CARACO PHARMACEUTICAL LABORATORIES LTD
Form 10-Q
February 09, 2011

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

FORM 10-Q

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

for the quarterly period ended December 31, 2010

£ 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 T No £

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

Yes £ No £

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

Large Accelerated Filer £	Accelerated Filer T	Non- Accelerated Filer £	Smaller Reporting Company £

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

Yes £ No T

As of February 9, 2011, the registrant had 40,179,194 shares of common stock issued and outstanding.

PART 1: FINANCIAL INFORMATION

ITEM 1: FINANCIAL STATEMENTS

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

	DECEMBER 31, 2010 UNAUDITED	MARCH 31, 2010 AUDITED
ASSETS		
Current assets		
Cash and cash equivalents	$ 53,693,785	$55,392,648
Short-term investments	10,000,000	10,000,000
Accounts receivable, net	-	94,736,759
Inventories	52,052,066	103,182,850
Prepaid expenses and deposits	10,665,328	6,556,346
Income tax receivable	4,349,732	1,602,621
Deferred income taxes	544,845	519,554
Total current assets	131,305,756	271,990,778
Property, plant and equipment		
Land	975,311	975,311
Buildings and improvements	30,526,478	29,157,542
Equipment	30,224,478	29,929,050
Furniture and fixtures	1,550,639	1,522,564
Construction in progress	-	286,250
Total	63,276,906	61,870,717
Less accumulated depreciation	22,091,421	18,627,773
Net property, plant and equipment	41,185,485	43,242,944
Intangible assets, net	1,213,200	1,285,992
Deferred income taxes	20,702,724	21,579,057
Total assets	$ 194,407,165	$338,098,771
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable, trade	$ 2,288,347	$4,342,502
Accounts payable, Sun Pharma	20,733,141	160,913,483
Balances payable to customers, net	2,788,315	-
Accrued expenses	3,812,933	2,156,921
Long term debt, current portion	12,600,000	15,300,000
Total liabilities (all current)	42,222,736	182,712,906

Stockholders' equity		
Series B convertible preferred stock, no par value; issued and outstanding -0- shares (December 31, 2010) 1,088,000 shares (March 31, 2010)	-	11,320,640
Common stock, no par value; authorized 50,000,000 shares, issued and outstanding 40,179,194 shares (December 31, 2010) 39,090,194 shares (March 31, 2010)	141,654,375	130,330,615
Additional paid in capital	3,825,048	3,696,288
Retained earnings	6,705,006	10,038,322
Total stockholders' equity	152,184,429	155,385,865
Total liabilities and stockholders' equity	$ 194,407,165	$338,098,771

See accompanying notes

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

	Nine Months ended December 31,		Quarter ended December 31,	
	2010 (UNAUDITED)	2009 (UNAUDITED)	2010 (UNAUDITED)	2009 (UNAUDITED)
Net sales	$ 268,205,415	$ 178,435,869	$ 40,386,809	$ 51,989,958
Cost of goods sold	245,842,635	167,148,654	37,061,173	48,905,076
Reserve for inventory seized by FDA	-	15,950,188	-	-
Gross profit (loss)	22,362,780	(4,662,973)	3,325,636	3,084,882
Selling, general and administrative expenses	20,399,479	15,855,217	6,592,397	5,402,641
Research and development costs	7,824,822	8,346,916	1,726,940	2,753,965
Non-recurring (income)	-	(20,000,000)	-	-
Operating loss	(5,861,521)	(8,865,106)	(4,993,701)	(5,071,724)
Other income (expense)				
Interest expense	(397,270)	(402,174)	(18,645)	(144,089)
Interest income	1,018,552	464,835	185,519	200,175
Gain / (loss) on sale of equipment	7,205	(114,272)	4,705	-
Other income	3,649	120,698	3,649	74,390
Other income - net	632,136	69,087	175,228	130,476
Loss before income tax benefit	(5,229,385)	(8,796,019)	(4,818,473)	(4,941,248)
Income tax benefit	(1,896,069)	(3,008,190)	(1,783,205)	(1,907,934)
Net loss	$ (3,333,316)	$ (5,787,829)	$ (3,035,268)	$ (3,033,314)
Net loss per common share				
Basic	$ (0.08)	$ (0.15)	$ (0.08)	$ (0.08)
Diluted	$ (0.08)	$ (0.15)	$ (0.08)	$ (0.08)

See accompanying notes

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

	Nine months ended December 31,	
	2010 (UNAUDITED)	2009 (UNAUDITED)
Cash flows from operating activities		
Net loss	$ (3,333,316)	$ (5,787,829)
Adjustments to reconcile net loss to net cash provided by operating activities		
Depreciation and amortization	3,599,156	3,375,864
(Gain) / loss on sale of equipment	(7,205)	114,272
Common stock option expense	115,137	179,725
Common stock grant expense	13,623	-
Net deferred income taxes	851,042	(6,447,073)
Changes in operating assets and liabilities which provided / (used) cash:		
Accounts receivable	97,525,074	(67,030,731)
Inventories	51,130,784	13,388,805
Prepaid expenses and deposits	(4,108,982)	2,146,337
Accounts payable	(142,234,497)	71,766,769
Accrued expenses	1,656,012	(1,238,535)
Income taxes receivable	(2,747,111)	5,063,120
Net cash provided by operating activities	2,459,717	15,530,724
Cash flows from investing activities		
Purchases of property, plant and equipment	(1,473,200)	(2,354,225)
Proceeds from sale of equipment	11,500	310
Purchase of short-term investments	-	(10,000,000)
Net cash used in investing activities	(1,461,700)	(12,353,915)
Cash flows from financing activities		
Repayments of loans payable to financial institutions	(2,700,000)	(1,800,000)
Proceeds from exercise of common stock options	3,120	-
Net cash used in financing activities	(2,696,880)	(1,800,000)
Net (decrease)/increase in cash and cash equivalents	(1,698,863)	1,376,809
Cash and cash equivalents, beginning of period	55,392,648	65,314,397
Cash and cash equivalents, end of period	$ 53,693,785	$ 66,691,206

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
Conversion of preferred stock into common stock	(1,088,000)	(11,320,640)	1,088,000	11,320,640	-	-	-
Common stock options exercised	-	-	1,000	3,120	-	-	3,120
Common stock options expensed	-	-	-	-	115,137	-	115,137
Common stock grants	-	-	-	-	13,623	-	13,623
Net loss	-	-	-	-	-	(3,333,316)	(3,333,316)
Balances at December 31, 2010	-	$-	40,179,194	$141,654,375	$3,825,048	$6,705,006	$152,184,429

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 has been derived from our audited financial statements for the year then ended. 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, in first and second quarters of Fiscal 2010, which ended June 30, 2009 and September 30, 2009, respectively, of a write-off of inventory seized by the U.S. Food and Drug Administration ("FDA") and non-recurring income, as discussed below. Interim results are not necessarily indicative of results for the full fiscal year.

The financial statements contained herein should be read in conjunction with the financial statements and notes thereto included in our 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, chain drugstores and managed care providers, throughout the U.S and Puerto Rico. The Company's primary facility, measuring approximately 222,000 square feet, is located in Detroit, Michigan, which contains our production, research and development and corporate office. In addition, the Company has a packaging facility located in Farmington Hills, Michigan and a leased warehouse, measuring approximately 137,500 square feet, located in Wixom, Michigan for finished goods distribution and storage of inventory.

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 52 prescription products, in 117 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") pursuant to two agreements (See "6 Sun Pharmaceutical Industries Limited" below) 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 which are manufactured at its facilities, 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.

