

CARACO PHARMACEUTICAL LABORATORIES LTD  
Form 10-K  
June 09, 2010

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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FORM 10-K

(Mark one)

Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the Fiscal Year ended March 31, 2010

Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Commission File No. 1-31773

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

Michigan  
(State of Incorporation)

38-2505723  
(I.R.S. Employer Identification No.)

1150 Elijah McCoy Drive, Detroit, MI 48202  
(Address of principal executive office)

(313) 871-8400  
(Registrant's telephone number)

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Securities Registered Pursuant to Section 12(b) of the Exchange Act:

Title of Each Class to be so Registered	Name of Each Exchange On which Each Class is to be Registered
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Common Stock, No Par Value	NYSE Amex
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Securities Registered Pursuant to Section 12(g) of the Exchange Act: None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15 (d) of the Exchange Act. Yes  No

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  No

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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 such shorter period that the registrant was required to submit and post such files).

Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendments to this Form 10-K.

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 definition of an "accelerated filer" and "large accelerated filer" in Rule 12b-2 of the Exchange Act

Large Accelerated Filer  Accelerated Filer  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

The aggregate market value of the voting common stock held by non-affiliates, based on the last sale price of the common stock as of September 30, 2009, the last day of the Registrant's most recently completed second quarter, as reported on the NYSE Amex Stock Exchange, was \$48,879,275.

Indicate the number of shares outstanding of each of the registrant's classes of Common Stock, as of the latest practicable date.

As of June 7, 2010, there were 39,090,194 shares of common stock outstanding.

Documents Incorporated By Reference:

Portions of the Proxy Statement for the 2010 Annual Meeting of Shareholders (to be filed with the Securities and Exchange Commission not later than 120 days after the end of the registrant's fiscal year) are incorporated by reference in Part III hereof.

CARACO PHARMACEUTICAL LABORATORIES, LTD.  
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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 those referenced in Part I, Item 1A below. 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.

PART I

Item 1. Business

Introduction

Caraco Pharmaceutical Laboratories, Ltd. (“Caraco” which is also referred to as the “Company,” the “Corporation,” “we,” “us,” or “our”) is a corporation organized under Michigan law in 1984, engaged in the business of developing, licensing, manufacturing, marketing and distributing generic, prescription and over-the-counter pharmaceuticals to the nation's largest wholesalers, distributors, warehousing and non-warehousing chain drugstores and managed care providers, throughout the U.S. and Puerto Rico.

Generic pharmaceutical products are the chemical and therapeutic equivalents of reference brand drugs. A reference brand drug is an approved drug product listed in the U.S. Food and Drug Administration (“FDA”) publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, popularly known as the “Orange Book.” The Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman Act”) provides that generic drugs may enter the market after the approval of an Abbreviated New Drug Application (“ANDA”) and the expiration, invalidation or circumvention of any patents on the corresponding brand drug, or the end of any other market exclusivity periods related to the brand drug. Generic drugs are bioequivalent to their brand name counterparts. Accordingly, generic products provide a safe, effective and cost-efficient alternative to users of these brand products. Branded generic pharmaceutical products are generic products that are more responsive to the promotion efforts generally used to promote brand products. Growth in the generic pharmaceutical industry has been driven by the increased market acceptance of generic drugs, as well as the number of brand drugs for which patent terms and/or other market exclusivities have expired.

The Company’s principal executive offices are located at 1150 Elijah McCoy Drive, Detroit, Michigan 48202, and its telephone number is (313) 871-8400. The Company files annual reports, quarterly reports, current reports, proxy statements and other information with the U.S. Securities and Exchange Commission. You may read and copy any of the Company’s SEC filings at the SEC’s Public Reference Room at 100 F Street, NE Washington, DC 20549. You may call the SEC at 1-800-SEC-0330 for further information about the Public Reference Room. Our SEC filings are also available to the public on the SEC’s website at <http://www.sec.gov> and at our principal Internet address at [www.caraco.com](http://www.caraco.com). We believe that these reports are made available as soon as reasonably practicable after we electronically file with or furnish them to the SEC.

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This Form 10-K covers the audited fiscal year, April 1, 2009 to March 31, 2010 (“Fiscal 2010”), and comparative information for the audited fiscal year, April 1, 2008 to March 31, 2009 (“Fiscal 2009”), and for the audited fiscal year, April 1, 2007 to March 31, 2008 (“Fiscal 2008”). Additional information is provided with respect to the audited fiscal year, April 1 2006 to March 31, 2007 (“Fiscal 2007”) and the audited fiscal year, April 1, 2005 to March 31, 2006 (“Fiscal 2006”). (See Item 6 below).

During Fiscal 2010, the Company formed a wholly-owned subsidiary, Caraco Pharma, Inc. To date, this subsidiary has not entered into any financial transactions.

## Overview

Our manufacturing facility was originally constructed in 1991, pursuant to a \$9.1 million loan from the Economic Development Corporation of the City of Detroit (the "EDC"). Since August 1997 a significant source of our funding had been from Sun Pharmaceutical Industries Limited, a specialty pharmaceutical corporation organized under the laws of India ("Sun Pharma"). Sun Pharma has contributed equity capital and has advanced us loans. In addition, among other things, Sun Pharma had in the past, acted as a guarantor on loans to Caraco, has supplied us with a substantial portion of raw materials for our products, entered into various marketing and distribution agreements, helped us obtain machinery and equipment to enhance our production capacities at competitive prices and transferred certain generic products and technology to us. Sun Pharma, along with its subsidiaries, own approximately 75% of the outstanding shares of the Company (approximately 76% including the convertible Series B Preferred Stock), (See "Current Status" and "Sun Pharmaceutical Industries Limited" below.). During Fiscal 2009 the Company completed the expansion of its Detroit, Michigan facility increasing the usable space from 82,000 square feet to 222,000 square feet. During the fourth quarter of Fiscal 2009 we obtained a term loan of \$18 million from RBS Citizens, N.A. d/b/a Charter One Bank ("Charter One Bank"). The proceeds from the loan are expected to be deployed to fund any product or assist in any potential acquisition to fuel our future growth. The Company obtained a \$15 million line of credit with Charter One Bank and a letter of credit was issued to the FDA against this line of credit. (See "Current Status" below).

## Current Status

As previously disclosed, on June 25, 2009, U.S. Marshals, at the request of the FDA, arrived and seized drug products manufactured in our Michigan facilities that the FDA stated in its complaint were adulterated. The seizure also included ingredients and in-process materials held at these same facilities. The estimated cost of such seized inventory as of March 31, 2010 was \$24.0 million. Caraco-owned products (those products for which Caraco owns the ANDAs) or licensed products distributed by Caraco that are manufactured outside of these facilities are not impacted, and distribution and marketing of these products continues. The Company has also transferred certain Caraco-owned products to additional manufacturing sites that would allow the Company to regain revenues from those products. The Company has filed with the FDA supplements to ANDAs, for its approval, for some of these transferred products.

Also as previously disclosed, the Company voluntarily entered into a Consent Decree of Condemnation, Forfeiture and Permanent Injunction ("Consent Decree") with the FDA on September 29, 2009. As stipulated in the Consent Decree, the Company will attempt to have the seized inventory released. The Company believes that, except for the raw materials which were opened solely for the purpose of sampling, the estimated cost of which is \$8.1 million, all other seized inventory would be difficult to recondition. Accordingly, such inventory in the amount of \$15.9 million has been written off as of March 31, 2010. In accordance with the Consent Decree, the Company has 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 January 29, 2010, we received a letter from the FDA, seeking clarification on certain points. We submitted our response to the letter on March 24, 2010. Subsequent to our response, the FDA sent us a letter asking for additional information on April 7, 2010, to which we have submitted our response on June 3, 2010.

As a result of the FDA action, we have voluntarily ceased manufacturing operations and instituted, in two phases, indefinite layoffs of approximately 430 of our employees. The Company has subsequently started recalling some of these employees in conjunction with its efforts to restart its manufacturing activities. The Consent Decree provides a series of measures that, when satisfied, will permit the Company to resume manufacturing and distributing those products which are manufactured in its Michigan facilities. The Company has engaged a consulting firm which is comprised of current good manufacturing practice ("cGMP") experts, in accordance with the Consent Decree, and 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.

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

During Fiscal 2010 we recorded net sales of \$233.7 million compared to \$337.2 million during Fiscal 2009. During Fiscal 2010, the sales of Caraco-owned products were \$22.3 million, as compared to \$111.8 million during Fiscal 2009, while the sales of distributed products during Fiscal 2010 were \$211.4 million, as compared to \$225.4 million during Fiscal 2009. We incurred \$10.1 million in R&D expense during Fiscal 2010 as compared to \$22.5 million during Fiscal 2009. We incurred a net pre-tax loss of \$13.2 million during Fiscal 2010, as compared to earning net pre-tax income of \$29.5 million during Fiscal 2009. Net pre-tax income in Fiscal 2010 was lower primarily due to the cessation of manufacturing at the Company's Michigan facilities resulting in the loss of revenues from such products, as disclosed above and also due to write off of inventory, in the amount of \$15.9 million, relating to inventory seized by the FDA, as disclosed above, partially offset by non-recurring income earned during Fiscal 2010 in the amount of \$20.0 million as part of an asset purchase agreement arising out of a settlement agreement entered into by the Company. Such income is not expected to recur in future periods. The Company provided an income tax benefit of \$4.5 million for Fiscal 2010, as compared to an income tax expense of \$8.9 million during Fiscal 2009. We incurred a net loss of \$8.7 million during Fiscal 2010, as compared to net income of \$20.5 million during Fiscal 2009. We generated cash from operations of \$5.7 million during Fiscal 2010, as compared to \$18.7 million during Fiscal 2009. At March 31, 2010, our inventory increased to \$103.2 million from \$79.5 million at March 31, 2009. Inventory as of March 31, 2010 was higher to support anticipated sales levels of various products including recently launched products which we distribute on behalf of Sun Pharma. At March 31, 2010, we had stockholders' equity of \$155.4 million, as compared to stockholders' equity of \$163.8 million at March 31, 2009. See "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations."

Pursuant to our products agreement with Sun Pharma Global Inc. ("Sun Global"), a wholly-owned subsidiary of Sun Pharma, we had selected, through March 31, 2008, all of the 25 products to be transferred to us by Sun Global. All of these 25 products had passed their bio-equivalency studies as of March 31, 2008. The final product was transferred to Caraco during the third quarter of Fiscal 2008 which concluded the obligations between the parties under this agreement. Sun Global earned 544,000 preferred shares for each product. See "Sun Pharmaceutical Industries Limited" and "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations – Future Outlook."

We filed two ANDAs relating to two products with the FDA during Fiscal 2010. We have not received FDA approval for any ANDAs during the Fiscal 2010 and do not expect to receive any approvals for products out of our Michigan facilities until we resolve the FDA's concerns as discussed above. The total number of ANDAs pending approval by the FDA as of March 31, 2010 was 31 (including four tentative approvals) relating to 27 products out of our Michigan facilities. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – FDA Compliance" below.

#### Overview of the Generic Drug Industry

We believe that sales of generic pharmaceuticals have increased in recent years due to a number of factors including (i) increased number of formerly patented drugs which have become available to generic competition; (ii) changes in governmental and third-party payer healthcare reimbursement policies to encourage cost containment; (iii) increased acceptance of generic drugs by physicians, pharmacists and consumers; (iv) modification of state and federal laws to permit or require substitution of generic drugs by pharmacists; and (v) enactment of ANDA procedures for obtaining FDA approval to manufacture generic prescription drugs.

