CARACO PHARMACEUTICAL LABORATORIES LTD
Form 10-Q
October 24, 2008

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

for the quarterly period ended September 30, 2008

o TRANSITION REPORT PURSUANT TO SECTION 13

OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

for the transition period from _____ to _____

Commission File No. 0-24676

CARACO PHARMACEUTICAL LABORATORIES, LTD.

(Exact name of registrant as specified in its charter)

MICHIGAN	38-2505723
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
1150 ELIJAH MCCOY DRIVE, DETROIT, MICHIGAN	48202
(Address of principal executive offices)	(Zip Code)

TELEPHONE: (313) 871-8400

Registrant's telephone number, including area code

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

Yes x No o

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

Large Accelerated Filer o Accelerated Filer x Non- Accelerated Filer o Smaller Reporting Company o

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

Yes o No x

As of October 23, 2008 the registrant had 34,738,094 shares of common stock issued and outstanding.

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

	SEPTEMBER 30, 2008	MARCH 31, 2008
	UNAUDITED	AUDITED
ASSETS		
Current assets		
Cash and cash equivalents	$ 33,602,197	$ 56,906,051
Accounts receivable, net	109,410,114	135,927,027
Inventories	115,104,648	298,665,680
Prepaid expenses and deposits	8,115,194	8,161,319
Deferred income taxes	416,985	361,707
Total current assets	**266,649,138**	**500,021,784**
Property, plant and equipment		
Land	975,311	975,311
Buildings and improvements	13,638,765	13,102,557
Equipment	21,631,596	17,046,501
Furniture and fixtures	1,272,910	1,175,403
Construction in progress	8,851,958	405,689
Total	46,370,540	32,705,461
Less accumulated depreciation	12,866,514	11,438,027
Net property, plant and equipment	**33,504,026**	**21,267,434**
Net intangible assets	1,431,576	—
Deferred income taxes	18,703,870	16,985,968
Total assets	**$ 320,288,610**	**$ 538,275,186**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable, trade	$ 3,995,746	$ 4,781,739
Accounts payable, Sun Pharma	151,102,649	388,286,127
Accrued expenses	2,110,552	2,284,513
Income taxes payable	2,102,983	142,494
Total liabilities (all current)	**159,311,930**	**395,494,873**
Stockholders' equity		
	44,227,200	58,137,280

	SEPTEMBER 30, 2008	MARCH 31, 2008
Series B convertible preferred stock, no par value; issued and outstanding 5,440,000 shares (September 30, 2008) 7,616,000 shares (March 31, 2008)		
Common stock, no par value; authorized 50,000,000 shares, issued and outstanding 34,738,094 shares (September 30, 2008) 32,551,094 shares (March 31, 2008)	97,423,717	83,332,487
Additional paid in capital	3,300,350	3,149,171
Retained Earnings / Accumulated deficit	16,025,413	(1,838,625)
Total stockholders' equity	**160,976,680**	**142,780,313**
Total liabilities and stockholders' equity	**$ 320,288,610**	**$ 538,275,186**

See accompanying notes.

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

	Six months ended September 30,		Quarter ended September 30,	
	2008	**2007**	**2008**	**2007**
	(UNAUDITED)	**(UNAUDITED)**	**(UNAUDITED)**	**(UNAUDITED)**
Net sales	**$ 230,465,165**	**$ 76,754,883**	**$ 122,188,425**	**$ 41,354,567**
Cost of goods sold	184,879,891	42,871,307	100,186,562	23,338,768
Gross profit	**45,585,274**	**33,883,576**	**22,001,863**	**18,015,799**
Selling, general and administrative expenses	8,055,246	6,436,725	4,237,244	3,034,058
Research and development costs - affiliate	—	5,440,000	—	5,440,000
Research and development costs - other	11,065,940	8,389,210	5,581,711	5,103,723
Operating income	**26,464,088**	**13,617,641**	**12,182,908**	**4,438,018**
Other income				
Interest income	420,259	886,455	142,486	419,162
Other income	**420,259**	**886,455**	**142,486**	**419,162**
Net income before income taxes	**26,884,347**	**14,504,096**	**12,325,394**	**4,857,180**
Income taxes	9,020,309	1,367,966	3,901,421	236,265
Net income	**$ 17,864,038**	**$ 13,136,130**	**$ 8,423,973**	**$ 4,620,915**
Net income per common share				
Basic	0.54	0.46	0.25	0.16
Diluted	0.44	0.34	0.21	0.12

See accompanying notes.

