CARACO PHARMACEUTICAL LABORATORIES LTD
Form 10-Q
November 09, 2009

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, 2009

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. 1-31773

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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes o 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 November 6, 2009, the registrant had 39,090,194 shares of common stock issued and outstanding.

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

	SEPTEMBER 30, 2009 (UNAUDITED)	MARCH 31, 2009 (AUDITED)
ASSETS		
Current assets		
Cash and cash equivalents	$ 72,700,493	$65,314,397
Short-term investments	10,000,000	-
Accounts receivable, net	48,982,036	15,181,197
Inventories	88,292,526	79,510,832
Prepaid expenses and deposits	6,973,373	9,440,942
Deferred income taxes	5,999,648	416,985
Total current assets	232,948,076	169,864,353
Property, plant and equipment		
Land	975,311	975,311
Buildings and improvements	28,466,328	28,148,447
Equipment	27,684,543	26,216,521
Furniture and fixtures	1,512,852	1,509,582
Construction in progress	2,676,571	2,708,137
Total	61,315,605	59,557,998
Less accumulated depreciation	16,801,151	14,734,961
Net property, plant and equipment	44,514,454	44,823,037
Intangible assets, net	1,334,524	1,383,048
Deferred income taxes	21,955,930	20,417,885
Total assets	$ 300,752,984	$236,488,323
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable, trade	$ 2,621,036	$7,979,341
Accounts payable, Sun Pharma	114,962,237	43,928,166
Accrued expenses	1,974,508	2,757,361
Income taxes payable	2,890,684	-
Long term debt, current portion	17,100,000	2,700,000
Total current liabilities	139,548,465	57,364,868
Long term debt, net of current portion	-	15,300,000
Total liabilities	139,548,465	72,664,868
Stockholders' equity		

Series B convertible preferred stock, no par value; issued and outstanding 1,088,000 shares (September 30, 2009) 2,720,000 shares (March 31, 2009)	11,320,640	23,081,920
Common stock, no par value; authorized 50,000,000 shares, issued and outstanding 39,090,194 shares (September 30, 2009) 37,458,194 shares (March 31, 2009)	130,330,615	118,569,335
Additional paid in capital	3,609,824	3,474,246
Retained Earnings	15,943,440	18,697,954
Total stockholders' equity	161,204,519	163,823,455
Total liabilities and stockholders' equity	$ 300,752,984	$236,488,323

See accompanying notes

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

	Six Months ended September 30,		Quarter ended September 30,	
	2009 (UNAUDITED)	2008 (UNAUDITED)	2009 (UNAUDITED)	2008 (UNAUDITED)
Net sales	$126,445,911	$ 230,465,165	$78,375,895	$ 122,188,425
Cost of goods sold	118,243,578	184,879,891	75,010,528	100,186,562
Gross profit before reserve for inventory seized by FDA	8,202,333	45,585,274	3,365,367	22,001,863
Reserve for inventory seized by FDA	15,950,188	-	7,503,654	-
Gross (loss) profit	(7,747,855)	45,585,274	(4,138,287)	22,001,863
Selling, general and administrative expenses	10,452,575	8,055,246	6,793,364	4,237,244
Research and development costs	5,592,951	11,065,940	(1,492,184)	5,581,711
Operating (loss) income prior to non-recurring income	(23,793,381)	26,464,088	(9,439,467)	12,182,908
Non-recurring income	20,000,000	-	20,000,000	-
Operating (loss) income	(3,793,381)	26,464,088	10,560,533	12,182,908
Other (expense) income				
Interest expense	(258,085)	-	(127,135)	-
Interest income	264,660	420,259	160,204	142,486
Loss on sale of equipment	(114,272)	-	-	-
Other income	46,309	-	11	-
Other (expense) income - net	(61,388)	420,259	33,080	142,486
(Loss) income before income taxes	(3,854,769)	26,884,347	10,593,613	12,325,394
Income tax (benefit) expense	(1,100,256)	9,020,309	3,925,076	3,901,421
Net (loss) income	$(2,754,513)	$ 17,864,038	$6,668,537	$ 8,423,973
Net (loss) income per common share				
Basic	(0.07)	0.54	0.17	0.25
Diluted	(0.07)	0.44	0.16	0.21

See accompanying notes

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

	Six months ended September 30,	
	2009 (UNAUDITED)	2008 (UNAUDITED)
Cash flows from operating activities		
Net (loss) income	$(2,754,513)	$ 17,864,038
Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities		
Depreciation and amortization	2,240,245	1,452,749
Loss on sale of equipment	114,272	-
Common stock option expense	135,578	151,179
Common stock grant expense	-	169,900
Net deferred income taxes	(7,120,708)	(1,773,180)
Changes in operating assets and liabilities which (used) / provided cash:		
Accounts receivable	(33,800,840)	26,516,913
Inventories	(8,781,694)	183,561,032
Prepaid expenses and deposits	2,467,568	46,124
Accounts payable	65,675,766	(237,969,471)
Accrued expenses	(782,853)	(173,958)
Income taxes payable	2,890,684	1,960,489
Net cash provided by (used in) operating activities	20,283,505	(8,194,185)
Cash flows from investing activities		
Purchases of property, plant and equipment	(1,997,719)	(13,665,079)
Proceeds from sale of equipment	310	-
Purchase of short-term investment	(10,000,000)	-
Purchases of intangibles	-	(1,455,840)
Net cash used in investing activities	(11,997,409)	(15,120,919)
Cash flows from financing activities		
Repayments of loans payable to financial institutions	(900,000)	-
Proceeds from exercise of stock options	-	11,250
Net cash (used in) provided by financing activities	(900,000)	11,250
Net increase (decrease) in cash and cash equivalents	7,386,096	(23,303,854)
Cash and cash equivalents, beginning of period	65,314,397	56,906,051
Cash and cash equivalents, end of period	$72,700,493	$ 33,602,197

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 IN	RETAINED	TOTAL STOCKHOLDERS'
	SHARES	AMOUNT	SHARES	AMOUNT	CAPITAL	EARNINGS	EQUITY
Balances at April 1, 2009	2,720,000	$23,081,920	37,458,194	$118,569,335	$3,474,246	$18,697,953	$163,823,454
Conversion of preferred stock into common stock	(1,632,000)	(11,761,280)	1,632,000	11,761,280			-
Common stock options expensed					135,578		135,578
Net loss						(2,754,513)	(2,754,513)
Balances at September 30, 2009	1,088,000	$11,320,640	39,090,194	$130,330,615	$3,609,824	$15,943,440	$161,204,519

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, 2009 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, with the exception of a reserve for inventory seized by the U.S. Food and Drug Administration ("FDA"), as discussed below. 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, 2009 of Caraco Pharmaceutical Laboratories, Ltd. ("Caraco," the "Company," or the "Corporation" and which is also referred to as "we," "u or "our"). In preparing these financial statements, the Company has evaluated events and transactions for potential recognition or disclosure through October 26, 2009, the date the financial statements were available to be issued.

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 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 33 prescription products, in 80 strengths, in various package sizes. This represents products we distribute for Sun Pharmaceutical Industries Limited, a specialty pharmaceutical corporation organized under the laws of India ("Sun Pharma") and products manufactured by other third parties relating to Caraco-owned products. This does not include those Caraco-owned products for which the Company has temporarily ceased manufacturing and marketing, due to the enforcement actions of the FDA. 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 had been from Sun Pharma. Since August 1997, Sun Pharma has contributed equity capital and had advanced us loans. In addition, among other things, Sun Pharma had 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, transferred certain generic products to us and provided us with qualified technical professionals. Sun Pharma has also provided services as a Clinical Research Organization, ("CRO") by performing certain bio-equivalency studies on our future potential products. Sun Pharma owns approximately 75% 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

As previously disclosed, on June 25, 2009, U.S. Marshals, at the request of the FDA, arrived and seized drug products manufactured in our Michigan facilities. The seizure also included ingredients and in-process materials held at these same facilities. The estimated value of such seized inventory as of September 30, 2009 was $24.0 million. Products sold and distributed by Caraco that are manufactured by third parties and outside of these facilities are not impacted and we continue distribution and marketing of these products.

The Company voluntarily entered into a Consent Decree of Condemnation, Forfeiture and Permanent Injunction ("Consent Decree") with the FDA on September 29, 2009. As stipulated in the Consent Decree, the Company will attempt to have the seized inventory released. The Company believes that, except for the raw materials which were opened solely for the purpose of sampling, the estimated value of which is $8.1 million, all other seized inventory would be difficult to recondition. Accordingly, a reserve in the amount of $15.9 million has been created as of September 30, 2009 for this remaining inventory. As a result of the FDA action, we have voluntarily ceased manufacturing operations and instituted, in two phases, indefinite layoffs of approximately 430 of our employees. The Consent Decree provides a series of measures that, when satisfied, will permit the Company to resume manufacturing and distributing those products which are manufactured in its Michigan facilities. The Company has engaged a consulting firm which is comprised of current good manufacturing practice ("cGMP") experts, in accordance with the Consent Decree.

As a result of this event, there has been a material adverse effect on our current operations and there may be a material adverse effect on our near term operations. Under the terms of the Consent Decree, Caraco's cessation of manufacturing operations will continue until it receives written notification from independent experts and the FDA that it is in compliance with the Consent Decree and regulations and can resume operations. However, there is no assurance that the steps being taken will be successful or result in resolution of the FDA complaint. We are also not able, at this time, to estimate, the cost of these actions. We anticipate working with the FDA to resolve its concerns as effectively and expeditiously as possible in accordance with the terms of the Consent Decree. The Consent Decree also requires the Company to abide by certain conditions and restrictions. If the Company violates any portion of the Consent Decree, it could incur penalties, such as monetary fines, forfeiture of the seized goods and other penalties.

During the second quarter ended September 30, 2009 and first six months of our current fiscal year ("Fiscal 2010") ended September 30, 2009, we generated net sales of $78.4 million and $126.4 million, respectively, compared to $122.2 million and $230.5 million, respectively, during the corresponding periods of Fiscal 2009. We incurred $(1.5) million and $5.6 million, respectively, in research and development ("R&D") expenses during the second quarter and first six months of Fiscal 2010, as compared to $5.6 million and $11.1 million, respectively, during the corresponding periods of Fiscal 2009. We generated cash from operations in the amount of $20.3 million during the first six months of Fiscal 2010, as compared to using cash from operations in the amount of $8.2 million during the corresponding period of Fiscal 2009. We earned a net pre-tax income of $10.6 million during the second quarter and incurred a net pre-tax loss of $3.9 million during the first six months of Fiscal 2010, as compared to earning net pre-tax income of $12.3 million and $26.9 million, respectively, during the corresponding periods of Fiscal 2009. Net pre-tax income in both periods of the current fiscal year were lower as we have created a reserve in the amount of $7.5 million and $15.9 million, respectively, during the second quarter and first six months of Fiscal 2010 relating to the inventory seized by the FDA as disclosed above and also due to the cessation of manufacturing at the Company's Michigan facilities resulting in loss of revenues of such products, as also disclosed above. Net pre-tax income was also positively affected by non-recurring income earned in the amount of $20.0 million as part of an asset purchase agreement arising out of a settlement agreement entered into by the Company during the current period that is not expected to recur in future periods. The Company recorded an income tax expense of $3.9 million and provided an income tax benefit of $1.1 million for the second quarter and first six months of Fiscal 2010, respectively, as compared to an income tax expense of $3.9 million and $9.0 million, respectively, in the corresponding periods of Fiscal 2009. We earned a net income of $6.7 million during the second quarter and incurred a net loss of $2.8 million for the first six months of Fiscal 2010, as compared to net income of $8.4 million and $17.9 million, respectively, during the corresponding periods of Fiscal 2009. At September 30, 2009, we had stockholders' equity of $161.2 million, as compared to stockholders' equity of $163.8 million at March 31, 2009. (See "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.").

We have filed two Abbreviated New Drug Applications ("ANDAs") relating to two products with the FDA during the first six months of Fiscal 2010. We have not received FDA approval for any ANDAs during the first six months of Fiscal 2010 and do not expect to receive any approvals for products out of our Michigan facilities until we resolve the FDA's concerns as discussed above. The total number of ANDAs pending approval by the FDA as of September 30, 2009 was 31 (including four tentative approvals) relating to 27 products.

4. RECENT ACCOUNTING PRONOUNCEMENTS

In May 2009, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 165, "Subsequent Events", which was primarily codified into FASB Accounting Standards Codification ("ASC") Topic 855. This pronouncement provides guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. This standard is effective for interim or fiscal periods ending after June 15, 2009 and became effective for the Company beginning with its quarterly period ended June 30, 2009. Its adoption did not have an impact on the Company's results of operations, financial position or cash flows.

In June 2009, the FASB issued SFAS No. 168, "FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles- a replacement of Financial Statement No. 162", which was primarily codified into ASC Topic 105 — "Generally Accepted Accounting Principles." This standard identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of non-governmental entities that are presented in conformity with GAAP. This statement is effective for financial statements issued for interim and annual periods ending after September 15, 2009. Accordingly, the Company adopted this standard effective with its quarterly report ended September 30, 2009. The adoption of this standard has changed how we reference various elements of GAAP when preparing our financial statement disclosures, but had no impact on the Company's consolidated 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 2010, ended September 30, 2009, were 38,723,585 and 40,468,406, respectively, and were both 38,138,937 for the first six months of Fiscal 2010. Correspondingly, 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.

6. SUN PHARMACEUTICAL INDUSTRIES LIMITED

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

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 common 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 Pharma Global, Inc. ("Sun Global"), an affiliate of Sun Pharma.

Under the agreement, 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 are selected by mutual agreement. Under this agreement, Caraco conducts at its own expense all tests, including bio-equivalency studies. The Corporation also markets the products consistent with its customary practices. In return for the technology transfer, Sun Global receives 544,000 shares of Series B Convertible Preferred Stock for each generic drug transferred when such drug has 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 had been selected, and all 25 products had passed their respective bio-equivalency studies as of March 31, 2008.

On July 10, 2009, Caraco entered into an agreement with Alkaloida Chemical Company ZRT, a Hungarian corporation ("Alkaloida") and indirect subsidiary of Sun Pharma, pursuant to which Alkaloida will provide for certain products an exclusive, non-transferable license to Caraco to manufacture and market the products in the United States, its territories and possessions, including Puerto Rico. The license for a product is for a period of five (5) years from the commencement of marketing of the product, however, Caraco may extend the license for a further five (5) year period. Alkaloida is required to deliver the product technology for a product as soon as it is developed or available or as agreed to by Caraco and Alkaloida.

The agreement expires five years from the date of approval of the first ANDA, unless renewed or extended for consecutive one (1) year periods, however, the licenses remain valid pursuant to the terms of the agreement. Under certain conditions, the agreement may be terminated in its entirety or with respect to one or more products. The agreement is governed by and construed in accordance with the laws of the State of Michigan. The agreement was approved by Caraco's Independent Committee. No technology for any product has been transferred under this agreement to date.

Sun Pharma operates 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. Sun Pharma continues to provide Clinical Research Services on a product by product basis. Also, five of the eight 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 the fiscal year ended March 31, 2007 (“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 the fiscal year ended March 31, 2008 (“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 (“Paragraph 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 Company markets and distributes the same as part of its current product offerings in the U.S., its territories and possessions, including Puerto Rico. The license granted with respect to a product terminates upon the end of an 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 currently receives a fixed gross profit 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 2010 the Corporation made net sales of $75.9 million and $110.9 million, respectively, and during corresponding periods of Fiscal 2009, the Corporation made net sales of $89.9 million and $166.2 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 2010, Sun Global converted 1,632,000 shares of Series B Preferred Stock into 1,632,000 shares of Common Stock. Through March 31, 2009 Sun Global had converted 10,880,000 shares of Series B Preferred Stock into 10,880,000 shares of Common Stock, respectively. Sun Pharma’s current beneficial ownership is 75% (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 satisfaction of FDA concerns, its continuing ability to attract and retain key employees, obtain timely approvals of its ANDAs, and develop new products.

7. ACCOUNTING FOR STOCK BASED COMPENSATION

The Company follows the provisions of ASC Topic 718, "Stock Compensation'" 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 2010, the Company has recognized expenses amounting to $49,795 and $135,578 respectively, related to common stock options as compared to $86,574 and $151,179 respectively, for the corresponding periods of Fiscal 2009. As of September 30, 2009, total unrecognized compensation cost related to stock options granted was $277,696. The unrecognized stock option compensation cost is expected to be recognized over a period of approximately three years. Stock options to purchase 6,000 shares of common stock were granted to Directors during the first six months of Fiscal 2010, which vest in the amount of one-third on each anniversary following the date of grant. Additionally, during the first quarter of Fiscal 2009, the Company recorded an expense of $169,900 related to a stock grant of 10,000 common shares issued to its then CEO on May 2, 2008, as part of his employment agreement, which vested immediately upon issuance.

8. COMMON STOCK ISSUANCES

There were no common stock issuances to Directors or employees during the first six months of Fiscal 2010. We issued 1,000 shares of common stock to our employees upon exercise of their stock options during the first six months of Fiscal 2009. Also, during the first quarter of Fiscal 2009, the Company issued a stock grant of 10,000 common shares to its former CEO on May 2, 2008, as noted above.

During the first six months of Fiscal 2010, Sun Global converted 1,632,000 shares of Series B Preferred Stock into 1,632,000 shares of Common Stock. (See "Part II – Other Information: Item 2. Unregistered Sales of Equity Securities and Use of Proceeds" below).

9. PREFERRED STOCK ISSUANCES

No shares of preferred stock were issued during the first six months of Fiscal 2010 or Fiscal 2009.

10. SALES AND CUSTOMERS

Sales of distributed products were significantly lower for the second quarter and first six months of Fiscal 2010, in comparison to the corresponding periods of Fiscal 2009 primarily as a result of significantly higher sales of Paragraph IV products during both periods of Fiscal 2009. See "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations – Second Quarter and First Six Months of Fiscal 2010 Compared to Second Quarter and First Six Months of Fiscal 2009." Sales of distributed products were also lower due to price erosion for the products sold. We continue to remain competitive on products sold and marketed during the first six months of Fiscal 2010. However, during the second quarter and first six months, sales of Caraco-owned products (those products for which Caraco owns the ANDAs) were adversely affected by the actions of the FDA and the cessation of manufacturing, as disclosed above and in part due to the negative impact of our voluntary recalls,. Our organization is focused on correcting any and all manufacturing issues to allow us to emerge as a stronger company. In the interim,

we will continue to focus our sales and marketing team on distributed product sales.

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 2010, the Company's three largest wholesale customers, Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health, accounted for approximately 5%, 3% and 3%, respectively, of the Company's total net sales during the second quarter and 7%, 6% and 5%, respectively, of total net sales for the first six months of Fiscal 2010. During the corresponding period of Fiscal 2009, shipments to 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 of Fiscal 2009, and 6%, 15 and 25%, respectively, of total net sales for the first six months of Fiscal 2009. 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. During the second quarter and first six months of Fiscal 2010, sales to CVS Caremark Corporation accounted for approximately 74% and 60% of our net sales. The sales to CVS Caremark Corporation have increased as we have entered into a new contract with it towards the end of Fiscal 2009.

11. DEBT

As a consequence of the FDA actions disclosed above, on June 29, 2009, JP Morgan Chase Bank N.A. ("JP Morgan") temporarily suspended the Company's $10 million Credit Agreement until such time as the matters with the FDA are resolved to the satisfaction of JP Morgan bank or such Credit Agreement expires. The Credit Agreement is set to expire on November 30, 2009. However, there were no borrowings under the Credit Agreement at any time during the current fiscal year. Under the Credit Agreement, JP Morgan may make loans and issue letters of credit to the Corporation for 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, 2009. 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 (provided the prime rate is not less than the prevailing one month LIBOR Rate plus 250 basis points). The effective rates were 1.35% and 2.25%, respectively, at June 30, 2009 subsequent to which the line of credit was suspended. The Credit Agreement requires that certain financial covenants be met on a quarterly basis.

During the fourth quarter of Fiscal 2009 the Company entered into a term loan of $18 million with RBS Citizens, N.A. d/b/a Charter One Bank ("Charter One Bank"). The loan is secured by a mortgage covering the Company's manufacturing facility and equipment located in Detroit, Michigan. The rate of interest is calculated as LIBOR plus an applicable margin thereto (based upon various leverage levels and current applicable rate is 50 basis points). The aggregate rate applicable to the Company as of September 30, 2009 was 1.5%. The principal loan payments and accrued interest are payable on a quarterly basis beginning July 2009. The principal is to be repaid in equal quarterly installments of $900,000 for ten quarters through October 2011, and thereafter, if not renewed, the remaining balance of $9 million is due in the subsequent quarter by January 2012. Subsequently, the terms of the loan were modified and we entered into an amended agreement. The amended agreement amended the loan to add to the equipment term loan for the purposes of financing new machinery and equipment and building improvements, a one year line of credit note for $15 million against which the Company can borrow funds for working capital purposes or can get letters of credit issued. The line of credit carries an interest rate of LIBOR plus 150 basis points, and if letters of credit are issued, the associated fees are 0.7% of such letters of credit on annualized basis. Also, there is an unused fee of 0.25% on an annualized basis to the extent the line remains idle. Both the line of credit and outstanding term loan are cross collaterized by all of the Company's fixed assets and cash deposit accounts held with Charter One Bank in the same amount. These cash deposits earn interest at prevailing rates applicable to such money market acoounts. Against this line of credit, the Bank has issued an Irrevocable Standby Letter of Credit in an amount of $15 million, in favor of the United States of America, as required to be placed with the FDA in accordance with the Consent Decree, as disclosed above. We are continuing discussions with Charter One Bank to resolve its concerns and get the cash collateral released. Charter One Bank has temporarily suspended our required compliance with the covenants in the loan

agreements relating to FDA enforcement actions as previously disclosed, and has suspended testing of certain other compliance requirements until February 26, 2010. On or before such date, we anticipate either entering into revised agreements or repaying the loan in full. Currently, as the loan is in technical default due to the FDA enforcement action, the entire outstanding balance has been classified as a short-term liability.

As required pursuant to the terms of the Loan Agreement, the Company has entered into an Interest Rate Swap Agreement with Charter One Bank to hedge the interest rate applicable on the loan. The notional amount for the swap is $17.1 million which will continue to amortize down as principal payments are made on the related debt. The annualized fixed rate of interest as it applies to this agreement is 2.41%. Thus as of September 30, 2009 the effective rate of interest to the Company for the term loan was 2.91% (2.41% swap rate plus applicable margin of 50 basis points). The fair value of this swap agreement at September 30, 2009 was not material.

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 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 as well as a section viii statement with regard to the patent's method claim. 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. Earlier this year, the Company filed a supplemental answer and counterclaim challenging Novo Nordisk's recent Orange Book use code amendment by Novo Nordisk in reference to Prandin®. On September 25, 2009, the District Court entered an injunction requiring Novo Nordisk to correct its amended use code description for Prandin® on the ground that it does not accurately characterize the referenced method patent. Novo Nordisk has appealed that injunction and briefing on the appeal has been expedited. On October 14, 2009, the parties entered into a stipulation regarding the appeal. On October 27, 2009, the United States Court of Appeals for the Federal Circuit entered an Order staying the use code injunction during the appeal. We expect briefing on the appeal to be completed sometime in November of 2009..If the Company prevails on the use code injunction appeal, Novo Nordisk will stipulate to noninfringement based on Caraco's proposed section viii split-certification. If Novo Nordisk prevails on the use code injunction appeal, the parties will proceed to trial on patent validity and unenforceability. Currently, the trial is anticipated to begin in February, 2010.

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 (the “’712 patent”). The ANDA contains Paragraph IV Certifications challenging the ‘712 patent, as well as two other Forest-owned patents, the 6,916,941 (“the ‘941 patent”) and 7,420,069 ("the '069 patent"). Forest did not assert the '941 patent or '069 patent, so the Company brought declaratory judgment actions seeking a declaration that it did not infringe those patents. The Company vigorously litigated all three cases.

On July 10, 2009, the Company announced that it has reached an agreement with Forest to settle the Lexapro® litigation. On October 2, 2009, the Company announced that it closed the Asset Purchase Agreement (the “APA”) related to that settlement. In accordance with the previously disclosed settlement:

1. Forest has agreed to provide licenses to the Company for any patents related to Lexapro® with respect to the marketing of the Company’s generic version of the product as of the date that any third party generic enters the market with final approval from the FDA other than an authorized generic or the first filer with Hatch-Waxman exclusivity.

2. Forest has reimbursed the Company for a portion of its attorney’s fees related to this litigation.

3. Pursuant to the APA, the Company is taking over the commercialization and sale of several products from Forest’s Inwood business and received compensation payment from Forest in connection with its Inwood business. Caraco has paid Forest an advance against royalties and will pay royalties on net sales of these products.

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 asserted claims of the reissue patent were 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. On August 25, 2008, Ortho-McNeil filed a notice of appeal with respect to that judgment with the United States Court of Appeals for the Federal Circuit. The appeal was fully briefed and was argued on July 7, 2009. On August 26, 2009, the Court of Appeals reversed a portion of the previously decided summary judgment. Although the Court did find that a portion of the patent was not valid, the Court remanded the litigation back to the lower court for further proceedings. Caraco subsequently filed a combined petition for a panel rehearing and a rehearing en banc. That combined petition for rehearing remains pending before the Court.

As previously disclosed, on May 5, 2009, Wyeth filed a complaint against the Company and Sun Pharma in the United States District Court for the Eastern District of Michigan. The complaint alleges that the package insert for Sun Pharma's product that is distributed by the Company and which is a generic version of Wyeth's Protonix® (pantoprazole) pharmaceutical product contains false and misleading statements regarding the active ingredient of that product in violation of federal and state laws. The complaint requests damages, injunctive relief and attorneys' fees and costs. The Company and Sun Pharma believe that they have not engaged in any improper conduct and intend to vigorously contest these allegations. On July 6, 2009, the Company and Sun Pharma filed a Motion to Dismiss the Complaint for Failure to State a Claim Upon Which Relief May Be Granted. Plaintiff's brief in response to the Company's and Sun Pharma's Motion to Dismiss was filed on July 30, 2009. Caraco and Sun Pharma filed a reply memorandum of law in support of its Motion to Dismiss on August 13, 2009. The Motion has been fully briefed and we are awaiting a decision from the Court.

As previously disclosed, on June 25th, 2009, at the direction of the FDA, the U.S. Marshal Service, arrived and seized drug products manufactured, work in process materials, and ingredients held, at the Company's Michigan facilities. The estimated value of such seized inventory as of September 30, 2009 was $24.0 million. The office of the United States Attorney, on behalf of the FDA and Department of Justice, filed a Warrant for Arrest In Rem to seize certain materials at the Company's Michigan facilities in the United States District Court for the Eastern District of Michigan. A Complaint for forfeiture of those materials was filed with the court by the FDA. The Complaint alleged that the drug products and materials are adulterated, in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing and holding do not conform to cGMP requirements. Also as previously disclosed, on September 29, 2009, the Company voluntarily entered into a Consent Decree with the FDA. The Consent Decree provides a series of measures that, when satisfied, will permit the Company to resume manufacturing and distributing those products which are manufactured in its Michigan facilities. Nothing in the Consent Decree prohibits the Company from distributing FDA approved drug products that are manufactured by third parties. We intend to continue to work with the FDA under the terms of the Consent Decree to resolve its concerns as effectively and expeditiously as possible.

As previously disclosed, on July 17, 2009 and July 23, 2009, two purported class action lawsuits were filed in the United States District Court for the Eastern District of Michigan against the Company and certain of its executive officers. The lawsuits allege securities violations related to the Company’s public statements on FDA compliance issues made between May 29, 2008 and June 25, 2009. On September 15, 2009, plaintiffs in both of the purported lawsuits filed motions for consolidation of the cases and for approval of lead plaintiff. The Company believes the allegations to be without merit and intends to vigorously defend itself.

On September 29, 2009, Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc. (“Taro”) filed suit against Caraco and Sun Pharma and certain of its affiliates. The complaint, as it pertains to Caraco, alleges misappropriation and misuse of trade secrets, unfair competition, tortious interference with business relationships, fraud and unjust enrichment. The claims against Caraco arise out of Caraco’s purported access to information from Taro as a part of the due diligence conducted for Sun Pharma’s tender offer for Taro Pharmaceuticals Industries Ltd. Caraco intends to vigorously defend this action.

The Company is also involved in certain other 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 of these certain 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, 2009	March 31, 2009
Raw materials	$ 18,325,368	$ 17,954,511
Goods in transit (Distributed)	22,191,773	29,236,869
Work in process	7,183,097	9,279,009
Finished goods (Caraco- Owned)	10,141,321	9,749,721
Finished goods (Distributed)	46,401,155	13,290,722
Inventories before reserves	$ 104,242,714	$ 79,510,832
Less : Reserve for certain inventory under control of the FDA	15,950,188	-
Total Inventories	$ 88,292,526	$ 79,510,832

Total inventories at September 30, 2009 and March 31, 2009 includes materials purchased in the amount of $3,257,323 and $2,875,885, respectively, related to products for which the Company has filed ANDAs with the FDA, and the commercial launch of such products will commence once the approvals are received.

As disclosed above, on June 25, 2009, certain drug products manufactured, work in process, and ingredients held, at the Company's Michigan facilities were seized at the direction of the FDA . The estimated value of such seized inventory as of September 30, 2009 was $24.0 million. The Company voluntarily entered into a Consent Decree with the FDA on September 29, 2009. As stipulated in the Consent Decree, the Company will attempt to have the seized inventory released. The Company believes that, except for the raw materials which were opened solely for the purpose of sampling, the estimated value of which is $8.1 million, all other seized inventory would be difficult to recondition. Accordingly, a reserve in the amount of $15.9 million has been created as of September 30, 2009 for this remaining inventory which consists of work in process relating to those materials which are in various stages of production within our manufacturing facilities, all finished goods and those raw material ingredients which are partially consumed in process. The Company believes that it will be able to use the inventory of raw materials which were opened solely for sampling purposes, however, in the event the Company is unable to recondition or recover all of such inventory, the Company will adjust the value of its inventory accordingly in future periods, which would result in a negative impact on the future operating results of the Company.

14. INCOME TAXES

The provision for income taxes is as follows:

	Six Months Ended	
	September 30, 2009	September 30, 2008
Current	$5,820,451	$10,743,489
Deferred	(7,120,707)	(1,773,180)
Total	$(1,300,256)	$8,970,309

The provision for income taxes is different from that which would be obtained by applying the statutory federal income tax rate to income before income taxes. The items causing the difference for the first six months of Fiscal 2010 and Fiscal 2009, respectively, are as follows:

	Six Months Ended	
	September 30, 2009	September 30, 2008
Provision for income taxes at federal statutory rate	$(1,349,169)	$ 9,409,521
Permanent items and other	48,913	(439,212)
Income taxes	$(1,300,256)	$ 8,970,309

Deferred taxes consist of the following:

	September 30, 2009	March 31, 2009
Deferred tax assets:		
Net operating loss carryforwards	$664,693	$797,631
Intangibles	25,254,680	26,458,255
Reserve for inventory	5,582,662	-
Other	416,986	417,136
Total deferred tax assets	$31,919,021	$27,673,022
Deferred tax liabilities:		
Intangibles	$3,090,493	$6,180,987
Depreciation	872,950	657,165
Total deferred tax liabilities	$3,963,443	$6,838,152
Net deferred tax assets	$27,955,578	$20,834,870

15. SEGMENT INFORMATION

The Company operates in two reportable segments consisting of (1) Caraco-owned products (those products for which Caraco owns the ANDAs) and (2) those products distributed under various agreements with Sun Pharma and its affiliates and with others. The sales and gross profits earned on these categories of products are as follows

Fiscal 2009:	Quarter Ended September 30, 2009		Six Months Ended September 30, 2009	
Category	Net Sales	Gross Profit	Net Sales	Gross Profit
Caraco-Owned Products	$ 2,492,443	$ (10,650,146)	$ 15,573,630	$ (17,542,360)
Distributed Products	75,883,452	6,511,859	110,872,281	9,794,505
Total	$ 78,375,895	$ (4,138,287)	$ 126,445,911	$ (7,747,855)

Fiscal 2008:	Quarter Ended September 30, 2008		Six Months Ended September 30, 2008	
Category	Net Sales	Gross Profit	Net Sales	Gross Profit
Caraco-Owned 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

16. SUBSEQUENT EVENTS

None

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 2009 Annual Report on Form 10-K as of and for the year ended March 31, 2009 (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, valuation of overhead components in inventory and the reserve for 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, both manufactured and distributed, 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 received 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 the change is determined. 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 the change is determined. 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 Allowances

Our gross sales for the second quarter and first six months of Fiscal 2010 were $131.5 million and $213.8 million, respectively, as compared to $250.6 million and $430.7 million, respectively, for the corresponding periods of Fiscal 2009. Sales allowances, which include chargebacks, returns, discounts, other customary customer deductions and other sales costs, constituted approximately 40% and 41% of gross sales, respectively, for the second quarter and first six months of Fiscal 2010 as compared to 51% and 46% of gross sales, respectively, for the corresponding periods of Fiscal 2009. Net sales for the second quarter and first six months of Fiscal 2010 were $78.4 million and $126.4 million, respectively, as compared to $122.2 million and $230.5 million, respectively, for the corresponding periods of Fiscal 2009. The primary cause of the decreased sales allowances for both periods of Fiscal 2010 is due to the impact of higher sales to customers other than wholesalers, which carry lower deductions from gross sales, since sales made to wholesale customers includes deductions related to chargebacks, which represent differences between wholesale acquisition costs (WAC) and the contractual prices at which the wholesalers ship to our end use customers.

The following is a roll forward of the provisions for chargebacks, shelf stock adjustments, returns and allowances and estimated doubtful account allowances during Fiscal 2009 and the first six months of Fiscal 2010.

($ 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 2009					
Chargebacks, rebates & shelf stock adjustments	$78,905	$291,070	-0-	$319,947	$50,028
Returns and other allowances	5,273	19,870	-0-	18,588	6,555
Doubtful Accounts	118	231	-0-	271	78
For the first six months of Fiscal 2010					
Chargebacks, rebates & shelf stock adjustments	$50,028	$81,798	-0-	$65,983	$65,843
Returns and other allowances	6,555	5,573	-0-	6,540	5,588
Doubtful Accounts	78	9	-0-	9	78

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 the ANDAs for these transferred formulations for FDA approval. In our experience, generally the submission of the ANDA to the FDA was 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 ingredients 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 FASB, the Company did not capitalize the technology formulas transferred, as the probability of the future economic benefit to be derived from such formulations was uncertain at the time of technology transfer.

In addition, we have reported the technology transfers as research and development expenses pursuant to ASC Topic 730, "Research and Development," 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.

Short-Term Investments

During the first quarter of Fiscal 2010 the Company invested $10,000,000 in a bank certificate of deposit. The term of deposit is for twelve months and earns interest at a rate of 4.5% APY. If such deposit is withdrawn prior to maturity, the Company will earn interest at the applicable LIBOR rate as on the date of such withdrawal.

Intangible Assets

The Company made a cash payment in the first quarter of Fiscal 2009 in the amount of $1,100,000 for the purchase of certain assets which included brand products, associated New Drug Applications ("NDAs") and trademarks. These assets are recorded as intangible assets in the Company's balance sheet at September 30, 2009. Additionally during the second quarter of Fiscal 2009, the Company paid $356,000 in cash towards product and establishment fees for these products. The total gross carrying amount for these assets is $1,456,000 as of September 30, 2009. These intangible assets are being amortized equally over a period of 15 years, the period during which the Company expects to receive economic benefits from these intangible assets. The Company recorded $49,000 in amortization expense in the first six months of Fiscal 2010, bringing the total accumulated amortization related to these intangible assets to $121,000 as of September 30, 2009.

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 $28.0 million and $20.8 million at September 30, 2009 and March 31, 2009, 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 income tax expense of $3.9 million and an income tax benefit of $1.1 million, respectively, for the second quarter and first six months of Fiscal 2010 as compared to income tax expense of $3.9 million and $9.0 million, respectively, during the second quarter and first six months of Fiscal 2009. The income tax benefit for first six months of Fiscal 2010 was predominantly due to losses incurred as a result of FDA actions including the seizure of inventory for which a reserve has been created. We have not provided for any valuation allowance as of September 30, 2009 or March 31, 2009. Based upon the level of projected future taxable income 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, 2009, we had federal NOLs of approximately $1.9 million, which are restricted by limitations of Internal Revenue Code Section 382, available to reduce future taxable income. The NOLs will expire between 2010 and 2012.

The Company is subject to U.S. federal income tax as well as income tax in certain state jurisdictions. As previously disclosed, the IRS has initiated an examination of the Company's tax return for the fiscal year ended March 31, 2007. The examination has been completed and the IRS has notified the Company that no adjustments are required to be made to the tax return filed for the period under review. The Company's federal statute of limitations has expired for years prior to 2003.

Inventory

We value inventories at the lower of cost or market. We determine the cost of raw materials, work in process and finished goods using the specific identification cost method. We analyze our inventory levels quarterly and write down inventory that has become obsolete and inventory that has a cost basis in excess of its expected net realizable value. Expired inventory is disposed of and the related costs are written off. Materials acquired solely for R&D are written off in the year of acquisition. Inventory includes material purchased related to products for which the Company has filed ANDAs with the FDA and the commercial launch of such products will commence once the approvals are received. 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.

As disclosed above, on June 25, 2009, certain drug products manufactured, work in process, and ingredients held, at the Company's Michigan facilities were seized at the direction of the FDA. The estimated value of such seized inventory as of September 30, 2009 was $24.0 million. The Company has voluntarily entered into a Consent Decree and is in the process of getting the material released. The Company believes that, except for the raw materials which were opened solely for the purpose of sampling, the estimated value of which is $8.1 million, all other seized inventory would be difficult to recondition. A reserve in the balance amount of $15.9 million has been created as of September 30, 2009 which consists of work in process relating to those materials which are in various stages of production within our manufacturing facilities, all finished goods and those raw material ingredients which are partially consumed in process. The Company believes that it will be able to use the inventory of raw materials which were opened solely for sampling purposes, however, in the event the Company is unable to recondition or recover all of such inventory, the Company will adjust the value of its inventory accordingly in future periods, which would result in a negative impact on the future operating results of the Company.

OVERVIEW

The Company voluntarily entered into a Consent Decree with the FDA on September 29, 2009. As stipulated in the Consent Decree, the Company will attempt to have the seized inventory released. The estimated value of this inventory of drug products manufactured in Caraco's Michigan facilities including ingredients and in-process materials was $24.0 million, as of September 30, 2009. The Company believes that, except for the raw materials which were opened solely for the purpose of sampling, the estimated value of which is $8.1 million, all other such inventory would be difficult to recondition. Accordingly, a reserve in the amount of $15.9 million has been created as of September 30, 2009 for this remaining inventory. As a result of the FDA action, Caraco has voluntarily ceased manufacturing operations and instituted, in two phases, indefinite layoffs of approximately 430 employees. Products sold and distributed by Caraco that are manufactured by third parties and outside of these facilities are not impacted and the Company continues distribution and marketing of these products. The Consent Decree provides a series of measures that, when satisfied, will permit the Company to resume manufacturing and distribution of those products that are manufactured in its Michigan facilities. The Company has engaged a consulting firm which is comprised of cGMP experts, in accordance with the Consent Decree.

As a result of this event, there has been a material adverse effect on our current operations and there may be a material adverse effect on our near term operations. Under terms of the Consent Decree, Caraco's cessation of manufacturing operations will continue until it receives written notification from independent experts and the FDA that it is in compliance with the Consent Decree and regulations and can resume operations. However, there is no assurance that the steps being taken will be successful or result in resolution of the FDA complaint. We are also not able, at this time, to estimate, the cost of these actions. We anticipate working with the FDA to resolve its concerns as effectively and expeditiously as possible in accordance with the terms of the Consent Decree. The Consent Decree also requires the Company to abide by certain conditions and restrictions. If the Company violates any portion of the Consent Decree, it could incur penalties, such as monetory fines, forfeiture of the seized goods and other penalties.

During the second quarter ended September 30, 2009 and first six months of our current fiscal year (“Fiscal 2010”) ended September 30, 2009, we generated net sales of $78.4 million and $126.4 million, respectively, compared to $122.2 million and $230.5 million, respectively, during the corresponding periods of Fiscal 2009. We incurred $(1.5) million and $5.6 million, respectively, in research and development (“R&D”) expenses during the second quarter and first six months of Fiscal 2010, as compared to $5.6 million and $11.1 million, respectively, during the corresponding periods of Fiscal 2009. We generated cash from operations in the amount of $20.3 million during the first six months of Fiscal 2010, as compared to using cash from operations in the amount of $8.2 million during the corresponding period of Fiscal 2009. We earned a net pre-tax income of $10.6 million during the second quarter and incurred a net pre-tax loss of $3.9 million during the first six months of Fiscal 2010, as compared to earning net pre-tax income of $12.3 million and $26.9 million, respectively, during the corresponding periods of Fiscal 2009. Net pre-tax income in both periods of the current fiscal year were lower as we have created a reserve in the amount of $7.5 million and $15.9 million, respectively, during the second quarter and first six months of Fiscal 2010 relating to the inventory seized by the FDA, as disclosed above and also due to the cessation of manufacturing at the Company’s Michigan facilities resulting in a loss of revenues from such products, as also disclosed above. Net pre-tax income was also positively affected by non-recurring income earned in the amount of $20.0 million as part of an asset purchase agreement arising out of a settlement agreement entered into by the Company during the current period that is not expected to recur in future periods. The Company recorded an income tax expense of $3.9 million and provided an income tax benefit of $1.1 million for the second quarter and first six months of Fiscal 2010, respectively, as compared to an income tax expense of $3.9 million and $9.0 million, respectively, in the corresponding periods of Fiscal 2009. We earned a net income of $6.7 million during the second quarter and incurred a net loss of $2.8 million for the first six months of Fiscal 2010, as compared to net income of $8.4 million and $17.9 million, respectively, during the corresponding periods of Fiscal 2009. At September 30, 2009, we had stockholders’ equity of $161.2 million, as compared to stockholders’ equity of $163.8 million at March 31, 2009. (See “Item 2. Management’s Discussion and Analysis of

Financial Condition and Results of Operations.”).

During Fiscal 2008, the Company commenced construction on the expansion of its primary facility located in Detroit, Michigan. The expansion occurred on the acreage the Company acquired for $0.3 million directly adjacent to its existing manufacturing facility. The expansion was completed during the fourth quarter of Fiscal 2009 and added approximately 140,000 square feet to our manufacturing facility. The expanded facility encompasses 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. As disclosed, however, the Company has voluntarily ceased manufacturing as a result of the FDA action. 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 square foot facility was previously owned and operated by a third party packager of our portfolio of products. As disclosed, however, the Company has voluntarily ceased manufacturing as a result of the FDA action and accordingly operations in this facility have temporarily been suspended.

FDA COMPLIANCE

During Fiscal 2009, the FDA inspected both the Elijah McCoy manufacturing facility and the Farmington packaging facility. Forms FDA 483 were issued at the conclusion of both inspections detailing the FDA investigators' observations. Responses to these observations were submitted to the FDA detailing the Company's actions taken in response to the observations. On October 31, 2008, the Company received a warning letter from the Detroit District of the FDA for its manufacturing facility in Detroit Michigan. In this letter, the Agency reiterated some of the concerns detailed in the previous Form 483 issued as a result of our inspection that concluded in June 2008. These concerns included inadequate and untimely investigations by our quality control unit of certain incidents contrary to the Company's standard operating procedures. The warning letter also stated that the FDA expressed serious concerns regarding "a) your firm's compliance history including several past inspections that documented significant CGMP deficiencies, b) the serious nature of the observed violations, c) your plans for expansion under these violative conditions, and d) the risk to consumers associated with the CGMP deviations involving potential product contamination." The FDA also raised concerns about our corrective action plans. The FDA added that failure to promptly correct the deficiencies may result in legal action without further notice, including, without limitation, seizure and injunction. It also noted that other federal agencies may take this warning letter into account when considering the award of contracts. Additionally, the FDA may withhold approval of requests for export certificates, or approval of pending new drug applications. We promptly responded to the warning letter on November 24, 2008 for the deficiencies noted and provided our corrective actions. The Detroit District acknowledged our response on December 22, 2008. It noted that our corrective actions would be evaluated during the FDA's next scheduled inspection of our Detroit facility. On March 11, 2009 the FDA began an inspection as a follow-up to the October 2008 warning letter. This inspection covered all the quality and production systems of the Company and concluded on May 12, 2009. The FDA investigators provided the Company with a list of their observations on FDA Form 483. Some of the observations were relative to the recent recalls and compliance, whereas others were focused on inventory controls. The FDA's inspection found unresolved violations of current Good Manufacturing Practice (cGMP) requirements as previously disclosed in our last SEC filing on Form 10-K filed June 15, 2009. On March 31, 2009, we recalled all tablets of Digoxin, USP, 0.125 mg, and Digoxin, USP, 0.25 mg, distributed prior to March 31, 2009 to the consumer level. As a precautionary measure, in April 2009, we initiated recalls of certain product lots manufactured in our Detroit, Michigan facility, primarily to the retail and wholesale levels. The total sales revenue, related to these recalls, we believe, is approximately $4.2 million. These recalls were voluntarily initiated by the Company with the knowledge of the FDA. The recalls were made as a precautionary measure. The Company provided a written response to these observations on June 19, 2009. On June 25, 2009, U.S. Marshals, at the request of the FDA, seized drug products manufactured in our Michigan facilities. The seizure also included ingredients held at these same facilities as

well as work in process. Products distributed by Caraco that are manufactured outside of these facilities are not impacted. In its complaint relating to its seizure, the FDA stated, among other things, that the May 12, 2009 inspection and the Company's written response thereto revealed continuing significant cGMP violations. The FDA also stated that the drug products are adulterated in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and/or holding do not conform to and are not operated and administered in conformity with cGMP requirements. As a result of the FDA action, we voluntarily ceased manufacturing operations and instituted an indefinite reduction in our workforce of approximately 430 employees in two phases. This has resulted and will result in a material adverse effect on our current and near term operations.

On September 29, 2009, Caraco voluntarily entered into a Consent Decree with the FDA regarding the Company's drug manufacturing operations. The Consent Decree provides a series of measures that, when satisfied, will permit Caraco to resume manufacturing and distributing those products that are manufactured in its Michigan facilities. The Company is working expeditiously to satisfy the requirements of the Consent Decree and has already retained independent cGMP experts for review of the Company's operations and to facilitate a successful result.

Under terms of the Consent Decree, Caraco's cessation of manufacturing operations will continue until it receives written notification from independent experts and the FDA that it is in compliance with the Consent Decree and regulations and can resume operations. Nothing in the Consent Decree prohibits Caraco from distributing FDA approved drug products that are manufactured by third parties. There is no assurance that the steps taken will be successful or result in resolution of the FDA complaint. We are also not able, at this time, to estimate the cost of these actions. We intend to continue to work with the FDA to resolve its concerns as effectively and expeditiously as possible.

We have not obtained FDA approvals of our ANDAs since the first quarter of Fiscal 2009. It is unlikely that we will receive any approvals for product out of our Michigan facilities until the FDA reviews our remediation response and makes a determination of our status. We have changed our leadership in both manufacturing and quality control in early 2009, in order to better align these areas with our corporate goals and taken other steps, as stated below, to improve cGMP compliance.

Customer confidence could diminish based on the recent recalls and our status with the FDA. As previously disclosed, certain government contracts have been and could be affected by the warning letter and our current status. In the fourth quarter of Fiscal 2009, due to our status with the FDA, the Veterans Administration has not renewed certain product contracts we had with it that were expiring. Once we have resolved our current issues with the FDA, we may regain this business when these contracts come up for renewal, which occurs on an annual basis.

We have engaged a consulting firm which is comprised of cGMP experts in accordance with the Consent Decree. The new leadership in both our quality and production areas are effecting change as rapidly as possible in order to provide continual improvement.

Second Quarter and First Six Months Fiscal 2010 Compared to Second Quarter and First Six Months Fiscal 2009
Net Sales. Net sales for the second quarter and first six months of Fiscal 2010, ended September 30, 2009, were $78.4 million and $126.4 million respectively, as compared to $122.2 million and $230.5 million, respectively, for the second quarter and first six months of Fiscal 2009, reflecting a decrease of 36% and 45% in the respective periods. The sales for both of the periods of Fiscal 2009 included high levels of sales of Paragraph IV products which were launched by the Company during the fourth quarter of Fiscal 2008 under the distribution and sale agreement with Sun Pharma. These product sales may or may not be sustainable, as previously disclosed. The sales of distributed products were also lower due to price erosion on the products sold, partially offset by new product launches. Sales of one product (oxcarbazepine), launched under the marketing agreement during the third quarter of Fiscal 2008 were significantly higher during the first six months of Fiscal 2009. This product was launched with 180 days shared exclusivity, which allowed its higher sales during the first quarter of Fiscal 2009. Subsequent to the end of the exclusivity period, which occurred during the first quarter of Fiscal 2009, the net realizations for this product have decreased significantly as several other competitors have entered the market for this generic product. Sales of Caraco-owned products (those products which Caraco owns the ANDAs) during the second quarter were negligible as we have stopped marketing, effective June 25, 2009, all the products which were being manufactured out of our Michigan facilities on account of the FDA actions, as previously discussed. Similarly, the sales of Caraco-owned products for first six months of Fiscal 2010 were lower due to, the FDA's seizure of certain of our inventory and cessation of manufacturing, as previously disclosed, and in part due to the negative impact of our voluntary recalls of certain products. We did not distribute any digoxin during the period subsequent to the recall of digoxin that occurred on March 31, 2009. We also had a recall on various products on April 17, 2009, as previously disclosed. The subsequent sales on some of those manufactured products were negatively impacted by the recall. Net sales for distributed products were $75.9 million and $110.9 million, respectively, for the second quarter and first six months of Fiscal 2010, as compared to $89.9 million and $166.2 million, respectively, for the corresponding periods of Fiscal 2009. Net sales for Caraco-owned products were $2.5 million and $15.6 million, respectively, for the second quarter and first six months of Fiscal 2010, as compared to $32.2 million and $64.3 million, respectively, for the corresponding periods of Fiscal 2009. We were manufacturing and marketing all except two of our approved products. However, as a result of action taken by the FDA, we have ceased manufacturing operations of the products which we manufacture at our facilities located in the state of Michigan. We continue to have manufacturing products sales that are manufactured by third party manufacturers including Sun Pharma.

Overall sales of one product accounted for approximately 77% and 65% of net sales for the second quarter and first six months of Fiscal 2010 as compared to sales of two products which accounted for approximately 61% and 59% of net sales for the corresponding periods of Fiscal 2009.

Gross Profit. We incurred a gross loss of $4.1 million and $7.7 million, respectively, during the second quarter and first six months of Fiscal 2010, as compared to gross profit of $22.0 million and $45.6 million, respectively, during the corresponding periods of Fiscal 2009. The gross loss in the second quarter and first six months of Fiscal 2010 were, in large part, due to a reserve of $7.5 million and $15.9 million we provided on the inventory seized by the FDA during the respective periods. (See "Inventory" above). The gross profit has also decreased due to negligible sales in the second quarter of Caraco-owned products and lower sales of both distributed as well as Caraco-owned products in the first six months of Fiscal 2010. As disclosed above, due to the actions of the FDA, all shipments of products which were being manufactured at the Company's Michigan facilities have ceased effective June 25, 2009, which has led to diminished sales of Caraco-owned products.

The gross profit margin for the second quarter and first six months of Fiscal 2010 as a percentage of net sales decreased to (5%) and (6%), respectively, as compared to 18% and 20%, respectively, during the corresponding periods of Fiscal 2009. As disclosed above, we have created a reserve in the amount of $7.5 million and $15.9 million, respectively, during the second quarter and first six months of Fiscal 2010 for the inventory seized by the FDA. Excluding the impact of the inventory reserve, the gross profit margins in the second quarter and first six months of Fiscal 2010 were 4% and 6% respectively, as compared to 18% and 20%, respectively, for the corresponding periods of Fiscal 2009. This decrease was 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 9% for both the second quarter and first six months of Fiscal 2010, as compared to 7% and 8% for the corresponding periods of Fiscal 2009. The gross profit margin for Caraco-owned products was (427%) and (113%) for the second quarter and first six months of Fiscal 2010, as compared to 48% and 49% for the corresponding periods of Fiscal 2009. Excluding the impact of the inventory reserves, the gross profit margin in the second quarter and first six months of Fiscal 2010 was (126)% and (10)%, respectively. Caraco-owned product margins have decreased mainly due to impact of overhead absorption, having similar levels of direct overhead in the first quarter and decreased levels in the second quarter, with lower sales for the second quarter and first six months of Fiscal 2010, which contributed 108% and 40%, respectively, to the decreases in gross profit margin. Price erosion on certain products and changes in the sales mix of the Caraco-owned products sold also contributed to the decrease. Also, we had initiated a recall of one product (digoxin) during the fourth quarter of Fiscal 2009. There were no sales of this product during the first six months of Fiscal 2010. The loss of sales of this product also adversely affected the gross profit margins for the referred periods. Further, as disclosed earlier, there were significantly low levels of sales of Caraco-owned products (which included none of the products which were manufactured at the Company's Michigan facilities). Also during the second quarter of Fiscal 2010, we have written off certain non-seized inventories of approximately $0.4 million, partly relating to one DESI product which is being discontinued as stipulated in the Consent Decree, and partly related to products we purchased along with the brand, which have now become obsolete. We cannot determine the mix of distributed product sales versus Caraco-owned 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 2010 were $6.8 million and $10.5 million, respectively, as compared to $4.2 million and $8.1 million, respectively, during the corresponding periods of Fiscal 2009, representing increases of 60% and 30%, respectively. SG&A expenses, as a percentage of net sales increased to 8% for the first six months of Fiscal 2010, as compared to 3% for the corresponding period of Fiscal 2009. The higher percentage of SG&A is partly due to the lower sales in the current period versus the corresponding period last year. Also during the second quarter of Fiscal 2010, the Company recorded additional expenses related to a) severance paid to its former CEO, b) legal and professional consultation fees related to FDA issues and c) payments made to its customers in lieu of contractual unfulfilled product supply obligations.

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Research and Development Expenses. Total R&D expenses incurred for the second quarter and first six months of Fiscal 2010 were $(1.5) million and $5.6 million respectively, as compared to $5.6 million and $11.1 million, respectively, during the corresponding periods of Fiscal 2009. The R&D expenses during the second quarter of Fiscal 2010 were primarily lower compared to those during the corresponding period of Fiscal 2009 as we were reimbursed a certain amount relating to certain product litigation costs, as part of a settlement agreement, as previously disclosed. Also, the R&D costs were lower due to non-incurrence of any major expenses in the second quarter relating to bio-equivalency studies and material costs for development.

Non-Recurring Income. We earned a one-time non-recurring income in the amount of $20.0 million during the second quarter and first six months of Fiscal 2010 arising out of a product litigation settlement and an asset purchase agreement, as previously disclosed.

Net Other Income (Expense). We earned net other income of $33 thousand during the second quarter and incurred net other expense of $0.1 million during the first six months of Fiscal 2010, as compared to earnings of net other income of $0.1 million and $0.4 million, respectively, during the corresponding periods of Fiscal 2009. The lower net other income/expense was primarily due to interest expense incurred in relation to the Company's term loan with Charter One Bank and a loss on removal of certain assets during the first quarter of Fiscal 2010.

Income Taxes. We recorded income tax expense of $3.9 million during the second quarter and provided an income tax benefit of $1.1 million during the first six months of Fiscal 2010, respectively, compared to income tax expense of $3.9 million and $9.0 million, respectively, during the corresponding periods of Fiscal 2009. The benefit in the current six-month period is due to the losses incurred. (See discussion under "Income Taxes" above).

Results of Operations. We earned pre-tax income of $10.6 million during the second quarter of Fiscal 2010 and incurred a net pre-tax loss of $3.9 million during the first six months of Fiscal 2010, as compared to a net pre-tax income of $12.3 million and $26.9 million, respectively, during the corresponding periods of Fiscal 2009. We earned net income of $6.7 million for the second quarter and incurred a net loss of $2.8 million for the first six months of Fiscal 2010, as compared to net income of $8.4 million and $17.9 million, respectively, during the corresponding periods of Fiscal 2009.

Liquidity and Capital Resources We generated cash from operations in the amount of $20.3 million during the first six months of Fiscal 2010, as compared to using cash in operations in the amount of $8.2 million during the corresponding period of Fiscal 2009. The cash flow from operations was lower in the first six months of Fiscal 2009 primarily due to a decrease in accounts payable balances offset, in part, by decreases in accounts receivable and inventory balances. Accounts receivable increased by $33.8 million to $49.0 million as of September 30, 2009, as compared to $15.2 million at the end of Fiscal 2009. Accounts receivable is 59 days sales outstanding ("DSO") as of September 30, 2009 versus 27 days as of March 31, 2009. The lower level in DSO at March 31, 2009 was temporary and is mainly due to the timing of payments made by the wholesale customers. However, a deduction for chargebacks will be made by these wholesale customers as they continue to sell to retail chain stores and managed care organizations with whom we have contractual pricing. The Company believes that it has provided adequate reserves for chargeback deductions which are likely to be taken by the wholesale customers in subsequent periods. Certain wholesale customers purchased quantities of a certain product based on their own forecast, to ensure an in-stock position for such product, as there were uncertainties related to the future availability of such product and continued shipments from the Company. Inventory levels are equivalent to 167 days sales on hand, as compared to 140 days on hand as of March 31, 2009. Excluding the reserve created for inventory seized by FDA, inventory levels were equivalent to 198 days sales on hand. The inventory as of September 30, 2009 includes higher levels of inventory of Paragraph IV products to support anticipated sales in the near term period. At March 31, 2009 we had negligible stock of such product on hand. If the sale of the Paragraph 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. The accounts payable balance relating to Sun Pharma has also increased from $43.9 million at March 31, 2009 to $115.0 million at September 30, 2009 in line with increased levels of inventory relating to distributed products and accounts receivable balances.

As disclosed above the FDA has initiated certain actions and, as a consequence, production at the Company's Michigan facilities has voluntarily been ceased. This will adversely affect the overall profitability of the Company in the near term. The Company has initiated a reduction in various expenses in an effort to bring its expenses in line with its current levels of sales. Such reduction is expected to continue until FDA concerns are resolved and the Company resumes its manufacturing activities, of which there is no assurance. The sales of distributed products and certain manufactured products made by third parties will continue and will contribute to the ongoing cash flows. Also, the Company has recently entered into an agreement with Forest, which, is expected to provide certain additional products to the Company's product portfolio, and such products will generate incremental revenues under Caraco-owned product sales. The Company owns four products that are manufactured by other third party manufacturers including Sun Pharma and its affiliates. As of September 30, 2009, we have $73 million in cash and another $10 million in short-term investments, including the proceeds from a loan in the amount of $17.2 million, currently classified as a short term liability. The Company believes that its cash flow from operations and cash balances will continue to support its ongoing business requirements, however, because of, among other things, decreased customer confidence, the uncertainty of future costs of FDA compliance and associated costs, there can be no assurance.

At September 30, 2009, we had working capital of $93.4 million, compared to working capital of $112.5 million at March 31, 2009.

During the fourth quarter of Fiscal 2009 the Company entered into a term loan of $18 million with Charter One Bank. The loan is secured by a mortgage covering the Company's manufacturing facility and equipment located in Detroit, Michigan. The rate of interest is calculated as LIBOR plus an applicable margin thereto (based upon various leverage levels and current applicable rate is 50 basis points). The aggregate rate applicable to the Company as of September 30, 2009 was 1.5%. The principal loan payments and accrued interest are payable on a quarterly basis beginning July 2009. The principal is to be repaid in equal quarterly installments of $900,000 for ten quarters through October 2011, and thereafter, if not renewed, the remaining balance of $9 million is due in the subsequent quarter by January 2012. Subsequently, the terms of the loan were modified and we entered into an amended agreement. The amended

agreement amended the loan to add to the equipment term loan for the purposes of financing new machinery and equipment and building improvements, a one year line of credit note for $15 million against which the Company can borrow funds for working capital purposes or can get letters of credit issued. The line of credit carries an interest rate of LIBOR plus 150 basis points, and if letters of credit are issued, the associated fees are 0.7% of such letters of credit on annualized basis. Also, there is an unused fee of 0.25% on an annualized basis to the extent the line remains idle. Both the line of credit and outstanding term loan are cross collaterized by all of the Company's fixed assets and cash deposit accounts held with Charter One Bank in the same amount. These cash deposits earn interest at prevailing rates applicable to such money market acoounts. Against this line of credit, the Bank has issued an Irrevocable Standby Letter of Credit in an amount of $15 million, in favor of the United States of America, as required to be placed with the FDA in accordance with the Consent Decree, as disclosed above. We are continuing discussions with Charter One Bank to resolve its concerns and get the cash collateral released. Charter One Bank has temporarily suspended our required compliance with the covenants in the loan agreements relating to FDA enforcement actions as previously disclosed, and has suspended testing of certain other compliance requirements until February 26, 2010. On or before such date, we anticipate either entering into revised agreements or repaying the loan in full. Currently, as the loan is in technical default due to the FDA enforcement action, the entire outstanding balance has been classified as a short-term liability.

As required pursuant to the terms of the Loan Agreement, the Company has entered into an Interest Rate Swap Agreement with Charter One Bank to hedge the interest rate applicable on the loan. The notional amount for the swap is $17.1 million which will continue to amortize down as principal payments are made on the related debt. The annualized fixed rate of interest as it applies to this agreement is 2.41%. Thus as of September 30, 2009 the effective rate of interest to the Company for the term loan was 2.91% (2.41% swap rate plus applicable margin of 50 basis points). The fair value of this swap agreement at September 30, 2009 was not material.

Future Outlook

We intend to continue to work with the FDA to effectively and expeditiously resolve remaining concerns, although there can be no assurance that we will succeed in reaching such a resolution or the terms thereof. We continue to focus on improving support and emphasis on quality assurance, quality control, and manufacturing areas in order to continually improve the performance of our quality system. We have hired external consultants who have experience in assisting manufacturers with FDA compliance issues. These consultants will review all of our systems, procedures, reporting structures, and processes, as well as review training on risk management and overall cGMP. As part of this comprehensive process we will evaluate our internal and external audit programs, and will make any improvements that we believe to be necessary to improve these programs. All audits are based on a historical look back, and offer improvements based on Caraco’s likely future requirements. These audits will also include follow up action on compliance issues that need to be addressed. Caraco would obtain assistance and guidance wherever required from the quality group of Sun Pharma to improve its quality systems. Though near term sales of Caraco-owned products face challenges, we believe we are effecting, and intend to effect, the changes required to improve our performance on sales of these products, on a long-term basis. We voluntarily entered into a Consent Decree with the FDA regarding the Company's drug manufacturing operations. The Consent Decree provides a series of measures that, when satisfied, will permit Caraco to resume manufacturing and distributing those products that are manufactured in its Michigan facilities. We are working expeditiously to satisfy the requirements of the Consent Decree and has already retained independent cGMP experts for review of the Company's operations and to facilitate a successful result.

Under terms of the Consent Decree, Caraco's cessation of manufacturing operations will continue until it receives written notification from independent experts and the FDA that it is in compliance with the Consent Decree and regulations and can resume operations. Nothing in the Consent Decree prohibits Caraco from distributing FDA approved drug products that are manufactured by third parties. There is no assurance that the steps taken will be successful or result in resolution of the FDA complaint. We intend to continue to work with the FDA to resolve its concerns as effectively and expeditiously as possible.

We believe that we will emerge a stronger company on a long-term basis. In the last two years we have added considerable amount of infrastructure in our quality control laboratories. Our current focus remains on manufacturing and quality assurance. In near term we will utilize part of our R&D team to help with technical validations and compliance initiatives. Our R&D expense will decline as a result. We anticipate gaining back our momentum on filings of new ANDAs internally once our compliance initiatives and technical needs are satisfied. Any third party development in process will continue. Our production capacity is primarily built, which should support the business for years to come once we can overcome our current obstacles.

Currently, we have 31 ANDAs pending approval at the FDA (including four tentative approvals) relating to 27 products. We continue to expand and upgrade our facilities, and expand our customer base. Our internal efforts, combined with Sun Pharma in developing new products have also picked up momentum. We now have 10 products, that we market (including Caraco-owned products being manufactured by third parties 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. The total portfolio consists of 33 products.

Although gross profit margins have come down due to mix of distributed products weight over Caraco-owned products, and also due to negligible sales of Caraco-owned products, we believe we can be successful in marketing distributed products and our products that are manufactured by third parties. We have had nine new distributed products launched during the first six months of Fiscal 2010 that Sun Pharma or its affiliates received approvals for from the FDA. We also may transfer certain manufactured products to an alternate manufacturing site that would allow the Company to quickly regain gain revenues from those products. Should the pricing pressures become more severe than anticipated; the result may be lower growth rates and gross margins. Management has worked, 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 increased cost reductions.

The Company intends to decrease its internal development of new products. It will continue to develop products with third parties, including Alkaloida, an indirect subsidiary of Sun Pharma (see “6. Sun Pharmaceutical Industries Limited”) Our R&D expense should decline based on this provided that patent related expenses remain stable or decline. We believe that we will continue to have the cash and other means available to meet our working capital requirements, fund potential litigation expenses relating to Paragraph IV certification and finance further capital investments. The third party product development is a critical element in meeting expectations in the future.

We believe that Sun Pharma is a partner with a proven track record, and one that already has provided the Company with quality products. Moreover, Sun Pharma's increased beneficial ownership in the Company to approximately 75% (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, clinical research services which have significantly helped the Company to date. In addition to the Sun Pharma products agreement, we have implemented additional development strategies with various third parties, both domestically and abroad, that will complement the Sun Pharma's development pipeline and our own.

The FDA's action and the Company's voluntary actions have had, and are expected to continue to have, a material adverse effect on operations and operating results. At September 30, 2009, the Company had $73 million in cash and $10 million in short-term investments including the proceeds from a loan in the amount of $17.2 million. The Company believes that its cash flow from operations and cash balances will continue to support its ongoing business requirements, however, because, among other things, of the uncertainty of future costs of FDA compliance and associated costs, there can be no assurance.

During Fiscal 2007, we 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 we have terminated an agreement earlier entered into with one company for two of these products. During Fiscal 2009, we entered into one agreement for one additional product, and subsequent to end of Fiscal 2009, we entered into one more agreement relating to one additional product. This brings the total number of products being developed by unaffiliated third party developers to six.

We anticipate additional development agreements will be entered into in order to eliminate gaps in our calendar of approvals from the FDA. 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 been marketing two products under this agreement including Pantoprazole sodium DR tablets. 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 Paragraph 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 an 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 effort to expand our product offerings and remain competitive. In this connection, see "6. Sun Pharmaceutical Industries Limited" relating to our products agreement with Alkaloida, an indirect subsidiary of Sun Pharma. 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.

Management's goals for Fiscal 2010 include:

- Compliance with Consent Decree.
- Resumption of manufacturing activities in conformance with FDA guidelines and the Consent Decree.
- Continue research and development activities for ANDA filings.
- Continue to invest in equipment, systems and facilities to meet requirements of projected short and long-term projects for compliance and quality.
- Increase cGMP training to accommodate staff and compliance.
- Increase market share for certain existing products and recently introduced products.
- Enhanced customer reach and satisfaction.
- Leverage distribution and marketing core competencies by marketing third party products through in-licensing agreements.
- Prompt introduction of new approved products to the market.
- Achieving further operational efficiencies by attaining economies of scale and cost reduction per unit.
- Increase revenue and cash by marketing ANDAs owned by Sun Pharma.
- Expand our relationships with financial institutions to fortify our credit position and borrowings as 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) material litigation from product recalls, (xxi) the purported class action lawsuits alleging federal securities laws violations, (xxii) delays in returning the Company’s products to market, including loss of market share, (xxiii) increased reserves against the FDA-seized inventory, and (xxiv) 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 Item 1A hereof and our Annual Report on Form 10-K for the year ended March 31, 2009, 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

Refer to "Item 7A. Quantitative and Qualitative Disclosures About Market Risk" in our Annual Report on Form 10-K for the year ended March 31, 2009 and "11. Debt" above for a discussion of our market risk.

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 2010 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 1A. RISK FACTORS

In addition to the risks set forth in our Form 10-K for the year ended March 31, 2009, the following are additional risks to our business:

The seizure by the FDA of drug products manufactured in our Michigan facilities and other ingredients, and our voluntary cessation of manufacturing operations, have had a material adverse effect on our current operations and are expected to have a material adverse effect on our near term operations.

As a result of the FDA action, we have voluntarily ceased manufacturing operations and instituted an indefinite reduction in our workforce of approximately 430 employees in two phases. The Company voluntarily entered into a Consent Decree with the FDA on September 29, 2009. As stipulated in the Consent Decree, the Company will attempt to have the seized inventory released. The Company believes that, except for the raw materials which were opened solely for the purpose of sampling, the estimated value of which is $8.1 million, all other seized inventory would be difficult to recondition. Accordingly, a reserve in the amount of $15.9 million has been created as of September 30, 2009 for this remaining inventory. As a result of the FDA action, we have voluntarily ceased manufacturing operations and instituted, in two phases, indefinite layoffs of approximately 430 of our employees. The Consent Decree provides a series of measures that, when satisfied, will permit the Company to resume manufacturing and distributing those products which are manufactured in its Michigan facilities. The Company has engaged a consulting firm which is comprised of cGMP experts, in accordance with the Consent Decree.

As a result of this event, there has been a material adverse effect on our current operations and there may be a material adverse effect on our near term operations. Under terms of the Consent Decree, Caraco's cessation of manufacturing operations will continue until it receives written notification from independent experts and the FDA that it is in compliance with the Consent Decree and regulations and can resume operations. However, there is no assurance that the steps being taken will be successful or result in resolution of the FDA complaint. We are also not able, at this time, to estimate, the cost of these actions. We anticipate working with the FDA to resolve its concerns as effectively and expeditiously as possible in accordance with the terms of the Consent Decree. The Consent Decree also requires the Company to abide by certain conditions and restrictions. If the Company violates any portion of the Consent Decree, it could incur penalties, such as monetary fines, forfeiture of the seized goods and other penalties.

Class action lawsuits have been filed against the Company and certain of its executive officers.

The purported class action litigation (See “12. Litigation” above) alleging violations of federal securities laws by the Company and certain of its executives involves claims which, if successful, could adversely affect our financial condition, operating results or cash flows and the market value of our common stock.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITES AND USE OF PROCEEDS

During the first six months of Fiscal 2010, 1,632,000 shares of Series B Preferred Stock previously issued to Sun Global were converted into 1,632,000 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 14, 2009 in Dearborn, Michigan for the purpose of electing three directors for a three-year term expiring in 2012 and upon the election and qualification of their successors.

Director Name	Votes For	Votes Withheld
Dilip S. Shanghvi	31,160,511	1,881,535
Gurpartap Singh Sachdeva	31,576,242	1,465,804

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

Director Name	Term
Jitendra N. Doshi	2011
Sailesh T. Desai	2011
Timothy S. Manney	2010
Madhava Reddy	2010
Sudhir V. Valia	2010
F. Folsom Bell	2012

The Board of Directors appointed F. Folsom Bell to fill the vacancy created by John D. Crissman's decision to not stand for re-election, for a term commencing immediately following the 2009 annual meeting of shareholders and ending immediately following the 2012 annual meeting of shareholders. Mr. Bell, however, resigned as a Director effective immediately prior to the Special Meeting of Shareholders held on October 26, 2009, and was elected by the shareholders at such Special Meeting as a Director to fill the vacancy created by his resignation and to serve for the remainder of the term ending immediately following the 2012 annual meeting of shareholders. As disclosed in the proxy statement relating to the Special Meeting, on August 27, 2009, the Company received a shareholder demand letter demanding that the Company take action against certain officers and directors of the Company to recover certain damages caused by their alleged breach of fiduciary duties relating to the Company's violation of cGMP requirements. The demand letter further provided that if the Board did not commence such an action, the shareholder making the demand would commence a shareholder derivative proceeding on behalf of the Company seeking appropriate relief. As disclosed in such proxy statement, the election of Mr. Bell by shareholders was necessary in order for him to be an 'independent director' under Michigan law who could determine in good faith after conducting a reasonable investigation upon which his conclusions are based as to whether or not the maintenance of the derivative proceeding is in the best interests of the Company. Following his election by shareholders, the Board has authorized Mr. Bell, as a disinterested independent director, to conduct an investigation and make such a determination with respect to the allegations set forth in the demand letter.

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ITEM 6. EXHIBITS

2.01*	Asset Purchase Agreement by and between Forest Laboratories, Inc. and Caraco Pharmaceutical Laboratories, Ltd., dated July 10, 2009, and as amended on September 8, 2009, September 11, 2009 and September 22, 2009.
3.01	Registrant's Articles of Incorporation as of October 26, 2009.
3.02	Registrant's By-laws as of October 26, 2009.
10.24*	Settlement Agreement by and between Forest Laboratories, Inc., H. Lundbeck A/S, Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries Ltd., dated July 10, 2009.
10.25	Separation Agreement and Release of All Claims between Daniel Movens and Caraco Pharmaceutical Laboratories, Ltd., dated July 28, 2009.
10.26	Employment Agreement of Jitendra N. Doshi, dated as of August 31, 2009.
10.27	Agreement with Alkaloida Chemical Company ZRT dated July 10, 2009.
10.28	Indemnification Agreement with F. Folsom Bell dated September 14, 2009.
10.29	Form of Grant of Independent Director's Stock Options.
10.30	Form of Grant of Employee Stock Option.
10.31	First Amendment to Loan Agreement with RBS Citizens, N.A. dated as of August 11, 2009.
10.32	Second Amendment to Loan Agreement with RBS Citizens, N.A. dated as of October 9, 2009.
31.1	Certification of Chief Executive Officer
31.2	Certification of interim Chief Financial Officer.
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Confidential treatment has been requested for portions of this exhibit.

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: November 9, 2009

By: /s/ Jitendra N. Doshi
Jitendra N. Doshi
Chief Executive Officer

Date: November 9, 2009

By: /s/ Mukul Rathi
Mukul Rathi
Interim Chief Financial Officer