CARACO PHARMACEUTICAL LABORATORIES LTD
Form 10-Q
August 05, 2010

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

FORM 10-Q

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

for the quarterly period ended June 30, 2010

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

for the transition period from _____ to _____

Commission File No. 1-31773

CARACO PHARMACEUTICAL LABORATORIES, LTD.
(Exact name of registrant as specified in its charter)

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

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

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

Yes x No o

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

Yes o No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definition of "large accelerated filer", "accelerated filer" and "smaller reporting

company” in Rule 12b-2 of the Exchange Act.

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

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

Yes o No x

As of August 4, 2010, 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, 2010 (UNAUDITED)	MARCH 31, 2010 (AUDITED)
ASSETS		
Current assets		
Cash and cash equivalents	$ 57,046,403	$55,392,648
Short-term investments	10,000,000	10,000,000
Accounts receivable, net	139,955,174	94,736,759
Inventories	145,281,902	103,182,850
Prepaid expenses and deposits	6,970,550	6,556,346
Income tax receivable	1,583,829	1,602,621
Deferred income taxes	544,818	519,554
Total current assets	361,382,676	271,990,778
Property, plant and equipment		
Land	975,311	975,311
Buildings and improvements	29,912,502	29,157,542
Equipment	30,022,592	29,929,050
Furniture and fixtures	1,526,782	1,522,564
Construction in progress	152,261	286,250
Total	62,589,448	61,870,717
Less accumulated depreciation	19,795,326	18,627,773
Net property, plant and equipment	42,794,122	43,242,944
Intangible assets, net	1,261,728	1,285,992
Deferred income taxes	20,899,303	21,579,057
Total assets	$ 426,337,829	$338,098,771
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable, trade	$ 2,564,135	$4,342,502
Accounts payable, Sun Pharma	250,153,722	160,913,483
Accrued expenses	2,584,613	2,156,921
Long term debt, current portion	14,400,000	15,300,000
Total liabilities (all current)	269,702,470	182,712,906
Stockholders' equity		
Series B convertible preferred stock, no par value; issued and outstanding 1,088,000 shares (June 30, 2010) 1,088,000 shares (March 31, 2010)	11,320,640	11,320,640
Common stock, no par value; authorized 50,000,000 shares, issued and outstanding 39,090,194 shares (June 30, 2010) 39,090,194 shares (March 31, 2010)	130,330,615	130,330,615

Additional paid in capital	3,736,014	3,696,288
Retained Earnings	11,248,090	10,038,322
Total stockholders' equity	156,635,359	155,385,865
Total liabilities and stockholders' equity	$ 426,337,829	$338,098,771

See accompanying notes

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

	Three months ended June 30,	
	2010 (UNAUDITED)	2009 (UNAUDITED)
Net sales	$130,028,760	$ 48,070,016
Cost of goods sold	120,487,714	51,679,584
Gross profit (loss)	9,541,046	(3,609,568)
Selling, general and administrative expenses	5,839,240	3,659,211
Research and development costs	2,119,099	7,085,135
Operating income (loss)	1,582,707	(14,353,914)
Other income (expense)		
Interest expense	(198,264)	(130,950)
Interest income	498,607	104,455
Loss on sale of equipment	-	(114,272)
Other income	-	46,298
Other income (expense) - net	300,343	(94,469)
Income (loss) before income tax expense (benefit)	1,883,050	(14,448,383)
Income tax expense (benefit)	673,282	(5,025,332)
Net income (loss)	$1,209,768	$ (9,423,051)
Net income (loss) per common share		
Basic	$0.03	$ (0.25)
Diluted	$0.03	$ (0.25)

See accompanying notes

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

	Three months ended June 30,	
	2010 (UNAUDITED)	2009 (UNAUDITED)
Cash flows from operating activities		
Net income (loss)	$1,209,768	$ (9,423,051)
Adjustments to reconcile net income (loss) to net cash provided by operating activities		
Depreciation and amortization	1,191,817	1,116,015
Loss on sale of equipment	-	114,272
Common stock option expense	39,726	85,783
Net deferred income taxes	654,490	(5,025,332)
Changes in operating assets and liabilities which (used) / provided cash:		
Accounts receivable	(45,218,415)	7,844,893
Inventories	(42,099,052)	(28,655,000)
Prepaid expenses and deposits	(414,202)	(366,205)
Accounts payable	87,461,871	36,146,619
Accrued expenses	427,691	(436,425)
Income taxes receivable	18,792	-
Net cash provided by operating activities	3,272,486	1,401,569
Cash flows from investing activities		
Purchases of property, plant and equipment	(718,731)	(1,654,447)
Proceeds from sale of equipment	-	310
Purchase of short-term investments	-	(10,000,000)
Net cash used in investing activities	(718,731)	(11,654,137)
Cash flows from financing activities		
Repayments of loans payable to financial institution	(900,000)	-
Net cash used in financing activities	(900,000)	-
Net increase (decrease) in cash and cash equivalents	1,653,755	(10,252,568)
Cash and cash equivalents, beginning of period	55,392,648	65,314,397
Cash and cash equivalents, end of period	$57,046,403	$ 55,061,829

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, 2010	1,088,000	$11,320,640	39,090,194	$130,330,615	$ 3,696,288	$10,038,322	$ 155,385,865
Common stock option expense	-	-	-	-	39,726	-	39,726
Net income	-	-	-	-	-	1,209,768	1,209,768
Balances at June 30, 2010	1,088,000	$11,320,640	39,090,194	$130,330,615	$ 3,736,014	$11,248,090	$ 156,635,359

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, 2010 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 write-off of 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, 2010 of Caraco Pharmaceutical Laboratories, Ltd. ("Caraco," the "Company," or the "Corporation" and which is also referred to as "we," "u or "our").

The accounting policies followed by the Corporation with respect to the unaudited interim financial statements are consistent with those stated in the Corporation's Annual Report on Form 10-K.

2. ORGANIZATION AND NATURE OF BUSINESS

Caraco is a corporation organized under Michigan law in 1984, engaged in the business of developing, licensing, manufacturing, marketing and distributing generic prescription and over-the-counter pharmaceuticals to the nation's largest wholesalers, distributors, warehousing and non-warehousing chain drugstores and managed care providers, throughout the U.S and Puerto Rico.

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 48 prescription products, in 105 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 Caraco-owned products (those products for which Caraco owns the Abbreviated New Drug Applications ("ANDAs")) manufactured by Sun Pharma or other third parties. This does not include those Caraco-owned products for which the Company has temporarily ceased manufacturing and marketing, due to the enforcement actions of the FDA. The products are intended to treat a variety of disorders including but not limited to the following: hypertension, arthritis, epilepsy, diabetes, depression and pain management.

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, had 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

The Company has been actively working with current good manufacturing practice or cGMP consultants towards the resumption of manufacturing activities at its Michigan facilities. These consultants were appointed by the Company in accordance with the previously disclosed Consent Decree, of Condemnation, Forfeiture and Permanent Injunction ("Consent Decree"), which the Company entered into with the FDA on September 29, 2009. The FDA approved the Company's work plan on March 17, 2010, and the Company is in the process of implementing the corrective actions and remedial measures as stipulated in the work plan. On June 24, 2010, the FDA notified Caraco that its protocol for third party cGMP certification, detailing the activities to be conducted by the cGMP consultants, was acceptable.

On June 25, 2010, the FDA released certain previously seized raw materials which had been opened solely for the purpose of sampling.

Caraco-owned products or licensed products distributed by Caraco that are manufactured outside of the Company's Michigan facilities are not impacted and distribution and marketing of these products continues. The Company has also transferred certain Caraco-owned products to additional manufacturing sites that would allow the Company to regain revenues from those products. The Company has filed with the FDA supplements to ANDAs, for its approval, for some of these transferred products.

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

During the first quarter of our current fiscal year ("Fiscal 2011") ended June 30, 2010, we generated net sales of $130.0 million, as compared to $48.1 million for the corresponding period of our previous fiscal year ("Fiscal 2010") ended June 30, 2009. During the first quarter of Fiscal 2011, the sales of Caraco-owned products were $2.9 million, as compared to $13.1 million during the corresponding period of Fiscal 2010, while the sales of distributed products during the first quarter of Fiscal 2011 were $127.1 million, as compared to $35.0 million during the corresponding period of Fiscal 2010. We earned a gross profit of $9.5 million during the first quarter Fiscal 2011, as compared to incurring a gross loss of $3.6 million during the corresponding period of Fiscal 2010. The gross loss in the first quarter of Fiscal 2010 was, in large part, due to a reserve of $8.4 million created by the Company for the inventory seized by the FDA. We earned pre-tax income of $1.9 million during the first quarter of Fiscal 2011, as compared to incurring a pre-tax loss of $14.4 million during the corresponding period of Fiscal 2010. Pre-tax income in the first quarter of Fiscal 2011 is higher due to increased sales of certain distributed products. The sales of such products at these levels are not expected to continue in future periods. The Company recorded income tax expense of $0.7 million for the first quarter of Fiscal 2011, as compared to providing for an income tax benefit of $5.0 million in the corresponding period of Fiscal 2010. We earned net income of $1.2 million during the first quarter of Fiscal 2011, as compared to incurring a net loss of $9.4 million during the corresponding period of Fiscal 2010. We generated cash from operations in the amount of $3.3 million during the first quarter of Fiscal 2011, as compared to generating cash from operations in the amount of $1.4 million during the corresponding period of Fiscal 2010. At June 30, 2010, we had stockholders' equity of $156.6 million, as compared to stockholders' equity of $155.4 million at March 31, 2010. (See "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.").

