

CARACO PHARMACEUTICAL LABORATORIES LTD  
Form 10-Q  
February 04, 2008

---

---

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

FORM 10-Q

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

for the quarterly period ended December 31, 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  
(State or other jurisdiction of  
incorporation or organization)

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

38-2505723  
(IRS Employer  
Identification No.)  
48202  
(Zip Code)

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

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

Yes  No

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

Large Accelerated Filer  Accelerated Filer  Non- Accelerated Filer

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

Yes  No

As of February 1, 2008 the registrant had 30,917,094 shares of common stock issued and outstanding.

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

	<b>DECEMBER 31, 2007</b>	<b>MARCH 31, 2007</b>
	<b>UNAUDITED</b>	<b>AUDITED</b>
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 54,401,976	\$ 33,897,622
Accounts receivable, net	55,427,714	26,125,146
Inventories	197,810,768	31,943,297
Prepaid expenses and deposits	7,186,927	3,473,340
Net deferred tax assets	485,183	—
<b>Total current assets</b>	<b>315,312,568</b>	<b>95,439,405</b>
<b>Property, plant and equipment</b>		
Land	975,311	975,311
Buildings and improvements	13,228,369	12,448,221
Equipment	18,330,719	15,292,499
Furniture and fixtures	1,055,241	992,013
<b>Total</b>	<b>33,589,640</b>	<b>29,708,044</b>
Less accumulated depreciation	12,492,927	10,678,157
<b>Net property, plant and equipment</b>	<b>21,096,713</b>	<b>19,029,887</b>
Deferred income taxes	15,992,537	—
<b>Total assets</b>	<b>\$ 352,401,818</b>	<b>\$ 114,469,292</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable, trade	\$ 3,985,238	\$ 3,350,024
Accounts payable, Sun Pharma	212,309,380	12,143,157
Accrued expenses	3,120,377	3,782,702
Income taxes payable	1,775,847	—

<b>Total liabilities (all current)</b>	<b>221,190,842</b>	<b>19,275,883</b>
--	--------------------	-------------------

**Commitments and contingencies (notes 11 and 12)****Stockholders' equity**

Series B convertible preferred stock, no par value; issued and outstanding 9,248,000 shares (December 31, 2007) 10,880,000 shares (March 31, 2007)	68,337,280	73,585,520
Common stock, no par value; authorized 50,000,000 shares, issued and outstanding 30,917,094 shares (December 31, 2007) 28,102,394 shares (March 31, 2007)	73,114,427	55,970,097
Additional paid in capital	3,076,786	2,864,522
Accumulated deficit	(13,317,517)	(37,226,730)
<b>Total stockholders' equity</b>	<b>131,210,976</b>	<b>95,193,409</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 352,401,818</b>	<b>\$ 114,469,292</b>

See accompanying notes

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

	Nine Months ended December 31,		Quarter ended December 31,	
	2007	2006	2007	2006
	UNAUDITED	UNAUDITED	UNAUDITED	UNAUDITED
<b>Net sales</b>	<b>\$ 158,614,840</b>	<b>\$ 84,288,303</b>	<b>\$ 81,859,956</b>	<b>\$ 31,257,187</b>
Cost of goods sold	101,445,849	41,915,021	58,574,542	16,126,034
<b>Gross profit</b>	<b>57,168,991</b>	<b>42,373,282</b>	<b>23,285,414</b>	<b>15,131,153</b>
Selling, general and administrative expenses	10,159,869	7,105,896	3,723,144	2,603,035
Research and development costs - affiliate	11,320,640	11,761,280	5,880,640	—
Research and development costs - other	12,476,952	6,778,204	4,087,742	2,734,727
<b>Operating income</b>	<b>23,211,530</b>	<b>16,727,902</b>	<b>9,593,888</b>	<b>9,793,391</b>
<b>Other income</b>				
Interest expense	—	(28,194)	—	—
Interest income	1,420,730	616,321	534,275	266,074
Loss on disposal of assets	(4,420)	—	(4,420)	—
Other income	—	39,897	—	6
<b>Other income</b>	<b>1,416,310</b>	<b>628,024</b>	<b>529,855</b>	<b>266,080</b>
<b>Net income before income taxes (benefit)</b>	<b>24,627,840</b>	<b>17,355,926</b>	<b>10,123,743</b>	<b>10,059,471</b>
Income taxes (benefit)	718,627	—	(649,339)	—
<b>Net income</b>	<b>\$ 23,909,213</b>	<b>\$ 17,355,926</b>	<b>\$ 10,773,082</b>	<b>\$ 10,059,471</b>
<b>Net income per common share</b>				
Basic	0.82	0.66	0.37	0.38
Diluted	0.63	0.45	0.28	0.26