6

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, transferred certain generic products to us, manufactures certain Caraco-owned products and provides 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 beneficially owns approximately 76% of the outstanding shares of the Company. (See "Current Status of the Corporation" and "Sun Pharmaceutical Industries Limited" below.)

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 previously disclosed Consent Decree of Condemnation, Forfeiture and Permanent Injunction ("Consent Decree"), and on its continuing ability to attract and retain key employees, obtain timely approvals of its ANDAs, and develop new products.

3. CURRENT STATUS OF THE CORPORATION

The Company has been actively working with current good manufacturing practice ("cGMP") consultants towards the resumption of manufacturing activities at its facilities. These consultants were appointed by the Company in accordance with the previously disclosed Consent Decree, which the Company entered into with the FDA on September 29, 2009. The Company's remediation efforts towards the resumption of manufacturing and distribution from its facilities are still ongoing, but the Company is unable to predict when such manufacturing and distribution will resume. The Company had previously disclosed its belief that two products would commence manufacture at its Michigan facilities prior to the end of Fiscal 2011. In evaluating and discussing with the cGMP experts the remediation steps completed to date and those yet to be completed, the Company has determined that it will not be able to begin the manufacture and distribution of products by the end of Fiscal Year 2011. As previously disclosed, and is always the case in matters such as these, there is no assurance that the remediation efforts will be successful or result in resolution of the FDA compliance issues.

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 and batch 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. In September 2010, the FDA released other seized materials, which were disposed of in September 2010, in accordance with the Consent Decree. As a result, the Company is now released from the Bond obligation under the Consent Decree. Accordingly, the Letter of Credit, in the amount of $15 million, which was issued in favor of FDA against this Bond, expired on October 9, 2010, and has not been renewed.

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 future operations. Under the terms of the Consent Decree, before resuming the manufacture of any product in the Company's facilities, a number of significant steps and processes are required to be completed, and certifications and approvals from both outside experts and the FDA are to be obtained.

All of the Company's prior approved products, together with the new products pending approval from the FDA, will be subject to these same processes, certification and approvals as set forth in the Consent Decree. The Company believes that, even assuming a successful remediation process, it will take significant time before the Company reaches its previous levels of manufacturing in its facilities. We are not able at this time to estimate the cost of these actions, which will be substantial, and once manufacturing resumes, will include the costs of operating our manufacturing facility at volumes well below the facility's capacity. The Consent Decree also requires the Company to abide by certain conditions and restrictions. If the Company violates any portion of Consent Decree, it could incur monetary fines and other penalties.

The Company intends to augment the loss of sales of manufactured products by the sale of Caraco- owned products manufactured at third party sites and through sales of distributed products, which are not impacted by the aforementioned actions of the FDA. However, any disruption in the supplies of the products manufactured by these third party sites due to cGMP issues, changes in the market conditions or any other issues would significantly affect the revenues from such products.

In addition to certain Caraco-owned products manufactured by Sun Pharma and its affiliates, we have transferred certain Caraco-owned products to alternate manufacturing sites of Sun Pharma and its affiliates that would allow the Company to realize revenues from those products. We have filed with the FDA supplements to ANDAs, for its approval, for these transferred products. There is no assurance that such approvals will be granted.

As previously disclosed, on December 3 2010 the Company received a proposal (the "Proposal") from Sun Pharma and Sun Pharma Global, Inc. ("Sun Global") for a going private transaction by which Sun Pharma and Sun Global, and/or one or more of their affiliates, would acquire all of the outstanding shares of the Company's common stock not held by Sun Pharma or Sun Global for $4.75 in cash per share. Subsequently, the Company's Board of Directors authorized the Independent Committee of the Board to:;(1) consider the Proposal including, but not limited to, reviewing (a) whether going private is appropriate for Caraco at this time is advisable or is inadvisable and should be rejected, (b) possible alternatives to the Proposal or opportunities which may be more advantageous to Caraco, and (c) the merits of the Proposal; (2) if deemed advisable, enter into discussions and negotiations with respect to the terms of the Proposal, including the proposed per share purchase price, with Sun Pharma and their advisors; and (3) make recommendations to the Board of Directors and as applicable, to the stockholders as to the Independent Committee's findings. The Independent Committee has also retained William Blair & Company as an independent financial advisor, and Carrington Coleman law firm as independent legal counsel, to assist it in evaluating the Proposal.

As previously disclosed, the Company's two distribution agreements with Sun Pharma have been extended until January 28, 2012, but will each terminate following these extensions. The Company and its Independent Committee of the Board approached Sun Pharma and attempted to negotiate long term renewals for each agreement; however, Sun Pharma exercised its right to end the agreements, following these extensions, on January 28, 2012. During the first six months of calendar 2011, the Company and Sun Pharma will discuss a transition plan to transition the marketing of the products covered by the respective agreements to Sun Pharma and/or its wholly-owned affiliates. Thereafter, if the parties have reached an understanding with respect to the transition plan, the parties will implement the transition plan so that upon the termination of the agreements Sun Pharma and its affiliates will commence marketing of the products. If the parties have not agreed on a transition plan prior to January 28, 2012, the agreements will still terminate on that date.

8

During the third quarter ended December 31, 2010 and first nine months of our current fiscal year ("Fiscal 2011") ended December 31, 2010, we generated net sales of $40.4 million and $268.2 million, respectively, as compared to $52.0 million and $178.4 million, respectively, for the corresponding periods of our previous fiscal year ("Fiscal 2010") ended December 31, 2009. During the third quarter and first nine months of Fiscal 2011, sales of Caraco-owned products were $5.7 million and $16.7 million, respectively, as compared to $3.3 million and $18.9 million, respectively, during the corresponding periods of Fiscal 2010. The sales of distributed products during the third quarter and first nine months of Fiscal 2011 were $34.7 million and $251.5 million, respectively, as compared to $48.7 million and $159.5 million, respectively, during the corresponding periods of Fiscal 2010. We earned a gross profit of $3.3 million and $22.4 million during the third quarter and first nine months of Fiscal 2011, respectively, as compared to earning a gross profit of $3.1 million and incurring a gross loss of $4.7 million, respectively, during the corresponding periods of Fiscal 2010. We incurred pre-tax losses of $4.8 million and $5.2 million, respectively, during the third quarter and first nine months of Fiscal 2011, as compared to incurring pre-tax losses of $4.9 and $8.8 million during the respective periods of Fiscal 2010. The Company recorded an income tax benefit of $1.8 million and $1.9 million, respectively, for the third quarter and first nine months of Fiscal 2011, as compared to recording income tax benefits of $1.9 million and $3.0 million during the corresponding periods of Fiscal 2010. We incurred net losses of $3.0 million and $3.3 million, respectively, during the third quarter and first nine months of Fiscal 2011, as compared to incurring net losses of $3.0 million and $5.8 million, respectively, during the corresponding periods of Fiscal 2010. We generated cash from operations in the amount of $2.5 million during the first nine months of Fiscal 2011, as compared to generating cash from operations in the amount of $15.5 million during the corresponding period of Fiscal 2010. At December 31, 2010, we had stockholders' equity of $152.2 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" for further information).