We filed two ANDAs relating to two products with the FDA during the first quarter of Fiscal 2011. These products have been developed in partnership with other product development and manufacturing companies. We have not received FDA approval for any ANDAs since the first quarter of Fiscal 2009 and do not expect to receive any approvals for products out of our Michigan facilities until we resolve the FDA's concerns as discussed above. The total number of ANDAs pending approval by the FDA as of June 30, 2010 was 33 (including four tentative approvals) relating to 29 products. Out of the 33 ANDAs pending approval, 31 (including four tentative approvals) are from our Detroit, Michigan manufacturing facility and the remaining two are from the manufacturing sites of our partner companies.

4. RECENT ACCOUNTING PRONOUNCEMENTS

In October 2009, the FASB issued an amendment to its accounting guidance on revenue arrangements with multiple deliverables, which addresses the unit of accounting for arrangements involving multiple deliverables and how consideration should be allocated to separate units of accounting, where applicable. The amendment requires that arrangement considerations be allocated at the inception of the arrangement to all deliverables using the relative selling price method and provides for expanded disclosures related to such arrangements. The amendment is effective for revenue arrangement entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is allowed. The Company is currently evaluating the impact of the adoption of this amendment on its financial statements.

In March 2010, the FASB ratified accounting guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions (Accounting Standards Update No. 2010-17). This guidance provides criteria that must be met to recognize consideration that is contingent upon achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The amendment is effective for milestones achieved in fiscal years beginning on or after June 15, 2010. Early adoption is allowed. Management is currently evaluating the impact of the adoption of this amendment on the Corporation's financial statements.

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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 2011, ended June 30, 2010, were 39,090,194 and 40,468,694, respectively. Correspondingly, 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.

6. SUN PHARMACEUTICAL INDUSTRIES LIMITED

The Company has a long relationship with Sun Pharma, a Mumbai, India based specialty pharmaceutical manufacturing company. In 1997 Sun Pharma made an initial investment of $7.5 million for the purchase of 5.3 million common shares of Caraco. Currently Sun Pharma owns approximately 75% of the outstanding shares of the Company (approximately 76% including the convertible Series B Preferred Stock). The Company and Sun Pharma have entered into various transactions and agreements including those as referenced hereunder.

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 affiliates supply the Corporation with certain raw materials and formulations, assist in acquiring machinery and equipment to enhance production capacities, and have provided qualified technical professionals who work as Caraco employees. Also, five of the current seven directors of Caraco are, or were, affiliated with Sun Pharma.

The Corporation has also obtained technical and scientific services, including bio-equivalency studies, from the Clinical Research Organization operated by Sun Pharma. The products, on which the Company decides to work with Sun Pharma, is determined on a case by case basis as mutually agreed upon by both companies.

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. This agreement was renewed for a period of one year in January 2010. Under the agreement, the Corporation purchases selected product formulations offered by Sun Pharma and its affiliates 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 its affiliates 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 its affiliates and offered for distribution. Paragraph IV certified (“Paragraph IV”) products may face litigation challenges with respect to claims of patent infringement. Under the agreement the Company shares in the sales opportunity and shares the litigation risk. The Company is indemnified by Sun Pharma of any risk beyond the percentage agreed to as its profit percentage thereby limiting the Company’s exposure. Sun Pharma is not obligated to offer Caraco products under this agreement, however, Caraco has the exclusive right to market in the U.S., its territories and possessions, including Puerto Rico, any products offered by Sun Pharma and accepted by Caraco. The Company markets and distributes the same as part of its current product offerings in the U.S., its territories and possessions, including Puerto Rico. The license granted with respect to a product terminates upon the end of an exclusivity period of 180 days or a non-appealable court decision, or until a third generic manufacturer launches the product, whichever is later, or until a settlement is reached, at which time the product will become part of the standard Caraco-Sun Pharma marketing agreement disclosed above. The Company currently receives a 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. The Company has a right to return the inventory of such products to Sun Pharma if the sale of such products is not allowed by any regulatory authority and Sun Pharma does not file a timely appeal. The Company can also return the inventory, or ask for replacements, under various conditions consistent with normal practices in the pharmaceutical industry. (See “Note 12. Litigation” for disclosure of litigation involving Paragraph IV products).

During the quarters ended June 30, 2010 and June 30, 2009, the Corporation made net sales of $127.1 million and $35.0 million of the marketed products under the aforesaid agreements, respectively.

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

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

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 supported Caraco's operations in the past, there can however, be no assurance that such support will, in fact, continue, or that the current terms and conditions will remain the same in the future.

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 satisfying the terms of the Consent Decree and on its continuing ability to attract and retain key employees, obtain timely approvals of its ANDAs, and develop new products.

7. ACCOUNTING FOR STOCK BASED COMPENSATION

The Company follows the provisions of ASC Topic 718, “Stock Compensation’” which requires employee share-based compensation to be accounted for under the fair value method and requires the use of an option pricing model for estimating the fair value of stock options at the date of grant. The Company estimates the fair value of stock options granted using the Black-Scholes option-pricing model, which requires the Company to estimate the expected term of the stock option grants and expected future stock price volatility over the term. The term represents the expected period of time the Company believes the options will be outstanding based on historical information. Estimates of expected future stock price volatility are based on the historical volatility of the Company’s common stock. The Company calculates the historical volatility as the standard deviation of the differences in the natural logarithms of the weekly stock closing price, adjusted for dividends and stock splits.

For the first quarter of Fiscal 2011, the Company has recognized expenses amounting to $39,726 related to common stock options as compared to $85,783 for the corresponding period of Fiscal 2010. As of June 30, 2010, total unrecognized compensation cost related to stock options granted was $167,657. The unrecognized stock option compensation cost is expected to be recognized over a period of approximately three years.

8. COMMON STOCK ISSUANCES

There were no common stock issuances to Directors or employees during the first quarters of Fiscal 2011 or Fiscal 2010.

9. PREFERRED STOCK ISSUANCES

No shares of preferred stock were issued during the first quarters of Fiscal 2011 or Fiscal 2010.

10. SALES AND CUSTOMERS

Net sales increased during the first quarter of Fiscal 2011, in comparison to the corresponding period of Fiscal 2010, primarily as a result of higher sales of distributed products. See “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations – First Quarter Fiscal 2011 Compared to First Quarter Fiscal 2010.”

As is typical in the U.S. pharmaceutical industry, many of our customers are serviced through their designated wholesalers. During the first quarter of Fiscal 2011, the Company's three largest wholesale customers, Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health, accounted for approximately 4%, 45% and 24%, respectively, of the Company's total net sales. During the corresponding period of Fiscal 2010, shipments to Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health, accounted for approximately 10%, 10% and 8%, respectively, of the Company's total net sales. A part of these net sales include sales to various customers of Caraco that have underlying direct contracts with our Company that are facilitated through our wholesale customers. During the first quarter of Fiscal 2011, sales to CVS Caremark Corporation were insignificant, however during the first quarter of Fiscal 2010, they accounted for approximately 38% of our net sales for the period. A significant portion of the sales to CVS Caremark Corporation are a result of a contract between it and the Company entered into towards the end of Fiscal 2009. The sales contract for CVS Caremark Corporation includes special payment terms, and accordingly, collections of the related accounts receivable balance from these sales have been spread over an extended period and the remaining collections are expected to occur over the next six months.