See accompanying notes

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

	<b>Nine Months ended December 31,</b>	
	<b>2007</b>	<b>2006</b>
	<b>UNAUDITED</b>	<b>UNAUDITED</b>
<b>Cash flows from operating activities</b>		
Net income	\$ 23,909,213	\$ 17,355,926
Adjustments to reconcile net income to net cash flow from operating activities		
Depreciation	1,820,350	1,400,118
Loss on disposal of Assets	4,420	—
Capital stock issued or to be issued to affiliate in exchange for product formula	11,320,640	11,761,280
Stock option expense	212,264	—
Stock grant expense	357,750	—
Common stock issued to former officer & director	115,950	—
Net deferred income taxes	(16,477,720)	—
Changes in operating assets and liabilities which (used) / provided cash:		
Accounts receivable	(29,302,568)	(5,409,026)
Inventories	(165,867,471)	(5,373,604)
Prepaid expenses and deposits	(3,713,588)	(162,222)
Accounts payable	200,801,437	(546,023)
Accrued expenses	(662,326)	665,631
Income taxes payable	1,775,848	—
<b>Net cash provided by operating activities</b>	<b>24,294,199</b>	<b>19,692,080</b>
<b>Cash flows from investing activities</b>		
Purchases of property, plant and equipment	(3,891,595)	(5,640,740)
<b>Net cash used in investing activities</b>	<b>(3,891,595)</b>	<b>(5,640,740)</b>
<b>Cash flows from financing activities</b>		
Proceeds from loans payable to financial institutions	—	5,000,000
Repayments of loans payable to financial institutions	—	(5,000,000)
Proceeds from exercise of stock options	101,750	18,240
<b>Net cash provided by financing activities</b>	<b>101,750</b>	<b>18,240</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>	<b>20,504,354</b>	<b>14,069,580</b>
Cash and cash equivalents, beginning of period	33,897,622	11,924,245

<b>Cash and cash equivalents, end of period</b>	<b>\$ 54,401,976</b>	<b>\$ 25,993,824</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	1,088,000	11,320,640					11,320,640
Conversion of preferred stock into common stock	(2,720,000)	(16,568,880)	2,720,000	16,568,880			—
Common stock options exercised			34,700	101,750			101,750
Common stock issued to former director & officer			15,000	115,950			115,950
Stock options expensed					212,264		212,264
Stock grants			45,000	357,750			357,750
Net Income						23,909,213	23,909,213
Balances at December 31, 2007	9,248,000	\$ 68,337,280	30,917,094	\$ 73,114,427	\$ 3,076,786	\$ (13,317,517)	\$ 131,210,976

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 49 prescription products, in 107 strengths, in various package sizes. These include both Caraco manufactured products, as well as products we distribute for Sun Pharmaceutical Industries Limited, a specialty pharmaceutical corporation organized under the laws of India (“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 earlier funding has been from 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 69%

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 third quarter and the first nine months of our current fiscal year (“fiscal 2008”), we generated net sales of \$81.9 million and \$158.6 million, respectively, compared to \$31.3 million and \$84.3 million during the corresponding periods of fiscal 2007. We incurred \$10.0 million and \$23.8 million, respectively, in R&D expense during the third quarter and the first nine months of fiscal 2008, as compared to \$2.7 million and \$18.5 million during the corresponding periods of fiscal 2007. This included \$5.9 million and \$11.3 million in third quarter and the first nine months of fiscal 2008 in non-cash R&D expense, as compared to no expenses in third quarter of fiscal 2007 and \$11.8 million during the first nine months of fiscal 2007. We generated cash from operations of \$24.3 million during the first nine months of fiscal 2008, as compared to \$19.7 million during the corresponding period of fiscal 2007. We earned a net pre-tax income of \$10.1 million and \$24.6 million during the third quarter and the first nine months of fiscal 2008, as compared to a net pre-tax income of \$10.1 million and \$17.4 million during the corresponding periods of fiscal 2007. During the third quarter we provided for a net income tax benefit of \$0.7 million. During the first nine months of fiscal 2008, we provided a net income tax provision of \$0.7 million. There was no such provision or benefit for the corresponding periods of fiscal 2007. We earned net income of \$10.8 million and \$23.9 million during the third quarter and the first nine months of fiscal 2008, respectively, as compared to net income of \$10.1 million and \$17.4 million during the corresponding periods of fiscal 2007. At December 31, 2007, our inventory increased to \$197.8 million from \$31.9 million at March 31, 2007. This increase was to support our increased sales levels and in preparation of potential product launches on our behalf and on behalf of Sun Pharma. At December 31, 2007, we had stockholders’ equity of \$131.2 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 December 31, 2007, all products out of the 25 products to be transferred to us by Sun Global. All of these 25 products have passed their bio-equivalency studies as of December 31, 2007. The final product was transferred to Caraco during the third quarter which concludes the obligations between the parties under this agreement. 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 five Abbreviated New Drug Applications (“ANDAs”) relating to five products with the FDA during the first nine months of fiscal 2008. We have received FDA approval for 10 ANDAs relating to 10 products and FDA tentative approval for five ANDAs during the first nine months of fiscal 2008. Subsequent to end of the third quarter, we have received two FDA approvals relating to two products. This brings our total number of ANDAs pending approval by the FDA to 26 (including five tentative approvals) relating to 19 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 third quarter of fiscal 2008 were 29,197,836 and 38,169,114, respectively, and were 29,197,836 and 38,035,421, respectively, for the first nine months of fiscal 2008. Correspondingly, the basic and diluted weighted average numbers of common shares outstanding for the third quarter of fiscal 2007 were 26,434,238 and 39,119,085, respectively, and were 26,434,238 and 38,756,119, respectively, for the first nine 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 and all of these 25 products have passed bio-equivalency studies through December 31, 2007. The final product was transferred to Caraco during the third quarter which concludes the obligations between the parties under