The generic pharmaceutical business is highly competitive. Although generic pharmaceuticals must meet the same quality standards as branded pharmaceuticals, they could potentially be sold at prices that reflect a discount up to 95% (in some cases even more) than the price of their branded counterparts. The discount is primarily driven by the number of competitors selling any given product.



Companies aspiring to differentiate themselves and earn higher margins for generic drugs may have a strategy of manufacturing niche products, or hard to replicate products. For instance, products that are difficult to develop, requiring difficult-to-source raw materials or representing smaller therapeutic niche markets, are generally marketed by fewer companies and may also offer margins that are higher than those where barriers to entry do not exist. Companies may also employ a litigious strategy of patent challenges. The developer of a generic product that is the first to have its ANDA accepted for filing by the FDA and whose filing includes a Paragraph IV Certification that the patent on the brand-name drug is invalid, unenforceable and/or not infringed may be eligible to receive a 180-day period of generic market exclusivity (“first to file”). During that 180-day period, the exclusive generic product generally earns higher margins on a higher volume of sales than in a situation in which other generic competition was also present. Recently this strategy has also seen reduced margins as authorized generics (an industry term that describes instances when the brand innovator has licensed its brand product to a generic manufacturer or has chosen to produce another label and provide the brand drug generically at typical generic discounts) have become more prevalent.

### Caraco's Products and Product Strategy

Our present product portfolio includes 42 prescription products, in 93 strengths, in various package sizes. This represents products we distribute for Sun Pharma, and Caraco-owned products manufactured by Sun Pharma or other third parties. This does not include those Caraco-owned products for which the Company has temporarily ceased manufacturing and marketing, due to the enforcement actions of the FDA. The products are intended to treat a variety of disorders including but not limited to the following: hypertension, arthritis, epilepsy, diabetes, depression and pain management

We have submitted 73 ANDAs to the FDA for approval as of March 31, 2010, including two filed during Fiscal 2010, which includes three products with multiple ANDAs. Of these 73 ANDAs filed, the FDA has approved 42 through March 31, 2010. Accordingly, we have 31 pending ANDAs (including four tentative approvals) relating to 27 products. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – FDA Compliance" below.

To date, our strategy has been to analyze the marketplace and try to determine opportunities for products having good market potential, that are difficult to develop, that require difficult-to-source raw materials and/or products representing smaller therapeutic niche markets. We are marketing and developing products which will face potential patent litigation, and/or first to file opportunities. See "Item 3. Legal Proceedings." We anticipate also seeking opportunities to in-license authorized generics and other generic pharmaceuticals. We will also look to market other third party products that do not conflict with our current pipeline of products that we develop internally, or that we market or will market on behalf of Sun Pharma.

### Sun Pharmaceutical Industries Limited

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

In August 1997, we entered into an agreement whereby Sun Pharma was required to transfer to us the technology formula for 25 mutually agreed upon generic pharmaceutical products over a period of five years through August 2003. We exchanged 544,000 shares of our common stock for each such technology transfer of an ANDA product (when bio-equivalency studies were successfully completed) and 181,333 shares for each technology transfer of a DESI (Drug Efficacy Study Implementation Program-DESI) product. DESI products are Pharmaceutical products marketed prior to 1962 that required only a demonstration of safety. With the passage of the Drug Amendments of 1962, this changed and the law required drug products also show efficacy. Under the terms of this agreement, we conducted, at our expense, all tests including bio-equivalency studies. Sun Pharma delivered 13 out of a possible 25 products to us under this agreement. This agreement expired on November 21, 2002, and we entered into a new technology transfer agreement with Sun Global.

Under the agreement with Sun Global, which was approved by our independent directors, Sun Global agreed to provide us with 25 new mutually agreed upon generic drugs over a five-year period. Our rights to the products are limited to the United States and its territories or possessions, including Puerto Rico. Sun Global retains rights to the products in all other territories. Under this agreement, we conduct, at our expense, all tests including bio-equivalency studies. We are also obligated to market the products consistent with our customary practices and to provide marketing personnel. Sun Global received 544,000 shares of Series B Preferred Stock for each generic drug transferred, after such drug passed its bio-equivalency studies. The preferred shares are non-voting, do not receive dividends and are convertible into common shares after three years (or immediately upon a change in control) on a one-to-one basis. The preferred shares have a liquidation preference equal to the value attributed to them on the dates on which they were earned. While such preferred shares are outstanding, we cannot, without the consent of the holders

of a majority of the outstanding shares of the preferred stock, amend or repeal our articles of incorporation or bylaws if such action would adversely affect the rights of the preferred stock. In addition, without such consent, we cannot authorize the issuance of any capital stock having any preference or priority superior to the preferred stock.

In 2004, the products agreement was amended by the Independent Committee, comprised of the three independent directors, to eliminate the provision requiring that the Independent Committee concur in the selection of each product, and provides instead, that each product satisfy certain objective criteria developed by management and approved by the Independent Committee. Pursuant to such objective criteria, we have selected all 25 products, and all of the 25 products had passed bio-equivalency studies as of March 31, 2008. See Part II – Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Future Outlook.”

During the first quarter of 2004, Sun Pharma acquired 3,452,291 additional shares of common stock and 1,679,066 stock options from two former directors and a significant shareholder. Sun exercised these stock options during the fourth quarter of 2004.

Sun Pharma has been instrumental in our growth. It operates Research and Development Centers in Mumbai and Vadodara, India, where the development work for products is performed. In addition, pursuant to oral agreements between Caraco and Sun Pharma, Sun Pharma and its subsidiaries supply us with certain raw materials and formulations and assist us in acquiring machinery and equipment to enhance our production capacities. We obtain a substantial portion of our current raw materials from Sun Pharma and its subsidiaries. We purchase 28 active pharmaceutical ingredients from Sun Pharma and 63 active pharmaceutical ingredients from other third parties. Caraco currently purchases four formulations from Sun Pharma under aforementioned oral arrangements in addition to various formulations/products obtained from Sun Pharma and its subsidiaries under our marketing agreements. Sun Pharma also provides manufacturing services on certain of our products which Caraco is currently not in a position to manufacture due to the cessation of operations at its Michigan facilities, or when it is cost beneficial and will assist the Company in minimizing any capacity constraints at its manufacturing facilities. During Fiscal 2010, Fiscal 2009 and Fiscal 2008, we made net purchases of approximately \$241.7 million, \$8.4 million and \$498.5 million, respectively, in raw materials and formulations under these agreements from Sun Pharma and its subsidiaries. Sun Pharma and its affiliates provide such raw materials and formulations to Caraco on terms not materially less favorable in the aggregate than would be usual and customary in similar transactions between unrelated parties dealing at arm's length, which allows product returns and replacements in accordance with normal industry terms and practice. We acquired \$8 thousand worth of machinery, spares and equipment during Fiscal 2010 from Sun Pharma and its affiliates as compared to \$46 thousand and \$0.3 million, respectively, during Fiscal 2009 and Fiscal 2008. Such machinery and equipment was sold to us at Sun Pharma's cost. During Fiscal 2010 the Company made a sale of equipment of approximately \$0.2 million to Sun Pharma and its subsidiaries. No such sale was made in Fiscal 2009 or Fiscal 2008. Caraco has also obtained technical and scientific services, including bioequivalency studies, from the Clinical Research Organization (CRO) division of Sun Pharma. The products on which the Company decides to work with Sun Pharma is decided on a case by case basis as mutually agreed upon by both companies with terms that are not materially less favorable to the Company than would be obtained in similar arms'-length transactions between unrelated parties. During Fiscal 2010 and Fiscal 2009, we incurred \$1.5 million and \$0.3 million, respectively, related to these services. In the event that we would be required to identify a new supplier of raw materials, formulations or equipment currently supplied by Sun Pharma and its subsidiaries under the oral agreements, we believe we could do so without significant difficulty. In the case of specific raw materials and formulations, the transition to any new supplier could be accomplished in approximately nine to twelve months, based on the approval of the FDA of the new supplier. Caraco uses Sun Pharma and its affiliates to procure certain equipment and machinery only when it is financially beneficial to Caraco to do so. For the most part, we procure equipment from third parties other than Sun Pharma. We believe that any change to a new supplier of specific raw materials, formulations or equipment under our oral agreements would not have a material adverse effect on our operations.

Additionally, Sun Pharma has provided us with a number of highly qualified technical professionals who now work as Caraco employees.

Sun Pharma uses Caraco as a contract manufacturer and/or distributor for two of their products pursuant to agreements entered into in December 2004 and in January 2005, of which only one was being marketed until Caraco ceased all manufacturing operations at its Michigan facilities due to actions taken by the FDA as discussed above.

During Fiscal 2007, the Corporation entered into a three-year marketing agreement with Sun Pharma, which was reviewed and approved by the Board's Independent Committee. This agreement was further renewed for a period of one year in January 2010. Under the agreement, the Corporation purchases selected product formulations offered by Sun Pharma and markets and distributes the same as part of the current product offerings in the U.S., its territories and

possessions, including Puerto Rico. Sun Pharma is not obligated to offer Caraco products under this agreement, however, Caraco has the exclusive right to market in the U.S., its territories and possessions, including Puerto Rico, any products offered by Sun Pharma and accepted by Caraco.

During Fiscal 2008, the Corporation entered into a three-year distribution and sale agreement with Sun Pharma, which was reviewed and approved by the Board's Independent Committee. Under this agreement the Company purchases selected formulations which have been filed under Paragraph IV certification process with the FDA by Sun Pharma and offered for distribution. Paragraph IV certified ("Paragraph IV") products may face litigation challenges with respect to claims of patent infringement. See "Item 3. Legal Proceedings." 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.

Net sales from products selected under these agreements were \$211.4 million during Fiscal 2010, \$225.4 million during Fiscal 2009 and \$225.1 million during Fiscal 2008.

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

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

During the fiscal years ended March 31, 2010 and March 31, 2009, Sun Global converted 1,632,000 shares and 4,896,000 shares of Series B Preferred Stock into 1,632,000 shares and 4,896,000 shares of Common Stock, respectively. As of March 31, 2009, Sun Pharma's current beneficial ownership is 75%, (76% including its convertible Series B Preferred Stock).

In addition to its substantial relationship with, and dependence on Sun Pharma as described above, the Corporation is subject to certain risks associated with companies in the generic pharmaceutical industry. Profitable operations are dependent on the Corporation's ability to market its products at reasonable profit margins. In addition to maintaining profitable operations, the ongoing success of the Corporation will depend, in part, on its continuing ability to attract and retain key employees, obtain timely approvals of its ANDAs, and develop new products. See "Item IA. Risk

Factors” for further information.

#### Marketing

We believe the primary factors driving competition in the generic pharmaceutical industry are price, product development, timely FDA approval, manufacturing capabilities, product quality, customer service, reputation and consistent supplies.

Generally, Caraco competes effectively with respect to each of these factors; however the recalls initialted in the last year and the uncertainty on future approvals could have an impact on the Company’s perceived ability to compete effectively. Price remains a key competitive factor in the generic pharmaceutical business. To compete effectively on the basis of price and remain profitable, a generic drug manufacturer must manufacture its products in a cost-effective manner. In addition, we must maintain an adequate level of inventories to meet customer demands in a timely manner.

Our products are effectively marketed among all classes of customers, including wholesalers, buying groups, managed care organizations, chain retail pharmacies, distributors, independent retail pharmacies, hospitals, etc. Increased competition, the emergence of large buying groups representing independent retail pharmacies, the continued growth of managed care organizations and consolidation among wholesalers has resulted in higher discounts on pharmaceutical products. As the influence of these entities continues to grow, the Company will continue to face pricing pressure on our portfolio of products.