11. DEBT

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, 2010 was 0.8%. The principal loan payments and accrued interest are payable on a quarterly basis beginning July 2009. The principal is to be repaid in equal quarterly installments of $900,000 for ten quarters through October 2011, and thereafter, if not renewed, the remaining balance of $9 million is due in the subsequent quarter by January 2012. Subsequently, in October 2009 the terms of the loan were modified and we entered into an amended agreement. The amendment adds to the loan a one year line of credit note for $15 million against which the Company can borrow funds for working capital purposes or can get letters of credit issued. Against this line of credit, the Bank has issued an Irrevocable Standby Letter of Credit in an amount of $15 million, in favor of the United States of America, as required to be placed with the FDA in accordance with the Consent Decree, as disclosed above. The line of credit carries an interest rate of LIBOR plus 150 basis points, and if letters of credit are issued, the associated fees are 0.7% of such letters of credit on annualized basis. Also, there is an unused fee of 0.25% on an annualized basis to the extent the line remains idle. Both the line of credit and outstanding term loan are cross collateralized by all of the Company's fixed assets and cash deposit accounts held with Charter One Bank, equivalent to the amount of outstanding loans and the letter of credit. These cash deposits earn interest at prevailing rates applicable to such money market accounts. The Company is continuing discussions with Charter One Bank to allow the release of the cash collateral. Charter One Bank has temporarily suspended the required compliance with the covenants in the loan agreements relating to FDA enforcement actions, and has suspended certain other compliance requirements until October 9, 2010. On or before such date, the Company anticipates either entering into revised agreements or repaying the loan in full.

Currently, as the loan is in technical default due to the FDA enforcement action, the entire outstanding balance has been classified as a short-term liability.

As required pursuant to the terms of the Loan Agreement, the Company has entered into an Interest Rate Swap Agreement with Charter One Bank to hedge the interest rate applicable on the loan. The notional amount for the swap is $14.4 million which will continue to amortize down as principal payments are made on the related debt. The annualized fixed rate of interest as it applies to this agreement is 2.41%. Thus as of June 30, 2010, 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). During the quarters ended June 30, 2010 and March 31, 2010, the Company has made provisions of $72,000 and $331,000, respectively, to record the fair value of this swap agreement, with such amounts included in Interest Expense and Accrued Expenses. The fair value of this Swap Agreement at June 30, 2010 was ($403,000).

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.

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, unenforceable 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. On May 26th, 2010, the Company received correspondence from the FDA forwarding a letter sent by Sandoz Inc. to the FDA challenging the Company's 180 day exclusivity based on when the Company received tentative approval for its product. The Company responded to the FDA on June 17, 2010. On June 28th, 2010, Sandoz Inc. replied to the Company's correspondence. The Company issued a further letter to the FDA stating its position regarding the 180 day exclusivity on July 9, 2010. The Company believes it received tentative approval timely, and that it has the potential to obtain 180 day exclusivity for this product. It intends to defend that position vigorously.

The Company filed a supplemental answer and counterclaim challenging Novo Nordisk's Orange Book use code amendment by Novo Nordisk in reference to Prandin®. On September 25, 2009, the District Court entered an injunction requiring Novo Nordisk to correct its amended use code description for Prandin® on the ground that it does not accurately characterize the referenced method patent. Novo Nordisk then appealed that injunction. On October 14, 2009, the parties entered into a stipulation regarding the appeal. On October 27, 2009, the United States Court of Appeals for the Federal Circuit entered an Order staying the use code injunction during the appeal. Under the stipulation, if the Company were to prevail on the use code injunction appeal, Novo Nordisk would stipulate to non-infringement based on Caraco's proposed section viii split-certification. If Novo Nordisk prevails on the use code injunction appeal, the parties will proceed to trial on patent validity and unenforceability. On April 14, 2010, the Court of Appeals reversed the decision of the District Court. Subsequently, on May 14, 2010, the Company filed a petition for rehearing by the panel and rehearing en banc with the Court of Appeals for the Federal Circuit. Those petitions were denied by the Court of Appeals on July 29, 2010. The trial regarding the validity and unenforceability of the patent began on June 1, 2010 and continued through June 10th. Due to the Court's schedule, there has been a break and the trial is currently scheduled to resume on August 5, 2010.

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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 non-infringement by the district court with the United States Court of Appeals for the Federal Circuit. On January 19, 2007, the United States Court of Appeals for the Federal Circuit affirmed the 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 United States District for New Jersey on April 17, 2008. Final judgment has been granted. On August 25, 2008, Ortho-McNeil filed a notice of appeal with respect to that judgment with the United States Court of Appeals for the Federal Circuit. The appeal was fully briefed and was argued on July 7, 2009. On August 26, 2009, the Court of Appeals reversed a portion of the previously decided summary judgment. Although the Court did find that a portion of the patent was not valid, the Court remanded the litigation back to the lower court for further proceedings. Caraco subsequently filed a combined petition for a panel rehearing and a rehearing en banc. That combined petition was denied, and the case has been remanded back to the Court for further proceedings.

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 requested damages, injunctive relief and attorneys' fees and costs. On March 2, 2010, the Court dismissed Wyeth's complaint, without prejudice. On March 31, 2010, Wyeth filed a Notice of Appeal with United States District Court for the Sixth Circuit.

Additionally, Sun Pharma and Wyeth are involved in a separate Paragraph IV product lawsuit in the United States District Court for the District of New Jersey, regarding the validity of the patents in Wyeth's Protonix® (pantoprazole) product. On April 23, 2010, a Jury in the New Jersey patent lawsuit returned a verdict that the patent at issue is not invalid. The Court reserved decision on the issue of the effect to be given to the Jury's determinations regarding obviousness type double patenting defenses, which Sun Pharma has argued, is to be decided by the Court. In the event of a Jury award of damages against Sun Pharma for patent infringement, Caraco's obligation to Sun Pharma is capped at its fixed margin percentage, in accordance with the terms of the Distribution and Sale Agreement with Sun Pharma. As a result of the ongoing patent case in the United States District Court for the District of New Jersey, on May 6, 2010, Wyeth, Sun Pharma and the Company filed a Joint Motion to Hold Case in Abeyance with the Sixth Circuit Court of Appeals regarding the alleged false and misleading statements in the package insert (as discussed above). On May 6, 2010, the Court agreed to hold Wyeth's appeal of that case in abeyance.

On July 16, 2010 the Court ruled against the arguments put forth by Sun Pharma regarding the obviousness type double patenting defenses. The Court did not issue a ruling regarding the defenses of patent misuse and unclean hands. The ultimate outcome of the patent litigation cannot be determined at this time. While the New Jersey patent lawsuit works toward completion, the Company has currently put all shipments of this product on hold and will continually re-evaluate marketing the product as a part of its at-risk launch of pantoprazole. Sales of this product may resume at any time as market and other conditions permit.

In 2007, Sun Pharma filed an ANDA to market an oxaliplatin product designed to treat stage III colon cancer, and the generic equivalent of Sanofi-Aventis' Eloxatin® product. The ANDA contained a paragraph IV certification of non-infringement of the patents which support Eloxatin®. Pursuant to an agreement with Sun Pharma, the Company has the right to serve as a distributor for Sun Pharma for this generic product. In July of 2007, Sanofi-Aventis U.S. LLC and certain of its affiliates filed a patent infringement action against Sun Pharma and the Company in the United States District Court for the District of New Jersey, alleging that Sun Pharma's ANDA infringed U.S. Patent Number 5,338,874. Sanofi-Aventis also filed similar patent infringement actions against other generic manufacturers. The Court consolidated all of these pending actions. In August of 2008, Sanofi-Aventis amended its claim against Sun Pharma and the Company to add a claim for infringement of an additional Eloxatin® patent (U.S. Patent Number 5,959,133). Sun Pharma and the Company denied Sanofi-Aventis' allegations and asserted affirmative defenses and counterclaims for invalidity and unenforceability of the relevant patents.

In June 2009, Sun Pharma, the Company and Sanofi-Aventis completed negotiations and agreed to a settlement agreement and a license agreement pursuant to which Sun Pharma and the Company are authorized to market, sell and distribute an oxaliplatin product in the United States under certain conditions. In October, 2009 and March, 2010, the Court confirmed the entry and enforceability of the settlement agreement and license agreement. In August, 2009, the FDA issued final approvals for the Sun Pharma ANDA and for other ANDAs for generic oxaliplatin products, after certain Court decisions. At such time, several other generic manufacturers launched in the marketing of their FDA-approved generic oxaliplatin products in the United States. In January of 2010, the Company began selling Sun Pharma's FDA-approved generic oxaliplatin product in the United States market, serving as Sun Pharma's distributor.

In March 2010, Sanofi-Aventis announced settlements with all of the other defendants in the pending patent action. Those defendants agreed to stop selling their respective generic oxaliplatin products as of June 30, 2010. Sanofi-Aventis thereafter asserted that Sun Pharma and the Company must also cease selling the generic oxaliplatin product as of June 30, 2010 pursuant to the terms of the license agreement. Sun Pharma and the Company dispute that the license agreement requires Sun Pharma and the Company to stop selling. On April 22, 2010, Sanofi-Aventis obtained a Court judgment which required Sun Pharma and the Company to cease selling generic oxaliplatin from June 30, 2010 until either August 9, 2012 or on occurrence of any event that triggers permission of sales under the license agreement. Sun Pharma and the Company have appealed the court's order, and that appeal remains pending. On May 20, 2010, Sun Pharma and the Company filed a motion to stay, during the appeal, the injunction within the April 22 Order that otherwise will require Sun Pharma and the Company to cease selling on June 30, 2010. The court denied that motion. On June 30, 2010, the Company ceased selling Sun Pharma's oxaliplatin product in the United States market, pending the appeal.