this agreement. 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 Pharma 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 \$49.6 million and \$63.0 million during the third quarter and the first nine 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, August 28, 2007, and December 7, 2007 Sun Global converted 544,000 shares, 1,088,000 shares and 1,088,000 shares, respectively, of Series B Preferred Stock into 544,000 shares 1,088,000 shares and 1,088,000 shares, respectively, 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 Company is subject to certain risks associated with companies in the generic pharmaceutical industry. Profitable operations are dependent on the Company’s ability to market its products at reasonable profit margins. In addition to maintaining profitable operations, the ongoing success of the Company 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 third quarter and the first nine months of fiscal 2008, the Company has recognized expenses amounting to \$71,678 and \$212,264, respectively, related to share-based compensation as compared to \$110,665 for both of the corresponding periods of fiscal 2007. As of December 31, 2007, total unrecognized compensation cost related to stock options granted was \$476,009. 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 nine 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 9,000 shares of common stock to our employees and directors upon exercise of their stock options during the third quarter of fiscal 2008.

During the third quarter of fiscal 2008, Sun Global converted 1,088,000 shares of Series B Preferred Stock into 1,088,000 shares of Common Stock. See "Part II – Other Information: Item 2. Unregistered Sales of Equity Securities and Use of Proceeds" below.

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

We issued 544,000 shares of preferred stock to Sun Global during the third quarter of fiscal 2008. See "Part II – Other Information: Item 2. Unregistered Sales of Equity Securities and Use of Proceeds" below.

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

Our Company has been successful in executing its operating plan effectively during the third quarter and for fiscal 2008 to date. 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 nine months of fiscal 2008, these wholesale accounts equate to 57% of our net sales, as compared to 57% of our net sales for the first nine 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. This includes sales to the Veterans Administration, an agency of the United States Government. No other single customer represented more than 10% of our net sales during the relevant periods.

Excluding the sales of one new product, oxcarbazepine (See "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations-Overview."), the sales of four products accounted for 51% and 54% of net sales for the third quarter and the first nine months of fiscal 2008, respectively, as compared to sales of four products accounting for approximately 70% and 72% of net sales during corresponding periods of fiscal 2007. Overall, net sales for three products accounted for approximately 66% of net sales for the third quarter of fiscal 2008 and for 50% of net sales for the first nine months of fiscal 2008, as compared to sales of four products accounting for approximately 70% and 72% of net sales during the corresponding periods of fiscal 2007.

#### 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, 2008. 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 30, 2008. 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 5.58% and 6.25%, respectively at December 31, 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 December 31, 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 ("the New Jersey action"). A nearly identical complaint was filed on October 5, 2006, in the Eastern District of Michigan ("the Michigan action"). Both complaints allege, inter alia, that Sun Pharma's 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 Pharma's ANDA, or will induce others to infringe by marketing and/or selling Sun Pharma'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 Pharma's ANDA any earlier than the claimed expiration date. On August 17, 2007, the New Jersey action was consolidated with other patent infringement cases filed by Schering against other ANDA filers for Schering's Clarinex® drug product, while the Michigan action was stayed pending the outcome of the New Jersey action. The ANDA filed by Sun Pharma contains a Paragraph IV certification challenging the '274 patent. Sun Pharma believes that the '274 patent is invalid, unenforceable and/or will not be infringed by Sun Pharma's or the Company's manufacture, use or sale of the product. Sun Pharma further believes it is first to file a Paragraph IV certification for this drug product and both Sun Pharma 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 contains Paragraph IV Certifications challenging Forest's Patent Nos. Re. 34,712 ("the '712 patent") and 6,916,941 ("the '941 patent"). The Company believes that the '712 and '941 patents 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 affirmed the district court's opinion on September 5, 2007.

