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.

1

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%

6

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:		
Intangibles	$ 9,271,481	$ 12,361,976
Depreciation	608,540	580,967
Total deferred tax liabilities	$ 9,880,021	$ 12,942,943
Net deferred tax assets	**$ 19,120,855**	**$ 17,347,675**

15. SEGMENT INFORMATION

The Company operates in two reportable segments consisting of products that it manufactures on its own, as well as those distributed under various agreements with of Sun Pharma. The sales and gross profits earned on these categories of products for the second quarters and six-month periods ended September 30, 2008 and September 30, 2007 are as follows:

Fiscal 2009:	**Quarter Ended September 30, 2008**		**Six Months Ended September 30, 2008**	
Category	Net Sales	Gross Profit	Net Sales	Gross Profit
Manufactured Products	$ 32,242,502	$ 15,359,842	$ 64,277,867	$ 31,747,703
Distributed Products	89,945,923	6,642,021	166,187,298	13,837,571
Total	$ 122,188,425	$ 22,001,863	$ 230,465,165	$ 45,585,274

Fiscal 2009:	Quarter Ended September 30, 2008	Six Months Ended September 30, 2008

17

Fiscal 2008:	Quarter Ended September 30, 2007		Six Months Ended September 30, 2007	
Category	Net Sales	Gross Profit	Net Sales	Gross Profit
Manufactured Products	$ 34,938,459	$ 16,915,864	$ 63,313,843	$ 31,136,586
Distributed Products	6,416,108	1,099,935	13,441,040	2,746,990
Total	$ 41,354,567	$ 18,015,799	$ 76,754,883	$ 33,883,576

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 2008 Annual Report on Form 10-K as of and for the year ended March 31, 2008 (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 second quarter and first six months of Fiscal 2009 were $250.6 million and $430.7 million, respectively, as compared to $108.6 million and $192.1 million, respectively, for the corresponding periods of Fiscal 2008. Sales allowances, which include chargebacks, returns, discounts, other customary customer deductions and other sales costs, constituted approximately 51% and 46% of gross sales, respectively, for the second quarter and first six months of Fiscal 2009, as compared to 62% and 60% of gross sales, respectively, for the corresponding periods of Fiscal 2008. Net sales for the second quarter and six-month period ended September 30, 2008 were $122.2 million and $230.5 million, respectively, as compared to $41.4 million and $76.8 million, respectively, for the second quarter and first six months of Fiscal 2008. The increase in net sales for both periods is primarily due to sales of

distributed products by the Company under the distribution and sale agreement with Sun Pharma, sales of other products launched in Fiscal 2008 under the marketing agreements with Sun Pharma and sales of manufactured products launched during the period.

The following is a roll forward of the provisions for chargebacks, shelf stock adjustments, returns and allowances and estimated doubtful account allowances during Fiscal 2008 and the first six months of Fiscal 2009.

($ 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 2008					
Chargebacks, rebates & shelf stock adjustments	$32,638	$ 273,070	-0-	$226,803	$78,905
Returns and other allowances	3,752	15,168	-0-	13,647	5,273
Doubtful Accounts	100	346	-0-	328	118
For the first six months of Fiscal 2009					
Chargebacks, rebates & shelf stock adjustments	$78,905	$190,578	-0-	$181,068	$88,415
Returns and other allowances	5,273	9,644	-0-	9,901	5,016
Doubtful Accounts	118	48	-0-	31	135

Research and Development Costs

Series B convertible preferred stock was issued to Sun Pharma and its affiliates under the Products Agreement between the Corporation and Sun Global in exchange for the technology of formulation products delivered by Sun Global to the Corporation. Such Products Agreement has been completed with the last technology transfer occurring during the third quarter of fiscal 2008. Accordingly, no further non-cash research and development expense will be incurred thereunder. The amount of non-cash research and development expense which was incurred for past technology transfers under the Products Agreement was charged to operations and was determined based on the fair value of the preferred shares on the date the respective product formula passed its bio-equivalency studies. The fair value of such shares was based upon a valuation performed by Donnelly Penman & Partners, an independent, third party valuation firm. The exchange of shares was prior to the initial ANDA submission to the FDA.