We filed two ANDAs relating to two products with the FDA during the first nine months of Fiscal 2011. These products have been developed in partnership with other product development and manufacturing companies, one of which is an affiliate. 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 facilities until we resolve the FDA's concerns as discussed above. The total number of ANDAs pending approval by the FDA as of December 31, 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 December 2010, the FASB issued an update on (Topic 720) Other Expenses, Relating to Fees paid to the Federal Government by Pharmaceutical Manufacturers, defining how pharmaceutical manufacturers should recognize and classify in their income statements fees mandated by the Patent Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act (Accounting Standards Update No. 2010-27). This guidance specifies that liability for the annual fees which will be imposed on the pharmaceutical manufacturers by these acts starting January 2011, based upon the gross receipts from sale of branded prescription drugs to any specified government program or in accordance with coverage under any government program, should be estimated and recorded in full upon the first qualifying sale with a corresponding deferred cost that is amortized to expense using a straight-line method of allocation or any other method which is provides better allocation The amendment is effective for calendar years which begins on January 1, 2011. Management is currently evaluating the impact of the adoption of this amendment on the Corporation's financial statements.

5. COMPUTATION OF LOSS PER SHARE

Loss 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 third quarter of Fiscal 2011, were both 39,788,933, and were both 39,397,227 for the first nine months of Fiscal 2011. Correspondingly, the basic and diluted weighted average numbers of common shares outstanding for the third quarter of Fiscal 2010, were both 39,090,194, and were both 38,457,176 for the first nine months of Fiscal 2010.

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 beneficially owns approximately 76% of the outstanding shares of the Company. The Company and Sun Pharma have entered into various transactions and agreements including those referenced hereunder.

On December 3, 2010, the Company received a Proposal from Sun Pharma and Sun Global for a going private transaction by which Sun Pharma and Sun Global, and/or one or more of their affiliates, would acquire all of the outstanding shares of the Company’s common stock not held by Sun Pharma or Sun Global for $4.75 in cash per share. Subsequently, the Company’s Board of Directors authorized the Independent Committee of the Board to: (1) consider the Proposal including, but not limited to, reviewing (a) whether going private is appropriate for Caraco at this time is advisable or is inadvisable and should be rejected, (b) possible alternatives to the Proposal or opportunities which may be more advantageous to Caraco, and (c) the merits of the Proposal; (2) if deemed advisable, enter into discussions and negotiations with respect to the terms of the Proposal, including the proposed per share purchase price, with Sun Pharma and their advisors; and (3) make recommendations to the Board of Directors and as applicable, to the stockholders as to the Independent Committee's findings. The Independent Committee has also retained William Blair & Company as an independent financial advisor, and the Carrington Coleman law firm as independent legal counsel, to assist it in evaluating the Proposal.

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, four 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 are 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. This agreement has been extended and is currently scheduled to expire on January 28, 2012. The Company and its Independent Committee of the Board approached Sun Pharma and attempted to negotiate a long term renewal for the agreement; however, Sun Pharma exercised its right to end the agreement, following its extension, on January 28, 2012.

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). The initial term of the distribution and sale agreement was set to expire on January 29, 2011. This agreement has been extended and is currently scheduled to expire on January 28, 2012. The Company and its Independent Committee of the Board approached Sun Pharma and attempted to negotiate a long term renewal for the agreement; however, Sun Pharma exercised its right to end the agreement, following its extension, on January 28, 2012.

During the third quarter and first nine months of Fiscal 2011, the Corporation made net sales of $34.7 million and $251.5 million, respectively, as compared to $48.7 million and $159.5 million, respectively during the corresponding periods of Fiscal 2010, of the marketed products under the aforesaid agreements.

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 is to provide, with respect to certain products and others agreed upon by the parties, 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 agreement was approved by Caraco's Independent Committee. No technology for any product has been transferred under this agreement to date. Under the agreement, Caraco is obligated, among other things, to perform all bio-equivalency studies and complete and submit ANDAs to the FDA. Any license for a product would be for a period of five years from the commencement of marketing of the product, and Caraco may extend the license for a further five year period. The agreement terminates five years from the date of approval of the first ANDA, unless renewed or extended for consecutive one year periods.

While Sun Pharma has provided substantial support to Caraco as disclosed above, there can be no assurance that such support will continue, or that the current terms and conditions will remain the same in the future.

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 third quarter and first nine months of Fiscal 2011, the Company has recognized expenses amounting to $37,554 and $115,137, respectively, related to common stock options as compared to $44,147 and $179,725, respectively, for the corresponding periods of Fiscal 2010. As of December 31, 2010, total unrecognized compensation cost related to stock options granted was $92,423. The unrecognized stock option compensation cost is expected to be recognized over a period of approximately two years. The Company granted a total of 15,000 shares of restricted common stock to its Independent Directors during the first nine months of Fiscal 2011, which will vest at the end of each Independent Director’s respective term. The Company amortizes the expense over the vesting period and has recognized expenses amounting to $11,458 and $13,623 during the third quarter and first nine months of Fiscal 2011, respectively, related to these restricted stock grants.

8. COMMON STOCK ISSUANCES

We issued 1,000 shares of common stock to our employees upon exercise of their stock options during the first nine months of Fiscal 2011. The Company granted 15,000 shares of restricted common stock to its Independent Directors during the first nine months of Fiscal 2011, which will vest ratably on the anniversary dates through their remaining respective terms. There were no common stock issuances to Directors or employees during the first nine months of Fiscal 2010.

During the first nine months of Fiscal 2011, Sun Global converted 1,088,000 shares of Series B Preferred Stock into 1,088,000 shares of Common Stock. (See "Part II – Other Information: Item 2. Unregistered Sales of Equity Securities and Use of Proceeds" below).

9. PREFERRED STOCK ISSUANCES

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

10. SALES AND CUSTOMERS

Net sales decreased during the third quarter and increased during the first nine months of Fiscal 2011, in comparison to the corresponding periods of Fiscal 2010, primarily as a result of lower and higher sales of distributed products, respectively. See "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations – Third Quarter and First Nine Months Fiscal 2011 Compared to Third Quarter and First Nine Months Fiscal 2010."

As is typical in the U.S. pharmaceutical industry, many of our customers are serviced through their designated wholesalers. During the third quarter and first nine months of Fiscal 2011, shipments to the Company's three largest wholesale customers, Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health, accounted for approximately 18%, 17% and 15%, respectively, of the Company's total net sales during the third quarter and 13%, 29% and 26%, respectively, of total net sales for the first nine months of Fiscal 2011. During the corresponding periods of Fiscal 2010, shipments to Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health, accounted for approximately 14%, 11% and 6%, respectively, of the Company's total net sales during the third quarter of Fiscal 2010, and 9%, 7% and 6%, respectively, of total net sales for the first nine months of Fiscal 2010. 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 nine months of Fiscal 2011, sales to CVS Caremark Corporation were insignificant, however during the first nine months of Fiscal 2010, they accounted for approximately 52% of our net sales. 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.

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 December 31, 2010 was 0.8%. (effective rate was 2.91% taking into consideration the Interest Rate SWAP Agreement entered into by the Company details of which are given hereunder). 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 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. On October 9, 2010 this Letter of Credit expired and was not renewed, as the Company was released from this obligation under the terms of the Consent Decree. 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. The outstanding term loan is 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. 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 April 9, 2011. 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 on the Company's Balance Sheets.

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 $12.6 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 December 31, 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 third quarter and first nine months of Fiscal 2011 the Company made adjustments of $(93,000) and $40,000, 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 December 31, 2010 was ($371,000).

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 (the '358 patent). 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 Company believes that the '358 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 entitled to 180 day exclusivity. On May 26, 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. The Company responded, and stated to the FDA its position regarding the 180 day exclusivity.