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. The stay was later extended, but eventually lifted on December 3, 2007. Discovery is currently ongoing.

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 before the U.S. Court of Appeals for the Federal Circuit. The appeal is fully briefed and was argued on December 4, 2007. The parties are currently awaiting a ruling.

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. The ANDA filed by the Company contains a Paragraph IV Certification challenging the Ortho-McNeil patent. The Company asserted that the Ortho-McNeil patent is invalid and/or will not be infringed by the Company's manufacture, use or sale of the product. Since filing this action, Ortho-McNeil authorized a generic manufacturer to provide a generic version of Ortho-McNeil's product while another manufacturer launched its approved generic at risk. On October 19, 2005, the Company's motion for summary judgment was granted. On December 19, 2005, the FDA approved the manufacture, use and sale of the Company's generic product. Ortho-McNeil filed an appeal of the finding of non-infringement by the district court with the United States Court of Appeals for the Federal Circuit. On January 19, 2007, the United States Court of Appeals for the Federal Circuit affirmed the United States District Court for the Eastern District of Michigan decision granting the Company's motion for summary judgment. Additionally, the United States Patent and Trademark Office approved Ortho-McNeil's request for a reissue patent. Although the district court had determined that the Company does not infringe Ortho-McNeil's original patent, on July 31, 2006, Ortho-McNeil filed a lawsuit against the Company in the United States District Court for the District of New Jersey, alleging that the Company's generic version of Ultracet® brand tramadol/acetaminophen drug product infringes its reissue patent. On September 26, 2006, the Company filed an answer denying, among other things, that its generic product infringes any valid claims of Ortho-McNeil's reissue patent. The Company recently filed a motion for summary judgment of invalidity, which has not yet been fully briefed. The Company believes that, like its original patent, Ortho-McNeil's reissue patent is invalid and/or is not infringed by the Company's manufacture, use or sale of the product and the Company intends to vigorously defend this action. There is no assurance, however, that the Company will prevail in this action.



Deferred taxes consist of the following:

	<u>December 31, 2007</u>	<u>March 31, 2007</u>
Deferred tax assets:		
Net operating loss carryforwards	\$ 1,129,978	\$ 6,354,984
Intangibles	29,453,486	398,886
Other	485,183	1,343,139
	<u>                    </u>	<u>                    </u>
Total deferred tax assets	<u>\$ 31,068,647</u>	<u>\$ 8,097,009</u>
Deferred tax liabilities:		
Intangibles	\$ 13,910,059	—
Depreciation	680,868	\$ 595,528
	<u>                    </u>	<u>                    </u>
Total deferred tax liabilities	<u>\$ 14,590,927</u>	<u>\$ 595,528</u>
Net deferred tax assets before valuation allowance	\$ 16,477,720	\$ 7,501,481
Valuation allowance	—	6,962,422
	<u>                    </u>	<u>                    </u>
Net deferred tax assets	<u>\$ 16,477,720</u>	<u>\$ 539,059</u>

#### 15. SUBSEQUENT EVENTS

On January 29, 2008, the Company executed a distribution and sale agreement with Sun Pharma. This agreement covers certain mutually agreed upon products that have been filed or will be filed with the FDA with a Paragraph IV certification. A Paragraph IV certification states that the filer believes that it either does not infringe the patent or believes that the patent is invalid. Paragraph IV certified products face litigation challenges with respect to claims of patent infringement. Under the agreement, the Company participates in the sales opportunity on the products and also shares the litigation risks to a limited extent based on percentage. The first product under this agreement is Pantoprazole sodium DR tablets.

On January 30, 2008, the Company commercially launched, Pantoprazole Sodium DR tablets. Sun Pharma authorized Caraco to distribute the product following the December 22, 2007 launch of Teva Pharmaceutical's generic version of the product and following the January 29, 2008 launch of an authorized generic by the innovator, Wyeth. Sun Pharma recently received approval from the FDA for its ANDA for generic Protonix®, and being one of the first-to-file an ANDA with a Paragraph IV certification, shares a 180-day marketing exclusivity with Teva. The launch of Pantoprazole sodium DR tablets was considered an "at risk launch" as Sun Pharma is in patent litigation in the US District Court of New Jersey with Wyeth and Altana (recently acquired by Nycomed), and a final decision on the outcome of the patent infringement has not yet been determined. Although no trial date has been set, in September 2007 the District Court denied a motion filed by Wyeth and Altana for a preliminary injunction. Wyeth and Altana have appealed the District Court's decision. If the claims of Wyeth and Altana are successful, they could have a material adverse effect on the Company.