Our marketing objective is to compete effectively, encourage long-term relationships and supply contracts, increase our market share on products that have not matured, gain market share on new products that are to be launched, and continue to expand our customer base.

#### Sales and Customers

Net sales decreased during Fiscal 2010, in comparison to Fiscal 2009, primarily as a result of the adverse effect on sales of Caraco-owned products due to the actions of the FDA and the cessation of manufacturing, as disclosed above, and in part due to the negative impact of our voluntary recalls. See “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations – Fiscal 2010 Compared to Fiscal 2009.” Sales of distributed products were also lower due to price erosion for the products sold. We continue to remain competitive on products sold and marketed during Fiscal 2010. Our organization is focused on correcting any and all manufacturing issues to allow us to resume the manufacturing and sales of Caraco-owned products and emerge as a stronger company. In the interim, we will continue to focus our sales and marketing team on distributed product sales.

As is typical in the US retail sector, many of our customers are serviced through their designated wholesalers. For Fiscal 2010, the Company’s three largest wholesale customers, Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health, accounted for approximately 13%, 8% and 12%, respectively, of the Company’s total net sales. During Fiscal 2009 and Fiscal 2008, shipments to Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health, accounted for approximately 9%, 16% and 20%, respectively and 8%, 28% and 21%, respectively, of the Company’s total net sales. The majority of these net sales include sales for various customers of ours that have underlying direct contracts with our Company that are facilitated through our wholesale customers. During Fiscal 2010, sales to CVS Caremark Corporation accounted for approximately 37% of our net sales. The sales to CVS Caremark Corporation have increased as we entered into a new contract with them towards the end of Fiscal 2009. The sales contracts for CVS Caremark Corporation includes special payment terms, and accordingly, collections of the related accounts receivable balances from these sales are expected to occur over an extended period. No other single customer accounted for more than 10% of net sales for Fiscal 2010, Fiscal 2009 or Fiscal 2008. Balances due from the three wholesale customers represented approximately 53% and 47% of gross accounts receivable as at March 31, 2010 and 2009, respectively. The balance due from CVS Caremark Corporation represented approximately 30% of gross accounts receivable as at March 31, 2010.

#### Seasonality

The Company's business, taken as a whole, is not materially affected by seasonal factors.

#### Research and Development

The development of new prescription ANDA products, including formulation, stability testing and the FDA approval process, averages from two to five years. A drug is “bioequivalent” to a brand-name drug if the rate and extent of absorption of the drug tests are not significantly different from those of the brand-name drug. We perform our own stability testing. Bioequivalence testing is done through independent testing laboratories and also through a division of Sun Pharma. The Company’s research and development includes conducting market research and patent research on



brand name and generic pharmaceuticals in order to determine which products we may want to develop. We develop selected products, which include product formulation, bioequivalence testing, and analysis, and manage the development process of all our potential filings. We have also coordinated development provided by Sun Pharma and continue that development and testing in order to scale up to commercial batch sizes. We also integrate the work of other third party developers whose development projects run parallel with our own in order to improve the number of filings we submit annually. Our development list consists of both near term launches and launches that we intend to market several years in the future.

We incurred total R&D Expenses for Fiscal 2010, Fiscal 2009 and Fiscal 2008 as set forth below:

Fiscal 2010	\$10.1 million
Fiscal 2009	\$22.5 million
Fiscal 2008	\$29.7 million

The non-cash R&D Expenses for Fiscal 2010, Fiscal 2009 and Fiscal 2008 are set forth below:

Fiscal 2010	\$ 0
Fiscal 2009	\$ 0
Fiscal 2008	\$11.3 million

The R&D cash expenses during Fiscal 2010 were lower compared to Fiscal 2009 as we were reimbursed a certain amount relating to certain product litigation costs during the second quarter of Fiscal 2010, as part of a settlement agreement, as previously disclosed.

The non-cash technology transfer charges in Fiscal 2008 were for research and product development provided by Sun Global. Series B convertible preferred stock was issued in the past to Sun Pharma and its affiliates under the Products Agreement between the Corporation and Sun Global in exchange for the formulations of technology products delivered by Sun Global to the Corporation. The resulting amount of research and development expense was charged to operations and is 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 and Partners, an independent, third party valuation firm. The exchange of shares for each formulation was prior to the initial ANDA submission to the FDA. As disclosed previously, technologies for all of the 25 products under the products agreement have been transferred and all of the related preferred shares have been issued. This concluded the obligations between the parties and there will be no further issuances of preferred stock under this agreement.

We were responsible for submission of the ANDAs for these transferred formulations for FDA approval. In our experience, generally we submit an ANDA to the FDA approximately thirty days after receipt of the 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, 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.

## Regulation

The research and development, manufacturing and marketing of our products are subject to extensive regulation by the FDA and by other federal, state and local entities, which regulate, among other things, research and development activities, testing, manufacturing, labeling, storage, record keeping, advertising and promotion of pharmaceutical products.

The Federal Food, Drug and Cosmetic Act, the Public Health Services Act, the Controlled Substances Act and other federal statutes and regulations govern or influence our business. Noncompliance with applicable requirements can result in fines and other judicially imposed sanctions, including product seizures, injunction actions and criminal prosecutions. In addition, administrative remedies can involve voluntary recall of products, and the total or partial suspension of products as well as the refusal of the government to approve pending applications or supplements to approved applications. The FDA also has the authority to withdraw approval of drugs in accordance with statutory due process procedures.

FDA approval is required before any dosage form of any new unapproved drug, including a generic equivalent of a previously approved drug, can be marketed. All applications for FDA approval must contain information relating to product formulation, stability, manufacturing processes, packaging, labeling and quality control. To obtain FDA approval for an unapproved new drug, a prospective manufacturer must also demonstrate compliance with the FDA's cGMP regulations as well as provide substantial evidence of safety and efficacy of the drug product. Compliance with cGMP is required at all times during the manufacture and processing of drugs. Such compliance requires considerable Company time and resources in the areas of production and quality control.

We are subject to the periodic inspection of our facilities, procedures and operations and/or the testing of our products by the FDA, the Drug Enforcement Administration ("DEA") and other authorities, which conduct periodic inspections to ensure that the Company's facilities remain in compliance with cGMP regulations. In addition, in connection with its review of our applications for new products, the FDA conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems and processes comply with cGMP and other FDA regulations.

Typically, after the FDA completes its inspection, it will issue the Company a report on Form 483, containing the FDA's observations of possible violations of cGMP. Such observations may be minor or severe in nature. The degree of severity of the observation is generally determined by the time necessary to remediate the cGMP violation, any consequences upon the consumer of the Company's drug products, and whether the observation is subject to a warning letter from the FDA. FDA guidelines specify that a warning letter be issued only for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action.

The failure of a facility to be in compliance may lead to regulatory action that could result in production interruptions, product recalls or delays in drug approvals. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. The impact of one or more of these actions could have a material adverse effect on the Company's business. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – FDA Compliance" for disclosure of FDA inspections of our facilities in Fiscal 2009 and subsequent thereto.

There are generally two types of applications that would be used to obtain FDA approval for pharmaceutical human use products:

1) New Drug Application (“NDA”). Generally, the NDA procedure is required for drugs with active ingredients and/or with a dosage form, dosage strength or delivery system of an active ingredient not previously approved by the FDA. We do not have any NDAs pending approval with the FDA as of March 31, 2010.

2) Abbreviated New Drug Application (“ANDA”). The Hatch-Waxman Act established a statutory procedure for submission of ANDAs to the FDA covering generic equivalents of previously approved brand-name drugs. Under the ANDA procedure, an applicant is not required to submit complete reports of preclinical and clinical studies of safety and efficacy, but instead is required to provide bioavailability data illustrating that the generic drug formulation is bioequivalent to a previously approved drug. Bioavailability measures the rate and extent of absorption of a drug's active ingredient and its availability at the site of drug action, typically measured through blood levels. A generic drug is bioequivalent to the previously approved drug if the rate and extent of absorption of the generic drug are not significantly different from that of the previously approved brand-name drug.

The FDA may deny an ANDA if applicable regulatory criteria are not satisfied. The FDA may withdraw product approvals if compliance with regulatory standards is not maintained or if new evidence demonstrating that the drug is unsafe or lacks efficacy for its intended uses becomes known after the product reaches the market.

FDA policy and its stringent requirements have increased the time and expense involved in obtaining ANDA approvals and in complying with FDA's cGMP standards. The ANDA filing and approval process takes approximately 12 to 20 months, or may at times take even longer. The timing of final FDA approval of ANDA applications depends on a variety of factors, including whether or not the maker of the applicable branded drug is entitled to the protection of one or more statutory exclusivity periods, during which the FDA is prohibited from approving generic products. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on the patent expiration date. For example, the FDA may now extend the exclusivity of a product by six months past the date of a patent expiration if the manufacturer undertakes studies on the effect of their product in children (a so-called “pediatric extension”). FDA approval is required before each dosage form of any new drug can be marketed. Applications for FDA approval must contain information relating to bio-equivalency, product formulation, raw material suppliers, stability, manufacturing processes, packaging, labeling and quality control. FDA procedures require full-scale manufacturing equipment to be used to produce test batches for FDA approval. Validation of manufacturing processes by the FDA also is required before a company can market new products. The FDA conducts pre-approval and post-approval reviews and plant inspections to enforce these rules. Supplemental filings are required for approval to transfer products from one manufacturing site to another and may be under review for a year or more. In addition, certain products may only be approved for transfer once new bio-equivalency studies are conducted.

The Hatch-Waxman Act provides incentives for generic pharmaceutical manufacturers to challenge patents on branded pharmaceutical products and/or their methods of use, as well as to develop non-infringing forms of the patented subject matter. The Hatch-Waxman legislation places significant burdens on the challenger to ensure that such suits are not frivolous, but also offers the opportunity for significant financial reward if the challenge is successful.

If there is a patent listed in the FDA's Orange Book at the time of filing an ANDA with the FDA and the generic drug company intends to market the generic equivalent prior to the expiration of that patent, the generic company files with its ANDA a certification asserting that the patent is invalid, unenforceable and/or not infringed (a so-called "Paragraph IV Certification"). After receiving notice from the FDA that its application is acceptable for filing, the generic company sends the patent holder and the holder of the NDA for the brand-name drug a notice explaining why it believes that the patents in question are invalid, unenforceable or not infringed. Upon receipt of the notice from the generic company, the patent holder has 45 days during which to bring a patent infringement suit in federal district court against the generic company. The discovery, trial and appeals process in such suits can take several years.

If a suit is commenced by the patent holder, the Hatch-Waxman Act provides for an automatic stay on the FDA's ability to grant final approval of the ANDA for the generic product. The period during which the FDA may not approve the ANDA and the patent challenger therefore may not market the generic product is 30 months, or such

shorter or longer period as may be ordered by the court. The 30-month period may or may not, and often does not, coincide with the timing of the resolution of the lawsuit or the expiration of a patent, but if the patent challenge is successful or the challenged patent expires during the 30-month period, the FDA may approve the generic drug for marketing, assuming there are no other obstacles to approval such as exclusivities given to the NDA holder.

Under the Hatch-Waxman Act, the developer of a proposed generic drug which is the first to file and have its ANDA accepted for filing by the FDA, and whose filing includes a Paragraph IV Certification, may be eligible to receive a 180-day period of generic market exclusivity. This period of market exclusivity may provide the patent challenger with the opportunity to earn a return on the risks taken and its legal and development costs and to build its market share before competitors can enter the market.