We were responsible for submission of these transferred formulations for FDA approval. In our experience, generally, the submission of an ANDA to the FDA is approximately thirty days after the receipt of notice that the proposed drug product formula passes its bio-equivalency study and accelerated stability studies. An ANDA contains data related to a generic drug product which is submitted to the FDA for review and approval. The FDA must first determine the completeness of the filing and may deny the filing if it is incomplete. There are various reviews that are completed, including bio-equivalency, chemistry, manufacturing, and labeling. The bio-equivalency of a generic drug product is established by measuring the rate and level of active ingredient(s) in the bloodstream of healthy human subjects over a period of time. These pharmacokinetic parameters and results are compared with the innovator’s drug product. The bio-equivalency results of the proposed generic drug product must meet pharmacokinetic standards set forth by the FDA. Accordingly, the generic version of a drug product must generally deliver the same amount of active ingredient(s) into the bloodstream within the same timeframe as that of the innovator drug product. Following an indication that the generic drug product has passed its bio-equivalency study, the generic drug product will undergo reviews for chemistry, manufacturing and labeling. In each case, the FDA has an opportunity to raise questions or comments, or issue a deficiency letter. In the event that one or more deficiency letters are issued by the FDA, the submission of the ANDA may be halted or delayed as necessary to accommodate the correction of any such deficiencies and the completion of any additional reviews required. Minor deficiencies traditionally could delay the approval anywhere from 10 days to 90 days or more. Major deficiencies could stop the evaluation process. A restart of the FDA review process after a major deficiency could take up to as many as 180 days or more. Generally, any deficiencies we have experienced have been minor, though at times, approvals have faced considerable delays. Based on these delays, the economic benefit may not be realized at its highest potential as the delay could cause our approval to be behind our competition’s approval of the same generic product.

Based on the definition and characteristics of an asset, set forth in paragraphs 25 and 26 of Statement of Financial Accounting Concepts No. 6 issued by the Financial Accounting Standards Board (“FASB”),

the Company did not capitalize the technology formulas transferred, as the probability of the future economic benefit to be derived from such formulations is uncertain at the time of technology transfer.

In addition, we have reported the technology transfers as research and development expenses pursuant to FASB 2, “Accounting for the Research and Development Costs.” In connection therewith, the research and development technology transferred by Sun Global under the Products Agreement was always specific research and development technology for a specific product formula. There were no alternative future uses (in other research and development projects or otherwise) for such products. For example, Caraco has never acquired technology from Sun Global with the purpose of selling such technology and, in fact, has never sold or held for sale any of the technology transferred by Sun Global to a third party. Caraco has always developed the research and development technology into manufactured product for its own business purposes.

Research and development costs settled in cash are charged to expense as incurred.

Intangible Assets

The Company made a payment in the first quarter of Fiscal 2009 in the amount of $1.3 million for certain tangible and intangible assets purchased. The assets purchased included $1.1 million towards certain brand products associated New Drug Applications (“NDAs”) and trademarks, which are recorded as intangible assets in the Company’s balance sheet at September 30, 2008, and $0.2 million towards purchases of finished goods of these products. Additionally the Company paid $0.4 million towards product and establishment fees for these products. These intangible assets are being amortized over a period of 15 years, the period during which the Company expects to receive economic benefits from these intangible assets.

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 had net deferred tax assets of $19.1 million and $17.3 million at September 30, 2008 and March 31, 2008, 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 an income tax provision of $3.9 million and $9.0 million, respectively, during the second quarter and first six months of Fiscal 2009, as compared to an income

tax provision of $0.2 million and $1.4 million, respectively, during the second quarter and first six months of Fiscal 2008. We have not provided for any valuation allowance as of September 30, 2008, or March 31, 2008. 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 September 30, 2008, we had federal net operating loss carryforwards ("NOLs") of approximately $2.7 million, which are restricted by limitations of Internal Revenue Code Section 382, available to reduce future taxable income. The NOLs will expire between 2008 and 2012.