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

	Six months ended September 30,	
	2008	**2007**
	(UNAUDITED)	**(UNAUDITED)**
Cash flows from operating activities		
Net income	$ 17,864,038	$ 13,136,130
Adjustments to reconcile net income to net cash (used in) provided by operating activities		
Depreciation and amortization	1,452,749	1,079,010
Capital stock issued or to be issued to affiliate in exchange for product formula	—	5,440,000
Stock option expense	151,179	140,586
Stock grant expense	169,900	357,750
Common stock issued to former officer & director	—	115,950
Net deferred income taxes	(1,773,180)	(9,131,743)
Changes in operating assets and liabilities which provided / (used) cash:		
Accounts receivable	26,516,913	(17,751,601)
Inventories	183,561,032	(3,665,272)
Prepaid expenses and deposits	46,124	(2,679,154)
Accounts payable	(237,969,471)	7,448,930
Accrued expenses	(173,958)	(1,485,863)
Income taxes payable	1,960,489	8,249,070
Net cash (used in) provided by operating activities	**(8,194,185)**	**1,253,793**
Cash flows from investing activities		
Purchases of property, plant and equipment	(13,665,079)	(2,001,609)
Purchases of intangibles	(1,455,840)	—
Net cash used in investing activities	**(15,120,919)**	**(2,001,609)**
Cash flows from financing activities		
Proceeds from exercise of stock options	11,250	20,560
Net cash provided by financing activities	**11,250**	**20,560**
Net decrease in cash and cash equivalents	**(23,303,854)**	**(727,256)**
Cash and cash equivalents, beginning of period	56,906,051	33,897,622
Cash and cash equivalents, end of period	**$ 33,602,197**	**$ 33,170,366**

	Six months ended September 30,	

See accompanying notes.

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

	PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID INCAPITAL	RETAINED EARNINGS / ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT	SHARES	AMOUNT			
Balances at April 1, 2008	7,616,000	$ 58,137,280	32,551,094	$83,332,487	$ 3,149,171	$ (1,838,625)	$ 142,780,313
Conversion of preferred stock into common stock	(2,176,000)	(13,910,080)	2,176,000	13,910,080	—	—	—
Common stock options exercised	—	—	1,000	11,250	—	—	11,250
Stock options expensed	—	—	—	—	151,179	—	151,179
Stock grants	—	—	10,000	169,900	—	—	169,900
Net Income	—	—	—	—	—	17,864,038	17,864,038
Balances at September 30, 2008	5,440,000	$ 44,227,200	34,738,094	$97,423,717	$ 3,300,350	$ 16,025,413	$ 160,976,680

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, 2008 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, 2008 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 53 prescription products, in 115 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 72%

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of the outstanding shares of the Company (approximately 76% including the convertible Series B Preferred Stock). (See “Current Status of the Corporation” and “Sun Pharmaceutical Industries Limited” below.)