As previously disclosed, on June 25, 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 office of the United States Attorney, on behalf of the FDA and Department of Justice, filed a Warrant for Arrest In Rem to seize certain materials at the Company's Michigan facilities in the United States District Court for the Eastern District of Michigan. A Complaint for forfeiture of those materials was filed with the court by the FDA, which alleged that the drug products and materials are adulterated, in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing and holding do not conform to cGMP requirements. Also as previously disclosed, on September 29, 2009, the Company voluntarily entered into a Consent Decree with the FDA, which provides a series of measures that, when satisfied, will permit the Company to resume manufacturing and distributing products from its Michigan facilities. Nothing in the Consent Decree prohibits the Company from distributing FDA approved drug products that are manufactured by third parties.

On July 17, 2009 and July 23, 2009, two purported class action lawsuits were filed in the United States District Court for the Eastern District of Michigan against the Company and certain of its executive officers. The lawsuits allege securities violations related to the Company's public statements on FDA compliance issues made between May 29, 2008 and June 25, 2009. On September 15, 2009, plaintiffs in both of the purported lawsuits filed motions for consolidation of the cases and for approval of lead plaintiff. On November 9, 2009, a Stipulation and Order of Dismissal was entered by the Court dismissing one of the two cases, effectively consolidating the cases. On January 13, 2010, the Court entered a Stipulation and Order appointing the lead plaintiff and lead counsel for plaintiff. On February 11, 2010, the plaintiffs filed a consolidated and amended complaint, which also names Sun Pharma as an additional defendant. The defendants filed a Motion to Dismiss on April 12, 2010, which has been briefed to the Court by the parties. Oral argument on the motion is currently scheduled for August 26, 2010.

On September 29, 2009, Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc. ("Taro") filed suit against Caraco and Sun Pharma and certain of its affiliates in the United States District Court for the Southern District of New York. The complaint, as it pertains to Caraco, alleges misappropriation and misuse of trade secrets, unfair competition, and tortuous interference with business relationships, fraud and unjust enrichment. The claims against Caraco arise out of Caraco's purported access to information from Taro as a part of the due diligence conducted for Sun Pharma's tender offer for Taro Pharmaceuticals Industries Ltd. The complaint also, inter alia, sought to enjoin Sun Pharma's tender offer for Taro Pharmaceuticals Industries Ltd. based on violations of the Williams Act. On December 18, 2009, the Defendants filed a Motion to dismiss the complaint. On July 13, 2010, the Court issued an order dismissing Taro's Williams Act claim. The Court also ruled that it does not have jurisdiction, due to inadequately pled allegations regarding citizenship of the parties and amount in controversy, to hear the state law claims regarding use of confidential information against Caraco. On July 27, 2010, Taro filed a motion: (1) for leave to file an amended complaint with regard to the state law claims, including misappropriation of trade secrets, fraud and unfair competition; and (2) entry of a final judgment in the Williams Act claim regarding the tender offer in order to permit an immediate appeal. Caraco's and Sun Pharma's response to the Taro motion is due on August 10, 2010.

On December 3, 2009, a shareholder derivative complaint was filed in the Circuit Court for the County of Wayne, State of Michigan, by Anil Diwadkar, derivatively on behalf of the Company, against certain current and former officers and directors of the Company. The complaint alleges that the individual defendants breached their fiduciary duties by, among other things, knowingly causing or allowing the Company to manufacture products in violation of the FDA's current Good Manufacturing Practice requirements, despite repeated warnings by the FDA. The complaint adds that the defendants knowingly failed to take the actions and steps necessary in order to bring the Company's manufacturing facilities in line with applicable FDA standards. The complaint seeks damages in an amount exceeding $25,000, appropriate equitable relief and costs. As permitted under Michigan law, the Board of Directors asked Mr. F. Folsom Bell, a disinterested Director, elected by the shareholders and designated as independent by the Board of Directors, to make a determination in good faith after conducting a reasonable investigation upon which his conclusions are based, as to whether or not the maintenance of the derivative proceeding requested by the shareholder is in the best interests of the Company. Under Michigan law, and assuming no legal viable challenges thereto, a determination that the maintenance of the derivative proceedings is not in the best interests of the Company requires the Court to dismiss the case. On March 15, 2010, Mr. Bell issued his report that concluded that the maintenance of the complaint against the named defendants is not in the best interests of the Company. On March 30, 2010, the Company filed a Motion for Summary Disposition. On July 23, 2010, the Company's motion to dismiss was granted by the Court.

The Company is also currently involved, and from time to time becomes involved, in certain other legal proceedings relating to the conduct of its business, including those pertaining to product liability, contract and employment claims. With respect to employee claims the Company is currently involved in one employment lawsuit, which however, involves multiple plaintiffs. The Company carries employment practices liability insurance. Additionally, the Company does not believe these claims constitute material litigation matters. With respect to product liability claims, we are currently involved in a total of 11 cases, 10 of which involve products alleged to have been manufactured by the Company. The Company carries product liability insurance in an amount it believes is sufficient for its needs. The Company is also a defendant in one product liability case, where it is alleged that the Company distributed a product manufactured by another party. In that instance, the Company is contractually indemnified by the product manufacturer. While the outcome of any of such proceedings cannot be accurately predicted, the Company does not believe that the ultimate resolution of any of these existing proceedings will have a material adverse effect on the Company's financial condition or liquidity.

13. INVENTORIES

Inventories consist of the following amounts:

	June 30, 2010	March 31, 2010
Raw materials	$ 12,976,772	$ 14,545,370
Goods in transit (Distributed)	4,192,234	28,406,006
Finished goods (Caraco- Owned)	5,974,415	4,460,252
Finished goods (Distributed)	122,138,481	55,771,222
Total Inventories	$ 145,281,902	$ 103,182,850

Total inventories at June 30, 2010 and March 31, 2010 includes materials purchased in the amount of $2,224,027 and $2,249,878, respectively, related to products for which the Company has filed ANDAs that are awaiting approval from the FDA, and the commercial launch of such products will commence once the approvals are received.

As disclosed above, certain drug products manufactured, work in process, and ingredients held, at the Company's Michigan facilities were seized at the direction of the FDA. The estimated cost of such seized inventory was $24.0 million. As stipulated in the Consent Decree, the Company attempted to have the seized inventory released. The Company believes that, except for the raw materials which were opened solely for the purpose of sampling, the estimated value of which was $8.1 million, all other seized inventory would be difficult to recondition. Accordingly, the Company had written off all other seized inventory in the amount of $15.9 million during Fiscal 2010. In accordance with the Consent Decree, on June 25, 2010, the FDA released the raw materials which were opened solely for the purpose of sampling.

14. INCOME TAXES

The provision (benefit) for income taxes is as follows:

	Quarter Ended	
	June 30, 2010	June 30, 2009
Current	$20,996	$--
Deferred	652,286	(5,025,332)
Total	$673,282	$(5,025,332)

The provision (benefit) 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 quarter of Fiscal 2011 and Fiscal 2010, respectively, are as follows:

	June 30, 2010	June 30, 2009
Provision (benefit) for income taxes at federal statutory rate	$659,068	$(5,056,934)
Permanent items and other	14,214	31,602
Income taxes	$673,282	$(5,025,332)

Deferred taxes consist of the following:

	June 30, 2010	March 31, 2010
Deferred tax assets:		
Net operating loss carryforwards	$731,162	$797,631
Intangibles	23,478,840	24,079,523
Other	544,818	519,554
Total deferred tax assets	$24,754,820	$25,396,708
Deferred tax liabilities:		
Depreciation	$3,310,699	$3,298,097
Total deferred tax liabilities	$3,310,699	$3,298,097
Net deferred tax assets	$21,444,121	$22,098,611

15. SEGMENT INFORMATION

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

Category	Quarter Ended June 30, 2010 Net Sales	Quarter Ended June 30, 2010 Gross (Loss) Profit	Quarter Ended June 30, 2009 Net Sales	Quarter Ended June 30, 2009 Gross (Loss) Profit
Caraco-Owned Products	$2,890,894	$(1,701,369)	$13,081,187	$(6,892,214)
Distributed Products	127,137,866	11,242,415	34,988,829	3,282,646
Total	$130,028,760	$9,541,046	$48,070,016	$(3,609,568)

16. SUBSEQUENT EVENTS

None

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

The following discussion and analysis provides information that management believes is relevant to an understanding of the Corporation's results of operations and financial condition. The discussion should be read in conjunction with the financial statements and notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in the Company's 2010 Annual Report on Form 10-K as of and for the year ended March 31, 2010 (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, title and risk of ownership have been transferred to the buyer which is assumed to occur when the product reaches its destination, 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.