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 on income tax 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 research and development ("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

For the second quarter and first six months of Fiscal 2009, ended September 30, 2008, we recorded net sales of $122.2 million and $230.5 million, respectively, as 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 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. The non-cash R&D expenses, last recorded in Fiscal 2008, consisted of technology transfer costs associated with Sun Global having earned 544,000 preferred shares for each product transferred that had passed its bio-equivalency study, as per the terms of the technology transfer agreement. 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 $1.3 millionduring the corresponding period of Fiscal 2008. The decrease in cash flows from operations was primarily due to a decrease in accounts payable balances, offset, in part, by decreases in accounts receivable and inventory balances. During the second quarter of Fiscal 2009, we generated cash flow from operations in the amount of $19.2 million which partially offset the negative cash flow in the first quarter of Fiscal 2009 in the amount of $27.4 million. 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. The increase was primarily due to higher net sales. During the second quarter and first six months of Fiscal 2009, we recorded an income tax provision of $3.9 million and $9.0 million, respectively, as compared to an income tax provision of $0.2 million and $1.4 million, respectively, recorded during the corresponding periods of Fiscal 2008. During the second quarter and first six months of Fiscal 2009, we earned a net income of $8.4 million, and $17.9 million, respectively, as compared to a 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.

During Fiscal 2008, the Company commenced construction on the expansion of its primary facility located in Detroit, Michigan. This project will encompass additional space required for manufacturing, quality control laboratories, raw material storage and administrative offices. It will also introduce additional automated equipment and process flow efficiencies in order to reduce long term costs associated with our production while maintaining quality. The expansion is currently in progress on the acreage the Company acquired directly adjacent to its existing manufacturing facility. Currently the project remains on time and once completed will add approximately 140,000 square feet to our manufacturing facility. The expanded facility is expected to be operational by end of Fiscal 2009. In addition, the Company continued updating its packaging facility located in Farmington Hills, Michigan. During Fiscal 2007, the Company acquired this packaging facility for $1.7 million. We have improved the infrastructure and process flow by replacing manual packaging lines with automated lines thereby having less human intervention. This has already improved quality control in our packaging operations and will result in improved capacity. This 33,369 sq. ft. facility was previously owned and operated by a third party packager of our portfolio of products. This acquisition has already improved our overall costs in packaging, bottling and increased our production.

A union represents substantially all of our permanent, full-time and regular part-time hourly employees. In September 2008, the Company successfully negotiated a new four-year collective bargaining agreement with the union. This agreement sets forth minimum wage increases and growth opportunities which the union employees will be eligible for in each of the next four years, thereby giving the

Company and the union employees, the Company believes, a measure of certainty and stability. The collective bargaining agreement with the union is set to expire in September 2012.

FDA COMPLIANCE

The FDA concluded an inspection in June 2008. This was a general cGMP inspection and Pre-Approval Inspection for three products. The Company was issued a notice on Form 483. The Company has responded accordingly and we believe we remain substantially compliant. We continue to focus on improving the amount of support in quality assurance, quality control, and manufacturing areas in order to continually improve our performance in quality. This support is derived from the improvement of systems, training on risk management and cGMP, while adding the appropriate level of personnel to support our growth. Additionally we have invested in more automation for improved quality and increase in output with less human intervention. During Fiscal 2008, and currently in Fiscal 2009, in addition to our own internal audits, we have retained outside companies to audit both the laboratory and manufacturing areas of our Company. We also have and continue to provide external training to our employees as a supplement to our internal training in order to improve and or maintain our systems of operation. All audits are based on a historical look back and offer improvements based on Caraco's future requirements. The audits also included follow up on recommendations of best practices made by the FDA. We have focused our attention for continual improvement of our Corrective and Preventative Actions and cGMP, while adding the appropriate level of personnel to support our growth during Fiscal 2009. The Company has received approvals for seven ANDAs relating to two products since the inspection that concluded in June 2008.