3. **CURRENT STATUS OF THE CORPORATION**

During the second quarter ended September 30, 2008 and first six months of our current fiscal year ending March 31, 2009 (“Fiscal 2009”), we generated net sales of $122.2 million and $230.5 million, respectively, compared to $41.4 million and $76.8 million, respectively, during the corresponding periods of Fiscal 2008. We incurred $5.6 million and $11.1 million, respectively, in total research and development (“R&D”) expenses during the second quarter and first six months of Fiscal 2009, as compared to $10.5 million and $13.8, respectively, during the corresponding periods of Fiscal 2008. There were no non-cash R&D expenses incurred during the second quarter or six month period ended September 30, 2008, as compared to $5.4 million during both of the corresponding periods of Fiscal 2008. We used cash from operations in the amount of $8.2 million during the first six months of Fiscal 2009, as compared to generating cash from operations of $1.3 million during the corresponding period of Fiscal 2008. We earned net pre-tax income of $12.3 million and $26.9 million, respectively, during the second quarter and first six months of Fiscal 2009, as compared to net pre-tax income of $4.9 million and $14.5 million, respectively, during the corresponding periods of Fiscal 2008. During the second quarter and first six months of Fiscal 2009, we provided for an income tax expense of $3.9 million and $9.0 million, respectively, as compared to income tax expense provisions of $0.2 million and $1.4 million in the corresponding periods of Fiscal 2008. We earned net income of $8.4 million and $17.9 million, respectively, during the second quarter and first six months of Fiscal 2009, as compared to net income of $4.6 million and $13.1 million, respectively, during the corresponding periods of Fiscal 2008. At September 30, 2008, we had stockholders’ equity of $161.0 million, as compared to stockholders’ equity of $142.8 million at March 31, 2008. (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 had selected, through Fiscal 2008, all products out of the 25 products to be transferred to us by Sun Global under a technology transfer agreement entered into in 2002, and all of these 25 products had passed their bio-equivalency studies as of December 31, 2007. The final product was transferred to Caraco during the third quarter of Fiscal 2008, which concluded the obligations between the parties under this agreement. Sun Global had 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 one New Drug Application (“NDA”) relating to one product and four Abbreviated New Drug Applications (“ANDAs”) relating to three products with the FDA during the first six months of Fiscal 2009. We have received FDA approval for eight ANDAs relating to three products during the first six months of Fiscal 2009. This brings our total number of ANDAs pending approval by the FDA to 23 (including four tentative approvals) relating to 19 products and one NDA product pending approval.

4. **RECENT ACCOUNTING PRONOUNCEMENTS**

In September 2006, the Financial Accounting Standards Board ("FASB") issued SFAS No. 157, "Fair Value Measurements" ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value within generally accepted accounting principles and expands required disclosures about fair value measurements. SFAS 157 establishes a three–tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions. In November 2007, the FASB provided a one year deferral for the implementation of SFAS 157 for non-financial assets and liabilities. The Company adopted SFAS 157 on April 1, 2008, as required. The adoption of SFAS 157 did not have any impact on the Company's financial condition and results of operations.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities–Including an amendment of FASB Statement No. 115" ("SFAS 159"). SFAS 159 permits companies to measure many financial instruments and certain other items at fair value at specified election dates. The Company adopted SFAS 159 on April 1, 2008. Since the Company has not utilized the fair value option for any allowable items, the adoption of SFAS 159 did not have any impact on the Company's financial condition and results of operations.

In December 2007, the FASB issued SFAS No. 160, "Noncontrolling Interests in Consolidated Financial Statements" ("SFAS 160"). SFAS 160 re-characterizes minority interests in consolidated subsidiaries as non-controlling interests and requires the classification of minority interests as a component of equity. Under SFAS 160, a change in control will be measured at fair value, with any gain or loss recognized in earnings. The effective date for SFAS 160 is for annual periods beginning on or after December 15, 2008 (the Corporation's Fiscal 2010). Early adoption and retroactive application is not permitted

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "Business Combinations" ("SFAS 141R") which replaces SFAS No. 141, "Business Combinations" ("SFAS 141"). SFAS 141R establishes principles and requirements for recognizing and measuring identifiable assets and goodwill acquired, liabilities assumed and any non-controlling interest in a business combination at their fair value at acquisition date. SFAS 141R provides updated guidance and makes significant amendments to previous guidance in SFAS 141 and other standards including the treatment of acquisition related costs, business combinations achieved in stages (referred to as a step acquisition), the treatment of gains from a bargain purchase, the recognition of contingencies in business combinations, the treatment of IPR&D in a business combination as well as the treatment of recognizable deferred tax benefits. SFAS 141R is effective for financial statements issued for fiscal years beginning after December 15, 2008 (the Corporation's Fiscal 2010). Early adoption is prohibited.

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133" ("SFAS 161"). This statement is intended to improve transparency in financial reporting by requiring enhanced disclosures of an entity's derivative instruments and hedging activities and their effects on the entity's financial position, financial performance and cash flows. SFAS 161 applies to all derivative instruments within the scope of SFAS

133, “Accounting for Derivative Instruments and Hedging Activities”. The effective date for SFAS 161 is fiscal years and interim periods beginning after November 15, 2008 (the Corporation’s Fiscal 2010), with early application encouraged. The Corporation is currently reviewing SFAS 161 and does not expect its adoption to have a material impact on the Company’s financial statements.