The Generic Drug Enforcement Act of 1992 establishes penalties for wrongdoing in connection with the development or submission of an ANDA by authorizing the FDA to permanently or temporarily bar companies or individuals from submitting or assisting in the submission of an ANDA, and to temporarily deny approval and suspend applications to market off-patent drugs. The FDA has authority to withdraw approval of an ANDA under certain circumstances and to seek civil penalties. The FDA can also significantly delay the approval of a pending ANDA under certain circumstances and to seek civil penalties. The FDA can also significantly delay the approval of a pending ANDA under its “Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Policy.” Manufacturers of drugs must also comply with the FDA's cGMP standards or risk sanctions such as the suspension of manufacturing or the seizure of drug products and the FDA's refusal to approve additional ANDAs.

The DEA conducts inspections of pharmaceutical company facilities bi-annually. Each domestic drug product-manufacturing establishment must be registered with the FDA. Establishments, like ours, handling controlled substances, must be licensed by the DEA. We are licensed by both the FDA and DEA.

We are also subject to regulation under other federal, state and local regulations regarding work place safety, environmental protection and hazardous substance controls, among others. Specifically, we are licensed by the Michigan Board of Pharmacy as a manufacturer and wholesaler of prescription drugs and as a distributor of controlled substances. We are also licensed by the Michigan Liquor Control Commission to use alcohol in the manufacture of drugs.

Reimbursement legislation, such as Medicaid, Medicare, and other programs, governs reimbursement levels. All pharmaceutical manufacturers rebate to individual states a percentage of their revenues arising from Medicaid-reimbursed drug sales. Generic drug manufacturers currently rebate an applicable percentage of calculated average manufacturer price (AMP) marketed under ANDAs. We believe that the federal and state governments may continue to enact measures in the future aimed at reducing the cost of drugs and devices to the public. We cannot predict the nature of such measures or their impact on our profitability.

#### Environment

The Company is subject to federal, state, and local laws and regulations relating to the protection of the environment. These evolving laws and regulations may require expenditures over a long period of time to control environmental impacts. The Company has established procedures for the ongoing evaluation of its operations to identify potential environmental exposures and assure compliance with regulatory policy and procedures.

The Company believes that its operations comply in all material respects with applicable laws and regulations concerning the environment. While it is impossible to accurately predict the future costs associated with environmental compliance and potential compliance with environmental laws, any compliance is not expected to require significant capital expenditures and has not had, and is not presently expected to have, a material adverse effect on the Company's earnings or competitive position.

#### Suppliers and Materials

The principal components used in our business are active and inactive pharmaceutical ingredients and packaging materials. Some of these components are purchased from single sources; however, the majority of the components have an alternate source of supply. Development and approval of our pharmaceuticals are dependent upon our ability to procure components from FDA approved sources. Because the FDA approval process requires manufacturers to specify their proposed suppliers of components in their applications, FDA approval of a new supplier would be required if components were no longer available from the specified suppliers. We have been, and continue to be, actively identifying and validating alternate suppliers for our components. Our purchases of components are made



from manufacturers in the U.S. and from abroad, including Sun Pharma. See “Sun Pharmaceutical Industries Limited.” Purchases of components are primarily made in U.S. Dollars.

Although to date no significant difficulty has been encountered in obtaining components required for products and sources of supply are considered adequate, there can be no assurance that we will continue to be able to obtain components as required.

### Competition

The generic pharmaceutical industry is undergoing rapid and significant changes due to increasing numbers of generic manufacturers, introduction of authorized generics, technological advancement and consolidation among the customers. Many of our competitors have greater financial, production, and research and development resources and greater name recognition. Competition continues to be intense, which could result in further erosion of prices and profit margins. The number of generic manufacturers, both domestic and from overseas is increasing, resulting in increased pricing pressure. The most significant means of competition are price, innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, customer service and reputation. Other principal competitive factors in the generic pharmaceutical market are the ability to be the first company, or among the first companies, to introduce a generic product after the related patent expires, methods of distribution, maintenance of inventories for timely delivery, and breadth of product line. Approvals for new products may have a synergistic effect on a company's entire product line since orders for new products are frequently accompanied by, or bring about, orders for other products available from the same source. We believe that price is the most significant competitive factor in the generic industry, particularly as the number of generic entrants with respect to a particular product increases. As competition from other manufacturers intensifies, selling prices typically decline. We compete by keeping our prices competitive, selecting appropriate products, based on therapeutic segments, market sizes and number of competitors manufacturing the products, by providing reliability in the timely delivery, and in the continued quality, of our products.

### Loans Payable to Financial Institution

During the fourth quarter of Fiscal 2009 the Company entered into a term loan of \$18 million with Charter One Bank. The loan is secured by a mortgage covering the Company's manufacturing facility and equipment located in Detroit, Michigan. The rate of interest is calculated as LIBOR plus an applicable margin thereto (based upon various leverage levels and current applicable rate is 50 basis points). The aggregate rate applicable to the Company as of March 31, 2010 was 1.2%. The principal loan payments and accrued interest are payable on a quarterly basis beginning July 2009. The principal is to be repaid in equal quarterly installments of \$900,000 for ten quarters through October 2011, and thereafter, if not renewed, the remaining balance of \$9 million is due in the subsequent quarter by January 2012. Subsequently, in October 2009 the terms of the loan were modified and we entered into an amended agreement. The amendment adds to the loan a one year line of credit note for \$15 million against which the Company can borrow funds for working capital purposes or can get letters of credit issued. Against this line of credit, the Bank has issued an Irrevocable Standby Letter of Credit in an amount of \$15 million, in favor of the United States of America, as required to be placed with the FDA in accordance with the Consent Decree, as disclosed above. The line of credit carries an interest rate of LIBOR plus 150 basis points, and if letters of credit are issued, the associated fees are 0.7% of such letters of credit on annualized basis. Also, there is an unused fee of 0.25% on an annualized basis to the extent the line remains idle. Both the line of credit and outstanding term loan are cross collateralized by all of the Company's fixed assets and cash deposit accounts held with Charter One Bank, equivalent to the amount of outstanding loans and outstanding letter of credit. These cash deposits earn interest at prevailing rates applicable to such money market accounts. We are continuing discussions with Charter One Bank to allow the release of the cash collateral. Charter One Bank has temporarily suspended our required compliance with the covenants in the loan agreements relating to FDA enforcement actions, as previously disclosed, and has suspended certain other compliance requirements until October 9, 2010. On or before such date, we anticipate either entering into revised agreements or repaying the loan in full. Currently, as the loan is in technical default due to the FDA enforcement action, the entire outstanding balance has been classified as a short-term liability.

As required pursuant to the terms of the Loan Agreement, the Company has entered into an Interest Rate Swap Agreement with Charter One Bank to hedge the interest rate applicable on the loan. The notional amount for the swap is \$15.3 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 March 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 a provision of \$0.3 million to record the fair value of this swap agreement at March 31, 2010.

## Employees

We had a total of 535 and 667 full-time equivalent and contract employees at March 31, 2010 and 2009, respectively, engaged in research and development, manufacturing, quality assurance, quality control, administration, sales and marketing, materials management, facility management and packaging. Most of our scientific and engineering employees have had prior experience with pharmaceutical or medical products companies, including Sun Pharma. See “Sun Pharmaceutical Industries Limited.” As a result of the FDA action as discussed above, we have voluntarily ceased manufacturing operations and instituted, in two phases, indefinite layoffs. Out of 535 employees at March 31, 2010, 323 employees are on indefinite layoff. The Company has been recalling certain employees in conjunction with its efforts to restart its manufacturing activities.

A union represents substantially all of the Company’s permanent, full-time and regular part-time hourly employees. In September 2008, the Company successfully negotiated a new four-year collective bargaining agreement with the union. This agreement sets forth minimum wage increases and growth opportunities which the union employees will be eligible for in each of the next four years, thereby giving the Company and the union employees, the Company believes, a measure of certainty and stability. The collective bargaining agreement with the union is set to expire in September 2012, whereupon the Company expects to enter into a new agreement with the union.

## Product Liability and Insurance

We currently maintain general and product liability insurance, with coverage limits of \$10 million per incident and in the aggregate. Our insurance policies provide coverage on a claims made basis and are subject to annual renewal. Such insurance may not be available in the future on acceptable terms or at all. There can be no assurance that the coverage limits of such policies will be adequate to cover our liabilities, should they occur. See “Item 3. Legal Proceedings.”

## Item 1A. Risk Factors:

The following discussion highlights some of the risks related to our business and others are discussed elsewhere in this report. These and other risks could materially and adversely affect our business, financial condition, operating results or cash flows and the market value of our common stock. These risk factors may not include all of the important factors that could affect our business or our industry or that could cause our future financial results to differ materially from historic or expected results or cause the market price of our common stock to fluctuate or decline.

### Risks Related to Our Industry

If brand pharmaceutical companies are successful in limiting the use of generics through litigation, legislature and regulatory efforts, our sales of generic products may suffer.

Many brand pharmaceutical companies increasingly have used state and federal legislative and regulatory and other litigation as means to delay generic competition. These efforts have included:

- pursuing new patents for existing products which may be granted just before the expiration of one patent, which could extend patent protection for additional years or otherwise delay the launch of our generic product;
- submitting for changes in U. S. Pharmacopoeia which is an organization that publishes industry wide compendia of drug standards;
  - using the Citizen’s Petition process to request amendments to FDA standards;

- attaching patent extension amendments to non-related federal legislation;
- engage in state-by-state initiative to enact legislation that restricts substitution of certain generic drugs which could possibly impact products that we are developing.

FDA approval is required before any generic drug products can be marketed. The process of obtaining FDA approval to manufacture and market new and generic pharmaceutical products is rigorous, time-consuming, costly and largely unpredictable.

We, or a business partner, may be unable to obtain requisite FDA approvals on a timely basis for new generic products that we may develop, license or otherwise acquire. Additionally, other pharmaceutical companies may not be able to obtain approval to manufacture products, which we plan to distribute on their behalf. The timing and cost of obtaining FDA approvals for Caraco, our business partners, and other manufacturers for which we distribute products (including Sun Pharma) could adversely affect our product introduction plans, financial position and results of operations and could cause the market value of our common stock to decline.

The ANDA approval process may result in the FDA granting final ANDA approvals to more competitors than anticipated for a given product at the time a patent claim for a corresponding brand product or other market exclusivity expires resulting in lower than anticipated margins and sales.

The addition of more competition when we introduce a generic product into the market potentially lowers our gross profit margin and overall sales. Additionally, ANDA approvals often continue to be granted for a given product subsequent to the initial launch of the generic product. These circumstances generally result in significantly lower prices, as well as reduced margins, for generic products compared to brand product's pricing. New generic market entrants generally cause continued price and margin erosion over the generic product life cycle.

Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities.

All pharmaceutical companies are subject to complex, costly regulations that continue to evolve as set forth by the federal government; principally the FDA, and to a lesser extent the DEA and state government agencies. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other federal statutes and regulations govern the testing, manufacturing, storage, packing, labeling, record keeping, safety, sales and marketing, promotion, and distribution of our products.

We are also subject to various federal, state and local laws regulating working conditions, as well as environmental protection laws and regulations, including those governing the discharge of materials into the environment. Although we have not incurred significant costs associated with complying with environmental provisions in the past, if changes to such environmental laws and regulations are made in the future that require significant changes in our operations or if we engage in the development and manufacturing of new products requiring new or different environmental controls, we may be required to expend significant funds. Such changes could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

New legislation or regulatory proposals may adversely affect our revenues

A number of legislative and regulatory proposals have been proposed and could be proposed in the future that are aimed at changing the health care system, easing safeguards that limit importation and reimportation of prescription products from countries outside the United States, providing preferential treatment to manufacturers of generic pharmaceutical products, imposing additional and possibly conflicting reporting requirements on prescription pharmaceutical companies, reducing the level at which pharmaceutical companies are reimbursed for sales of their products, and requiring significant monitoring initiatives by manufacturers in an attempt to reduce the misuse and abuse of controlled substances. Additionally, the Company may also be impacted by The Patient Protection and Affordable Care Act.