The Company filed a supplemental answer and counterclaim challenging Novo Nordisk's Orange Book use code amendment to Prandin®, which caused the FDA to reject Caraco's request to use a non-infringing generic repaglinide label. 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 and that injunction was vacated by the Federal Circuit Court of Appeals. The Company's petition for rehearing by the panel and rehearing en banc were denied. The Company has filed a Writ of Certiorari to have the use code issue heard by the United States Supreme Court. Additionally, Caraco is seeking approval for a label that would infringe the '358 patent. The trial regarding the validity and unenforceability of the patent concluded on August 11, 2010. On January 19, 2011, the Court issued a judgment that the '358 patent is invalid because of obviousness, and not enforceable due to inequitable conduct. On January 26, 2011, Novo Nordisk filed a Notice of Appeal of the Court's ruling regarding the '358 patent. The Company has site transferred this product to an affiliate. There is no assurance that the Company will be able to take advantage of what it believes is its 180-day first filer exclusivity with respect to this product.

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 alleging 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 in that case is not invalid. In the event of a Jury award of damages against Sun Pharma for patent infringement, Caraco's obligation to Sun Pharma for its portion of any such award 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, Wyeth, Sun Pharma and the Company agreed to hold the above case regarding the packaging insert in abeyance. The ultimate outcome of the patent litigation cannot be determined at this time.

In 2007, Sun Pharma filed an ANDA to market a generic equivalent of Sanofi-Aventis' Eloxatin® product. The ANDA contains a paragraph IV certification of non-infringement of the patents which support Eloxatin®. Pursuant to the Distribution and Marketing Agreement with Sun Pharma, the Company currently 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. Sanofi-Aventis also filed similar patent infringement actions against other generic manufacturers. The Court consolidated all of these pending actions. 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 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 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 successfully appealed this Court order and are considering their next steps.

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 November 9, 2009, a Stipulation and Order of Dismissal was entered by the Court dismissing one of the two cases, effectively consolidating the cases. The plaintiffs subsequently filed a consolidated and amended complaint, which also names Sun Pharma as an additional defendant. The defendants then filed a Motion to Dismiss; however, the Court denied the Motion to Dismiss, except as to one count against Sun Pharma.

On November 12, 2010, Hospira, Inc. and Orion Corporation filed a patent infringement suit in the United States District Court for the Eastern District of Michigan against the Company alleging that Caraco's ANDA for dexmedetomidine hydrochloride injection infringes U.S. Patent No. 6,716,867 (the "'867 Patent") that supports the Plaintiffs' drug Precedex®. The complaint asks the court to, among other things, order: (a) that the Company has infringed the '867 Patent; (b) that Caraco's ANDA be approved no earlier than the expiration of the '867 Patent; (c) an injunction against the Company from launching its product; and (d) a grant of attorneys fees.

On December 9, 2010, and subsequent thereto, several purported class action lawsuits were filed in the Wayne Court Circuit Court against the Company, Sun Pharma, Sun Global, and the members of the Board of Directors of the Company, arising out of the previously disclosed proposal by Sun Pharma and Sun Global to acquire all of the shares of the Company's common stock not held by Sun Pharma and Sun Global at a price of $4.75 cash per share. The suits allege breaches of fiduciary duties in relation to the Proposal and Sun Pharma and Sun Global's attempt to take the Company private at an alleged unfair price and with an unfair process. Generally, the complaints ask the Court to: (a) declare the case as a class action; (b) declare that the defendants breached their fiduciary duty; (c) declare that the Proposal is not procedurally and financially fair to the Company's minority shareholders and enjoin the transaction; (d) rule that the Company's Independent Directors are incapable of evaluating the Proposal; and (e) award any damages and attorneys fees.

Additionally, the Company received a shareholder letter dated December 14, 2010, that purports to be on behalf of a shareholder, demanding that the Board of Directors take actions to remedy the alleged breaches of fiduciary duty in connection with the Proposal.

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 product liability claims, we are currently involved in a total of 16 cases, 14 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 two product liability cases, where it is alleged that the Company distributed a product manufactured by another party. In those instances, 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:

	December 31, 2010	March 31, 2010
Raw materials	$ 7,774,185	$ 14,545,370
Goods in transit (Distributed)	8,216,624	28,406,006
Finished goods (Caraco- Owned)	2,163,578	4,460,252
Finished goods (Distributed)	33,897,679	55,771,222
Total Inventories	$ 52,052,066	$ 103,182,850

Total inventories at December 31, 2010 and March 31, 2010 includes materials purchased in the amount of $1,110,800 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. We do not expect to receive any approvals for products out of our facilities until we resolve the FDA’s concerns as discussed above.

As disclosed above, certain drug products manufactured, work in process, and ingredients held, at the Company's 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 believed 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. Subsequently, in September 2010, the FDA released all other seized materials, which were thereafter disposed of by the Company, in accordance with the Consent Decree.

14. INCOME TAXES

The benefit for income taxes is as follows:

	Nine Months Ended	
	Dec. 31, 2010	Dec. 31, 2009
Current (benefit) / expense	$ (2,744,669)	$ 4,982,518
Deferred expense / (benefit)	848,600	(7,990,708)
Total Benefit	$ (1,896,069)	$ (3,008,190)

The 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 nine months of Fiscal 2011 and Fiscal 2010, respectively, are as follows:

	Nine Months Ended	
	Dec. 31, 2010	Dec. 31, 2009
Benefit for income taxes at federal statutory rate	$ (1,830,285)	$ (3,078,606)
Permanent items and other	(65,784)	70,416
Income taxes	$ (1,896,069)	$ (3,008,190)

Deferred taxes consist of the following:

	Dec. 31, 2010	March 31, 2010
Deferred tax assets:		
Net operating loss carryforwards	$ 797,631	$ 797,631
Intangibles	22,855,545	24,079,523
Other	544,845	519,554
Total deferred tax assets	$ 24,198,021	$ 25,396,708
Deferred tax liabilities:		
Depreciation	$ 2,950,452	$ 3,298,097
Total deferred tax liabilities	$ 2,950,452	$ 3,298,097
Net deferred tax assets	$ 21,247,569	$ 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:

Fiscal 2011:	Quarter Ended December 31, 2010		Nine Months Ended December 31, 2010	
Category	Net Sales	Gross (Loss) Profit	Net Sales	Gross (Loss) Profit
Caraco-Owned Products	$ 5,706,595	$ (590,962)	$ 16,705,339	$ (1,100,335)
Distributed Products	34,680,214	3,916,598	251,500,076	23,463,115
Total	$ 40,386,809	$ 3,325,636	$ 268,205,415	$ 22,362,780

Fiscal 2010:	Quarter Ended December 31, 2009		Nine Months Ended December 31, 2009	
Category	Net Sales	Gross (Loss) Profit	Net Sales	Gross (Loss) Profit
Caraco-Owned Products	$ 3,322,070	$ (1,124,630)	$ 18,895,700	$ (18,666,990)
Distributed Products	48,667,888	4,209,512	159,540,169	14,004,017
Total	$ 51,989,958	$ 3,084,882	$ 178,435,869	$ (4,662,973)

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 inventory reserves. 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 ASC Topic 605-45, "Principal Agent Considerations." The Company has evaluated the various indicators described under ASC Topic 605-45 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. (3) The Company is responsible for the sales process, pricing, marketing and delivery of the products; and (4) 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.

20

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.