5. **COMPUTATION OF EARNINGS PER SHARE**

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

The basic and diluted weighted average numbers of common shares outstanding for the second quarter of Fiscal 2009, ended September 30, 2008, were 33,389,920 and 40,593,328, respectively, and were 33,035,602 and 40,565,004, respectively, for the first six months of Fiscal 2009. Correspondingly, the basic and diluted weighted average numbers of common shares outstanding for the second quarter of Fiscal 2008, ended September 30, 2007, were 28,739,315 and 38,640,844, respectively, and were 28,739,315 and 38,483,864, respectively for the first six months of Fiscal 2008.

6. **SUN PHARMACEUTICAL INDUSTRIES LIMITED**

Pursuant to a stock purchase agreement, a Mumbai, India based specialty pharmaceutical manufacturing company, Sun Pharma, made an initial investment of $7.5 million for the purchase of 5.3 million common shares of Caraco in 1997.

In August 1997, Caraco entered into an agreement, whereby Sun Pharma was required to transfer the technology formulas for 25 generic pharmaceutical products over a five-year period in exchange for 544,000 shares of Caraco common stock for each technology transfer of an ANDA product (when bio-equivalency studies were successfully completed) and 181,333 shares for each technology transfer of a Drug Efficacy Study Implementation (“DESI”) product. The products provided to the Corporation from Sun Pharma were selected by mutual agreement. Under such agreement, Caraco conducted, at its own expense, all tests including bio-equivalency studies. Pursuant to such agreement through 2002, Sun Pharma delivered the technology formula for 13 products. This agreement expired on November 21, 2002, and the Corporation entered into a new technology transfer agreement with Sun Global, Inc. (“Sun Global”), an affiliate of Sun Pharma.

Under the agreement with Sun Global, which was approved by the Corporation’s independent directors, Sun Global agreed to provide the formulations for 25 new generic drugs over a five-year period. Caraco’s rights to the products are limited to the United States and its territories or possessions, including Puerto Rico. Sun Global retains rights to the products in all other territories. The products were selected by mutual agreement. Under this agreement, Caraco conducted at its own expense all tests, including bio-equivalency studies. The Corporation markets the products consistent with its customary practices. In return for the technology transfer, Sun Global received 544,000 shares of Series B Preferred Stock for each generic drug transferred when such drug passed its bio-equivalency studies.

The products agreement was amended by the Independent Committee, comprised of the three independent directors, in the first quarter of 2004 to eliminate the provision requiring that the Independent Committee concur in the selection of each product, and provides instead that each product satisfy certain objective criteria developed by management and approved by the Independent Committee. Pursuant to such objective criteria, all 25 of the products under this agreement have been selected, and all of 25 products have passed their respective bio-equivalency studies prior to the end of Fiscal 2008. The products agreement has been completed and there will be no further issuance of Series B Preferred Stock under this agreement.

Sun Pharma has established research and development centers in Mumbai and Vadodara in India, where the development work for products is performed.

Sun Pharma and its subsidiaries supply the Corporation with certain raw materials and formulations, assist in acquiring machinery and equipment to enhance production capacities, and have provided 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 and January 2005, Caraco entered into agreements for two such products, of which one is currently being marketed.

During Fiscal 2007, the Corporation entered into a three-year marketing agreement with Sun Pharma, which was reviewed and approved by the Board's Independent Committee. Under the agreement, the Corporation purchases selected product formulations offered by Sun Pharma and markets and distributes the same as part of the current product offerings in the U.S., its territories and possessions, including Puerto Rico. Sun Pharma is not obligated to offer Caraco products under this agreement, however, Caraco has the exclusive right to market in the U.S., its territories and possessions, including Puerto Rico, any products offered by Sun Pharma and accepted by Caraco.

During Fiscal 2008, the Corporation entered into a three-year distribution and sale agreement with Sun Pharma, which was reviewed and approved by the Board's Independent Committee. Under this agreement, the Company purchases selected formulations which have been filed under Paragraph IV certification process with the FDA by Sun Pharma and offered for distribution. Paragraph IV certified ("Para IV") products may face litigation challenges with respect to claims of patent infringement. Under the agreement the Company shares in the sales opportunity and shares the litigation risk. The Company is indemnified by Sun Pharma of any risk beyond the percentage agreed to as its profit percentage, thereby limiting the Company's exposure. Sun Pharma is not obligated to offer Caraco products under this agreement, however, Caraco has the exclusive right to market in the U.S., its territories and possessions, including Puerto Rico, any products offered by Sun Pharma and accepted by Caraco. The license granted with respect to a product terminates upon the end of its exclusivity period of 180 days or a non-appealable court decision, or until a third generic manufacturer launches the product, whichever is later, or until a settlement is reached, at which time the product will become part of the standard Caraco-Sun Pharma marketing agreement disclosed above. The Company purchases selected Para IV products