**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 December 31, 2007 and the related statements of income for the three and nine months ended December 31, 2007 and 2006, the statement of stockholder's equity for the nine months ended December 31, 2007, and the statements of cash flows for the nine months ended December 31, 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 income, 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.  
January 23, 2008

**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 customers' inventory cost to better reflect current market prices. The determination to grant a shelf stock adjustment to a customer following a price decrease is at our discretion.

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

#### *Product returns and other allowances*

In the pharmaceutical industry, customers are normally granted the right to return product for credit if the product has not been used prior to its expiration date. Our return policy typically allows product returns for products within a 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 third quarter and the first nine months of fiscal 2008 were \$152.0 million and \$344.1 million, respectively, as compared to \$87.9 million and \$226.1 million for the corresponding periods of fiscal 2007. Sales allowances, which include chargebacks, returns, discounts, other customary customer deductions and other sales costs, constituted approximately 46% and 54% for the third quarter and the first nine months of fiscal 2008, respectively, as compared to 64% and 63% for the corresponding periods of fiscal 2007. Net sales for the third quarter and the first nine months of fiscal 2008 were \$81.9 million and \$158.6 million, respectively, as compared to \$31.3 million and \$84.3 million for the corresponding periods of fiscal 2007. The primary cause of the lower sales allowances by almost 18% for third quarter fiscal 2008 and by 9% for the nine month period is due to the impact of the gross sales versus the net sales on a product (oxcarbazepine tablets) reflecting lesser discounts between the gross sales and the net sales calculation than the rest of our product line. Sales on this product were a significant portion of our overall sales for the quarter. Excluding this product, sales allowances for both the periods of fiscal 2008 were 60% as compared to 64% and 63% for the corresponding periods of fiscal 2007. The lower discount percentage was also due to changes on our wholesale acquisition price (WAC) on various products during the current year to date combined with the change in the mix of customers and products we sell.

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

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 nine months of fiscal 2008.

(\$ in Thousands)

	Balances at beginning of period	Allowances charged to Gross Sales		Credits taken by customers	Balance at the end of period
		Current Period	Prior Period		
For all of fiscal 2007					
Chargebacks, rebates & 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 the first nine months of fiscal 2008					
Chargebacks, rebates & shelf stock adjustments	\$ 32,638	\$ 176,930	-0-	\$ 178,619	\$ 30,949
Returns and other allowances	3,752	8,558	-0-	8,572	3,738
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 \$16.5 million and \$7.5 million at December 31, 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 benefit of \$0.7 million during the third quarter of fiscal 2008 and a net federal tax provision of \$0.7 million during the first nine months of fiscal 2008. No such provision or benefit was recorded for the corresponding period of fiscal 2007. We have not provided for any valuation allowance as of December 31, 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 expects that it is more likely than not that it will realize the benefit of these temporary differences. As of December 31, 2007, we had federal net operating loss carryforwards ("NOLs") of approximately \$3.2 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 December 31, 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 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 third quarter of fiscal 2008, ended December 31, 2007, represents 27 quarters of successive sales revenue growth. During the third quarter and the first nine months of fiscal 2008, we recorded net sales of \$81.9 million and \$158.6 million, respectively, as compared to \$31.3 million and \$84.3 million during the corresponding periods of fiscal 2007. We incurred \$10.0 million and \$23.8 million in R&D expense during the third quarter and the first nine months of fiscal 2008, respectively, as compared to \$2.7 million and \$18.5 million during the corresponding periods of fiscal 2007. These include \$5.9 million and \$11.3 million for third quarter and the first nine months of fiscal 2008 in non-cash R&D expenses, respectively, as compared to no expenses during the third quarter of fiscal 2007 and \$11.8 million during the first nine months 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 under the agreement have passed their bio-equivalency studies. The final product was transferred to Caraco during the third quarter which concludes the obligations between the parties under this agreement. We generated cash from operations of \$24.3 million during the first nine months of fiscal 2008, as compared to \$19.7 million during the corresponding period of fiscal 2007. The higher cash results were primarily due to an increase in profits, due to the higher sales, partially offset by higher inventories and accounts receivable to support the increase in sales. We earned a net pre-tax income of \$10.1 million and \$24.6 million during the third quarter and the first nine months of fiscal 2008, respectively, as compared to a net pre-tax income of \$10.1 million and \$17.4 million during the corresponding periods of fiscal 2007. The increase for the first nine month period of fiscal 2008 was primarily due to an increase in sales for the period. Sales increased primarily due to the new product launch of oxcarbazepine. This product's sales were substantially higher due to less competition than anticipated which resulted in substantially more market share and associated sales. During the third quarter of fiscal 2008, we provided a net income tax benefit of \$0.7 million and during the first nine months of fiscal 2008, we provided a net income tax provision of \$0.7 million. There was no such provision or benefit for the corresponding periods of fiscal 2007. During the third quarter and the first nine months of fiscal 2008, we earned a net income of \$10.8 million and \$23.9 million, respectively, as compared to a net income of \$10.1 million and \$17.4 million during the corresponding periods of fiscal 2007. At December 31, 2007, our inventory increased to \$197.8 million from \$31.9 million at March 31,

