caraco ANDAs. For the first six months of fiscal 2008 we had eight FDA approvals on Caraco ANDAs relating to seven products and three tentative approvals and one tentative since then. During fiscal 2008 we also marketed three Sun products that were approved and launched during the period.

Although gross profit margins may come down over time due to price erosion and the change in sales mix and the weight of distributed products versus manufacturing products we are confident that our sales growth, expanding product portfolio and successful execution of our business plan will offset any long-term net 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 24 of these products have passed their respective bio-equivalency studies. Only one product remains as part of our development pipeline that pertains to this agreement. 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. Product development is a critical element in meeting expectations in the future.

The Company intends to aggressively move forward with the development of new products. We believe that Sun Pharma 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 68% (approximately 76% 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 Pharma products agreement, we have implemented additional development strategies with various third parties both domestically and abroad that will complement the Sun Pharma development pipeline.

During Fiscal 2007, the Company entered into three definitive agreements with different companies to develop four additional ANDAs for Caraco and provide additional opportunities for the future development of products. These agreements contain, for three products, both milestone payments to be paid in cash and profit sharing based upon future sales for a defined period, and for one product only milestone payments in cash without any obligation to share profits in the future. During the first six months of fiscal 2008, we have signed two definitive agreements for two additional products bringing the total to six products being developed by unaffiliated third party developers.

We anticipate additional development agreements will be entered into in order to eliminate any future gaps in our calendar of approvals that we anticipate from the FDA. We expect these agreements to run parallel to our own internal product development. In order to improve the amount of filings during the fiscal 2008, we continue to fortify our own research and development team by adding formulators and increasing the number of products we have in development internally. We filed 19 ANDAs in fiscal 2007, or 11 products. In the six months of fiscal 2008, we filed two ANDAs covering one product.

As previously mentioned, we have entered into a definitive agreement to market Sun Pharma ANDAs that are either approved or awaiting approval at the FDA. Accordingly, we have begun marketing a number of these products which are categorized as distributed products. While increased distributed products may lower our overall gross profit margins, we do not have any of the associated costs other than freight, carrying costs and actual purchase price. 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 Pharma, 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 Fiscal 2008 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.

Build or lease new facilities to meet the increased demand for production and warehousing in short and long term.

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.

Increase revenue and cash by marketing ANDAs owned by Sun Pharma.

Expand our relationships with financial institutions to fortify our credit position and borrowings if 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.

Increase focus on succession planning

Increase training in cGMP and risk assessment.

Increase management training and development.

Maintain balance in trade class.

### **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 on Form 10-K for the year ended March 31, 2007, 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 interim Chief Financial Officer have evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report (the Evaluation Date), and have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective in providing them with material information relating to the Company known to others within the Company which is required to be included in our periodic reports filed under the Exchange Act.

b. There has been no change in the Company's internal control over financial reporting that occurred during the second quarter of fiscal 2008 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 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

During the first quarter of fiscal 2008, 544,000 shares of Series B Preferred Stock previously issued to Sun Global were converted into 544,000 shares of Caraco common stock and issued to Sun Global.

During the first quarter of fiscal 2008, 15,000 shares of common stock were issued to a former officer and director of Caraco pursuant to the submission of a prior claim to arbitration under which the parties agreed that the officer and director would receive a minimum of 15,000 shares. As disclosed in previous filings, on April 20, 2006 the arbitrator entered a determination of no cause of action against such former officer and director and in favor of Caraco, capping Caraco's liability to the director at 15,000 shares.

During the second quarter of fiscal 2008, 1,088,000 shares of Series B Preferred Stock previously issued to Sun Global were converted into 1,088,000 shares of Caraco common stock and issued to Sun Global.

During the second quarter of fiscal 2008, we issued Sun Global 544,000 shares of Series B Preferred Stock in exchange for the transfer of one product.

All shares of Caraco preferred and common stock issued by the Company as set forth above were issued pursuant to exemptions from registration under Section 4(2) of the Securities Act of 1933.

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

The Annual Meeting of Shareholders of the Corporation was held on September 10, 2007 in Dearborn, Michigan for the purpose of electing three directors for a three-year term expiring in 2010 and upon the election and qualification of their successors.

<u>Name of the Director</u>	<u>Votes FOR</u>	<u>Votes Withheld</u>
Timothy S. Manney	26,566,242	414,837
Madhava Reddy	26,676,140	304,939
Sudhir Valia	24,011,224	2,969,855

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

<u>Name of the Director</u>	<u>Term</u>
Daniel H. Movens	2008
Sailesh T. Desai	2008
Georges Ugeux	2008
Dilip S. Shanghvi	2009
Jitendra N. Doshi	2009
Dr. John D. Crissman	2009

**ITEM 6. EXHIBITS**

- 10.20 Form of Stock Option Agreement - Daniel H. Movens.
- 10.21 Form of Restricted Stock Agreements - Daniel H. Movens.
- 31.1 Certification of Chief Executive Officer
- 31.2 Certification of interim Chief Financial Officer.



32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

**SIGNATURES**

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

CARACO PHARMACEUTICAL  
LABORATORIES, LTD.

Date: October 24, 2007

By: /s/ Daniel H. Movens  
\_\_\_\_\_

Daniel H. Movens  
Chief Executive Officer

Date: October 24, 2007

By: /s/ Mukul Rathi  
\_\_\_\_\_

Mukul Rathi  
interim Chief Financial Officer

EXHIBIT INDEX

- 10.20 Form of Stock Option Agreement Daniel H. Movens.
- 10.21 Form of Restricted Stock Agreement Daniel H. Movens.
- 31.1 Certificate of Chief Executive Officer
- 31.2 Certificate of interim 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.