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 an 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. Our manufacturing personnel are going through more rigorous training at the time of hire, and continually thereafter, in order to maintain our compliance and quality.

Second Quarter and First Six Months Fiscal 2009 Compared to Second Quarter and First Six Months Fiscal 2008

Net Sales. Net sales for the second quarter ended September 30, 2008 and first six months of Fiscal 2009, were $122.2 million and $230.5 million, respectively, as compared to $41.4 million and $76.8 million, respectively, for the second quarter and first six months of Fiscal 2008, reflecting increases of

195% and 200% in respective periods . The increase is primarily due to sales of distributed products by the Company under the distribution and sale agreement with Sun Pharma and to a lesser extent sales of other products launched in Fiscal 2008 under the marketing agreements with Sun Pharma as well as growth in sales of our own manufactured products. Net sales for distributed products were $89.9 million and $166.2 million, respectively, for the second quarter and first six months of Fiscal 2009, as compared to $6.4 million and $13.4 million, respectively, for the corresponding periods of Fiscal 2008. Net sales for manufactured products were $32.2 million and $64.3 million, respectively, for the second quarter and first six months of Fiscal 2009, as compared to $34.9 million and $63.3 million, respectively, for the corresponding periods of Fiscal 2008. Currently, we manufacture and market all except two of our approved products. Overall sales of two products accounted for approximately 61% and 59% of net sales, respectively, for the second quarter and first six months of Fiscal 2009, as compared to sales of four products which accounted for approximately 56% and 53% of net sales, respectively, for the second quarter and first six months of Fiscal 2008.

Gross Profit. We earned gross profit of $22.0 million and $45.6 million, respectively, during the second quarter and first six months of Fiscal 2009, as compared to gross profit of $18.0 million and $33.9 million, respectively, during the corresponding periods of Fiscal 2008, reflecting an increase of 22% and 35% in respective periods. The increase in gross profit was due to higher sales, primarily of distributed products including Para IV products under the agreements with Sun Pharma and to a lesser extent growth in the sales of our own manufactured products.

The gross profit margin as a percentage of net sales for the second quarter and first six months of Fiscal 2009 decreased to 18% and 20%, respectively, as compared to 44% during both of the corresponding periods of Fiscal 2008. This decrease was primarily due to the weight of increased sales of distributed products versus the sales of manufactured products, which had an impact on the overall margins. The gross profit margin on distributed products was 7% and 8%, respectively, for the second quarter and first six months of Fiscal 2009, as compared to 17% and 20%, respectively, for the corresponding periods of Fiscal 2008. The decrease was primarily due to the weight of increased sales of Para IV products, which earn lower margins as a percentage of sales versus the sale of other distributed products. Additionally, during the second quarter of Fiscal 2009, the Company wrote off non-saleable inventory of distributed products in the amount of $0.6 million, which contributed to the reduced the gross margin percentage on distributed products. The gross profit margin for manufactured products was 48% and 49%, respectively, for the second quarter and first six months of Fiscal 2009, as compared to 48% and 49%, respectively, for the corresponding periods of Fiscal 2008. Manufactured product margins have remained fairly stable period to period. This rate may or may not remain at current levels in future periods, as to date, we have experienced continued downward pricing pressure. We are hopeful that manufactured margins remain in line with Fiscal 2008 as we continue to manage, among other things, various factors such as changes in product sales mix, the balance of product sold to the various classes of trade, price erosion, new competitors entering the market and protecting and growing our market share. 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 second quarter and first six months of Fiscal 2009 were $4.2 million and $8.1 million, respectively, as compared to $3.0 million and $6.4 million, respectively, during the corresponding periods of Fiscal 2008, representing increases of 40% and 27% in the respective periods. These increases were mainly related to higher marketing and administrative efforts relative to the increase in sales. SG&A expenses, as a percentage of net sales improved to 4% for the first six months of Fiscal 2009, as compared to 8% for the corresponding period of Fiscal 2008. The lower percentage of SG&A is primarily due to increased sales of distributed products.