The Company makes sales of products under various marketing and distribution agreements. The Company recognizes revenue from such sales in accordance with Emerging Issues Task Force (“EITF”) Issue No. 99-19, “Reporting Revenue Gross as a Principal versus Net as an Agent.” The Company has evaluated the various indicators described under EITF No. 99-19 and has determined that such revenues should be considered on a gross reporting basis. The factors include the following, which led the Company in making such determination: (1) the title of the goods have been transferred to the Company and the Company assumes all general inventory risks; (2) the Company is the primary obligor in the arrangement. The Company is responsible for the sales process, pricing, marketing and delivery of the products; and (3) the Company is responsible for the collection of receivables and will have to account for bad debt losses if any occur.

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 2011 were $201.7 million as compared to $82.4 million for the corresponding period of Fiscal 2010. Sales allowances, which include chargebacks, returns, discounts, other customary customer deductions and other sales costs, constituted approximately 36% of gross sales for the first quarter of Fiscal 2011 as compared to 42% of gross sales for the corresponding period of Fiscal 2010. Net sales for the first quarter Fiscal 2011 were $130.0 million as compared to $48.1 million for the corresponding period of Fiscal 2010. The primary cause of the decreased sales allowances for first quarter of Fiscal 2011 is due to the impact of higher sales of such products which carry lower deductions related to chargebacks, which represent differences between wholesale acquisition costs (WAC) and the contractual prices at which the wholesalers ship to our end use customers.

The following is a roll forward of the provisions for chargebacks, shelf stock adjustments, returns and allowances and estimated doubtful account allowances during Fiscal 2010 and the first three months of Fiscal 2011 :

($ 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 2010					
Chargebacks, rebates & shelf stock adjustments	$50,028	$203,145	-0-	$188,365	$64,808
Returns and other allowances	6,555	16,016	-0-	15,104	7,467
Doubtful Accounts	78	53	-0-	-0-	131
For the first three months of Fiscal 2011					
Chargebacks, rebates & shelf stock adjustments	$64,808	$66,676	-0-	$59,403	$72,081
Returns and other allowances	7,467	5,009	-0-	3,339	9,137
Doubtful Accounts	131	-0-	-0-	-0-	131

Research and Development Costs

Series B convertible preferred stock was issued to Sun Pharma and its affiliates under a products agreement between the Corporation and Sun Pharma Global Inc. (“Sun Global”) dated November 21, 2002, in exchange for the technology of formulation products delivered by Sun Global to the Corporation. Such Products Agreement has been completed with the last technology transfer occurring during the third quarter of Fiscal 2008. Accordingly, no further non-cash research and development expense will be incurred there under. The amount of non-cash research and development expense which was incurred for past technology transfers under the Products Agreement was charged to operations and was determined based on the fair value of the preferred shares on the date the respective product formula passed its bio-equivalency studies. The fair value of such shares was based upon a valuation performed by Donnelly Penman & Partners, an independent, third party valuation firm. The exchange of shares was prior to the initial ANDA submission to the FDA.

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

Based on the definition and characteristics of an asset, set forth in paragraphs 25 and 26 of Statement of Financial Accounting Concepts No. 6 issued by the FASB, the Company did not capitalize the technology formulas transferred, as the probability of the future economic benefit to be derived from such formulations was uncertain at the time of technology transfer.

In addition, we have reported the technology transfers as research and development expenses pursuant to ASC Topic 730, "Research and Development," In connection therewith, the research and development technology transferred by Sun Global under the products agreement was always specific research and development technology for a specific product formula. There were no alternative future uses (in other research and development projects or otherwise) for such products. For example, Caraco has never acquired technology from Sun Global with the purpose of selling such technology and, in fact, has never sold or held for sale any of the technology transferred by Sun Global to a third party. Caraco has always developed the research and development technology into manufactured product for its own business purposes.

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

Short-Term Investments

During the first quarter of Fiscal 2010 the Company invested $10,000,000 in a bank certificate of deposit. In accordance with the term of deposit, in June 2010, the Certificate has been renewed for twelve months and earns interest at a rate of 2.7% 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

During Fiscal 2009 the Company made cash payments in the amount of $1,456,000 for the purchase of certain assets which included brand products, associated New Drug Applications ("NDAs") and trademarks and establishment fees for these products. These assets are recorded as intangible assets in the Company's balance sheet at June 30, 2010. 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 each of the first quarters of Fiscal 2011 and Fiscal 2010. The total accumulated amortization related to these intangible assets is $194,000 as of June 30, 2010.

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 $21.4 million and $22.1 million at June 30, 2010 and March 31, 2010, 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 expense of $0.7 million for the first quarter of Fiscal 2011 as compared to an income tax benefit of $5.0 million during the first quarter of Fiscal 2010. The income tax benefit for the first quarter of Fiscal 2010 was predominantly due to losses incurred as a result of FDA actions including the seizure of inventory for which a reserve had been created. We have not provided for any valuation allowance as of June 30, 2010 or March 31, 2010. 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, 2010, we had federal NOLs of approximately $2.1 million, which are restricted by limitations of Internal Revenue Code Section 382, available to reduce future taxable income. The NOLs will expire between 2010 and 2012.

The Company adopted the provisions of ASC 740 dealing with Accounting for Uncertainty in Income Taxes at the beginning of Fiscal 2008. The Company had determined that no adjustments for unrecognized tax benefits were necessary as a result of this adoption. There are no unrecognized tax benefits present at June 30, 2010.

The Company is subject to U.S. federal income tax as well as income tax in certain state jurisdictions. The IRS has initiated an examination of the Company's tax return for the fiscal year ended March 31, 2009. 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 2006.

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 research and development ("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. Total inventories at June 30, 2010 and March 31, 2010 include materials purchased in the amount of $2,224,027 and $2,249,878, respectively, related to products for which the Company has filed ANDAs that are awaiting approval from 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, certain drug products manufactured, work in process, and ingredients held, at the Company's Michigan facilities were seized at the direction of the FDA. The estimated cost of such seized inventory was $24.0 million. As stipulated in the Consent Decree, the Company attempted to have the seized inventory released. The Company believes that, except for the raw materials which were opened solely for the purpose of sampling, the estimated value of which was $8.1 million, all other seized inventory would be difficult to recondition. Accordingly, the Company had written off all other seized inventory in the amount of $15.9 million during Fiscal 2010. In accordance with the Consent Decree, on June 25, 2010, the FDA released the raw materials which were opened solely for the purpose of sampling.

OVERVIEW

The Company has been actively working with cGMP consultants towards the resumption of manufacturing activities at its Michigan facilities. These consultants were appointed by the Company in accordance with the Consent Decree, which the Company entered into with the FDA on September 29, 2009. The FDA approved the Company's work plan on March 17, 2010, and the Company is in the process of implementing the corrective actions and remedial measures as stipulated in the work plan. On June 24, 2010, the FDA notified Caraco that its protocol for third party cGMP certification, detailing the activities to be conducted by the cGMP consultants, was acceptable.

On June 25, 2010, the FDA released certain previously seized raw materials which had been opened solely for the purpose of sampling.

Caraco-owned products or licensed products distributed by Caraco that are manufactured outside of the Company's Michigan facilities are not impacted and distribution and marketing of these products continues. The Company has also transferred certain Caraco-owned products to additional manufacturing sites that would allow the Company to regain revenues from those products. The Company has filed with the FDA supplements to ANDAs, for its approval, for some of these transferred products.

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

During the first quarter of our current fiscal year ("Fiscal 2011") ended June 30, 2010, we generated net sales of $130.0 million, as compared to $48.1 million for the corresponding period of our previous fiscal year ("Fiscal 2010") ended June 30, 2009. During the first quarter of Fiscal 2011, the sales of Caraco-owned products were $2.9 million, as compared to $13.1 million during the corresponding period of Fiscal 2010, while the sales of distributed products during the first quarter of Fiscal 2011 were $127.1 million, as compared to $35.0 million during the corresponding period of Fiscal 2010. We earned a gross profit of $9.5 million during the first quarter Fiscal 2011, as compared to incurring a gross loss of $3.6 million during the corresponding period of Fiscal 2010. The gross loss in the first quarter of Fiscal 2010 was, in large part, due to a reserve of $8.4 million created by the Company for the inventory seized by the FDA. We earned pre-tax income of $1.9 million during the first quarter of Fiscal 2011, as compared to incurring a pre-tax loss of $14.4 million during the corresponding period of Fiscal 2010. Pre-tax income in the first quarter of Fiscal 2011 is higher due to increased sales of certain distributed products. The sales of such products at these levels are not expected to continue in future periods. (See "Note 12. Litigation" for disclosure of litigation involving Paragraph IV products). The Company recorded income tax expense of $0.7 million for the first quarter of Fiscal 2011, as compared to providing for an income tax benefit of $5.0 million in the corresponding period of Fiscal 2010. We earned net income of $1.2 million during the first quarter of Fiscal 2011, as compared to incurring a net loss of $9.4 million during the corresponding period of Fiscal 2010. We generated cash from operations in the amount of $3.3 million during the first quarter of Fiscal 2011, as compared to generating cash from operations in the amount of $1.4 million during the corresponding period of Fiscal 2010. At June 30, 2010, we had stockholders' equity of $156.6 million, as compared to stockholders' equity of $155.4 million at March 31, 2010.