21

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 third quarter and first nine months of Fiscal 2011 were $87.9 million and $464.6 million, respectively, as compared to $94.4 million and $308.2 million, respectively, for the corresponding periods of Fiscal 2010. Sales allowances, which include chargebacks, returns, discounts, other customary customer deductions and other sales costs, constituted approximately 54% and 42% of gross sales, respectively, for the third quarter and first nine months of Fiscal 2011 as compared to 45% and 42% of gross sales, respectively, for the corresponding periods of Fiscal 2010. Net sales for the third quarter and first nine months of Fiscal 2011 were $40.4 million and $268.2 million, respectively, as compared to $52.0 million and $178.4 million, respectively, for the corresponding periods of Fiscal 2010.

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 nine months of Fiscal 2011 :

($ in Thousands)

	Balances at beginning of period	Allowances created		Credits taken by customers	Balance at the end of period
		Current Period	Prior Period		
For 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 nine months of Fiscal 2011					
Chargebacks, rebates & shelf stock adjustments	$ 64,808	$ 183,512	$ 12,584	$ 208,846	$ 52,058
Returns and other allowances	7,467	12,863	-0-	14,687	5,643
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 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 thereunder. The amount of non-cash research and development expense which was incurred for past technology transfers under the Products Agreement was charged to operations and was determined based on the fair value of the preferred shares on the date the respective product formula passed its bio-equivalency studies. The fair value of such shares was based upon a valuation performed by Donnelly Penman & Partners, an independent, third party valuation firm. The exchange of shares was prior to the initial ANDA submission to the FDA.

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

Based on the definition and characteristics of an asset, set forth in paragraphs 25 and 26 of Statement of Financial Accounting Concepts No. 6 – Elements of Financial Statements 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 was 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 December 31, 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 $73,000 in amortization expense in each of the first nine-month periods of Fiscal 2011 and Fiscal 2010. The total accumulated amortization related to these intangible assets is $243,000 as of December 31, 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 $21.2 million and $22.1 million at December 31, 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 benefit of $1.8 million and $1.9 million for the third quarter and first nine months of Fiscal 2011, respectively, as compared to income tax benefits of $1.9 million and $3.0 million during the third quarter and first nine months of Fiscal 2010, respectively. The income tax benefit for the first nine months of Fiscal 2010 was predominantly due to losses incurred as a result of FDA actions including the seizure of inventory which was written off and destroyed. We have not provided for any valuation allowance as of December 31, 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 December 31, 2010, we had federal NOLs of approximately $2.3 million, which are restricted by limitations of Internal Revenue Code Section 382, available to reduce future taxable income. The NOLs will expire between 2011 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 December 31, 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 December 31, 2010 and March 31, 2010 include materials purchased in the amount of $1,110,800 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. We do not expect to receive any approvals for products out of our facilities until we resolve the FDA's concerns as discussed above. 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 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 believed 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. Subsequently, in September 2010, the FDA released all other seized materials, which were thereafter disposed of by the Company, in accordance with the Consent Decree.

OVERVIEW

The Company has been actively working with cGMP consultants towards the resumption of manufacturing activities at its facilities. These consultants were appointed by the Company in accordance with the previously disclosed Consent Decree, which the Company entered into with the FDA on September 29, 2009. The Company's remediation efforts towards the resumption of manufacturing and distribution from its facilities are still ongoing, but the Company is unable to predict when such manufacturing and distribution will resume. The Company had previously disclosed its belief that two products would commence manufacture at its Michigan facilities prior to the end of Fiscal 2011. In evaluating and discussing with the cGMP experts the remediation steps completed to date and those yet to be completed, the Company has determined that it will not be able to begin the manufacture and distribution of products by the end of Fiscal Year 2011. As previously disclosed, and is always the case in matters such as these, there is no assurance that the remediation efforts will be successful or result in resolution of the FDA compliance issues.

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 and batch 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. In September 2010, the FDA released other seized materials, which were disposed of in September 2010, in accordance with the Consent Decree. As a result, the Company is now released from the Bond obligation under the Consent Decree. Accordingly, the Letter of Credit, in the amount of $15 million, which was issued in favor of FDA against this Bond, expired on October 9, 2010, and has not been renewed.

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 future operations. Under the terms of the Consent Decree, before resuming the manufacture of any product in the Company's facilities, a number of significant steps and processes are required to be completed, and certifications and approvals from both outside experts and the FDA are to be obtained.

All of the Company's prior approved products, together with the new products pending approval from the FDA, will be subject to these same processes, certification and approvals as set forth in the Consent Decree. The Company believes that, even assuming a successful remediation process, it will take significant time before the Company reaches its previous levels of manufacturing in its facilities. We are not able at this time to estimate the cost of these actions, which will be substantial, and once the manufacturing resumes, will include the costs of operating our manufacturing facility at volumes well below the facility's capacity. The Consent Decree also requires the Company to abide by certain conditions and restrictions. If the Company violates any portion of Consent Decree, it could incur monetary fines and other penalties.

The Company intends to augment the loss of sales of manufactured products by the sale of Caraco-owned products manufactured at third party sites and through sales of distributed products, which are not impacted by the aforementioned actions of the FDA. However, any disruption in the supplies of the products manufactured by these third party sites due to cGMP issues, changes in the market conditions or any other issues would significantly affect the revenues from such products.

In addition to certain Caraco-owned products manufactured by Sun Pharma and its affiliates, we have transferred certain Caraco-owned products to alternate manufacturing sites of Sun Pharma and its affiliates that would allow the Company to realize revenues from those products. We have filed with the FDA supplements to ANDAs, for its approval, for these transferred products. There is no assurance that such approvals will be granted.

As previously disclosed, on December 3 2010 the Company received Proposal from Sun Pharma and Sun Global for a going private transaction by which Sun Pharma and Sun Global, and/or one or more of their affiliates, would acquire all of the outstanding shares of the Company's common stock not held by Sun Pharma or Sun Global for $4.75 in cash per share. Subsequently, the Company's Board of Directors authorized the Independent Committee of the Board to: (1) consider the Proposal including, but not limited to, reviewing (a) whether going private is appropriate for Caraco at this time is advisable or is inadvisable and should be rejected, (b) possible alternatives to the Proposal or opportunities which may be more advantageous to Caraco, and (c) the merits of the Proposal; (2) if deemed advisable, enter into discussions and negotiations with respect to the terms of the Proposal, including the proposed per share purchase price, with Sun Pharma and their advisors; and (3) make recommendations to the Board of Directors and as applicable, to the stockholders as to the Independent Committee's findings. The Independent Committee has also retained William Blair & Company as an independent financial advisor, and Carrington Coleman law firm as independent legal counsel, to assist it in evaluating the Proposal.

27

As previously disclosed, the Company's two distribution agreements with Sun Pharma have been extended until January 28, 2012, but will each terminate following these extensions. The Company and its Independent Committee of the Board approached Sun Pharma and attempted to negotiate long term renewals for each agreement; however, Sun Pharma exercised its right to end the agreements, following these extensions, on January 28, 2012. During the first six months of calendar 2011, the Company and Sun Pharma will discuss a transition plan to transition the marketing of the products covered by the respective agreements to Sun Pharma and/or its wholly-owned affiliates. Thereafter, if the parties have reached an understanding with respect to the transition plan, the parties will implement the transition plan so that upon the termination of the agreements, Sun Pharma and its affiliates will commence marketing of the products. If the parties have not agreed on a transition plan prior to January 28, 2012, the agreements will still terminate on that date.