Research and Development Expenses. Total R&D expenses for the second quarter and first six months of Fiscal 2009 were $5.6 million and $11.1 million, respectively, as compared to $10.5 million and $13.8 million, respectively, during the corresponding periods of Fiscal 2008. The Company did not incur any non-cash R&D expenses (technology transfer costs) during the second quarter or first six months of Fiscal 2009, as compared to $5.4 million for both of the corresponding periods of Fiscal 2008. The final product was transferred to Caraco by Sun Global during the third quarter of Fiscal 2008, which concluded the obligations between the parties under the technology transfer agreement. Series B convertible preferred stock was issued to Sun Global under the products agreement between the Company and Sun Global in exchange for the technology of formulation products delivered by Sun Global to the Company. The resulting amount of R&D expense was charged to operations and was determined based upon the fair value of the preferred shares on the date the respective product formulas passed their bio-equivalency studies. The fair value of such shares was based upon a valuation performed by Donnelly Penman and Partners, an independent, third party valuation firm. The exchange of shares was prior to the initial ANDA submissions to the FDA. Cash R&D will continue to increase in an effort to develop additional products. The cash R&D expenses during the first six months of Fiscal 2009 were higher compared to those during the corresponding period of Fiscal 2008 due to increased R&D activity, including 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 $0.1 million and $0.4 million, respectively, during the second quarter and first six months of Fiscal 2009, as compared to $0.4 million and $0.9 million during the corresponding periods of Fiscal 2008. In both periods, the sole component of other income was interest income earned. The decrease in other income is primarily due to reduction in interest rates as prevailing in the market during the corresponding periods.

Income Taxes. We recorded income tax expense of $3.9 million and $9.0 million, respectively, during the second quarter and first six months of Fiscal 2009, compared to income tax expense of $0.2 million and $1.4 million, respectively, during the corresponding periods of Fiscal 2008. As the Company continues to be profitable, 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 $12.3 million and $26.9 million, respectively, during the second quarter and first six months of Fiscal 2009, as compared to a net pre-tax income of $4.9 million and $14.5 million during the corresponding periods of Fiscal 2008. We earned net income of $8.4 million and $17.9 million, respectively, for the second quarter and first six months of

Fiscal 2009, compared to net income of $4.6 million and $13.1 million, respectively, for the corresponding periods of Fiscal 2008.

Liquidity and Capital Resources

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. The decrease in cash flows from operations was primarily due to a decrease in accounts payable balances offset, in part, by decreases in accounts receivable and inventory balances. During the second quarter of Fiscal 2009, we generated cash flow from operations in the amount of $19.2 million. This partially offset the negative cash flow generated in the first quarter of Fiscal 2009 of $27.4 million. Accounts receivable decreased by $26.5 million to $109.4 million as of September 30, 2008, as compared to $135.9 million at the end of Fiscal 2008. Inventory levels are equivalent to 87 days sales on hand, as compared to 142 days on hand as of March 31, 2008. The inventory as of September 30, 2008 includes a build up of Para IV products launched in the fourth quarter of Fiscal 2008. We believe that such inventory will continue to generate future revenues and is realizable. In the event that future sale of the Para IV products are not allowed by any regulatory authority and Sun Pharma does not file a timely appeal, we would have various rights to return the product to Sun Pharma. Excluding the inventory for Para IV products, inventory levels were equivalent to 113 days sales as of September 30, 2008 as compared to 94 days as of March 31, 2008. Accounts receivable is 82 days sales outstanding (“DSO”) as of September 30, 2008 versus 63 days as of March 31, 2008. The increase in DSO is not significant considering the payment terms we provide our customers and the timing of sales in the period. It remains fairly consistent as an average for the six month period.

At September 30, 2008, we had working capital of $107.3 million, compared to working capital of $104.5 million at March 31, 2008. 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. Currently the credit line has no outstanding balances.