2007. This increase was to support our increased sales levels and in preparation of potential product launches on our behalf and on behalf of Sun Pharma. At December 31, 2007, we had stockholders' equity of \$131.2 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 2008, 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 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. We continue to grow the analytical staff which is currently at 69 employees, thereby enabling the laboratory to better cope with a significantly increased workload with improved timeliness, higher quality, and increased cGMP compliance. Several members of the lab staff attend supplemental professional training courses and conferences, which increases the laboratory's technical and cGMP proficiency. The lab facility has also undergone major upgrades, including a significant increase in working space to improve analyst efficiency and safety. Additional lab instruments and equipment have been purchased which will enable increased compliance with cGMP requirements, cut future costs by enabling in-house rather than contract analyses, and speed sample testing. Significant resources have also been spent to improve overall lab operations. Such expenditures demonstrate to the regulators, clients and shareholders that upper management is continually committed to adding quality individuals to the work force, providing the resources necessary to upgrade lab equipment and improve the effectiveness of lab operations and cGMP compliance.

#### **Third Quarter and the First Nine Months of Fiscal 2008 Compared to Third Quarter and the First Nine Months of Fiscal 2007**

**Net Sales.** Net sales for the third quarter and the first nine months of fiscal 2008 were \$81.9 million and \$158.6 million, respectively, as compared to \$31.3 million and \$84.3 million for the corresponding periods of fiscal 2007, reflecting an increase of 162% and 88%, respectively. The increase is primarily due to the launch of Oxcarbazepine Tablets (oxcarbazepine), which is a generic version of Trileptal®. Oxcarbazepine is a product approved under an ANDA of Sun Pharma. The sales of oxcarbazepine were significantly higher than our budgeted projections due to less competition than anticipated when we entered the market. Excluding oxcarbazepine sales, overall sales continue to grow due to introduction of newer products of both Caraco and of Sun Pharma combined with the sales of existing products to new

and existing customers. This is partially offset due to price erosion and change in our sales mix. Currently, we manufacture and market all except three of our approved products. Excluding oxcarbazepine, the sales mix amongst various products continues to be more diversified as the sales of four products accounted for 51% and 54% of net sales for the third quarter and the first nine months of fiscal 2008, respectively, as compared to sales of four products accounting for approximately 70% and 72% of net sales during corresponding periods of fiscal 2007. Overall, sales for three products (including oxcarbazepine) accounted for approximately 66% of net sales for the third quarter of fiscal 2008 and for 50% of net sales for the first nine months of fiscal 2008, as compared to sales of four products accounting for approximately 70% and 72% of net sales during corresponding periods of fiscal 2007. We do not believe the oxcarbazepine sales are sustainable at current levels due to additional competitors having entered the market or about to enter the market and pricing will most likely erode as a result.

**Gross Profit.** We earned gross profit of \$23.3 million and \$57.2 million during the third quarter and the first nine months of fiscal 2008, respectively, as compared to gross profit of \$15.1 million and \$42.4 million during the corresponding periods of fiscal 2007, reflecting an increase of 54% and 35%, respectively. The increase in gross profit was due to higher sales, primarily of distributed products, partially offset by the change in sales mix and price erosion on certain products.

The gross profit margin for the third quarter and the first nine months of fiscal 2008 decreased to 28% and 36% as compared to 48% and 50% during the corresponding periods of fiscal 2007. The decrease was primarily due to increased sales of distributed products, mainly oxcarbazepine and the associated weight of those sales versus the weight of manufactured products which had an impact on the overall margin. Net sales for distributed products were \$49.6 million and \$63.0 million for the third quarter and the first nine months of fiscal 2008, respectively, as compared to \$1.0 million for both of the corresponding periods of fiscal 2007. The gross profit margin on distributed products sold was 15% and 16% for the respective periods of fiscal 2008, as compared to 24% for the corresponding periods of fiscal 2007. This percentage is near our expectations for gross profit percentage for distributed products. Net sales for manufactured products were \$32.3 million and \$95.6 million for the third quarter and the first nine months of fiscal 2008, respectively, as compared to \$30.3 million and \$83.3 million during the corresponding periods of fiscal 2007. The gross profit margin for manufactured products was 49% for both of the respective periods of fiscal 2008, as compared to 50% for both of the respective periods of fiscal 2007. Manufactured product margins have remained fairly stable and are slightly higher than second quarter fiscal 2008. We are hopeful that this continues as we manage among other things various factors such as changes in product sales mix, the balance of product sold to the various classes of trade and continued price erosion. As anticipated the distribution margins, as a percentage of sales, for current products were in the mid-teens. We can not determine the mix of distributed product sales versus manufactured product sales in any given 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 (SG&A) expenses during the third quarter and the first nine months of fiscal 2008 were \$3.7 million and \$10.2 million, respectively, as compared to \$2.6 million and \$7.1 million during the corresponding periods of fiscal 2007, representing an increase of 42% and 44% in respective periods. The increase was mainly due to higher marketing and administrative efforts relative to the increase in sales. SG&A expenses, as a