During the third quarter ended December 31, 2010 and first nine months of our current fiscal year ("Fiscal 2011") ended December 31, 2010, we generated net sales of $40.4 million and $268.2 million, respectively, as compared to $52.0 million and $178.4 million, respectively, for the corresponding periods of our previous fiscal year ("Fiscal 2010") ended December 31, 2009. During the third quarter and first nine months of Fiscal 2011, sales of Caraco-owned products were $5.7 million and $16.7 million, respectively, as compared to $3.3 million and $18.9 million, respectively, during the corresponding periods of Fiscal 2010. The sales of distributed products during the third quarter and first nine months of Fiscal 2011 were $34.7 million and $251.5 million, respectively, as compared to $48.7 million and $159.5 million, respectively, during the corresponding periods of Fiscal 2010. We earned a gross profit of $3.3 million and $22.4 million during the third quarter and first nine months of Fiscal 2011, respectively, as compared to earning a gross profit of $3.1 million and incurring a gross loss of $4.7 million, respectively, during the corresponding periods of Fiscal 2010. We incurred pre-tax losses of $4.8 million and $5.2 million, respectively, during the third quarter and first nine months of Fiscal 2011, as compared to incurring pre-tax losses of $4.9 and $8.8 million during the respective periods of Fiscal 2010. The Company recorded an income tax benefit of $1.8 million and $1.9 million, respectively, for the third quarter and first nine months of Fiscal 2011, as compared to recording income tax benefits of $1.9 million and $3.0 million during the corresponding periods of Fiscal 2010. We incurred net losses of $3.0 million and $3.3 million, respectively, during the third quarter and first nine months of Fiscal 2011, as compared to incurring net losses of $3.0 million and $5.8 million, respectively, during the corresponding periods of Fiscal 2010. We generated cash from operations in the amount of $2.5 million during the first nine months of Fiscal 2011, as compared to generating cash from operations in the amount of $15.5 million during the corresponding period of Fiscal 2010. At December 31, 2010, we had stockholders' equity of $152.2 million, as compared to stockholders' equity of $155.4 million at March 31, 2010. (See "Third Quarter and First Nine Months Fiscal 2011 Compared to Third Quarter and First Nine Months Fiscal 2010" below for further information).

We filed two ANDAs relating to two products with the FDA during the first nine months of Fiscal 2011. These products have been developed in partnership with other product development and manufacturing companies, one of which is an affiliate. 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 facilities until we resolve the FDA's concerns as discussed above. The total number of ANDAs pending approval by the FDA as of December 31, 2010 was 33 (including four tentative approvals) relating to 29 products. Out of the 33 ANDAs pending approval, 31 (including four tentative approvals) are out of our Michigan facilities and the remaining two are from our partners' facilities.

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 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 continue to 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 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. 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.

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 that are manufactured outside of these facilities are not impacted and distribution and marketing of these products continues.

Under the terms of the Consent Decree, before resuming the manufacture of any product in the Company's facilities, a number of significant steps and processes are required to be completed, and certifications and approvals from both outside experts and the FDA are to be obtained.

In evaluating and discussing with the cGMP experts the remediation steps completed to date and those yet to be completed, the Company has determined that it will not be able to begin the manufacture and distribution of products by the end of Fiscal Year 2011. The Company's remediation efforts towards the resumption of manufacturing and distribution from its facilities are still ongoing, but the Company is unable to predict when such manufacturing and distribution will resume. As previously disclosed, and as always is the case in matters such as these, there is no assurance that the remediation efforts will be successful or result in resolution of the FDA compliance issues.

All of the Company's prior approved products, together with the new products pending approval from the FDA, will be subject to these same processes, certification and approvals as set forth in the Consent Decree. The Company believes that, even assuming a successful remediation process, it will take significant time before the Company reaches its previous levels of manufacturing in its facilities.

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 facilities until the FDA reviews our remediation response and makes a determination of our status. Further, as stated above, the Company will also require approvals from the FDA for its previously approved ANDAs, as set forth in the Consent Decree.

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 was to be destroyed, approximating $0.3 million, the remainders of these materials, approximating $7.8 million, were released on June 25, 2010. Subsequently in September 2010, all other seized materials (drug products manufactured in our facilities, ingredients including the portion of raw materials amounting to $0.3 million, as mentioned above, and work in process) were released by the FDA and all such materials were disposed of by September 24, 2010 under the supervision of the FDA, in accordance with the Consent Decree.

Third Quarter and First Nine Months Fiscal 2011 Compared to Third Quarter and First Nine Months Fiscal 2010

Net Sales. Net sales for the third quarter and first nine months of Fiscal 2011, ended December 31, 2010, were $40.4 million and $268.2 million, respectively, as compared to $52.0 million and $178.4 million, respectively, for the comparable periods of Fiscal 2010, reflecting decrease of 22% and increase of 50%, respectively. Net sales decreased during the third quarter of Fiscal 2011 as compared to the corresponding period of Fiscal 2010 due to decreased sales of distributed products. Net sales increased during the first nine months of Fiscal 2011, in comparison to the corresponding period of Fiscal 2010, primarily as a result of higher sales of distributed products. Net sales for distributed products were $34.7 million and $251.5 million, respectively, for the third quarter and first nine months of Fiscal 2011, as compared to $48.7 million and $159.5 million, respectively, for the corresponding periods of Fiscal 2010. The sales of distributed products were lower in the third quarter of Fiscal 2011, as compared to the corresponding period of Fiscal 2010, as we stopped shipping certain Paragraph IV products prior to the quarter (see "Note 12. Litigation" for disclosure of litigation involving Paragraph IV products). Sales from such products were included in the third quarter of Fiscal 2010. Net sales of distributed products increased during the first nine months of Fiscal 2011, as compared to corresponding period of 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. As previously discussed the sales of such products at these levels were not expected to continue and have not occurred during the third quarter of Fiscal

2011 and are not expected to occur in future periods. Net sales for Caraco-owned products were $5.7 million and $16.7 million, respectively, for the third quarter and first nine months of Fiscal 2011, as compared to $3.3 million and $18.9 million, respectively, for the corresponding periods of Fiscal 2010. The increase in the sales of Caraco-owned products during the third quarter was primarily due to an increase in the number of products being contract manufactured, including certain Caraco-owned products which were acquired as part of the asset purchase agreement with Forest Laboratories, Inc. (“Forest”), as previously disclosed. Sales of Caraco-owned products during first nine months of Fiscal 2011 were 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 facilities on account of the FDA actions, as previously discussed, offset in part by higher sales of certain Caraco-owned products which are being contract manufactured, including those which were acquired as part of an asset purchase agreement with Forest which the Company started selling during Fiscal 2010. We were manufacturing and marketing all except two of our approved products, as of June 25, 2009. 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 generate sales of Caraco-owned products that are manufactured outside of the Company by other manufacturers including Sun Pharma.

Gross Profit. We earned gross profit of $3.3 million and $22.4 million, respectively, in the third quarter and first nine months of Fiscal 2011, as compared to earning a gross profit of $3.1 million and incurring a gross loss of $4.7 million, respectively, during the third quarter and first nine months of Fiscal 2010. The gross profit in the third quarter of Fiscal 2011 is primarily due to mix of products sold. As disclosed above, the sales of Paragraph IV products, which earn a lower gross margin than the Company's other products, were lower in the third quarter of the current fiscal year, as compared to the corresponding period of last fiscal year. The gross profit in the first nine months of Fiscal 2011, as compared to the same period last year, is higher due to the increased level of sales. Also, the gross loss in the first nine months of Fiscal 2010 was, in large part, due to a reserve in the amount of $15.9 million, which 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 facilities have ceased effective June 25, 2009, which has led to diminished sales of Caraco-owned products.