Future Outlook

We continue to remain competitive as we continue to grow. Due to our size and management structure, we believe that we are able to move swiftly and effectively. We are disciplined and have the aptitude to execute our plan. We believe we are substantially compliant with cGMP. We continue to invest in improved systems, equipment, training and personnel in quality and manufacturing to improve our overall performance in quality and production. In the last two years we have added considerable amount of infrastructure in our quality control laboratories. Our current focus is on manufacturing and quality assurance. With our planned expansion during Fiscal 2009, it remains important to have the proper management team in place to support the anticipated improvements and growth. We need to continue to improve our output on research and development by filing more ANDAs with the FDA so as to increase our own manufactured products portfolio. It is out intention to do so both internally and by utilizing third party developers. Our production capacity and output needs to be increased in order to maximize sales throughout Fiscal 2009 and beyond. Though we may decide to incur debt for target acquisitions or other business propositions, we currently remain free of loans.

The expansion of our facilities should provide us the capacity we need to supply our customers effectively. We are currently working on streamlining our procedures by adding improved systems and processes. Our training and succession planning is being enhanced both internally and by utilizing third parties, to support our growth and predict future operational efficiencies, and improved outcome in quality. We continue to work with local governments, universities and technical schools in order to provide the proper talented employees required to perform in a highly regulated business. We anticipate improved productivity and quality as our newer staff continues to increase their experience in their respective positions.

Currently, we have 23 ANDAs pending approval at the FDA (including four tentative approvals) relating to 19 products, and we also have one NDA pending approval relating to one product. We continue to expand and upgrade our facilities, attract and hire talented individuals and expand our customer base. Our internal efforts, combined with Sun Pharma in developing new products continue to pick up momentum and this should permit us to grow at the level of our guidance as provided below, although the current level of growth is at a high level, which may not be sustainable. We now have 27 products, that we market (including our own manufactured products and those distributed under various agreements with of Sun Pharma), whose market share is ranked third or higher against the same products of our generic competitors. We are focused on products that are currently in our portfolio and are yet to realize their full market potential. Based on our own development pipeline and the current agreements we have with Sun Pharma along with other third party developers we believe we will achieve 25% growth in sales for Fiscal 2009, compared to Fiscal 2008.

Although gross profit margins may come down over time due to price erosion, we are confident that our sales growth, expanding product portfolio and successful execution of our business plan will offset any long-term impact. However, should the pricing pressures become more severe than anticipated; the result may be lower growth rates and gross margins. Management has and will continue to work diligently to counter the pricing pressures through increased sales volumes, improved market share on existing products, expansion of our customer base, improved productivity, and better cost absorption of operational overheads, cost reductions and increased development plans.

The Company intends to aggressively move forward with the development of new products. We believe that R&D remains to be a significant driver of future growth. While the development of new products will continue to impact our cash R&D expense and EPS, we believe that we will continue to have the cash and other means available to meet increased working capital requirements, fund potential litigation expenses relating to Paragraph IV certification and finance further capital investments. Product development is a critical element in meeting expectations in the future. With non-cash R&D expenses eliminated, upon completion of the Sun Global products agreement in third quarter of Fiscal 2008, cash R&D expenses will continue to increase in an effort to file more products with the FDA.

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 72% (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 are intended to complement the Sun Pharma's 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 Fiscal 2008, we have signed two definitive agreements for two additional products. However the Company has terminated an agreement earlier entered into with one company for two of these products. This brings the total number of products being developed by unaffiliated third party developers to four.

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, 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 one NDA relating to one product and four ANDAs relating to three products in the first six months of Fiscal 2009. We continue to be on track in our development expectations and subsequent filings.

During the first six months of Fiscal 2009 we have purchased two products, and their respective trademarks and NDAs. We have recently commenced marketing of these products. Recently we have also divested two products as part of the Federal Trade Commission approved consent decree under which Caraco, due to Sun Pharma's majority ownership, was required to divest certain products in its effort to acquire Taro Pharmaceutical Industries Ltd. We will continue to sell these products as part of the supply agreement for the acquirer. The divestiture for these products will not have any material impact on our operations.