offered by Sun Pharma, and markets and distributes the same as part of its current product offerings in the U.S., its territories and possessions, including Puerto Rico and currently receives a fixed margin of 8%, or such other percentages as shall be mutually agreed upon. Under the agreement, Sun Pharma and Caraco mutually indemnify each other, capped by the fixed margin percentage, with respect to damages from infringement.

During the second quarter and first six months of Fiscal 2009 the Corporation made net sales of $89.9 million and $166.2 million, respectively, and during corresponding periods of Fiscal 2008, the Corporation made net sales of $6.4 million and $13.4 million, respectively, of the marketed products under the aforesaid agreements.

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

During the first six months of Fiscal 2009, Sun Global converted 2,176,000 shares of Series B Preferred Stock into 2,176,000 shares of Common Stock. During the fiscal years ended March 31, 2008 and March 31, 2007, Sun Global converted 4,352,000 shares and 1,632,000 shares of Series B Preferred Stock into 4,352,000 shares and 1,632,000 shares of Common Stock, respectively. As of September 30, 2008, Sun Pharma’s current beneficial ownership is 72% (76% including its convertible Series B Preferred Stock).

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

7. **ACCOUNTING FOR STOCK BASED COMPENSATION**

The Company follows the provisions of Statement of Financial Accounting Standards (“SFAS”) No. 123 (Revised 2004), “*Share-Based Payment*” (“Statement No. 123 (R)”), which requires employee share-based compensation to be accounted for under the fair value method and requires the use of an option pricing model for estimating the fair value of stock options at the date of grant. The Company estimates the fair value of stock options granted using the Black-Scholes option-pricing model, which requires the Company to estimate the expected term of the stock option grants and expected future stock price volatility over the term. The term represents the expected period of time the company believes the options will be outstanding based on historical information. Estimates of expected future stock price volatility are based on the historical volatility of the Company’s common stock. The Company calculates the historical volatility as the standard deviation of the differences in the natural logarithms of the weekly stock closing price, adjusted for dividends and stock splits.

For the second quarter and first six months of Fiscal 2009, the Company has recognized expenses amounting to $86,574 and $151,179, respectively, related to share-based compensation as compared to $69,104 and $140,586, respectively for the corresponding periods of Fiscal 2008. As of September 30, 2008, total unrecognized compensation cost related to stock options granted was $653,620. The unrecognized stock option compensation cost is expected to be recognized over a period of approximately three years.

Stock options to purchase 74,500 shares of common stock were granted to employees and Directors during the first six months of Fiscal 2009, which vests in the amount of one-third on each anniversary following the date of grant. Additionally, the Company recorded an expense of $169,900 related to a stock grant of 10,000 common shares issued to the CEO on May 2, 2008 as part of his employment agreement, which vested immediately upon issuance.

8. **COMMON STOCK ISSUANCES**

We issued 1,000 sharesof common stock to our employees upon exercise of their stock options during the first six months of Fiscal 2009. Also, the Company issued a stock grant of 10,000 common shares to the CEO on May 2, 2008, as noted above

During the first six months of Fiscal 2009, Sun Global converted 2,176,000 shares of Series B Preferred Stock into 2,176,000 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**

No shares of preferred stock were issued during the first six months of Fiscal 2009, as compared to 544,000 shares of preferred stock issued to Sun Global during the first six months of Fiscal 2008.

10. **SALES AND CUSTOMERS**

The Company effectively remained competitive in the market place during the second quarter and first six months of Fiscal 2009. The Company continues to be strengthened to meet the demands of a competitive U.S. generic pharmaceutical market, while providing additional support for our future growth and reducing costs where possible.

As is typical in the U.S. retail sector, many of our customers are serviced through their designated wholesalers. During the second quarter and first six months of Fiscal 2009, the Company’s three largest customers, Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health, accounted for approximately 7%, 10% and 38%, respectively, of the Company’s total net sales during the second quarter and 6%, 15 and 25%, respectively, of total net sales for the first six months of Fiscal 2009. Correspondingly, shipments to Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health, accounted for approximately 13%, 26% and 24%, respectively, of the Company’s total net sales during the second quarter of Fiscal 2008, and 14%, 26% and 20%, respectively, of total net sales for the first six months of Fiscal 2008. The majority of 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.