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We filed two ANDAs relating to two products with the FDA during the first quarter of Fiscal 2011. These products have been developed in partnership with other product development and manufacturing companies. We have not received FDA approval for any ANDAs since the first quarter of Fiscal 2009 and do not expect to receive any approvals for products out of our Michigan facilities until we resolve the FDA's concerns as discussed above. The total number of ANDAs pending approval by the FDA as of June 30, 2010 was 33 (including four tentative approvals) relating to 29 products. Out of the 33 ANDAs pending approval, 31 (including four tentative approvals) are from our Detroit, Michigan manufacturing facility and the remaining two are from the manufacturing sites of our partner companies.

FDA COMPLIANCE

As previously disclosed the Company received a warning letter from the Detroit District of the FDA in October 2008, for its manufacturing facility in Detroit, Michigan, to which the Company responded and the Detroit District acknowledged our response on December 22, 2008. The FDA commenced an inspection as a follow-up to the October 2008 warning letter from March 11, 2009 to May 12, 2009. The FDA investigators provided the Company with a list of their observations on FDA Form 483. The FDA's inspection found unresolved violations of cGMP requirements as previously disclosed in our SEC filing on Form 10-K filed June 15, 2009. The Company provided a written response to these observations on June 19, 2009. As previously disclosed on June 25, 2009, at the request of the FDA, drug products manufactured in our Michigan facilities were seized. 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 were not impacted. In its complaint relating to its seizure, the FDA stated, among other things, that the May 12, 2009 inspection and the Company's written response thereto revealed continuing significant cGMP violations. The FDA also stated that the drug products are adulterated in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and/or holding do not conform to and are not operated and administered in conformity with cGMP requirements. As a result of the FDA action, we voluntarily ceased manufacturing operations and instituted an indefinite reduction in our workforce of approximately 430 employees in two phases. The Company has subsequently started recalling some of these employees in conjunction with its efforts to restart its manufacturing activities. This FDA action has resulted and will result in a material adverse effect on our current and near term operations.

On September 29, 2009, Caraco voluntarily entered into a Consent Decree with the FDA regarding the Company's drug manufacturing operations. The Consent Decree provides a series of measures that, when satisfied, will permit Caraco to resume manufacturing and distributing those products that are manufactured in its Michigan facilities. The Company is working expeditiously to satisfy the requirements of the Consent Decree and has retained independent cGMP consultants for review of the Company's operations and to facilitate a successful result. The Company in accordance with the Consent Decree has submitted a work plan to the FDA in October 2009 for remedial actions leading to resumption of its manufacturing operations. The FDA approved the Company's work plan on March 17, 2010 after reviewing and suggesting certain modifications. The Company is in the process of implementing the corrective actions and remedial measures as stipulated in the work plan.

Under terms of the Consent Decree, Caraco's cessation of manufacturing operations will continue until it receives written notification from independent experts and the FDA that it is in compliance with the Consent Decree and regulations and can resume operations. Caraco-owned products or licensed products distributed by Caraco that are manufactured outside of these facilities are not impacted and distribution and marketing of these products continues. 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. Remediation activities are ongoing with the full knowledge of the cGMP consultants. A protocol for third party certification was submitted to the FDA on May 5, 2010. This protocol details the activities to be conducted by the cGMP consultants. On June 24, 2010, the FDA notified Caraco that the protocol was acceptable.

We have not received FDA approvals for any of our ANDAs since the first quarter of Fiscal 2009. It is unlikely that we will receive any approvals for product out of our Michigan facilities until the FDA reviews our remediation response and makes a determination of our status.

In accordance with the Consent Decree, we have also provided third party certification to the FDA and requested the release of raw materials which were opened solely for the purpose of sampling. On June 18, 2010, the FDA accepted the raw material certification and had instructed that these materials be released “with the understanding that a defined portion will be destroyed and the remainder will be available for use.” Except for the portion which will be destroyed, approximating $0.3 million, the remainder of these materials, approximating $7.8 million, were released on June 25, 2010.

First Quarter Fiscal 2011 Compared to First Quarter Fiscal 2010

Net Sales. Net sales for the first quarter of Fiscal 2011, ended June 30, 2010, were $130.0 million, as compared to $48.1 million for the first quarter of Fiscal 2010, reflecting an increase of 170%. Net sales increased during the first quarter of Fiscal 2011, in comparison to the corresponding period of Fiscal 2010, primarily as a result of higher sales of distributed products, offset, in part, by the adverse effect on sales of Caraco-owned products due to the actions of the FDA and the cessation of manufacturing, as disclosed above. Net sales for distributed products were $127.1 million for the first quarter of Fiscal 2011, as compared to $35.0 million for the corresponding period of Fiscal 2010. The sales of distributed products were higher in the first quarter of Fiscal 2011, as compared to corresponding period last year, primarily due to increased sales of Paragraph IV products, particularly sales of certain Paragraph IV products which were launched by the Company during the fourth quarter of Fiscal 2010 under the distribution and sale agreement with Sun Pharma. The sales of such products at these levels are not expected to continue in future periods. (See “Note 12. Litigation” for disclosure of litigation involving Paragraph IV products). Net sales for Caraco-owned products were $2.9 million for the first quarter of Fiscal 2011, as compared to $13.1 million for the corresponding period of Fiscal 2010. Sales of Caraco-owned products during first quarter of Fiscal 2011 were significantly lower than those during corresponding period of Fiscal 2010 as we have stopped marketing, effective June 25, 2009, all the products which were being manufactured out of our Michigan facilities on account of the FDA actions, as previously discussed, 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 sales of Caraco-owned products that are manufactured outside of the Company by other manufacturers including Sun Pharma. During Fiscal 2010 we have started selling two products which were acquired as part of an asset purchase agreement with Forest as previously disclosed.

Gross Profit. We earned gross profit of $9.5 million in the first quarter of Fiscal 2011, as compared to incurring a gross loss of $3.6 million during the first quarter of Fiscal 2010. The gross profit in first quarter of Fiscal 2011 is higher due to the higher level of sales. Also the gross loss in the first quarter of Fiscal 2010 was, in large part, due to a reserve of $8.4 million we had provided on the inventory seized by the FDA. As disclosed above, due to the actions of the FDA, all shipments of products which were being manufactured at the Company's Michigan facilities have ceased effective June 25, 2009, which has led to diminished sales of Caraco-owned products.

The gross profit margin for the first quarter of Fiscal 2011 as a percentage of net sales increased to 7%, as compared to (8%) during the corresponding period of Fiscal 2010. As disclosed above, we had created a reserve in the amount of $8.4 million during the first quarter of Fiscal 2010 for the inventory seized by the FDA. Excluding the impact of the inventory reserve, the gross profit margins in the first quarter of Fiscal 2010 was 10%. The decrease in gross profit margin as a percentage of net sales was due to lost sales of Caraco-owned products which were being manufactured at the Company's Michigan facilities

The gross profit margin on distributed products was 9% for the first quarters of both Fiscal 2011 and Fiscal 2010. The gross profit margin for Caraco-owned products was (59%) for the first quarter of Fiscal 2011, as compared to (53%) for the corresponding period of Fiscal 2010. Excluding the impact of the inventory reserve, the gross profit margin in the first quarter of Fiscal 2010 was 12%. Caraco-owned product margins have decreased mainly due to the impact of overhead absorption, with lower sales, which contributed 44% to the 65% decrease in gross profit margin excluding the impact of the inventory reserve in the first quarter of Fiscal 2010. Also during the first quarter of Fiscal 2011, we wrote off certain seized inventories of approximately $0.3 million as per the undertaking given to the FDA for getting the release of raw material drums which were opened solely for the purpose of sampling. The sales and related gross profits generated from the distribution and sale agreement dated January 29, 2008 and the marketing agreement dated January 19, 2007 are recognized under distributed products which we segregate from sales of Caraco-owned products and are accordingly disclosed in Note 15 of Notes to Financial statements under Segment Reporting.

Selling, General and Administrative Expenses. Selling, general and administrative ("SG&A") expenses during the first quarter of Fiscal 2011 were $5.8 million, as compared to $3.7 million during the corresponding period of Fiscal 2010, representing an increase of 60%. SG&A expenses were higher during Fiscal 2011 as the Company recorded additional expenses primarily related to professional consultation fees pertaining to FDA issues. SG&A expenses, as a percentage of net sales decreased to 4% for the first quarter of Fiscal 2011, as compared to 8% for the corresponding period of Fiscal 2010. The lower percentage of SG&A is mainly due to the higher sales in the current period versus the corresponding period last year.