The gross profit margin for both the third quarter and first nine months of Fiscal 2011, as a percentage of net sales, was 8%, as compared to 6% and (3%), respectively, during the corresponding periods of Fiscal 2010. As disclosed above, we had created a reserve in the amount of $15.9 million during the first nine months of Fiscal 2010 for the inventory seized by the FDA. Excluding the impact of the inventory reserve, the gross profit margins in the first nine months of Fiscal 2010 was 6%.

The gross profit margin on distributed products was 11% and 9%, respectively, for the third quarter and first nine months of Fiscal 2011, as compared to 9% in both comparable periods of Fiscal 2010. The gross profit margin for Caraco-owned products was (10%) and (7%), respectively, for the third quarter and first nine months of Fiscal 2011, as compared to (33%) and (99%), respectively, for the corresponding periods of Fiscal 2010. Excluding the impact of the inventory reserve, the gross profit margin for Caraco-owned products in the first nine months of Fiscal 2010 was (14%). Caraco-owned product margins have increased in the third quarter primarily due to higher sales of Caraco-owned products including those which were acquired as part of the asset purchase agreement with Forest. The gross margins on Caraco-owned products in first nine months of Fiscal 2011 were higher primarily due to a reserve in the amount of $15.9 million created during the first nine months of Fiscal 2010 for the inventory seized by the FDA. During the first nine months 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. Overall gross profit margins on Caraco-owned products are negative due to high absorption of overheads in relation to the lower levels of sales. During the first nine months of Fiscal 2011 and Fiscal 2010 our overheads were $8.7 million and $12.0 million, respectively. As disclosed above, due to the actions of the FDA, all shipments of products which were being manufactured at the Company's facilities have ceased effective June 25, 2009, which has led to diminished sales of Caraco-owned products. However the Company continues to incur costs to maintain such facilities and to facilitate the resumption of manufacturing operations. 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 (see Note 6 - Sun Pharmaceutical Industries Limited) 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 third quarter and first nine months of Fiscal 2011 were $6.6 million and $20.4 million, respectively, as compared to $5.4 million and $15.9 million, respectively, during the corresponding periods of Fiscal 2010, representing increases of 22% and 28%, respectively. SG&A expenses were higher during the third quarter of Fiscal 2011 as compared to the corresponding period of Fiscal 2010 predominantly due to certain customer related adjustments recorded during the period. SG&A expenses were higher during the first nine months of Fiscal 2011 due to customer related adjustments and the recording of additional expenses primarily related to professional consultation fees pertaining to FDA issues and royalties related to certain Caraco-owned products which were acquired as part of the asset purchase agreement with Forest SG&A expenses, as a percentage of net sales were 20% and 8%, respectively, for the third quarter and first nine months of Fiscal 2011, as compared to 10% and 9%, respectively, for the corresponding periods of Fiscal 2010. SG&A expenses, as a percentage of sales, were high during the third quarter of Fiscal 2011 primarily due to lower net sales during the period.

Research and Development Expenses. Total R&D expenses incurred for the third quarter and first nine months of Fiscal 2011 were $1.7 million and $7.8 million, respectively, as compared to $2.8 million and $8.3 million, respectively, during the corresponding periods of Fiscal 2010. The R&D expenses during the first nine months of Fiscal 2010 were reduced by the reimbursement of a certain amount relating to certain product litigation costs as part of a settlement agreement, as previously disclosed. R&D expenses continues to be further decreased since the Company ceased manufacturing operations, as the Company has focused primarily on FDA remediation.

Net Other Income (Expense). We earned net other income of $0.2 million and $0.6 million during the third quarter and first nine months of Fiscal 2011, respectively, as compared to net other income of $0.1 million during both corresponding periods of Fiscal 2010.

Income Taxes. We recorded income tax benefits of $1.8 million and $1.9 million, respectively, during the third quarter and first nine months of Fiscal 2011, as compared to recording income tax benefits of $1.9 million and $3.0 million during the corresponding periods of Fiscal 2010.

Results of Operations. We incurred pre-tax losses of $4.8 million and $5.2 million, respectively, during the third quarter and first nine months of Fiscal 2011, as compared to pre-tax losses of $4.9 million and $8.8 million during the corresponding periods of Fiscal 2010. We incurred net losses of $3.0 million and $3.3 million, respectively, for the third quarter and first nine months of Fiscal 2011, as compared to incurring net losses of $3.0 million and $5.8 million, respectively, during the corresponding periods of Fiscal 2010.

Liquidity and Capital Resources We generated cash from operations in the amount of $2.5 million during the first nine months of Fiscal 2011, as compared to generating cash from operations in the amount of $15.5 million during the corresponding period of Fiscal 2010. The cash flow from operations was lower in the first nine months of Fiscal 2011, primarily due to the decrease in accounts payable balances, offset by decreases in accounts receivable and inventory balances, and lower net loss. Accounts receivable decreased by $97.5 million during the first nine months of Fiscal 2011, and as of December 31, 2010 balances payable to customers net, was $2.8 million, as compared to accounts receivable net, of $94.7 million at the end of Fiscal 2010. Accounts receivable is equivalent to (6) days sales outstanding ("DSO") as of December 31, 2010 versus 154 days as of March 31, 2010. The negative level of DSO at December 31, 2010 is temporary and is mainly due to the reserves which have been created for likely credits to be received from our customers for price adjustments and increased chargebacks for certain products which were earlier sold, and also due to timing of payments made by the wholesale customers. The wholesale customers make payment for invoices on gross sales, however, a deduction for chargebacks will be made by these wholesale customers as they continue to sell to retail chain stores and managed care organizations with whom we have contractual pricing. The Company believes that it has provided adequate reserves for chargeback deductions which are likely to be taken by the wholesale customers in subsequent periods. The lower level in DSO is also due to lower levels of sales in the current period and collection of receivable balances from certain customers with whom we have entered into agreements which included special payment terms. The collections of the related accounts receivable balances from these previous period sales were spread over an extended period which ended in the third quarter of Fiscal 2011. Based on the third quarter cost of sales, which is most representative of current sales activity, inventory levels at December 31, 2010 were equivalent to 129 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 decrease in inventory levels is primarily due to higher levels of sales in the first nine months of Fiscal 2011 of certain distributed products for which the Company was carrying the inventory in previous periods and currently does not carry any inventory for such products. The inventory, as of March 31, 2010, included high levels of inventory of Paragraph IV products to support the anticipated sales which occurred in the current fiscal year. Also during the third quarter of Fiscal 2011 the Company wrote-off certain inventory of such Paragraph IV products amounting to $29.5 million, and recovered the cost from Sun Pharma in accordance with the terms of Distribution and Sale Agreement.

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 facilities had a material adverse affect on our current operations and there may be a material adverse affect on our future 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 are expected to continue and contribute to the cash flows. Also, the Company has entered into an agreement with Forest which, to date, has provided three 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 Sun Pharma

and its affiliates that would allow the Company to realize revenues from these products. There is no assurance that such approvals will be granted. As of December 31, 2010, we have $54 million in cash and another $10 million in short-term investments, including the proceeds from a loan in the amount of $12.6 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, as well as the uncertainty of resumption in manufacturing activities, future costs of FDA compliance and associated costs, various litigation proceedings (see “Note 12. Litigation”) and the expiration of the marketing agreement and Distribution and Sale agreement, on January 28, 2012, both signed with Sun Pharma, there can be no assurance of this belief.