percentage of net sales improved to 6% for the first nine months of fiscal 2008, as compared to 8% for the corresponding period of fiscal 2007. Excluding sales of oxcarbazepine, the expenses for the first nine months of fiscal 2008 as a percentage of net sales were 8%, which is consistent with the corresponding period of fiscal 2007.

**Research and Development Expenses.** Total research and development (R&D) expenses for the third quarter and the first nine months of fiscal 2008 were \$10.0 million and \$23.8 million, respectively, as compared to \$2.7 million and \$18.5 million during the corresponding periods of fiscal 2007. Actual cash R&D expenses were \$4.1 million and \$12.5 million during the third quarter and the first nine months of fiscal 2008, respectively, as compared to \$2.7 million and \$6.8 million during the corresponding periods of fiscal 2007. We incurred non-cash R&D expenses (technology transfer cost) of \$5.9 million and \$11.3 million for one product transfer and two product transfers during the third quarter and the first nine months of fiscal 2008, respectively, as compared to no expense during the third quarter of fiscal 2007 and \$11.8 million for three product transfers during the first nine months of fiscal 2007. Each product transfer earns 544,000 shares of preferred stock. The final product was transferred to Caraco during the third quarter which concludes the obligations between the parties under the technology transfer agreement. Cash R&D will continue to increase in an effort to develop additional products. The cash R&D expenses during the third quarter and the first nine 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 \$0.5 million and \$1.4 million during the third quarter and the first nine months of fiscal 2008, respectively, as compared to \$0.3 million and \$0.6 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 Benefit/Provisions.** We recorded a net income tax benefit of \$0.7 million during the third quarter of fiscal 2008 and a net income tax provision of \$0.7 million during the first nine months of fiscal 2008. There was no such provision or benefit recorded for the corresponding periods of fiscal 2007. As the Company continues to be profitable, substantially all of the net operating loss carryforwards 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 \$10.1 million and \$24.6 million during the third quarter and the first nine months of fiscal 2008, respectively, as compared to a net pre-tax income of \$10.1 million and \$17.4 million during the corresponding periods of fiscal 2007. We earned net income of \$10.8 million and \$23.9 million in the third quarter and the first nine months of fiscal 2008, respectively, as compared to net income of \$10.1 million and \$17.4 million during the corresponding periods of fiscal 2007.

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

We generated cash from operations of \$24.3 million during the first nine months of fiscal 2008 as compared to \$19.7 million during the corresponding period of fiscal 2007. Accounts receivable increased by \$29.3 million to \$55.4 as of December 31, 2007, as compared to \$26.1 million at the end of fiscal 2007 due to higher net sales. There has been cash outflow due to payment of federal income taxes

of \$15.4 million as a result of a change in the Company's tax position (see discussion under "Income Taxes" above). Inventory levels are equivalent to 222 days sales on hand as compared to 95 days for the relative period of fiscal 2007. The inventory as of December 31, 2007, includes goods in transit for a product of Sun Pharma of approximately \$142.5 million, which has been built up in anticipation of a potential launch of a product. If the sale of the product does not occur as anticipated, we would have the right to return the product. Excluding the inventory for this product, inventory levels were equivalent to 62 days sales as compared to 95 days for the relative period of fiscal 2007. Accounts receivables is 62 days sales outstanding (DSO) versus 77 days for the relative period of fiscal 2007.

At December 31, 2007, we had working capital of \$94.1 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, built up inventory for potential product launches, an increase in prepaids due to an increase in a contractual deposit with a customer, partially offset by higher current liabilities. Additionally, we have available a \$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.