Research and Development Expenses. Total R&D expenses incurred for the first quarter of Fiscal 2011 were $2.1 million, as compared to $7.1 million during the corresponding period of Fiscal 2010. Although R&D expenses have decreased in the current period due to the focus of the Company on remediating FDA concerns, they are likely to increase once the Company refocuses on new product filings and approvals with the FDA.

Net Other Income (Expense). We earned net other income of $0.3 million during the first quarter of Fiscal 2011, as compared to incurring net other expense of $0.1 million during the corresponding period of Fiscal 2010.

Income Taxes. We recorded income tax expense of $0.7 million during the first quarter of Fiscal 2011, as compared to providing for an income tax benefit of $5.0 million during the corresponding period of Fiscal 2010.

Results of Operations. We earned pre-tax income of $1.9 million during the first quarter of Fiscal 2011, as compared to incurring a pre-tax loss of $14.4 million during the corresponding period of Fiscal 2010. We earned net income of $1.2 million for the first quarter of Fiscal 2011, as compared to incurring a net loss of $9.4 million during the corresponding period of Fiscal 2010.

Liquidity and Capital Resources We generated cash from operations in the amount of $3.3 million during the first quarter of Fiscal 2011, as compared to generating cash from operations in the amount of $1.4 million during the corresponding period of Fiscal 2010. The cash flow from operations was higher in the first quarter of Fiscal 2010 primarily due to higher net income. Accounts receivable increased by $45.3 million to $140.0 million as of June 30, 2010, as compared to $94.7 million at the end of Fiscal 2010. Accounts receivable is 98 days sales outstanding (“DSO”) as of June 30, 2010 versus 154 days as of March 31, 2010. The lower level in DSO at June 30, 2010 is due to higher levels of sales in the current period and collection of receivable balances from certain customers with whom we have entered into agreements which include special payment terms. The collections of the related accounts receivable balances from these previous period sales were spread over an extended period and the remaining collection is expected to occur over the next six months. Based on the first quarter cost of sales, which is most representative of current sales activity, inventory levels at June 30, 2010 were equivalent to 110 days on hand, and similarly, based on the fourth quarter of Fiscal 2010 cost of sales, inventory levels at March 31, 2010 were equivalent to 182 days on hand. The inventory, both as of June 30, 2010 and March 31, 2010, include high levels of inventory of Paragraph IV products to support anticipated sales in the near term period. The accounts payable balance relating to Sun Pharma has also increased from $160.9 million at March 31, 2010 to $250.2 million at June 30, 2010 in line with increased levels of inventory relating to distributed products and accounts receivable balances, and also due to extended payment terms for certain of these distributed products purchased from Sun Pharma..

During the first quarter of Fiscal 2010 the Company had invested $10.0 million in a bank certificate of deposit which was renewed in June 2010 for twelve months in accordance with the terms of the deposit, and earns interest at a rate of 2.7% 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.

As disclosed above the FDA actions and the Company's voluntary cessation of production at its Michigan facilities had a material adverse affect on our current operations and there may be a material adverse affect on our near term operations. The Company initiated a reduction in various expenses in an effort to bring its expenses in line with its current levels of sales and other activities. The sales of distributed products and certain Caraco-owned products made by other manufacturers will continue and will contribute to the ongoing cash flows. Also, the Company has entered into an agreement with Forest which, to date, has provided two additional products to the Company's product portfolio, and such products have begun generating incremental revenues under Caraco-owned product sales. We expect additional products will be added to our portfolio as a result of this agreement. The Company owns seven products that are manufactured outside of the Company by other manufacturers including Sun Pharma and its affiliates. The Company has filed supplements to ANDAs for FDA approval, for the transfer of certain Caraco-owned products to regain revenues from these products. As of June 30, 2010, we have $57 million in cash and another $10 million in short-term investments, including the proceeds from a loan in the amount of $14.4 million, currently classified as a short term liability. The Company believes that its cash flow from operations and cash balances will continue to support its ongoing business requirements. However, because of, among other things, decreased customer confidence resulting in lower sales, the uncertainty of resumption in manufacturing activities, the uncertainty of future costs of FDA compliance and associated costs and the uncertainty of various litigation proceedings (see "Note 12. Litigation"), there can be no assurance of this belief.

At June 30, 2010, we had working capital of $91.7 million, compared to working capital of $89.3 million at March 31, 2010.

During Fiscal 2009 the Company entered into a term loan of $18 million with Charter One Bank. The loan is secured by a mortgage covering the Company's manufacturing facility and equipment located in Detroit, Michigan. The rate of interest is calculated as LIBOR plus an applicable margin thereto (based upon various leverage levels and current applicable rate is 50 basis points). The aggregate rate applicable to the Company as of June 30, 2010 was 0.8%. The principal loan payments and accrued interest are payable on a quarterly basis beginning July 2009. The principal is to be repaid in equal quarterly installments of $900,000 for ten quarters through October 2011, and thereafter, if not renewed, the remaining balance of $9 million is due in the subsequent quarter by January 2012. Subsequently, in October 2009 the terms of the loan were modified and we entered into an amended agreement. The amendment adds to the loan a one year line of credit note for $15 million against which the Company can borrow funds for working capital purposes or can get letters of credit issued. Against this line of credit, the Bank has issued an Irrevocable Standby Letter of Credit in an amount of $15 million, in favor of the United States of America, as required to be placed with the FDA in accordance with the Consent Decree, as disclosed above. The line of credit carries an interest rate of LIBOR plus 150 basis points, and if letters of credit are issued, the associated fees are 0.7% of such letters of credit on annualized basis. Also, there is an unused fee of 0.25% on an annualized basis to the extent the line remains idle. Both the line of credit and outstanding term loan are cross collateralized by all of the Company's fixed assets and cash deposit accounts held with Charter One Bank, equivalent to the amount of outstanding loans and line of credit. These cash deposits earn interest at prevailing rates applicable to such money market accounts. We are continuing discussions with Charter One Bank to allow the release of the cash collateral. Charter One Bank has temporarily suspended our required compliance with the covenants in the loan agreements relating to FDA enforcement actions, as previously disclosed, and has suspended testing of certain other compliance requirements until October 9, 2010. On or before such date, we anticipate either entering into revised agreements or repaying the loan in full. Currently, as the loan is in technical default due to the FDA enforcement action, the entire outstanding balance has been classified as a short-term liability.

As required pursuant to the terms of the Loan Agreement, the Company has entered into an Interest Rate Swap Agreement with Charter One Bank to hedge the interest rate applicable on the loan. The notional amount for the swap is $14.4 million which will continue to amortize down as principal payments are made on the related debt. The annualized fixed rate of interest as it applies to this agreement is 2.41%. Thus as of June 30, 2010, 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 Company has made provisions to record the fair value of this swap agreement, which was ($0.4) million at June 30, 2010.

Future Outlook

We voluntarily entered into a Consent Decree with the FDA regarding the Company's drug manufacturing operations. The Consent Decree provides a series of measures that, when satisfied, will permit Caraco to resume manufacturing and distributing those products that are manufactured in its Michigan facilities. We continue to focus on improving support to, 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 cGMP consultants who have experience in assisting manufacturers with FDA compliance issues. These consultants have reviewed all of our systems, procedures, reporting structures, and processes, as well as reviewed training on risk management and overall cGMP. As part of this comprehensive process we have evaluated our internal and external audit programs, and will make any improvements that we believe to be necessary to improve these programs. All audits are based on a historical look back, and offer improvements based on Caraco’s likely future requirements. These audits will also include follow up action on compliance issues that need to be addressed. Caraco will obtain assistance and guidance wherever required from the quality group of Sun Pharma to improve its quality systems. Though near term sales of Caraco-owned products face challenges, we believe we are effecting, and intend to effect, the changes required to improve our performance on sales of these products, on a long-term basis.

Under terms of the Consent Decree, Caraco's cessation of manufacturing operations will continue until it receives written notification from independent experts and the FDA that it is in compliance with the Consent Decree, cGMP and other regulations and can resume operations. The Company submitted a work plan to the FDA in October 2009 for remedial actions leading to resumption of its manufacturing operations. The FDA approved the Company’s work plan on March 17, 2010 after reviewing and suggesting certain modifications. The Company is in the process of implementing the corrective actions and remedial measures as stipulated in the work plan. On June 24, 2010, the FDA notified Caraco that its protocol for third party cGMP certification, detailing the activities to be conducted by the cGMP consultants, was acceptable. We intend to continue to work with the FDA to resolve its concerns as effectively and expeditiously as possible. We are hopeful that we will be able to resume our manufacturing operations by the end of Fiscal 2011. However, there is no assurance that the steps taken will be successful or result in resolution of the FDA complaint. Caraco-owned products or licensed products distributed by Caraco that are manufactured outside of these facilities are not impacted. and distribution and marketing of these products continues.