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 continue to market 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. 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. 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. We have started marketing two products under this agreement including 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 routine marketing costs including freight, carrying costs, and actual purchase price. Ultimately, the

sales of distributed products lower the SG&A as a percentage of sales. These agreements should provide for an alternate stream of products that will complement our internal research and development and our outsourced development. From time to time significant product launches such as we incurred under the distribution and sale agreement for Para IV products in Fiscal 2008 may occur that will add near term growth that may or may not be sustainable in future periods. Additionally we will continue to work with Sun Pharma in effort to transfer future product technology on a cash basis similar to other third party developers and in the future we may provide services to Sun Pharma, its affiliates and other third party pharmaceutical manufacturers relating to distribution of certain products, on a fee for service basis in an effort to expand our product offerings and remain competitive. It is our belief that our infrastructure and relationships we have with our customers, can be utilized to optimize sales for our own products, as well as of other companies that are entering or are planning to enter the U.S. market but do not have the infrastructure required to compete effectively.

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. We will continue to look at potential acquisitions that either complement, or are synergistic with, our current business platform. We will determine what is required to further capitalize any potential acquisition as opportunity targets are identified.

Management’s plans for Fiscal 2009 include:

- Continue to focus and improve on FDA compliance.
- Increase research and development activities, with a view to increase the number of ANDA filings.
- Look for potential acquisitions that either complement or are synergistic to our current business model.
- Continue to invest in equipment and facilities to expand capacity to meet requirements of projected short and long-term growth while improving quality.
- Increase cGMP training to accommodate growing staff and compliance.
- 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 and other third parties.
- 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 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, 2008, Part I, Item 1A, for more detailed discussion of such risks). These forward-looking statements represent our judgment as of the date of this report. We disclaim, however, any intent or obligation to update our forward-looking statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company has no debt or other market risk securities or transactions in foreign exchange.

ITEM 4. CONTROLS AND PROCEDURES

a. The term “disclosure controls and procedures” is defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the “Exchange Act”). These rules refer to the controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is recorded, processed, summarized and reported within required time periods. Our Chief Executive Officer and our interim Chief Financial Officer have evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report (the “Evaluation Date”), and have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective in providing them with material information relating to the Company known to others within the Company which is required to be included in our periodic reports filed under the Exchange Act.

b. There has been no change in the Company’s internal control over financial reporting that occurred during the second quarter of Fiscal 2009 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 SECURITES AND USE OF PROCEEDS

During the first six months of Fiscal 2009, 2,176,000 shares of Series B Preferred Stock previously issued to Sun Global were converted into 2,176,000 shares of Caraco common stock and issued to Sun Global.

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

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

The Annual Meeting of Shareholders of the Corporation was held on September 8, 2008 in Dearborn, Michigan for the purpose of electing three directors for a three-year term expiring in 2011 and upon the election and qualification of their successors.

Director Name	Votes For	Votes Withheld
Sailesh T. Desai	22,360,394	4,071,943
Daniel H. Movens	23,457,060	2,975,277
Georges Ugeux	26,274,021	158,316

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

Director Name	Term
Dilip S. Shangvi	2009
Dr. John D. Crissman	2009
Gurpartap Singh Sachdeva	2009
Timothy S. Manney	2010
Madhava Reddy	2010
Sudhir V. Valia	2010

The second matter voted on was the approval and adoption of the Caraco Pharmaceutical Laboratories, Ltd. 2008 Equity Participation Plan and the performance goals thereunder. The 2008 Equity Participation Plan was approved, with 23,520,232 shares voted for approval, while 445,670 shares voted against approval, 19,604 shares abstained and broker non-votes of 2,446,831.

ITEM 6. EXHIBITS

31.1 Certification of Chief Executive Officer
31.2 Certification of interim Chief Financial Officer.
32.1 Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

SIGNATURES

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

CARACO PHARMACEUTICAL

LABORATORIES, LTD.

Date: October 23, 2008

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

Chief Executive Officer

Date: October 23, 2008

By: /s/ Mukul Rathi
Mukul Rathi

interim Chief Financial Officer

EXHIBIT INDEX

31.1	Certification of Chief Executive Officer
31.2	Certification of interim Chief Financial Officer
32.1	Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002