While we cannot predict when or whether any of these proposals will be adopted or the effect these proposals may have on our business, these and other similar proposals may exacerbate industry-wide pricing pressures and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

#### Risks Related to Our Company

The Company is subject to periodic routine inspections from regulatory authorities.

The Company is subject to periodic routine inspection of our facilities, procedures, operations and the testing of our products by the FDA, the DEA and other authorities that regulate our business. These inspections are designed to confirm that we are in compliance with all applicable regulations. Following inspections, the FDA has issued notices on Form 483 and a subsequent warning letter. A Form 483 notice is generally issued at the conclusion of a FDA inspection and lists conditions the FDA inspectors believe may violate cGMP or other FDA regulations. FDA guidelines specify that a warning letter is issued only for violations of “regulatory significance” for which the failure to promptly and adequately achieve correction may be expected to result in an enforcement action. Possible sanctions could include among others, FDA issuance of adverse publicity, fines, product recalls, total or partial suspension of production and/or distribution, suspension of the FDA’s review of product applications, enforcement actions, injunctions, and civil or criminal prosecution. These sanctions, if imposed, could materially harm our operating results and financial condition. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Although we have internal compliance programs in place these programs may not meet regulatory agency standards or if compliance is deemed deficient in any significant way, it could materially harm our business. See “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations – FDA Compliance” with respect to disclosure of such FDA inspections in Fiscal 2009 and in Fiscal 2010, issuances to us of observations and a warning letter, recalls and delays in approvals of new products. Additionally see the discussion of the FDA seizure below.

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

As a result of the FDA enforcement action, we have voluntarily ceased manufacturing operations and instituted an indefinite reduction in our workforce of approximately 430 employees in two phases. The Company voluntarily entered into a Consent Decree with the FDA on September 29, 2009. The Company has engaged a consulting firm which is comprised of cGMP experts, in accordance with the Consent Decree. As stipulated in the Consent Decree, the Company will attempt to have the seized inventory released. The Company believes that, except for the raw materials which were opened solely for the purpose of sampling, the estimated value of which is \$8.1 million, all other seized inventory would be difficult to recondition. Accordingly, such inventory in the amount of \$15.9 million has been written off as of March 31, 2010. 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 January 29, 2010, we received a letter from the FDA, seeking clarification on certain points. In consultation with our third party cGMP experts, we provided such clarification in a letter to the FDA on March 24, 2010. Subsequent to our response, the FDA sent us a letter asking for additional information on April 7, 2010, to which we have submitted our response on June 3, 2010. Additionally, the Company has subsequently started recalling some of the laid-off employees in conjunction with its efforts to restart its manufacturing activities. The Consent Decree provides a series of measures that, when satisfied, will permit the Company to resume manufacturing and distributing those products which are manufactured in its Michigan facilities. The Company has submitted a remediation work plan, approved by our consultants, to the FDA in October 2009. Following the submission of some additional details and clarifications to the work plan, the FDA approved the work plan on March 17, 2010. The Company is in the process of implementing the corrective actions and remedial measures as stipulated in the work plan.

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

If we are unable to successfully develop or commercialize new products, our operating results will suffer.

Our future results of operations depend to a significant extent upon our ability to successfully commercialize new products in a timely manner. There are numerous difficulties in developing and commercializing new products, including:

- developing, testing and manufacturing products in compliance with regulatory standards in a timely fashion;



- receiving the requisite regulatory approvals for such products in a timely manner;
- the availability of raw materials at a competitive cost, including active pharmaceutical ingredients and other key ingredients;
- development and commercializing new products is time consuming, costly and subject to various factors, including litigation brought by our competitors or against those parties that manufacture products that we distribute (including Sun Pharma), that may delay or prevent the development and commercialization of new products expected to market.

Our gross profit may fluctuate from period to period depending upon our product sales mix, including new launches, our product pricing, customer class of trade, and our costs for active ingredients.

Some specific issues that could result in a fluctuation could include any or all of the following:

- the amount of new product introductions;
- the level of competition and associated pricing pressure in the marketplace for certain products;
- the availability of raw materials;
- the balance of sales between manufactured product margin and distributed products margin.

The profitability of our product sales is also dependent upon the prices we are able to charge for all our products, the costs of excipients purchased from third parties, and our ability to manufacture our products in a cost effective manner.

Our policies regarding returns and chargebacks by wholesalers may reduce our revenues in future fiscal periods.

Based on industry practice, generic product manufacturers including Caraco have liberal return policies and make decisions whether or not to provide shelf stock allowances (or credits) for inventories on hand for product that has already been sold to the customer. If a new competitor enters the marketplace and significantly lowers the price of any of its competing products, it is possible that we would make a decision to reduce the price of our product. As a result, we would be obligated to provide significant credits to our customers who are then holding inventories of such products, which could reduce sales revenue and gross margin for the period the credit is provided. Like our competitors, we also give credits for chargebacks to wholesale customers that have contracts with us for their sales to chain drug retail, group purchasing organizations, or other retail customers.

A chargeback represents an amount payable in the future to a wholesaler for the difference between the invoice price paid to us by our wholesale customer for a particular product and the negotiated contract price that the wholesaler's customer pays for that product. Although we believe we establish adequate reserves based on: (i) our historical experience, (ii) actual chargebacks received, (iii) current chargeback rates and (iv) on hand inventory remaining at our wholesale customers, we cannot ensure that our reserves are adequate or that actual product returns, allowances and chargebacks will not exceed our estimates, which could adversely affect our financial condition, cash flows and market price of our stock.

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

The class action litigation (See “Item 3. Legal Proceedings” below) alleging violations of federal securities laws by the Company and certain of its executives involves claims which, if successful, could adversely affect our financial condition, operating results or cash flows and the market value of our common stock.

We are and may become involved in various legal proceedings including, but not limited to, patent infringement, product liability, contract and employment claims involving substantial amounts of money or for other relief

The Company is currently involved, and from time to time becomes involved, in certain legal proceedings relating to the conduct of its business, including those related to patent disputes, product liability, contract and employment claims. See Item 3. – Legal Proceedings.

An adverse determination in a judicial or administrative proceeding relating to patent infringement and/or product liability could prevent us from manufacturing and selling a product(s), which could negatively affect our financial condition and results of operations. The manufacture, use and sale of new products that are the subject of conflicting patent rights have been and are the subject of substantial litigation in the pharmaceutical industry. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. We may have to defend against charges that we violated patents or proprietary rights of third parties. Litigation may be costly and time-consuming, and could divert the attention of our management and technical personnel. If it is found that we infringe on the rights of others, we could lose our right to develop or manufacture products or could be required to pay monetary damages or royalties to license proprietary rights from third parties. We market product formulations on behalf of Sun Pharma which have been filed under the Paragraph IV certification process with the FDA. Paragraph IV filings generally result in patent infringement litigation. While our liability for patent infringement is capped at the fixed margin percentage and we are indemnified by Sun Pharma, damages may be significant and could have a material adverse effect on our operations. Also see “Item - 3. Legal Proceedings” and “Item 7. “Management’s Discussion and Analysis of Financial Conditions and Results of Operations – Future Outlook” for further information.

Although we carry product liability insurance, we believe that no reasonable amount of insurance can fully protect against all such risks because, among other things, of the potential liability inherent in the business of producing pharmaceuticals for human consumption. To the extent that a loss occurs, depending on the nature of the loss and the level of insurance coverage maintained, it could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

The loss of our key personnel could cause our business to suffer.

The success of our present and future operations will depend, to a significant extent, upon the experience, abilities and continued services of key personnel. We cannot assure you that we will be able to attract and retain key personnel. We do not maintain key person insurance.

Sales of our products may continue to be adversely affected by the continuing consolidation of the distribution network and the concentration of customers.

Our principal customers are wholesale drug distributors, major retail drug store chains and managed care companies. These customers comprise a significant portion of the distribution network for pharmaceutical products in the U.S. This distribution network is continuing to undergo significant consolidation marked by mergers and acquisitions among wholesale distributors, large retail drug store chains, managed care companies and mergers of a combination of trade classes. As a result, a small number of large wholesale distributors and large chain drug stores and managed care providers control a significant share of the market. We expect that consolidation of drug wholesalers, retailers and managed care providers will increase competitive pressures on drug manufacturers, including Caraco.

Even if we are able to obtain regulatory approvals for our new pharmaceutical products, the success of those products is dependent upon market acceptance. Levels of market acceptance for our new products could be impacted by several factors, including:

- availability of alternate product from our competitors;
- the timing of our market entry;
- acceptance of our product on government and private formularies;
- the prices that we sell our products at versus our competitors’ prices.

From time to time, a relatively small group of products could represent a significant portion of our sales and if the sales of these products decline unexpectedly it could have a negative material effect on our business and could cause the market value of our common stock to decline.

Sales of a limited number of our products often represent a significant portion of our net revenues and net earnings. If the volume or pricing of our largest selling products declines in the future, our business, financial position and results of operations could be materially adversely affected, and the market value of our common stock could decline.

Our competitors may be able to develop products and processes competitive with or superior to our own for many reasons, including that they may have:

- proprietary processes or product delivery systems;
- larger research and development and marketing staffs;
- larger production capacity in general or for a given product;
- more financial resources than Caraco;
- more experience in developing new drugs.

Our reporting and payment obligations under Medicaid and other governmental programs are complex and may change periodically based upon new guidelines provided by those agencies.

Although the regulations regarding reporting and payment obligations are complex, we believe we are properly and accurately calculating and reporting the amounts owed in respect of Medicaid and other governmental pricing programs. Our calculations are subject to review and challenge by the applicable governmental agency, and it is possible that any such review could result in material changes. Any governmental agencies may initiate an investigation of the Company and could impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs (including Medicaid and Medicare).

We depend primarily on Sun Pharma to assist us in our research and development.

Sun Pharma could determine that its own research and development takes precedence over the research and development it provides to Caraco. Though we believe we have made efforts to mitigate this risk by working with other third party developers and increasing our own research and development capabilities, there could be a development gap if Sun Pharma chose to prioritize their internal projects over Caraco's development projects. This could cause a gap in our research and development timelines until we achieve further advancement of our own capabilities. Any gap could possibly cause future growth deficits until resolved.

We depend on Sun Pharma for the active pharmaceutical ingredients that we use to manufacture our products.

We typically purchase many active pharmaceutical ingredients (i.e. the chemical compounds that produce the desired therapeutic effect in our products) and other materials and supplies that we use in our manufacturing operations, as well as certain finished products, from Sun Pharma. Sun Pharma could face supply issues or not be capable of supplying the raw material for certain products we manufacture. While we have begun the process of identifying and contracting with other third party suppliers, any disruption in Sun's supply could cause lower sales or possibly lower margins until we negotiate with new suppliers and gain the requisite approvals to manufacture our product with a new raw material source.

We maintain safety stocks in our raw materials inventory and where we have listed only one supplier in our applications with the FDA, we have, in certain cases, received approval for the ability to use alternative suppliers should the need arise. However, there is no guarantee that we will always have timely and sufficient access to a critical raw material or finished product. A prolonged interruption in the supply of a single-sourced raw material, including the active ingredient, or finished product could cause our financial position and results of operations to be materially adversely affected, and the market value of our common stock could decline. In addition, our

manufacturing capabilities could be impacted by quality deficiencies in the products which our suppliers provide.

We have various marketing agreements with Sun Pharma and its affiliates that may not be renewed.

Sun Pharma, along with its affiliates, and Caraco have various marketing agreements that are based on an offer and acceptance to market various products that Sun Pharma has filed or will file with FDA. Though Sun Pharma's majority ownership would most likely provide a vested interest in the health and success of our Company, there is no assurance that Sun Pharma will offer us products under, or renew these marketing agreements.

DEA quotas may be restricted, limiting our ability to have enough product to manufacture and market these products each year.

The Company utilizes controlled substances in certain of its current products and products in development and therefore must meet the requirements of the Controlled Substances Act of 1970 and the related regulations administered by the DEA. These regulations relate to the manufacture, shipment, storage, sale and use of controlled substances. The DEA limits the availability of the active ingredients used in certain of our current products and products in development and, as a result, our procurement quota of these active ingredients may not be sufficient to meet commercial demand or complete clinical trials. We must annually apply to the DEA for procurement quota in order to obtain these substances. Any delay or refusal by the DEA in establishing our procurement quota for controlled substances could delay or stop our clinical trials or product launches, or could cause trade inventory disruptions for those products that have already been launched, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

A significant portion of our net sales are from sales to a limited number of customers. Should we lose a particular contract with a customer, the customer is acquired by a non-customer, or the customer is negatively impacted by any business or regulatory issues, our sales and operational results could face a significant decline.

A significant portion of our net revenues are derived from sales to a limited number of customers. As such, a reduction in or loss of business with one customer for any number of reasons, or if one customer were to experience difficulty in paying us on a timely basis, our business, financial position and results of operations could be materially adversely affected. See Item 1. Business – Sales and Customers for additional information.

An increase in product recalls could harm our business.

Product recalls or product field alerts may be issued at our discretion or at the discretion of the FDA, other government agencies or other companies having regulatory authority for pharmaceutical product sales. From time to time, we may recall products for various reasons, including failure of our products to maintain their stability through their expiration dates. Any recall or product field alert has the potential of damaging the reputation of the product or our reputation. To date, recalls have not had a direct, material adverse effect on our business, financial condition, results of operations or cash flows. However, we cannot assure that the number and significance of recalls will not increase in the future. Any significant recalls could materially affect our sales and the prescription trends for the products and damage the reputation of the products or our reputation. In these cases, our business, financial condition, results of operations and cash flows could be materially adversely affected. See Item 7. “Management’s Discussion and Analysis of Financial Conditions and Results of Operations – FDA Compliance” with respect to disclosure of certain product recalls.

We must maintain adequate internal controls and be able to demonstrate, and provide, on an annual basis an assertion as to the effectiveness of such controls. Failure to maintain adequate internal controls or to implement new or improved internal controls could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Effective internal controls are necessary for the Company to provide reasonable assurance with respect to our financial reports. We spend a substantial amount of management time and resources to comply with changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002 and new SEC regulations and rules. In particular, Section 404 of the Sarbanes-Oxley Act of 2002 requires management’s annual review and evaluation of our internal control systems, and attestations as to the effectiveness of these systems by our independent registered public accounting firm. If we fail to maintain the adequacy of our internal controls, we

may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting. Additionally, internal control over financial reporting may not prevent or detect misstatements because of its inherent limitations, including the possibility of human error, the circumvention or overriding of controls, or fraud. Therefore, even effective internal controls can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements. In addition, projections of any evaluation of effectiveness of internal control over financial reporting to future periods are subject to the risk that the control may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. If the Company fails to maintain the adequacy of its internal controls, including any failure to implement required new or improved controls, this could have a material adverse effect on our business, financial position and results of operations, and the market value of our common stock could decline.



Any of these factors and others could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Item 1B. Unresolved Staff Comments

None

Item 2. Properties.

Facilities

Our primary facility located in Detroit, Michigan, which was designed and constructed to our specifications and completed in 1994, contains our production, research and development and corporate office. During Fiscal 2006, we added approximately 10,000 square feet of manufacturing space, giving us a total of 82,000 square feet of usable space. We finished an expansion of this facility in 2009 that increased the usable space to 222,000 square feet. The expansion occurred on the acreage the Company acquired for \$0.3 million directly adjacent to its existing manufacturing facility. The expanded facility encompasses additional space required for manufacturing, quality control laboratories, raw material storage and administrative offices. It will also introduce additional automated equipment and process flow efficiencies in order to reduce long term costs associated with our production, while maintaining quality. The manufacturing portion of the facility has a special building and systems design, with each processing area equipped with independent zone and air handling units to provide temperature and humidity control to each room. These air handling units are designed to prevent product cross contamination through the use of pre-filter and final HEPA filter banks. All processing air quarters are maintained in a negative pressure mode using laminar airflow design. This system of airflow provides a measurable control of air borne particulate entrapment in each room. Environmental segregation of individual rooms within a particular zone is accomplished by the use of duct HEPA filter booster fan units that facilitate the isolation and confinement of room activities. These special dynamics provide an added dimension and flexibility in product selection and processing techniques. As disclosed, however, the Company has voluntarily ceased manufacturing as a result of the FDA action. The Detroit facility and the equipment therein are subject to a mortgage in connection with the \$15.3 million loan to the Company from Charter One Bank.

In addition, the Company continued updating its packaging facility located in Farmington Hills, Michigan. During Fiscal 2007, the Company acquired this packaging facility for \$1.7 million. We have improved the infrastructure and process flow by replacing manual packaging lines with automated lines, thereby having less human intervention. This has already improved quality control in our packaging operations and will result in improved capacity. This 33,369 square foot facility was previously owned and operated by a third party packager of our portfolio of products. This acquisition has already lowered our overall costs in packaging and bottling and has increased our production. As disclosed, however, the Company has voluntarily ceased manufacturing as a result of the FDA action and thus currently no operations are being carried out at this packaging facility also.

During Fiscal 2008, we leased an approximately 137,500 square foot facility located in a suburb of Detroit for finished goods distribution, storage of inventory and office space. The lease expires in 2018 and includes an option to renew until 2023.

We previously leased an approximately 55,000 square foot facility located near our primary facility for finished goods distribution, storage of inventory and office space. The lease expired in March 2009, and the Company did not renew the lease as these operations have been moved to the new expanded facility, as discussed above.

We also leased an approximately 13,000 square foot office space for our administrative, sales and marketing and accounting staff. The lease expired during Fiscal 2009, and the Company did not renew the lease as these offices have

been moved to the new expanded facility, as discussed above.

We have invested approximately \$3.1 million during Fiscal 2010, \$26.9 million during Fiscal 2009 and \$5.1 million during Fiscal 2008 to upgrade our facilities and production. We believe this investment will improve work flow, compliance and quality. Further, such capital investment will provide the capacity to grow over the next five years.

### Intangible Assets

The Company made a payment in the first quarter of Fiscal 2009 in the amount of \$1.1 million for the purchase of certain assets which included brand products, associated NDAs and trademarks. These assets are recorded as intangible assets in the Company's balance sheet at March 31, 2010. Additionally, the Company paid \$0.4 million towards product and establishment fees for these products. These intangible assets are being amortized ratably over a period of 15 years, the period during which the Company expects to receive economic benefits from these intangible assets. The Company annually reviews these assets to determine whether the carrying values have been impaired.

### Item 3. Legal Proceedings.

While it is not possible to determine with any degree of certainty the ultimate outcome of the following legal proceedings, the Company believes that it has meritorious defenses with respect to the claims asserted against it and intends to vigorously defend its position. An adverse outcome in any of these proceedings could have a material adverse effect on the Company's financial position and results of operations.

As previously disclosed, on June 9, 2005, Novo Nordisk A/S and Novo Nordisk, Inc. ("Novo Nordisk") filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Company's filing of an ANDA seeking approval to market its generic version of Novo Nordisk's Prandin® (repaglinide) drug product infringed Novo Nordisk's U.S. Patent No. 6,677,358. Novo Nordisk seeks an order from the Court which, among other things, directs the FDA not to approve the Company's ANDA any earlier than the claimed expiration date. The ANDA filed by the Company contains a Paragraph IV certification challenging the Novo Nordisk patent as well as a section viii statement with regard to the patent's method claim. The Company believes that this Novo Nordisk patent is invalid, unenforceable and/or will not be infringed by the Company's manufacture, use or sale of the product. The Company believes that it is the first to file an ANDA with a Paragraph IV certification for this drug product and it intends to defend this action vigorously to capitalize on the potential for obtaining 180 days exclusivity available for this product. The Company filed a supplemental answer and counterclaim challenging Novo Nordisk's recent Orange Book use code amendment by Novo Nordisk in reference to Prandin®. On September 25, 2009, the District Court entered an injunction requiring Novo Nordisk to correct its amended use code description for Prandin® on the ground that it does not accurately characterize the referenced method patent. Novo Nordisk then appealed that injunction. On October 14, 2009, the parties entered into a stipulation regarding the appeal. On October 27, 2009, the United States Court of Appeals for the Federal Circuit entered an Order staying the use code injunction during the appeal. Under the stipulation, if the Company were to prevail on the use code injunction appeal, Novo Nordisk would stipulate to noninfringement based on Caraco's proposed section viii split-certification. If Novo Nordisk prevails on the use code injunction appeal, the parties will proceed to trial on patent validity and unenforceability. On April 14, 2010, the Court of Appeals reversed the decision of the District Court. Subsequently, on May 14, 2010, the Company filed a petition for rehearing en banc in the Federal Circuit. The trial regarding the validity and unenforceability of the patent began on June 1, 2010.

As previously disclosed, on September 22, 2004, Ortho-McNeil Pharmaceutical, Inc. ("Ortho-McNeil") filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Company's filing of an ANDA seeking approval to market its generic version of Ortho-McNeil's Ultracet® brand tramadol/acetaminophen drug product infringed Ortho-McNeil's patent, which expires on September 6, 2011. Ortho-McNeil sought an order from the district court which, among other things, directed the FDA not to approve the Company's ANDA any earlier than the claimed expiration date. The ANDA filed by the Company contains a Paragraph IV Certification challenging the Ortho-McNeil patent. The Company asserted that the Ortho-McNeil patent is invalid and/or will not be infringed by the Company's manufacture, use or sale of the product. Since filing this action, Ortho-McNeil authorized a generic manufacturer to provide a generic version of Ortho-McNeil's Ultracet® product while another manufacturer launched its approved generic at risk. On October 19, 2005, the Company's motion for summary judgment was granted. On

December 19, 2005, the FDA approved the manufacture, use and sale of the Company's generic product. Ortho-McNeil filed an appeal of the finding of noninfringement by the district court with the United States Court of Appeals for the Federal Circuit. On January 19, 2007, the United States Court of Appeals for the Federal Circuit affirmed the lower court's decision granting the Company's motion for summary judgment.

Additionally, the United States Patent and Trademark Office approved Ortho-McNeil's request for a reissue patent. Although the district court had determined that the Company does not infringe Ortho-McNeil's original patent, on July 31, 2006, Ortho-McNeil filed a lawsuit against the Company in the United States District Court for the District of New Jersey, alleging that the Company's generic version of Ultracet® brand tramadol/acetaminophen drug product infringes its reissue patent. On September 26, 2006, the Company filed an answer denying, among other things, that its generic product infringes any valid claims of Ortho-McNeil's reissue patent. On December 10, 2007, the Company filed a motion for summary judgment that the asserted claims of the reissue patent were obvious and therefore invalid as a matter of law. This motion was granted by Judge Cavanaugh of the United States District for New Jersey on April 17, 2008. Final judgment has been granted. On August 25, 2008, Ortho-McNeil filed a notice of appeal with respect to that judgment with the United States Court of Appeals for the Federal Circuit. The appeal was fully briefed and was argued on July 7, 2009. On August 26, 2009, the Court of Appeals reversed a portion of the previously decided summary judgment. Although the Court did find that a portion of the patent was not valid, the Court remanded the litigation back to the lower court for further proceedings. Caraco subsequently filed a combined petition for a panel rehearing and a rehearing en banc. That combined petition was denied, and the case has been remanded back to the Court for further proceedings.

As previously disclosed, on May 5, 2009, Wyeth filed a complaint against the Company and Sun Pharma in the United States District Court for the Eastern District of Michigan. The complaint alleges that the package insert for Sun Pharma's product that is distributed by the Company and which is a generic version of Wyeth's Protonix® (pantoprazole) pharmaceutical product contains false and misleading statements regarding the active ingredient of that product in violation of federal and state laws. The complaint requests damages, injunctive relief and attorneys' fees and costs. The Company and Sun Pharma believe that they have not engaged in any improper conduct and intend to vigorously contest these allegations. On July 6, 2009, the Company and Sun Pharma filed a Motion to Dismiss the Complaint for Failure to State a Claim Upon Which Relief May Be Granted. Plaintiff's brief in response to the Company's and Sun Pharma's Motion to Dismiss was filed on July 30, 2009. Caraco and Sun Pharma filed a reply memorandum of law in support of its Motion to Dismiss on August 13, 2009. On March 2, 2010, the Court dismissed Wyeth's complaint, but without prejudice. On March 31, 2010, Wyeth filed a Notice of Appeal with United States District Court for the Sixth Circuit.

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

In 2007, Sun Pharma filed an ANDA to market an oxiplatin product designed to treat stage III colon cancer, and the generic equivalent of Sanofi-Aventis' Eloxatin® product. The ANDA contained a paragraph IV certification of non-infringement of the patents which support Eloxatin®. Pursuant to an agreement with Sun Pharma, the Company has the right to serve as a distributor for Sun Pharma's for this generic product. In July of 2007, Sanofi-Aventis U.S. LLC and certain of its affiliates filed a patent infringement action against Sun Pharma and the Company in the United

States District Court for the District of New Jersey, alleging that Sun Pharma's ANDA infringed U.S. Patent Number 5,338,874. Sanofi-Aventis also filed similar patent infringement actions against other generic manufacturers. The Court consolidated all of these pending actions. In August of 2008, Sanofi-Aventis amended its claim against Sun Pharma and the Company to add a claim for infringement of an additional Eloxatin® patent (U.S. Patent Number 5,959,133). Sun Pharma and the Company denied Sanofi-Aventis' allegations and asserted affirmative defenses and counterclaims for invalidity and unenforceability of the relevant patents.

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

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

As previously disclosed, on July 10, 2006, Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S (collectively, "Forest") filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Company's filing of an ANDA seeking approval to market its generic version of Forest's Lexapro® (escitalopram oxalate) drug product infringed Forest's Patent No. Re. 34,712 (the "'712 patent"). The ANDA contains Paragraph IV Certifications challenging the '712 patent, as well as two other Forest-owned patents, the 6,916,941 ("the '941 patent") and 7,420,069 ("the '069 patent"). Forest did not assert the '941 patent or '069 patent, so the Company brought declaratory judgment actions seeking a declaration that it did not infringe those patents. The Company vigorously litigated all three cases.

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

1. Forest has agreed to provide licenses to the Company for any patents related to Lexapro® with respect to the marketing of the Company's generic version of the product as of the date that any third party generic enters the market with final approval from the FDA other than an authorized generic or the first filer with Hatch-Waxman exclusivity.
2. Forest has reimbursed the Company for a portion of its attorney's fees related to this litigation.
3. Pursuant to the APA, the Company is taking over the commercialization and sale of several products from Forest's Inwood business and received compensation payment from Forest in connection with certain products that were not transferred through its Inwood business. Caraco has paid Forest an advance against royalties and will pay royalties on net sales of the products which have been taken over from Forest's Inwood business.

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

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



On September 29, 2009, Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc. (“Taro”) filed suit against Caraco and Sun Pharma and certain of its affiliates in the United States District Court for the Southern District of New York. The complaint, as it pertains to Caraco, alleges misappropriation and misuse of trade secrets, unfair competition, tortious interference with business relationships, fraud and unjust enrichment. The claims against Caraco arise out of Caraco’s purported access to information from Taro as a part of the due diligence conducted for Sun Pharma’s tender offer for Taro Pharmaceuticals Industries Ltd. On December 18, 2009, the Defendants filed a Motion to dismiss the complaint. That motion has been fully briefed by the parties and is pending before the Court.

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

The Company is also currently involved, and from time to time becomes involved, in certain other legal proceedings relating to the conduct of its business, including those pertaining to product liability, contract and employment claims. With respect to employee claims the Company is currently involved in three employment lawsuits, involving multiple plaintiffs. The Company carries employment practices liability insurance. Additionally, the Company does not believe these claims constitute material litigation matters. With respect to product liability claims, we are currently involved in a total of 10 cases, 9 of which involve products alleged to have been manufactured by the Company. The Company carries product liability insurance in an amount it believes is sufficient for its needs. The Company is also a defendant in one product liability case, where it is alleged that the Company distributed a product manufactured by another party. In that instance, the Company is contractually indemnified by the product manufacturer. While the outcome of any of such proceedings cannot be accurately predicted, the Company does not believe that the ultimate resolution of any of these existing proceedings will have a material adverse effect on the Company’s financial condition or liquidity.

## PART II

## Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer's and Affiliates' Purchases of Equity Securities.

Our common stock is listed on the NYSE Amex under the symbol "CPD." The following table sets forth for Fiscal 2010, Fiscal 2009 and Fiscal 2008, the high and low sales prices for each of the applicable quarters.

Fiscal 2010	High	Low
First Quarter	\$ 5.28	\$ 1.75
Second Quarter	\$ 5.29	\$ 2.78
Third Quarter	\$ 6.79	\$ 3.65
Fourth Quarter	\$ 6.94	\$ 4.22

Fiscal 2009	High	Low
First Quarter	\$ 18.70	\$ 12.58
Second Quarter	\$ 16.40	\$ 11.80
Third Quarter	\$ 12.71	\$ 2.93
Fourth Quarter	\$ 7.35	\$ 3.27

Fiscal 2008	High	Low
First Quarter	\$ 16.20	\$ 12.10
Second Quarter	\$ 17.12	\$ 12.71
Third Quarter	\$ 17.17	\$ 13.14
Fourth Quarter	\$ 18.50	\$ 14.90

As of June 7, 2010 there were 76 registered holders of our common stock.

During Fiscal 2010, Fiscal 2009 and Fiscal 2008, 1,632,000, 4,896,000 and 4,352,000 shares of preferred stock were converted into an equal number of shares of common stock and issued to Sun Pharma Global Inc.

Under the products agreement with Sun Global, as previously described, during Fiscal 2008 we issued to Sun Global 1,088,000 preferred shares in exchange for the transfer of two products. As of March 31, 2008, all 25 of the products under this agreement had been selected and all of these 25 products had passed their respective bio-equivalency studies. The final product was transferred to Caraco during the third quarter of Fiscal 2008, which concluded the obligations between the parties under this agreement.

All shares of preferred stock and common stock specified above that were issued by the Company were issued pursuant to exemptions from registration under Section 4(2) of the Securities Act of 1933.

The information in Item 12 relating to "Equity Compensation Plan Information" is incorporated herein by reference.

#### Dividend Policy

We have never declared or paid cash dividends on our common stock. We currently intend to retain all future earnings for the operation and expansion of our business. We do not anticipate declaring or paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends on the common stock will be made at the

discretion of the Board of Directors and will depend upon our results of operations, earnings, capital requirements, and other factors deemed relevant by our Board of Directors.

## Item 6. Selected Financial Data

The following selected financial data of the Company is qualified by reference to, and should be read in conjunction with, the financial statements and notes thereto and other financial information included elsewhere herein. The summary balance sheet data as of March 31, 2010 and 2009 and summary statements of operations data for the years ended March 31, 2010, 2009 and 2008, are derived from and qualified by reference to the audited financial statements of the Company which are included elsewhere herein. The summary balance sheet data as of March 31, 2008, 2007 and 2006 and the summary of the statements of operations for the year ended March 31, 2007 and 2006 is derived from the audited financial statements of the Company which are not included herein and have been previously filed with the SEC.

## Financial Data

(In thousands, except per share data)

Statements of operations data	Year ended March 31,				
	2010	2009	2008	2007	2006
Net sales	\$233,674	\$337,177	\$350,367	\$117,027	\$82,789
Cost of goods sold	234,073	269,382	265,652	59,243	41,873
Gross (loss) profit	(399 )	67,795	84,715	57,784	40,916
Selling, general and administrative expenses	22,769	16,418	14,322	9,880	8,183
Research and development costs – affiliate – (non cash)	-	-	11,321	11,761	35,055
Research and development costs – other	10,121	22,528	18,366	10,591	8,437
Non-recurring (income)	(20,000 )	-	-	-	-
Operating (loss) / income	(13,289 )	28,849	40,706	25,552	(10,759 )
Other income / (expense), net	115	603	1,688	1,306	336
(Loss) / income before income taxes	(13,174 )	29,452	42,394	26,858	(10,423 )
Income tax (benefit) / expense	(4,514 )	8,915	7,006	-	-
Net (loss) / income	(8,660 )	20,537	35,388	26,858	(10,423 )
Net (loss) / income per share					
Basic	(0.22 )	0.60	1.19	1.02	(0.39 )
Diluted	(0.22 )	0.51	0.89	0.72	(0.39 )
Weighted Average Shares Outstanding:					
Basic	38,613	34,227	29,657	26,447	26,392
Diluted	38,613	40,576	39,914	37,255	26,392

Financial Data (continued)

(In thousands)

Balance Sheet Data	As of March 31,				
	2010	2009	2008	2007	2006
Current assets	\$271,991	\$169,864	\$500,022	\$95,439	\$62,282
Property, plant and equipment, net	43,243	44,823	21,267	19,030	14,960
Intangible assets	1,286	1,383	-	-	-
Deferred income taxes	21,579	20,418	16,986	-	-
Total assets	338,099	236,488	538,275	114,469	77,242
Current liabilities	182,713	57,365	395,495	19,276	20,864
Working Capital	89,278	112,499	104,527	76,163	41,418
Long term debt	-	15,300	-	-	-
Total liabilities	182,713	72,665	395,495	19,276	20,864
Stockholders' Equity	155,386	163,823	142,780	95,193	56,378

## Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis provides information that the management believes is relevant to an understanding of our results of operations and financial condition. The discussion should be read in conjunction with the financial statements and notes thereto.

### Critical Accounting Policies and Estimates

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. 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. Our significant estimates include our provisions for price adjustments (primarily chargebacks), valuation allowances for deferred tax assets, and valuation of inventory.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements. 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, the selling price is fixed or determinable, and collectibility is reasonably probable. Our customers consist primarily of large pharmaceutical wholesalers who sell directly into the retail channel, chain drug stores, distributors, and managed care customers. Provisions for sales discounts, and estimates for chargebacks, rebates, and product returns are established as a reduction of product sales revenue at the time revenues are recognized, based on historical experience and current market trends adjusted to reflect known changes in the factors that impact these reserves. These revenue reductions are reflected as a direct reduction to accounts receivable through an allowance.