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 4.68% and 4.00%, respectively, at September 30, 2008). 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, 2008. There are no borrowings under this Credit Agreement at September 30, 2008.

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 Pharmaceutical Industries Ltd.'s ("Sun's") filing of an ANDA seeking approval to market its generic version of Schering's Clarinex® (desloratadine) drug product infringed Schering's U.S. Patent No. 6,100,274 ("the '274 patent"), which expires July 7, 2019. Schering further alleges that the Company either directly infringed the '274 patent by aiding in the filing of Sun's ANDA, or will induce others to infringe by marketing and/or selling Sun's generic version of Clarinex® upon receiving FDA approval. Schering's complaint seeks an order from the Court which, among other things, directs the FDA not to approve Sun's ANDA any earlier than the claimed expiration date. 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 contains a Paragraph IV certification challenging the '274 patent. Sun believes that the '274 patent is invalid, unenforceable and/or will not be infringed by Sun's or the Company's manufacture, use or sale of the product. Sun further believes it is one of several first generics to file a Paragraph IV certification for this drug product and both Sun and the Company intend to vigorously defend this action in order to

capitalize on the potential 180 days of marketing exclusivity available for this product. Discovery is presently ongoing and no trial date has yet been set.

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® (repaglinide) 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. Discovery is presently ongoing and no trial date has yet been set.

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 based on a patent term extension (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 ended on October 14, 2008.

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. On April 1, 2008, the Federal Circuit granted Caraco's appeal, holding that an actual case or controversy did exist and that Caraco should be allowed to maintain its declaratory judgment action regarding the '941 patent. Forest's request for a rehearing of Caraco's appeal *en banc* was denied. Forest has indicated its intention to file a petition for a writ of certiorari to challenge this decision with the Supreme Court.

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 Ultracet® 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 noninfringement 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 lower court's 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. On December 10, 2007, the Company filed a motion for summary judgment that the reissue patent was obvious and therefore invalid as a matter of law. This motion was granted by Judge Cavanaugh of the District of New Jersey on April 17, 2008. Final

judgment has been granted and Ortho-McNeil has filed a notice that it intends to appeal Judge Cavanaugh's decision.

The Company is also involved in certain legal proceedings from time to time incidental to normal business activities. While the outcome of any such proceedings cannot be accurately predicted, the Company does not believe the ultimate resolution of any existing matters would have a material adverse effect on its financial position or results of operations.

13. **INVENTORIES**

Inventories consist of the following amounts:

	September 30, 2008	**March 31, 2008**
Raw materials	$14,759,022	$9,803,735
Goods in transit	8,376,976	46,002,600
Work in process	7,205,741	7,308,480
Finished goods (Manufactured)	11,790,019	7,953,293
Finished goods (Distributed)	72,972,890	227,597,572
Total Inventories	$115,104,648	$298,665,680

14. **INCOME TAXES**

The provision for income taxes is as follows for the first six months of Fiscal 2009 and Fiscal 2008:

	Six Months Ended	
	September 30, 2008	**September 30, 2007**
Current	$ 10,793,489	$ 10,499,709
Deferred	(1,773,180)	(9,131,743)
Total	$ 9,020,309	$ 1,367,966

The provision for income taxes is different from that which would be obtained by applying the statutory income tax rate to income before income taxes. The items causing the difference for the first six months of Fiscal 2009 and Fiscal 2008, respectively, are as follows:

	Six Months Ended	
	September 30, 2008	**September 30, 2007**
Provision for income taxes at statutory rate	$ 9,409,521	$ 4,934,752
Change in valuation allowance	—	(2,862,422)
Other	(389,212)	(704,364)
Income taxes	$ 9,020,309	$ 1,367,966

Deferred taxes consist of the following:

	September 30, 2008	**March 31, 2008**
Deferred tax assets:		
Net operating loss carryforwards	$ 930,570	$ 1,063,509
Intangibles	27,653,321	28,865,403
Other	416,985	361,706
Total deferred tax assets	$ 29,000,876	$ 30,290,618

Deferred tax liabilities: