CARACO PHARMACEUTICAL LABORATORIES LTD
Form 10-Q
August 10, 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

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
for the transition period from_____ to _____

for the quarterly period ended June 30, 2009

Commission File No. 001-31773

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 ¨

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 ¨

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 ¨ Accelerated Filer x Non- Accelerated Filer ¨ Smaller Reporting Company ¨

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

Yes ¨ No x

As of August 7, 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

	June 30, 2009 (UNAUDITED)	MARCH 31, 2009 (AUDITED)
ASSETS		
Current assets		
Cash and cash equivalents	$ 55,061,829	$ 65,314,397
Short-term investments	10,000,000	—
Accounts receivable, net	7,336,304	15,181,197
Inventories	108,165,831	79,510,832
Prepaid expenses and deposits	9,807,147	9,440,942
Deferred income taxes	3,373,369	416,985
Total current assets	193,744,480	169,864,353
Property, plant and equipment		
Land	975,311	975,311
Buildings and improvements	28,353,101	28,148,447
Equipment	27,496,755	26,216,521
Furniture and fixtures	1,505,540	1,509,582
Construction in progress	2,641,627	2,708,137
Total	60,972,334	59,557,998
Less accumulated depreciation	15,701,181	14,734,961
Net property, plant and equipment	45,271,153	44,823,037
Intangible assets, net	1,358,784	1,383,048
Deferred income taxes	22,486,833	20,417,885
Total assets	$ 262,861,250	$ 236,488,323
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable, trade	$ 3,807,675	$ 7,979,341
Accounts payable, Sun Pharma	84,246,452	43,928,166
Accrued expenses	2,320,936	2,757,361
Long term debt, current portion	18,000,000	2,700,000
Total current liabilities	108,375,063	57,364,868
Long term debt, net of current portion	—	15,300,000

Total liabilities	108,375,063	72,664,868
Stockholders' equity		
Series B convertible preferred stock, no par value; issued and outstanding 2,176,000 shares (June 30, 2009), 2,720,000 shares (March 31, 2009)	18,702,720	23,081,920
Common stock, no par value; authorized 50,000,000 shares, issued and outstanding 38,002,194 shares (June 30, 2009), 37,458,194 shares (March 31, 2009)	122,948,535	118,569,335
Additional paid in capital	3,560,029	3,474,246
Retained earnings	9,274,903	18,697,954
Total stockholders' equity	154,486,187	163,823,455
Total liabilities and stockholders' equity	$ 262,861,250	$ 236,488,323

See accompanying notes

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

	Three months ended June 30,	
	2009 (UNAUDITED)	2008 (UNAUDITED)
Net sales	$48,070,016	$ 108,276,740
Cost of goods sold	51,679,584	84,693,329
Gross (loss) profit	(3,609,568)	23,583,411
Selling, general and administrative expenses	3,659,211	3,818,002
Research and development costs - other	7,085,135	5,484,229
Operating (loss) income	(14,353,914)	14,281,180
Other (expense) income		
Interest expense	(130,950)	-
Interest income	104,455	277,773
Loss on sale of equipment	(114,272)	-
Other income	46,298	-
Other (expense) income - net	(94,469)	277,773
(Loss) income before income tax (benefit) expense	(14,448,383)	14,558,953
Income tax (benefit) expense	(5,025,332)	5,118,888
Net (loss) income	$(9,423,051)	$ 9,440,065
Net (loss) income per common share		
Basic	(0.25)	0.29
Diluted	(0.25)	0.23

See accompanying notes

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

	Three months ended June 30,	
	2009 (UNAUDITED)	2008 (UNAUDITED)
Cash flows from operating activities		
Net (loss) income	$ (9,423,051)	$ 9,440,065
Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities		
Depreciation and amortization	1,116,015	653,053
Loss on sale of equipment	114,272	-
Common stock option expense	85,783	64,605
Common stock grant expense	-	169,900
Net deferred income taxes	(5,025,332)	(825,465)
Changes in operating assets and liabilities which provided / (used) cash:		
Accounts receivable	7,844,893	55,363,710
Inventories	(28,655,000)	68,063,053
Prepaid expenses and deposits	(366,205)	(2,011,847)
Accounts payable	36,146,619	(164,589,253)
Accrued expenses	(436,425)	332,384
Income taxes payable	-	5,944,353
Net cash provided by (used in) operating activities	1,401,569	(27,395,442)
Cash flows from investing activities		
Purchases of property, plant and equipment	(1,654,447)	(5,513,331)
Proceeds from sale of equipment	310	-
Purchase of short-term investment	(10,000,000)	-
Purchases of intangibles	-	(1,100,000)
Net cash used in investing activities	(11,654,137)	(6,613,331)
Cash flows from financing activities		
Proceeds from exercise of stock options	-	11,250
Net cash provided by financing activities	-	11,250
Net decrease in cash and cash equivalents	(10,252,568)	(33,997,523)
Cash and cash equivalents, beginning of period	65,314,397	56,906,051
Cash and cash equivalents, end of period	$ 55,061,829	$ 22,908,528

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	$18,697,954	$ 163,823,455
Conversion of preferred stock into common stock	(544,000)	(4,379,200)	544,000	4,379,200	-	-	-
Common stock options expensed	-	-	-	-	85,783	-	85,783
Net loss	-	-	-	-	-	(9,423,051)	(9,423,051)
Balances at June 30, 2009	2,176,000	$18,702,720	38,002,194	$122,948,535	$3,560,029	$9,274,903	$ 154,486,187

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 August 7, 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 and private-label pharmaceuticals to the nation's largest wholesalers, distributors, warehousing and non-warehousing chain drugstores and managed care providers, throughout the U.S.

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

Our present product portfolio includes 32 prescription products, in 78 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. 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

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 June 30, 2009 was $22.9 million. The Company is in the process of negotiating with the FDA to ascertain how much of such inventory it will be allowed to recondition and utilize in the future. The FDA 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 current good manufacturing practice ("cGMP") requirements. Products sold and distributed by Caraco that are manufactured outside of these facilities are not impacted. As a result of the FDA action, we have voluntarily ceased manufacturing operations and instituted an indefinite reduction in our workforce of approximately 350 employees. As a result of this event, there has been a material adverse effect on our current operations and may be a material adverse effect on our near term operations. While we believe that we have taken corrective actions and that continual improvements are in process in response to past FDA observations from past inspections as disclosed in our prior SEC filings, we also believe that we may need to take additional steps to correct our methods, facilities and controls used to manufacture, process, pack, label, hold and distribute pharmaceutical products which are manufactured at our Michigan facilities. 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 anticipate working with the FDA to resolve its concerns as effectively and expeditiously as possible.

During the first quarter of our new fiscal year ("Fiscal 2010") ended June 30, 2009, we generated net sales of $48.1 million compared to $108.3 million during the corresponding period of Fiscal 2009. We incurred $7.1 million in research and development ("R&D") expenses during the first quarter of Fiscal 2010, as compared to $5.5 million during the corresponding period of Fiscal 2009. We generated cash from operations in the amount of $1.4 million during the first quarter of Fiscal 2010, as compared to using cash from operations in the amount of $27.4 million during the corresponding period of Fiscal 2009. We incurred a net pre-tax loss of $14.4 million during the first quarter of Fiscal 2010, as compared to net pre-tax income of $14.6 million during the corresponding period of Fiscal 2009. Net pre-tax income was lower as we have created a reserve in the amount of $8.4 million at June 30, 2009 relating to the inventory seized by the FDA, as mentioned above. During the first quarter of Fiscal 2010, we provided for an income tax benefit of $5.0 million, as compared to an income tax expense of $5.1 million in the corresponding period of Fiscal 2009. We incurred a net loss of $9.4 million during the first quarter of Fiscal 2010, as compared to net income of $9.4 million during the corresponding period of Fiscal 2009. At June 30, 2009, we had stockholders' equity of $154.5 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 did not file any Abbreviated New Drug Applications ("ANDAs") with the FDA during the first quarter of Fiscal 2010. We have not received FDA approval for any ANDAs during the first quarter of Fiscal 2010 and do not expect to receive any approvals for products out of our Detroit facility until we resolve the FDA's concerns as discussed above. The total number of ANDAs pending approval by the FDA as of June 30, 2009 was 29 (including four tentative approvals) relating to 25 products.

4. RECENT ACCOUNTING PRONOUNCEMENTS

In May 2009, the FASB issued SFAS No. 165, "Subsequent Events" ("SFAS 165"), which 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. SFAS 165 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 July 2009, the FASB issued SFAS No. 168, "FASB Accounting Standards Codification" ("SFAS 168"), as the single source of authoritative nongovernmental U.S. generally accepted accounting principles ("GAAP"). The Codification is effective for interim and annual periods ending after September 15, 2009 and will become effective for the Company beginning with its quarterly period ending September 30, 2009. All existing accounting standards are superseded as described in SFAS 168. All other accounting literature not included in the Codification is non-authoritative. The Company is currently evaluating the impact of the adoption of SFAS 168 but does not expect the adoption of SFAS 168 to have a material impact on the Company's results of operations, financial position or cash flows.

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 first quarter of Fiscal 2010, ended June 30, 2009, were both 37,547,864. Correspondingly, the basic and diluted weighted average numbers of common shares outstanding for the first quarter of Fiscal 2009, ended June 30, 2008, were 32,677,391 and 40,536,369, respectively.

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.

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 nine directors of Caraco are, or were, affiliated with Sun Pharma.

Further, Sun Pharma and its affiliates may use Caraco as a contract manufacturer and/or distributor of their products. In December 2004 and January 2005, Caraco entered into agreements for two such products, of which one is currently being marketed.

During 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 ("Para IV") products may face litigation challenges with respect to

claims of patent infringement. Under the agreement the Company shares in the sales opportunity and shares the litigation risk. The Company is indemnified by Sun Pharma of any risk beyond the percentage agreed to as its profit percentage thereby limiting the Company's exposure. Sun Pharma is not obligated to offer Caraco products under this agreement, however, Caraco has the exclusive right to market in the U.S., its territories and possessions, including Puerto Rico, any products offered by Sun Pharma and accepted by Caraco. The 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 quarters ended June 30, 2009 and June 30, 2008, the Corporation made net sales of $35.0 million and $76.2 million of the marketed products under aforesaid agreements, respectively.

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 quarter of Fiscal 2010, Sun Global converted 544,000 shares of Series B Preferred Stock into 544,000 shares of Common Stock and subsequent to the end of first quarter Fiscal 2010, Sun Global converted 1,088,000 shares of Series B Preferred Stock into 1,088,000 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 Statement of Financial Accounting Standards ("SFAS") No. 123 (Revised 2004), "Share-Based Payment" ("Statement No. 123 (R)"), which requires employee share-based compensation to be accounted for under the fair value method and requires the use of an option pricing model for estimating the fair value of stock options at the date of grant. The Company estimates the fair value of stock options granted using the Black-Scholes option-pricing model, which requires the Company to estimate the expected term of the stock option grants and expected future stock price volatility over the term. The term represents the expected period of time the Company believes the options will be outstanding based on historical information. Estimates of expected future stock price

volatility are based on the historical volatility of the Company's common stock. The Company calculates the historical volatility as the standard deviation of the differences in the natural logarithms of the weekly stock closing price, adjusted for dividends and stock splits.

For the first quarter of Fiscal 2010, the Company has recognized expenses amounting to $85,783 related to common stock options as compared to $64,605 for the corresponding period of Fiscal 2009. As of June 30, 2009, total unrecognized compensation cost related to stock options granted was $423,497. The unrecognized stock option compensation cost is expected to be recognized over a period of approximately three years. 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 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 quarter of Fiscal 2010. We issued 1,000 shares of common stock to our employees upon exercise of their stock options during the first quarter of Fiscal 2009. Also, during the first quarter of Fiscal 2009, the Company issued a stock grant of 10,000 common shares to its CEO on May 2, 2008, as noted above.

During the first quarter of Fiscal 2010, Sun Global converted 544,000 shares of Series B Preferred Stock into 544,000 shares of Common Stock. Subsequent to the end of the first quarter of Fiscal 2010, Sun Global converted 1,088,000 shares of Series B Preferred Stock into 1,088,000 shares of Common Stock. (See "Part II – Other Information: Item 2. Unregistered Sales of Equity Securities and Use of Proceeds" below).

9. PREFERRED STOCK ISSUANCES

No shares of preferred stock were issued during the first quarters ended June 30, 2009 or June 30, 2008.

10. SALES AND CUSTOMERS

Sales on distributed products were significantly lower in comparison to the first quarter of Fiscal 2009 primarily as a result of significantly higher sales of Para IV product during the first quarter of Fiscal 2009. See "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations – First Quarter Fiscal 2010 Compared to First Quarter Fiscal 2009." Sales on distributed products were also lower due to price erosion on the products sold. Otherwise, sales on distributed products remain fairly stable and we continue to remain competitive on distributed products we have sold and marketed during the first quarter of Fiscal 2010. However, during the quarter, sales of our manufactured products were adversely affected due to the negative impact of our voluntary recalls and, in part, by the actions of the FDA and the cessation of manufacturing, as disclosed above. 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 first quarter of Fiscal 2010, the Company's three largest wholesale customers, Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health, accounted for

approximately 10%, 10% and 8%, respectively, of the Company's total net sales. During the corresponding period of Fiscal 2009, shipments to Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health, accounted for approximately 6%, 20% and 9%, respectively, of the Company's total net sales. 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 first quarter of Fiscal 2010, sales to CVS Caremark Corporation accounted for approximately 38% of our net sales. The sales to CVS Caremark Corporation have increased as we have recently entered into a new contract with it.

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 the 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 quarter ended June 30, 2009. 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. 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 June 30, 2009 was 2.01%. 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 January 2012. Subsequent to the end of first quarter Fiscal 2010, Charter One Bank has issued a technical default letter to the Company because of the FDA actions. We have entered into discussions with Charter One Bank to resolve its concerns. We anticipate either entering into revised agreements or repaying the loan in full. Currently, as the loan is in default, 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 $18 million which will 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 June 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 June 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. The Company has filed a motion for summary judgment of non-infringement, which has been stayed pending resolution of its supplemented answer and counterclaim challenging Novo Nordisk's recent Orange Book use code amendment by Novo Nordisk in reference to Prandin®. Trial should occur in the fall of 2009.

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. As part of that 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 will reimburse the Company for a portion of its attorney's fees related to this litigation.

3. Forest Laboratories, Inc. and the Company have entered into an Asset Purchase Agreement (the "APA"). Under the APA, the Company will take over the commercialization and sale of several products from Forest's Inwood business. Caraco will pay Forest an advance against royalties and royalties on net sales of these products.

The terms of the settlement have been submitted to the Federal Trade Commission and the Department of Justice pursuant to the Medicare Modernization Act. The APA is scheduled to close no sooner than 40 days after receipt of the documents by the FTC and DOJ, which the parties hope will provide the agencies with sufficient time to review the transaction. As the transaction must be submitted to the FTC and DOJ, there is a possibility that the transaction may need to either be revised, or it may not be consummated, and the litigation would be re-instituted.

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 has been fully briefed and was argued on July 7, 2009.

As previously disclosed, on February 24, 2009, MedImmune, LLC filed a complaint against the Company and Sun Pharma in the United States District Court for the District of Maryland. The complaint alleged that Caraco infringed U.S. Patent Nos. 5,424,471 and 5,591,731 by offering to sell or selling a generic version of the drug Ethyol® in the United States. The Company denied infringement and contended that the patents in suit are invalid and unenforceable. The Complaint is related to MedImmune Oncology, Inc. v. Sun Pharmaceuticals Industries Ltd., 1:04-cv-02612-MJG, which involves the same patents. Effective July 31, 2009, MedImmune, LLC, Sun Pharma, and the Company, entered into a Settlement and License Agreement (the "Settlement") to resolve this litigation. Under the Settlement, MedImmune granted Sun Pharma and its affiliates (including Caraco) a license to continue to market a generic version of Ethyol®. The terms of the settlement have been submitted to the Federal Trade Commission and the Department of Justice pursuant to the Medicare Modernization Act.

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.

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 June 30, 2009 was $22,939,316. 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 has also been filed with the court by the FDA. The Complaint alleges 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. This has resulted and will result in a material adverse effect on our current and near term operations. While we believe that we have taken corrective actions and that improvements are in process in response to past FDA observations from past inspections as disclosed in our prior SEC filings, we also believe that we may need to take additional steps to correct our methods, facilities and controls used to manufacture, process, pack, label, hold and distribute pharmaceutical products which are manufactured at our Michigan facilities. 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.

On July 17, 2009 and July 23, 2009, two purported class action lawsuits were filed in the United States District Court – 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. The Company believes the allegations to be without merit and intends to vigorously defend itself.

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:

	June 30, 2009	March 31, 2009
Raw materials	$ 19,701,349	$17,954,511
Goods in transit	14,024,648	29,236,869
Work in process	7,093,064	9,279,009
Finished goods (Manufactured)	10,194,512	9,749,721
Finished goods (Distributed)	65,598,792	13,290,722
Inventories before reserves	$ 116,612,365	$79,510,832
Less : Reserve for certain inventory under control of the FDA	8,446,534	-
Total Inventories	$ 108,165,831	$79,510,832

Total inventories at June 30, 2009 and March 31, 2009 includes materials purchased in the amount of $1,412,701 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 25th, 2009, at the direction of the FDA, the U.S. Marshal Service, arrived and seized drug products manufactured, work in process, and ingredients held, at the Company's Michigan facilities. The estimated value of such seized inventory as of June 30, 2009 was $22.9 million. The Company is in the process of negotiating with the FDA to ascertain how much of such inventory it will be allowed to recondition and utilize in the future. A reserve in the amount of $8.4 million has been created as of June 30, 2009 which consists of work in process relating to those materials which are in various stages of production within our manufacturing facilities, finished goods having a shelf life of one year or less as of June 30, 2009, and those products which will be difficult to recondition. Once we have further understanding and clarity from the FDA on the status of the entire inventory, we will make a determination of whether adjustments to the reserve need to be made. There is no assurance as to the amount of inventory which the Company will be able to recondition and distribute in future. In the event that the amount of inventory which the Company is unable to recondition is greater than the current reserve, 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:

	Quarter Ended	
	June 30, 2009	June 30, 2008
Current	$-	$5,944,353
Deferred	(5,025,332)	(825,465)
Total	$(5,025,332)	$5,118,888

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 quarters of Fiscal 2010 and Fiscal 2009, respectively, are as follows:

	June 30, 2009	June 30, 2008
Provision for income taxes at federal statutory rate	$ (5,056,934)	$ 5,095,634
Permanent items and other	31,602	23,254
Income taxes	$ (5,025,332)	$ 5,118,888

Deferred taxes consist of the following:	June 30, 2009	March 31, 2009
Deferred tax assets:		
Net operating loss carryforwards	$ 2,067,668	$ 797,631
Intangibles	25,856,468	26,458,255
Reserve for inventory	2,956,383	-
Other	416,986	417,136
Total deferred tax assets	$ 31,297,505	$ 27,673,022
Deferred tax liabilities:		
Intangibles	$ 4,635,740	$ 6,180,987
Depreciation	801,563	657,165
Total deferred tax liabilities	$ 5,437,303	$ 6,838,152
Net deferred tax assets	$ 25,860,202	$ 20,834,870

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15. SEGMENT INFORMATION

The Company operates in two reportable segments consisting of products that it manufactures on its own, as well as those distributed under various agreements with Sun Pharma and its affiliates and with others. The sales and gross profits earned on these categories of products are as follows

	Quarter Ended June 30, 2009		Quarter Ended June 30, 2008	
Category	Net Sales	Gross Profit	Net Sales	Gross Profit
Manufactured Products	$13,081,187	$(6,892,214)	$32,035,365	$16,387,861
Distributed Products	34,988,829	3,282,646	76,241,375	7,195,550
Total	$48,070,016	$(3,609,568)	$108,276,740	$23,583,411

16. SUBSEQUENT EVENTS

Settlement Agreement

As disclosed under “12. Litigation” above, on July 10, 2009, Caraco entered into a settlement agreement ("Settlement Agreement") with Forest and Sun Pharma, regarding the pending patent litigation arising from the filing by Caraco of an ANDA application to market a generic version of Forest's Lexapro® brand escitalopram oxalate product. As part of the Settlement Agreement, Caraco and Forest entered into an Asset Purchase Agreement dated July 10, 2009. Under the Asset Purchase Agreement, Caraco will take over the commercialization and sale of several products from Forest's Inwood business. Caraco's rights to market the products are subject to certain restrictions on its commercialization of competing products. The closing of the transaction is subject to the satisfaction or waiver of certain conditions as specified in the Asset Purchase Agreement, as disclosed under “12. Litigation” above, including the review of the transaction by the FTC and DOJ. Accordingly, there is a possibility that the transaction may either be revised or not consummated.

Agreement With Alkaloida Chemical Company ZRT

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 comprised of Caraco's four independent directors.

MedImmune Settlement

As disclosed under “12. Litigation” above, effective July 31, 2009, MedImmune, LLC, Sun Pharma, and the Company, entered into a Settlement and License Agreement (the “Settlement”) to resolve certain litigation. Under the Settlement, MedImmune grants, in exchange for certain payments, to Sun Pharma and its affiliates (including Caraco), a license to continue to market a generic version of MedImmune’s drug product Ethyol®.

The foregoing descriptions of the Settlement Agreement, Asset Purchase Agreement, agreement with Alkaloida and the MedImmune Settlement do not purport to be complete and are qualified in their entirety by reference to the text of such agreements, copies of which Caraco intends to file with its Quarterly Report on Form 10-Q for the quarter ending September 30, 2009, requesting confidential treatment for certain portions.

ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provides information that management believes is relevant to an understanding of the Corporation’s results of operations and financial condition. The discussion should be read in conjunction with the financial statements and notes thereto and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in the Company’s 2008 Annual Report on Form 10-K as of and for the year ended March 31, 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 first quarter of Fiscal 2010 were $82.4 million as compared to $180.1 million for the corresponding period of Fiscal 2009. Sales allowances, which include chargebacks, returns, discounts, other customary customer deductions and other sales costs, constituted approximately 42% for the first quarter of Fiscal 2010 as compared to 40% for the corresponding period of Fiscal 2009. Net sales for the first quarter of Fiscal 2010 were $48.1 million as compared to $108.3 million for the corresponding period of Fiscal 2009. The primary cause of the increased sales allowances by 2% for first quarter Fiscal 2010 is due to the impact of the increased difference 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 three 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 three months of Fiscal 2010					
Chargebacks, rebates & shelf stock adjustments	$50,028	$32,022	-0-	$36,345	$45,705
Returns and other allowances	6,555	2,263	-0-	4,056	4,762
Doubtful Accounts	78	-0-	-0-	-0-	78

Short-Term Investments

During the quarter ended June 30, 2009 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 June 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 June 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 $24,000 in amortization expense in the first quarter of Fiscal 2010, bringing the total accumulated amortization related to these intangible assets to $97,000 as of June 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 $25.9 million and $20.8 million at June 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 an income tax benefit of $5.0 million for the first quarter of Fiscal 2010 as compared to income tax expense of $5.1 million during the first quarter of Fiscal 2009. The income tax benefit for first quarter 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 June 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 June 30, 2009, we had federal NOLs of approximately $5.9 million, out of which $2.3 million are restricted by limitations of Internal Revenue Code Section 382, available to reduce future taxable income. The NOLs will expire between 2010 and 2025.

The Company is subject to U.S. federal income tax as well as income tax in certain state jurisdictions. The Company had not previously been a subject of an IRS examination however, as previously disclosed, the IRS has initiated an examination of the Company's tax return for the fiscal year ended March 31, 2007. The Company believes that it has complied with applicable IRS Codes and regulations, 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 25th, 2009, at the direction of the FDA, the U.S. Marshal Service, arrived and seized drug products manufactured, work in process, and ingredients held, at the Company's Michigan facilities. The estimated value of such seized inventory as of June 30, 2009 was $22.9 million. The Company is in the process of negotiating with the FDA to ascertain how much of such inventory it will be allowed to recondition and utilize in the future. A reserve in the amount of $8.4 million has been created as of June 30, 2009 which consists of work in process relating to those materials which are in various stages of production within our manufacturing facilities, finished goods having a shelf life of one year or less as of June 30, 2009, and those products which will be difficult to recondition. Once we have further understanding and clarity from the FDA on the status of the entire inventory, we will make a determination of whether adjustments to the reserve need to be made. There is no assurance as to the amount of inventory which the Company will be able to recondition and distribute in future. In the event that the amount of inventory which the Company is unable to recondition is greater than the current reserve, 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

On June 25, 2009, U.S. Marshals, at the request of the U. S. Food and Drug Administration ("FDA"), arrived and seized drug products manufactured in our Michigan facilities. The seizure also included ingredients and work in process held at these same facilities. The estimated value of such inventory was $22.9 million. The FDA 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 current good manufacturing practice ("cGMP") requirements. Products sold and distributed by Caraco that are manufactured outside of these facilities are not impacted. As a result of the FDA action, we have voluntarily ceased manufacturing operations and instituted an indefinite reduction in our workforce of approximately 350 employees. This has resulted and may result in a material adverse effect on our current and near term operations. While we believe that we have taken corrective actions and that continual improvements are in process in response to past FDA observations from past inspections as disclosed in our prior SEC filings, we also believe that we may need to take additional steps to correct our methods, facilities and controls used to manufacture, process, pack, label, hold and distribute pharmaceutical products which are manufactured at our Michigan facilities. 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.

During the first quarter of our new fiscal year ("Fiscal 2010") ended June 30, 2009, we generated net sales of $48.1 million compared to $108.3 million during the corresponding period of Fiscal 2009. We incurred $7.1 million in research and development ("R&D") expenses during the first quarter of Fiscal 2010, as compared to $5.5 million during the corresponding period of Fiscal 2009. There were no non-cash R&D expenses incurred during the first quarter of Fiscal 2010 or during the corresponding period of Fiscal 2009. We generated cash from operations in the amount of $1.4 million during the first quarter of Fiscal 2010, as compared to using cash from operations in the amount of $27.4 million during the corresponding period of Fiscal 2009. We incurred a net pre-tax loss of $14.4 million during the first quarter of Fiscal 2010, as compared to net pre-tax income of $14.6 million during the corresponding period of Fiscal 2009. Net pre-tax income was lower as we have created a reserve in the amount of $8.4 million at June 30, 2009 relating to the inventory seized by the FDA, as mentioned above. During the first quarter of Fiscal 2010, we provided for an income tax benefit of $5.0 million, as compared to an income tax expense provision of $5.1 million in the corresponding period of Fiscal 2009. We incurred a net loss of $9.4 million during the first quarter of Fiscal 2010, as compared to net income of $9.4 million during the corresponding period of Fiscal 2009. At June 30, 2009, we had stockholders' equity of $154.5 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. This acquisition has already lowered our overall costs in packaging and bottling and has increased our production.

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 have voluntarily ceased manufacturing operations and instituted an indefinite reduction in our workforce of approximately 350 employees. This has resulted and will result in a material adverse effect on our current and near term operations. While we believe that we have taken corrective actions and that continual improvements are in process in response to past FDA observations from past inspections as disclosed in our prior SEC filings, we also believe that we may need to take additional steps to correct our methods, facilities and controls used to manufacture, process, pack, label, hold and distribute pharmaceutical products which are manufactured at our Michigan facilities. In this connection, the Company has recently engaged an additional third-party consulting group to enhance our cGMP processes and quality systems. 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 Detroit facility 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 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 continue to focus on improving the the performance of our quality system. This support is derived from the improvement of systems, training on risk management and cGMP, while investing in more automation for improved quality with less human intervention. During Fiscal 2008 and Fiscal 2009, in addition to our own internal audits, we have retained outside companies to audit both the laboratory and manufacturing areas of our Company. The auditors are focusing in detail on compliance concerns noted in our most recent correspondence with the FDA. We also have, and will continue to, provide external training to our employees as a supplement to our internal training in order to improve and or maintain our systems of operation. All audits are based on both retrospective and prospective improvements based on Caraco's future requirements. We continue to gain support from Sun Pharma, in both quality systems and personnel, in the areas of quality and manufacturing. Further we have changed the leadership in both our quality and production areas in order to better align these areas with our corporate goals of compliance and quality. The new teams in these areas are affecting change as rapidly as possible in order to provide continual improvement. We have focused our attention for continual improvement on of our Corrective and Preventative Actions and cGMP. The Company continues to look back historically for any issues or concerns to ensure we remain compliant. Consultants are currently working to identify and any remaining gaps. Our manufacturing personnel are going through more rigorous training at the time of hire, and continually thereafter, in order to maintain our compliance and quality.

First Quarter Fiscal 2010 Compared to First Quarter Fiscal 2009

Net Sales. Net sales for the first quarter of Fiscal 2010, ended June 30, 2009, were $48.1 million, as compared to $108.3 million for the first quarter of Fiscal 2009, reflecting a decrease of 56%. The sales for the first quarter of Fiscal 2009 included high levels of sales of Para 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 quarter of Fiscal 2009. This product was launched with 180 days shared exclusivity, which allowed its higher sales during the period. 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. The manufactured products sales in the first quarter of Fiscal 2010 were lower due to the negative impact of our voluntary recalls of certain products, and, in part, the FDA's seizure of certain of our inventory and cessation of manufacturing, as previously disclosed. 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 $35.0 million for the first quarter of Fiscal 2010, as compared to $76.2 million for the corresponding period of Fiscal 2009. Net sales for manufactured products were $13.1 million for the first quarter of Fiscal 2010, as compared to $32.0 million for the corresponding period 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 46% of net sales for the first quarter of Fiscal 2010 as compared to sales of two products which accounted for approximately 57% of net sales for the first quarter of Fiscal 2009.

Gross Profit. We incurred a gross loss of $3.6 million during the first quarter of Fiscal 2010, as compared to gross profit of $23.6 million during the corresponding period of Fiscal 2009. The gross loss in the first quarter of Fiscal 2010 was due to a reserve of $8.4 million we provided on the inventory seized by the FDA. (See "Inventory" above). The gross profit has also decreased due to lower sales of both distributed as well as manufactured products, as disclosed above.

The gross profit margin for the first quarter of Fiscal 2010 as a percentage of net sales decreased to (8%), as compared to 22% during the corresponding period of Fiscal 2009. Excluding the impact of the inventory reserve, the gross profit margin in the first quarter of Fiscal 2010 was 10% as compared to 22% for the corresponding period 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 the first quarter of Fiscal 2010, as compared to 9% for the corresponding period of Fiscal 2009. The gross profit margin for manufactured

products was (53%) for the first quarter of Fiscal 2010, as compared to 51% for the corresponding period of Fiscal 2009. Excluding the impact of the inventory reserves, the gross profit margin in the first quarter of Fiscal 2010 was 12%. Manufactured product margins have decreased mainly due to impact of overhead absorption, having maintained similar levels of direct overhead with lower sales for the first quarter of Fiscal 2010, which contributed 26% to the decrease in gross profit margin. Price erosion on certain products and changes in the sales mix of the manufactured 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 quarter of Fiscal 2010. The loss of sales of this product also adversely affected the gross profit margins for the quarter. We can not determine the mix of distributed product sales versus manufactured product sales in any given period as it depends on our ability to gain market share on each product and is relative to when the FDA approves any given product in either category of product and the revenue potential of that product once it has been approved.

Selling, General and Administrative Expenses. Selling, general and administrative ("SG&A") expenses during the first quarter of Fiscal 2010 were $3.7 million, as compared to $3.8 million during the corresponding period of Fiscal 2009, representing a decrease of 4%. SG&A expenses, as a percentage of net sales increased to 8% for the first three months of Fiscal 2010, as compared to 4% for the corresponding period of Fiscal 2009. The higher percentage of SG&A is primarily due to the lower sales in the current period versus the corresponding period last year.

Research and Development Expenses. Total R&D expenses for the first quarter of Fiscal 2010 were $7.1 million, as compared to $5.5 million during the corresponding period of Fiscal 2009. The R&D expenses during the first quarter of Fiscal 2010 were higher compared to those during the corresponding period of Fiscal 2009 as we incurred increased expenses relating to bio-equivalency studies for certain products under development. We have also incurred increased patent related expenses in an effort to expand our product portfolio.

Net Other Expense. We incurred net other expense of $0.1 million during the first quarter of Fiscal 2010, as compared to net other income of $0.3 million during the corresponding period 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 current period.

Income Taxes. We recorded an income tax benefit of $5.0 million during the first quarter of Fiscal 2010, compared to an income tax expense of $5.1 million during the corresponding period of Fiscal 2009. The benefit in the current period is due to the losses incurred. (See discussion under "Income Taxes" above).

Results of Operations. We incurred a net pre-tax loss of $14.4 million during the first quarter of Fiscal 2010, as compared to a net pre-tax income of $14.6 million during the corresponding period of Fiscal 2009. We incurred a net loss of $9.4 million for the first quarter ended June 30, 2009, as compared to net income of $9.4 million for the three-month period ended June 30, 2008.

Liquidity and Capital Resources We generated cash from operations in the amount of $1.4 million during the first quarter of Fiscal 2010, as compared to using cash in operations in the amount of $27.4 million during the corresponding period of Fiscal 2009. The cash flow from operations was lower in the first quarter 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 decreased by $7.8 million to $7.3 million as of June 30, 2009, as compared to $15.2 million at the end of Fiscal 2009. Accounts receivable is 14 days sales outstanding ("DSO") as of June 30, 2009 versus 27 days as of March 31, 2009. The lower level in DSO is temporary and is mainly due to the timing of payments made by the wholesale customers and lower sales in the period. 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. Further, the accounts receivable balances are low as we have received payment from a certain wholesale customer which were not due at June 30, 2009. Inventory levels are equivalent to 205 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 221 days sales on hand. The inventory as of June 30, 2009 includes higher levels of inventory of Para 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 Para IV products are not allowed by any regulatory authority and Sun Pharma does not file a timely appeal, we would have various rights to return the product to Sun Pharma.

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, if it is consummated, is expected to provide certain additional products to the Company's product portfolio (see "16. Subsequent Events-Asset Purchase Agreement," and such products will generate incremental revenues under manufactured product sales manufactured by third parties. The Company has four manufactured products that are manufactured by other third party manufacturers including Sun Pharma and its affiliates. As of June 30, 2009, we have $55 million in cash and another $10 million in short-term investments (excluding borrowings). 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 June 30, 2009, we had working capital of $85.4 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 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 June 30, 2009 was 2.01%. 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 January 2012. Subsequent to the end of first quarter Fiscal 2010, Charter One Bank has issued a technical default letter to the Company because of the FDA actions. We have entered into discussions with Charter One Bank to resolve its concerns. We anticipate either entering into revised agreements or repaying the loan in full. Currently, as the loan is in default, 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 $18 million which will 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 June 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 June 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. Sun Pharma has provided assistance and guidance from its own corporate quality group. It also continues to provide improvements for our quality systems. Though near term sales of manufactured products face challenges, we believe we are effecting, and intend to effect, the changes required to improve our performance on manufactured product sales, on a long-term basis. Though we have made considerable improvements in our quality systems, we still have improvements to implement and measure as part of our continual improvement process. We expect to work with the FDA effectively and expeditiously to resolve remaining concerns. 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 to be 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. 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 R&D expense will decline as a result. 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 29 ANDAs pending approval at the FDA (including four tentative approvals) relating to 25 products. We continue to expand and upgrade our facilities, attract and hire talented individuals and expand our customer base. Our internal efforts, combined with Sun Pharma in

developing new products have also picked up momentum and this should permit us to grow at the level of our guidance as provided below. We now have 10 products, that we market (including our own manufactured products and those distributed under various agreements with of Sun Pharma), whose market share is ranked third or higher against the same products of our generic competitors. We are focused on products that are currently in our portfolio and are yet to realize their full market potential. The total portfolio consists of 32 products.

Although gross profit margins have come down due to mix of distributed products weight over manufactured products, we believe we can be successful in marketing distributed products and manufactured products that are manufactured by third parties. We have had five new distributed products launched during the first quarter of Fiscal 2010 that Sun Pharma or its affiliates received approvals for from the FDA. Subsequent to the first quarter of Fiscal 2010, Sun has had two more distributed products approved by the FDA which are being marketed and added to our portfolio of products. We also may transfer certain manufactured products to an alternate manufacturing site that could allow the Company to gain revenue from those products in less than six months. 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 “16. Subsequent Events-Agreement with Alkaloida Chemical Company ZRT) 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 June 30, 2009, the Company had $55 million in cash and $10 million in short-term investments (excluding borrowings). 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. While increased distributed products may lower our overall gross profit margins, we do not have any of the associated costs other than routine marketing costs including freight, carrying costs, and actual purchase price. Ultimately, the sales of distributed products lower the SG&A as a percentage of sales. These agreements should provide for an alternate stream of products that will complement our internal research and development and our outsourced development. From time to time significant product launches such as we incurred under the distribution and sale agreement for Para IV products in Fiscal 2008 may occur that will add near term growth that may or may not be sustainable in future periods. Additionally we will continue to work with Sun Pharma in 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 “16. Subsequent Events” relating to our products agreement with Alkoida, 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.

Management’s goals for Fiscal 2010 include:

Correcting outstanding issues related to FDA compliance.

Resumption of manufacturing activities in conformance with FDA guidelines and negotiations with the FDA.

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 project 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 MARKETRISK

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 first 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 350 employees. While we believe that we have taken corrective actions and that improvements are in process in response to past FDA observations from past inspections as disclosed in our prior SEC filings, we also believe that we will need to take additional steps to correct our methods, facilities and controls used to manufacture, process, pack, label, hold and distribute pharmaceutical products which are manufactured at our Michigan facilities. There is no assurance that the steps taken will be successful or result in resolution of the FDA complaint. In connection with such FDA action, we have engaged an additional third-party consultant on FDA matters and FDA counsel. We are not able, at this time, to estimate, the cost of these actions or any costs associated with additional remedial action which may be required by the FDA or any fines or penalties which may be assessed, which could be material.

Notwithstanding our voluntary actions, the FDA may take further enforcement action against the Company, which could include administrative action, civil enforcement by means of judicial proceedings and criminal prosecution of the Company or individuals. Such action might result in fines or penalties or the imposition of operating restrictions on the Company's business.

The Company is unable to determine how long it will take to resolve its problems with the FDA or the long-term effect on its financial position of any significant delays in returning the Company's manufactured products to market, including loss of market share as a result of the suspension of shipments.

The value of the seized inventory is $22.9 million. We have provided for a reserve against such inventory in the amount of $8.4 million. There is no assurance that such reserve is sufficient and that additional amounts may have to be reserved, which amounts may be material.

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 quarter of Fiscal 2010, 544,000 shares of Series B Preferred Stock previously issued to Sun Global were converted into 544,000 shares of Caraco common stock and issued to Sun Global. Subsequent to the end of the first quarter of Fiscal 2010, Sun Global converted 1,088,000 shares of Series B Preferred Stock into 1,088,000 shares of Common Stock.

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 6. EXHIBITS

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

SIGNATURES

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

CARACO PHARMACEUTICAL
LABORATORIES, LTD.

Date: August 10, 2009

By: /s/ Jitendra N. Doshi

Jitendra N. Doshi
Chief Executive Officer

Date: August 10, 2009

By: /s/ Mukul Rathi

Mukul Rathi
Interim Chief Financial Officer

EXHIBIT INDEX

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