At December 31, 2010, we had working capital of $89.1 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 December 31, 2010 was 0.8% (effective rate was 2.91% taking into consideration the Interest Rate SWAP Agreement entered into by the Company details of which are given hereunder). 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 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. On October 9, 2010 this Letter of Credit expired and was not renewed, as the Company was released from this obligation under the terms of the Consent Decree. 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. The outstanding term loan is 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. 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 April 9, 2011. 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 on its Balance Sheets.

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 $12.6 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 December 31, 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 December 31, 2010.

Future Outlook

As previously disclosed, on December 3, 2010, the Company received a Proposal from Sun Pharma and Sun Global for a going private transaction by which Sun Pharma and Sun Global, and/or one or more of their affiliates, would acquire all of the outstanding shares of the Company’s common stock not held by Sun Pharma or Sun Global for $4.75 in cash per share. Subsequently, the Company’s Board of Directors authorized the Independent Committee of the Board to: (1) consider the Proposal including, but not limited to, reviewing (a) whether going private is appropriate for Caraco at this time is advisable or is inadvisable and should be rejected, (b) possible alternatives to the Proposal or opportunities which may be more advantageous to Caraco, and (c) the merits of the Proposal; (2) if deemed advisable, enter into discussions and negotiations with respect to the terms of the Proposal, including the proposed per share purchase price, with Sun Pharma and their advisors; and (3) make recommendations to the Board of Directors and as applicable, to the stockholders as to the Independent Committee's findings. The Independent Committee has also retained William Blair & Company as an independent financial advisor, and the Carrington Coleman law firm as independent legal counsel, to assist it in evaluating the Proposal.

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 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 cGMP audit programs, and will make any improvements that we believe to be necessary to improve these programs. Caraco continues to 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 are in the process of remediation and intend to effect the changes required to improve our performance on sales of these products, on a long-term basis. The Company’s remediation efforts towards the resumption of manufacturing and distribution from its facilities are still ongoing, but the Company is unable to predict when such manufacturing and distribution will resume. As previously disclosed, and as always is the case in matters such as these, there is no assurance that the remediation efforts will be successful or result in resolution of the FDA compliance issues.

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.

Under the terms of the Consent Decree, before resuming the manufacture of any product in the Company's manufacturing facilities, a number of significant steps and processes are required to be completed, and certifications and approvals from both outside experts and the FDA are to be obtained. All of the Company's prior approved products, together with the new products pending approval from the FDA, will be subject to these same processes, certification and approvals as set forth in the Consent Decree.

In evaluating and discussing with the cGMP experts the remediation steps completed to date and those yet to be completed, the Company has determined that it will not be able to begin the manufacture and distribution of products by the end of Fiscal Year 2011. The Company believes that, even assuming a successful remediation process, it will take significant time before the Company reaches its previous levels of manufacturing in its facilities. We are not able at this time to estimate the cost of these actions, which will be substantial, and once the manufacturing resumes, will include the costs of operating our manufacturing facility at volumes well below the facility's capacity. 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 monetary fines and other penalties.

The Company intends to augment the loss of sales of manufactured products by the sale of Caraco-owned products manufactured at third party sites and through sales of distributed products. Caraco-owned products that are manufactured outside of these facilities are not impacted by the aforementioned actions of the FDA. However, any disruption in supplies of the products manufactured at these third party sites due to cGMP issues, changes in market conditions or any other issues would significantly impact the revenues from such products.

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 periods subsequent to the cessation of manufacturing due to the actions of the FDA. Development of products at third party sites, currently in process by our partner companies will continue. Our production capacity is in place, which should support the business for years to come once we overcome our current obstacles.

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, one of which is an affiliate. We continue to upgrade our facilities, and expand our customer base. We now have 16 products, that we market (including Caraco-owned products being manufactured by other parties, including Sun Pharma, and those distributed under various agreements with 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 52 products.

In addition to certain Caraco-owned products manufactured by Sun Pharma and its affiliates, we have also transferred certain Caraco-owned products to alternate manufacturing sites of Sun Pharma and its affiliates that would allow the Company to realize revenues from those products. We have filed with the FDA supplements to ANDAs, for its approval, for these transferred products. There is no assurance that such approvals will be granted.

Should pricing pressures become more severe than anticipated; the result may be reduced 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 FDA's action and the Company's voluntary cessation of manufacturing have had, and are expected to continue to have, a material adverse effect on operations and operating results. At December 31, 2010, the Company had $54 million in cash and $10 million in short-term investments including the proceeds from a loan in the amount of $12.6 million. The Company believes that its cash flow from operations and cash balances will continue to support its ongoing business requirements including working capital requirements, funding of potential litigation expenses relating to Paragraph IV certification and financing of further capital investments. 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.

The Company has decreased its internal development of new products. Beginning in Fiscal 2007, we entered into seven definitive agreements with various companies, one of which is an affiliate, 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 such companies to five. During the first nine months of Fiscal 2011, the Company filed ANDAs with the FDA for two of these products.

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 was renewed in January 2010, for a period of one year, and was further extended until January 28, 2012, on which date it will terminate. The Company and its Independent Committee of the Board approached Sun Pharma and attempted to negotiate a long term renewal for the agreement; however, Sun Pharma exercised its right to end the agreement, following the extension, on January 28, 2012.

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 several products under this agreement including Pantoprazole sodium DR tablets and Oxaliplatin. See "Note 12. Litigation." The initial term of the Distribution and Sale agreement was set to expire on January 29, 2011 and has been extended until January 28, 2012, on which date it will terminate. The Company and its Independent Committee of the Board approached Sun Pharma and attempted to negotiate a long term renewal for this agreement; however, Sun Pharma exercised its right to end the agreement, following the extension, on January 28, 2012.

Currently our revenues are highly dependent on these agreements as we have ceased all manufacturing activities due to the actions of the FDA. Once these agreements are terminated, the Company would incur significantly higher losses and such non-renewal would have a material adverse effect on its results of operations. The future termination of these agreements may also result in loss of sales of distributed products prior to the termination, and thus may have material adverse effect on the Company's results of operations.

The Company'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.
- Discuss transition plan for transfer of products to Sun Pharma, currently marketed under distribution agreements with Sun Pharma, scheduled to expire in January 2012.
- 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.
- Increase revenue and cash by marketing ANDAs owned by Sun Pharma, and the prompt introduction of new products to the market.
- 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.
- Increase management training and development.

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) inability to achieve successful remediation efforts; (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, (xx) material litigation from product recalls, (xxi) the purported class action lawsuits alleging federal securities laws violations, (xxii) delays in returning the Company's products to market, including loss of market share, (xxiii) excessive dependency for revenues on the marketing agreement and distribution and sale agreement, both signed with Sun Pharma; (xxiv) excessive dependency on Sun Pharma and other third parties for manufacture of Caraco-owned products; (xxv) inability to successfully transfer Caraco-owned products; and (xxvi) 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 third quarter of Fiscal 2011 that materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company has engaged an outside firm to support its internal audit function.

PART II -- OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The information presented in Note 12 of Part I, Notes to Financial Statements, is incorporated herein by reference.

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

During the first nine months of Fiscal 2011, 1,088,000 shares of Series B Preferred Stock previously issued to Sun Global were converted into 1,088,000 shares of Caraco common stock and issued to Sun Global.

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

ITEM 6. EXHIBITS

10.34 Fourth Amendment to Loan Agreement with RBS Citizens N.A. dated January 7, 2011.

10.35 Certificate of Suspension of Loan Covenants between Caraco and RBS Citizens N.A. dated January 7, 2011.

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: February 9, 2011

By: /s/ GP. Singh Sachdeva
GP. Singh Sachdeva
Chief Executive Officer

Date: February 9, 2011

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

Exhibit Index

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