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 manufacturing area and quality control laboratories. Our current focus remains on resumption of manufacturing and quality assurance. Currently we are utilizing part of our R&D team to help with technical validations and compliance initiatives and will continue to do so in the near term. As a result, our R&D expense has declined in the current periods. However, the R&D expenses are likely to increase once the Company refocuses on new product filings and approvals with the FDA. We anticipate gaining back our momentum on filings of new ANDAs internally once our compliance initiatives and technical needs are satisfied. Any third party development in process will continue. Our production capacity is primarily built, which should support the business for years to come once we overcome our current obstacles.

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Currently, we have 33 ANDAs pending approval at the FDA (including four tentative approvals) relating to 29 products. Out of the 33 ANDAs pending approval, 31 (including four tentative approvals) are filed from our Michigan facilities and the remaining two are filed from the manufacturing sites of our partner companies. We continue to upgrade our facilities, and expand our customer base. Our internal efforts, combined with Sun Pharma in developing new products have also picked up momentum. We now have 18 products, that we market (including Caraco-owned products being manufactured by third parties and those distributed under various agreements with of Sun Pharma), whose market share is ranked third or higher against the same products of our generic competitors. We are focused on products that are currently in our portfolio and are yet to realize their full market potential. The total portfolio consists of 48 products.

Sun Pharma is involved in legal proceedings relating to a product (Pantoprazole sodium DR tablets), which we have been distributing under agreements with Sun Pharma. This product was launched at-risk as a Paragraph IV product. Considering recent developments with respect to the patent litigation relating to this product, the Company has currently put further shipments of this product on hold and will continually re-evaluate marketing the product. Sales of this product may resume at any time as market and other conditions permit. See “Note 12. Litigation” for further information.

Although gross profit margins have come down due to negligible sales of Caraco-owned products, we believe we can be successful in marketing distributed products and our products that are manufactured by our partner companies. We have 14 new distributed products launched during Fiscal 2010 and additional six products launched subsequent to the end of Fiscal 2010 that Sun Pharma or its affiliates received FDA approvals. We have also transferred certain Caraco-owned products to additional alternate manufacturing sites that would allow the Company to regain revenues from those products. We have filed with the FDA supplements to ANDAs, for its approval, for some of these transferred products. Should the pricing pressures become more severe than anticipated; the result may be lower growth rates and gross margins. Management has worked, and will continue to work, diligently to counter the pricing pressures through increased sales volumes, improved market share on existing products, expansion of our customer base, improved productivity, and increased cost reductions.

The Company intends to decrease its internal development of new products. It will continue to develop products with third parties, including Alkaloida, an indirect subsidiary of Sun Pharma (see Note 6. - Sun Pharmaceutical Industries Limited). 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, 2010, the Company had $57 million in cash and $10 million in short-term investments including the proceeds from a loan in the amount of $14.4 million. The Company believes that its cash flow from operations and cash balances will continue to support its ongoing business requirements, however, because, among other things, of the uncertainty of future costs of FDA compliance and associated costs, there can be no assurance of this belief.

Beginning Fiscal 2007 through the first quarter of Fiscal 2011, we entered into seven definitive agreements with different companies to develop eight additional ANDAs for Caraco and provide additional opportunities for the future development of products. These agreements contain, both milestone payments to be paid in cash and profit sharing based upon future sales for a defined period, for certain products and only milestone payments in cash without any obligation to share profits in the future for other products. However we have terminated two agreements earlier entered for three of these products. This brings the total number of products being developed by unaffiliated third party developers to five. During the first quarter of Fiscal 2011, the Company filed ANDAs with the FDA for two of these products.

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. This agreement has been further renewed in January 2010, for a period of one year. 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 three products under this agreement including Pantoprazole sodium DR tablets and Oxaliplatin. See 'Note 12. Litigation." These agreements should provide for an alternate stream of products that will complement our internal research and development and our outsourced development. From time to time significant product launches such as we incurred under the distribution and sale agreement for Paragraph IV products in Fiscal 2008 may occur that will add near term growth that may or may not be sustainable in future periods. Additionally we will continue to work with Sun Pharma in an effort to transfer future product technology on a cash basis similar to other third party developers and in the future we may provide services to Sun Pharma, its affiliates and other third party pharmaceutical manufacturers relating to distribution of certain products, on a fee for service basis in effort to expand our product offerings and remain competitive. In this connection, see "Note 6 - Sun Pharmaceutical Industries Limited", relating to our products agreement with Alkaloida, an indirect subsidiary of Sun Pharma. It is our belief that our infrastructure and relationships we have with our customers, can be utilized to optimize sales for our own products, as well as of other companies that are entering or are planning to enter the U.S. market but do not have the infrastructure required to compete effectively.

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

Management's goals for the remainder of Fiscal 2011 include:

- Compliance with Consent Decree.
- Continue working towards resumption of manufacturing activities in conformance with FDA guidelines, the work plan approved by the FDA and the Consent Decree.
- Continue research and development activities for ANDA filings.
- Continue to invest in equipment, systems and facilities to meet requirements of projected short and long-term projects for compliance and quality.
- Increase cGMP training to accommodate staff and compliance.
- Increase market share for certain existing products and recently introduced products.
- Enhanced customer reach and satisfaction.
- Leverage distribution and marketing core competencies by marketing third party products through in-licensing agreements.
- Prompt introduction of new approved products to the market.
- Achieving further operational efficiencies by attaining economies of scale and cost reduction per unit.
- Increase revenue and cash by marketing ANDAs owned by Sun Pharma.
- Expand our relationships with financial institutions to fortify our credit position and borrowings as necessary.
- Research alternate product development sources and product licenses such as in licensing authorized generics from brand innovator companies and acquisitions of ANDAs from competitor manufacturers both domestically and abroad.
- Research possible development of brands for existing stream of products where such potential exists.

- Increase focus on succession planning.
- Increase management training and development.
- Maintain balance in trade class.

Forward Looking Statements

This report, other than the historical financial and business information, may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Without limitation, the words “believes,” “plans,” “expects,” and similar expressions are intended to identify forward-looking statements. Those statements include statements regarding our intent, belief, and current expectation. These statements are not guarantees of future performance and are subject to risks and uncertainties that cannot be predicted or quantified. Consequently, actual results could differ materially from those expressed or implied by such forward-looking statements.

Such risks and uncertainties include, but are not limited to: (i) that the information is of a preliminary nature and may be subject to further adjustment; (ii) not obtaining FDA approval for new products or delays in receiving FDA approvals; (iii) governmental restrictions on the sale of certain products; (iv) dependence on key personnel; (v) development by competitors of new or superior products or cheaper products or new technology for the production of products or the entry into the market of new competitors; (vi) market and customer acceptance and demand for new pharmaceutical products; (vii) availability of raw materials in a timely manner, at competitive prices, and in required quantities; (viii) timing and success of product development and launch; (ix) integrity and reliability of the Company’s data; (x) lack of success in attaining full compliance with regard to regulatory and cGMP compliance; (xi) experiencing difficulty in managing our recent rapid growth and anticipated future growth; (xii) dependence on limited customer base; (xiii) occasional credits to certain customers reflecting price reductions on products previously sold to them and still available as shelf-stock; (xiv) possibility of an incorrect estimate of charge-backs and the impact of such an incorrect estimate on net sales, gross profit and net income; (xv) dependence on few products generating majority of sales; (xvi) product liability claims for which the Company may be inadequately insured; (xvii) subjectivity in judgment of management in applying certain significant accounting policies derived based on historical experience, terms of contracts, our observations of trends of industry, information received from our customers and other sources, to estimate revenues, accounts receivable allowances including chargebacks, rebates, income taxes, values of assets and inventories; (xviii) litigation involving claims of patent infringement; (xix) litigation involving claims for royalties and/or options relating to a prior contract for one product and (xx) material litigation from product recalls, (xxi) the purported class action lawsuits alleging federal securities laws violations, (xxii) delays in returning the Company’s products to market, including loss of market share, and (xxiii) 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, 2010, Part I, Item 1A, for more detailed discussion of such risks). These forward-looking statements represent our judgment as of the date of this report. We disclaim, however, any intent or obligation to update our forward-looking statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Refer to "Item 7A. Quantitative and Qualitative Disclosures About Market Risk" in our Annual Report on Form 10-K for the year ended March 31, 2010 and "Note 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 2011 that materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. At the end of the quarter, the Company's internal audit function was under transition. However, this temporary status had no material impact or adverse effect on 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 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 5, 2010

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

Date: August 5, 2010

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