### **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 26 ANDAs pending approval at the FDA (including five tentative approvals) relating to 19 products. We continue to expand and upgrade our facilities, attract and hire talented individuals and expand our customer base. During the third quarter of fiscal 2008, the Company entered into a long-term lease to move distribution and storage of finished goods to a new facility which offers additional efficiency and scale. We also started our expansion project adjacent to our manufacturing facility which we anticipate to be completed by the end of calendar year 2008. We estimate this construction project will be under \$17 million. The State of Michigan and City of Detroit have collectively offered various tax abatements and tax exemptions relating to this construction and associated increases in employment opportunities of approximately \$14 million over a long-term period. We continue to improve our near-term capacity constraints, while strategically looking at our capacity based on our vision of our long-term plan. Our internal efforts, combined with Sun Pharma, in developing new products have also picked up momentum. Collectively, this should permit us to grow at the level of our revised sales growth guidance as provided below. We now have 21 products, whose market share is ranked third or higher against the same products of our generic competitors where there are more than three competitors. Additionally, during third quarter of fiscal 2008, we gained FDA approval on two products, three tentative approvals and two product approvals since then for Caraco ANDAs. Year-to-date fiscal 2008 we gained FDA approval on 12 Caraco ANDAs covering 12 products and five tentative approvals. During the first nine months of fiscal 2008, we also began marketing six Sun Pharma products that were approved and launched during the period.

On January 30, 2008, the Company commercially launched, Pantoprazole Sodium DR tablets. Sun Pharma authorized Caraco to distribute the product following the December 22, 2007 launch of Teva

Pharmaceutical's generic version of the product and following the January 29, 2008 launch of an authorized generic by the innovator, Wyeth. Sun Pharma recently received approval from the FDA for its ANDA for generic Protonix®, and being one of the first-to-file an ANDA with a Paragraph IV certification, shares a 180-day marketing exclusivity with Teva. The launch of Pantoprazole sodium DR tablets was considered an "at risk launch" as Sun Pharma is in patent litigation in the US District Court of New Jersey with Wyeth and Altana (recently acquired by Nycomed), and a final decision on the outcome of the patent infringement has not yet been determined. Although no trial date has been set, in September 2007 the District Court denied a motion filed by Wyeth and Altana for a preliminary injunction. Wyeth and Altana have appealed the District Court's decision. If the claims of Wyeth and Altana are successful, they could have a material adverse effect on the Company.

Through the first nine months of fiscal 2008, we have surpassed our previous sales growth guidance of 30% for fiscal 2008, compared to the full year fiscal 2007. This is primarily due to strong sales of oxcabazepine, which we began marketing on behalf of Sun Pharma during the third quarter of fiscal 2008. Sales for oxcabazepine are attributed to Sun Pharma sharing 180-day marketing exclusivity on its oxcabazepine ANDA with a Paragraph IV certification. We believe that sales of oxcabazepine will decrease from the third quarter fiscal 2008 level in the fourth quarter of fiscal 2008. Once the exclusivity period expires, April 10, 2008, we believe sales will continue to erode due to additional competitors entering the market. Although we do not believe the sales of this product to be sustainable at current levels past fiscal 2008, we have revised our guidance to reflect these strong sales. We now expect our sales for fiscal 2008, year ending March 31, 2008, to grow 75% over the corresponding period of fiscal 2007.

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 manufactured 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, a balanced sales approach, 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 all of these 25 products have passed their respective bio-equivalency studies. The final product was transferred to Caraco during the third quarter which concludes the obligations between the parties under this agreement.

The Company intends to aggressively move forward with the development of new products. 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.

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 69% (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 nine 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 first nine months of fiscal 2008, we filed five ANDAs covering five products.

As previously mentioned, in fiscal 2007 we 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. In addition, on January 29, 2008, the Company executed a distribution and sale agreement with Sun Pharma. This agreement covers certain mutually agreed upon products that have been filed or will be filed with the FDA with a Paragraph IV certification. A Paragraph IV certification states that the filer believes that it either does not infringe the patent or believes that the patent is invalid. Paragraph IV certified products face litigation challenges with respect to claims of patent infringement. Under the agreement, the Company participates in the sales opportunity on the products, and also shares the litigation risks to a limited extent based on percentage. If such claims are successful, however, they could have a material adverse effect on the Company. The first product under this agreement is Pantoprazole sodium DR tablets. 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. These agreement will provide for an alternate stream of products that will complement our internal research and development, our outsourced development. We will continue to work with Sun Pharma in effort to transfer future product technology.

The various agreements referenced above will provide four diverse paths of development, an increased product pipeline and potential revenue. These various paths mitigate the risk of each other, potentially allowing for an ongoing stream of approvals from the FDA.

Management's plans for the remainder of fiscal 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 third 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 third 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 third 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 6. EXHIBITS**

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: February 1, 2008

By: /s/ Daniel H. Movens

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

Date: February 1, 2008

By: /s/ Mukul Rathi

---

Mukul Rathi  
interim Chief Financial Officer

33

---

EXHIBIT INDEX

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.