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

### Chargebacks

Chargebacks represent our most significant provision against gross accounts receivable and related reduction to gross revenue. Chargebacks are retroactive credits given to our wholesale customers that represent the difference between the lower price they sell (contractual price) to retail, chain stores, managed care organizations, etc and what we charge

the wholesaler. We estimate chargebacks at the time of sale for our wholesale customers. We are currently unable to specifically determine whether the amounts allowed in specific prior periods for chargeback reserves have been over or understated. Wholesaler customers who submit chargebacks to the Company do not reference a specific invoice that the chargeback is related to when the chargeback is submitted to the Company. Thus, we cannot determine the specific period to which the wholesaler's chargeback relates.

We consider the following factors in the determination of the estimates of chargebacks.

1. The historical data of chargebacks as a percentage of sales, as well as actual chargeback reports received from our primary wholesaler customers.
2. Volume of all products sold to wholesaler customers and the average chargeback rates for the current quarter as compared to the previous quarter and compared to the last six month period.
3. The sales trends and future estimated prices of our products, wholesale acquisition cost (WAC), the contract prices with the retailers, chain stores, managed care organizations (end-users), and our wholesaler customer's contract prices.
4. We utilize remaining inventories on hand at our primary wholesaler customers at the end of the period in the calculation of our estimates.

Such estimated amounts, in addition to certain other deductions, are deducted from our gross sales to determine our net revenues. The amount of actual chargebacks claimed could be either higher or lower than the amounts we accrued. Changes in our estimates, if any, would be recorded in the income statement in the period the change is determined. If we materially over or under estimate the amount that will ultimately be charged back to us by our wholesale customers, there could be a material impact on our financial statements.

#### Shelf Stock Adjustments

Shelf stock adjustments are credits issued to our customers to reflect decreases in the selling prices of our product. These credits are customary in the industry and are intended to reduce the customers' inventory cost to better reflect current market prices. The determination to grant a shelf stock adjustment to a customer following a price decrease is at our discretion.

Factors considered when recording a reserve for shelf stock adjustments include estimated launch dates of competing products based on market intelligence, estimated decline in market price of our product based on historical experience and input from customers and levels of inventory held by customers at the date of the adjustments as provided by them.

#### Product returns and other allowances

In the pharmaceutical industry, customers are normally granted the right to return product for credit if the product has not been used prior to its expiration date. Our return policy typically allows product returns for products within a twelve month window from six months prior to the expiration date and up to six months after the expiration date. We estimate the level of sales that 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 quality related issues, such information from the customers is used to estimate an additional reserve. The amount of actual product return could be either higher or lower than the amounts we accrued. Changes in our estimates, if any, would be recorded in the income statement in the period the change is determined. If we over or under estimate the quantity of product which will ultimately be returned, there may be a material impact on our financial statements.



Discounts (trade and prompt payment discounts) are accrued at the end of every reporting period based on the gross sales made to the customers during the period and based on their terms of trade. We review the contracts between the customer and us as well as the historical data and percentages to estimate the discount accrual.

Customer rebates are estimated at every period end, based on direct or indirect purchases. If the purchases are direct (purchases made by end use customers directly from the Company), the rebates are recognized when products are purchased and a periodic credit is given. For indirect purchases (purchases by end use customers through wholesale customers), 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 Fiscal 2010 were \$452.8 million as compared to \$648.1 million for Fiscal 2009. Sales allowances, which include chargebacks, returns, discounts, other customary customer deductions and other sales costs, constituted approximately 48% for both Fiscal 2010 and Fiscal 2009. Net sales for Fiscal 2010 were \$233.7 million as compared to \$337.2 million for Fiscal 2009.

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

(\$ in Thousands)

	Balances at beginning of year	Allowances charged to Gross Sales		Credits taken by customers	Balance at the end of year
		Current Period	Prior Period		
Fiscal 2009					
Chargebacks, rebates & shelf stock adjustments	\$ 78,905	\$ 291,070	-0-	\$ 319,947	\$ 50,028
Returns and discounts	5,273	19,870	-0-	18,588	6,555
Doubtful Accounts	118	231	-0-	271	78
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

The above sales allowances at March 31, 2009 include \$4.2 million related to the product recalls initiated near the end of Fiscal 2009 and early Fiscal 2010.

### Short-Term Investments

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

### 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 \$22.1 million and \$20.8 million at March 31, 2010 and March 31, 2009, respectively. Valuation allowances are provided when based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. We have recorded an income tax benefit of \$4.5 million for Fiscal 2010, as compared to an income tax provision of \$8.9 million for Fiscal 2009. The income tax benefit for Fiscal 2010 was predominantly due to losses incurred as a result of FDA actions including the seizure of inventory which resulted in a write-off as discussed above. We have not provided for any valuation allowance as of March 31, 2010 or March 31, 2009. Based upon the level of projected future taxable incomes over the periods in which these deferred assets are deductible, the Company expects that it is more likely than not that it will realize the benefit of these temporary differences. As of March 31, 2010, we had federal net operating loss carryforwards ("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 March 31 2010.

The Company is subject to U.S. federal income tax as well as income tax in certain state jurisdictions. As previously disclosed, the IRS had initiated an examination of the Company's tax return for the fiscal year ended March 31, 2007. The examination has been completed and the IRS has notified the Company that no adjustments are required to be made to the tax return filed for the period under review. The Company's federal statute of limitations has expired for years prior to 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 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 March 31, 2010 and March 31, 2009 includes materials purchased in the amount of \$2.2 million and \$2.9 million, respectively, related to products for which the Company has filed ANDAs

with the FDA, and the commercial launch of such products will commence once the approvals are received. The determination of whether or not inventory costs will be realizable requires estimates by management. A critical estimate in this determination is the estimate of the future expected inventory requirements, whereby we compare our internal sales forecasts to inventory on hand. Actual results may differ from those estimates and inventory write-offs may be required. We must also make estimates about the amount of manufacturing overhead to allocate to our finished goods and work in process inventories. Although the manufacturing process is generally similar for our products, we must make judgments as to the portion of costs to allocate to purchased product, work in process and finished goods, and such allocations can vary based upon the composition of these components and the fact that each product produced does not necessarily require the same amount of time or effort for the same production step. Accordingly, the assumptions we make can impact the value of reported inventories and cost of sales.

As disclosed above, on June 25, 2009, certain drug products manufactured, work in process, and ingredients held, at the Company's Michigan facilities were seized at the direction of the FDA. The estimated cost of such seized inventory as of March 31, 2010 was \$24.0 million. The Company has voluntarily entered into a Consent Decree and is in the process of getting the material released. The Company believes that, except for the raw materials which were opened solely for the purpose of sampling, the estimated cost of which is \$8.1 million, all other seized inventory would be difficult to recondition. Accordingly, such inventory in the amount of \$15.9 million which consists of work in process relating to those materials which are in various stages of production within our manufacturing facilities, all finished goods and those raw material ingredients which are partially consumed in process, has been written off as of March 31, 2010. In accordance with the Consent Decree, the Company has 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 January 29, 2010, we received a letter from the FDA, seeking clarification on certain points. We submitted our response to the letter on March 24, 2010. Subsequent to our response, the FDA sent us a letter asking for additional information on April 7, 2010, to which we have submitted our response on June 3, 2010. The Company believes that it will be able to use the inventory of raw materials which were opened solely for sampling purposes, however, in the event the Company is unable to recondition or recover all of such inventory, the Company will adjust the value of its inventory accordingly in future periods, which would result in a negative impact on the future operating results of the Company.

#### FDA Compliance

On October 31, 2008, the Company received a warning letter from the Detroit District of the FDA for its manufacturing facility in Detroit, Michigan. In this letter, the Agency reiterated some of the concerns detailed in the previous Forms 483 issued as a result of previous inspections. We responded to the warning letter on November 24, 2008 for the deficiencies noted and provided our corrective actions. The Detroit District acknowledged our response on December 22, 2008. It noted that our corrective actions would be evaluated during the FDA's next scheduled inspection of our Detroit facility. 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. Some of the observations were relative to the recent recalls and compliance, whereas others were focused on inventory controls. The FDA's inspection found unresolved violations of current Good Manufacturing Practice (cGMP) requirements as previously disclosed in our last SEC filing on Form 10-K filed June 15, 2009. On March 31, 2009, we recalled all tablets of Digoxin, USP, 0.125 mg, and Digoxin, USP, 0.25 mg, distributed prior to March 31, 2009 to the consumer level. As a precautionary measure, in April 2009, we initiated recalls of certain product lots manufactured in our Detroit, Michigan facility, primarily to the retail and wholesale levels. The total sales revenue, related to these recalls, we believe, is approximately \$4.2 million. These recalls were voluntarily initiated by the Company with the knowledge of the FDA. The recalls were made as a precautionary measure. The Company provided a written response to these observations on June 19, 2009. On June 25, 2009, U.S. Marshals, at the request of the FDA, seized drug products manufactured in our Michigan facilities. The seizure also included ingredients held at these same facilities as well as work in process. Products distributed by Caraco that are manufactured outside of these facilities are not impacted. In its complaint relating to its seizure, the FDA stated, among other things, that the May 12, 2009 inspection and the Company's written response thereto revealed continuing significant cGMP violations. The FDA also stated that the drug products are adulterated in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and/or holding do not conform to and are not operated and administered in conformity with cGMP requirements. As a result of the FDA action, we voluntarily ceased manufacturing operations and instituted an indefinite reduction in our workforce of approximately 430 employees in two phases. The Company has subsequently started recalling some of these employees in conjunction with its efforts to restart its manufacturing activities. This FDA action has resulted and will result in a material adverse effect on our current and near term operations.

On September 29, 2009, Caraco voluntarily entered into a Consent Decree with the FDA regarding the Company's drug manufacturing operations. The Consent Decree provides a series of measures that, when satisfied, will permit

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

Under terms of the Consent Decree, Caraco's cessation of manufacturing operations will continue until it receives written notification from independent experts and the FDA that it is in compliance with the Consent Decree and regulations and can resume operations. Caraco-owned products or licensed products distributed by Caraco that are manufactured outside of these facilities are not impacted, and distribution and marketing of these products continues. There is no assurance that the steps taken will be successful or result in resolution of the FDA complaint. We are also not able, at this time, to estimate the cost of these actions. We intend to continue to work with the FDA to resolve its concerns as effectively and expeditiously as possible.

We have not received FDA approvals for any of our ANDAs since the first quarter of Fiscal 2009. It is unlikely that we will receive any approvals for product out of our Michigan facilities until the FDA reviews our remediation response and makes a determination of our status. We have submitted a remediation work plan, approved by our consultants, to the FDA in October 2009. Some additional details and clarifications to the work plan were submitted to the FDA in response to their letters, seeking such clarifications. The FDA, after reviewing our responses, informed the Company in a letter dated March 17, 2010, that it has approved the work plan. Remediation activities are ongoing with the full knowledge of the cGMP experts. 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 January 29, 2010, we received a letter from the FDA, seeking clarification on certain points. We submitted our response to the letter on March 24, 2010. Subsequent to our response, the FDA sent us a letter asking for additional information on April 7, 2010, to which we have submitted our response on June 3, 2010.

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

#### Overview of Fiscal 2010

The Company is engaged in the business of developing, licensing, manufacturing, marketing and distributing generic, prescription and over-the-counter pharmaceuticals to the nation's largest wholesalers, distributors, warehousing and non-warehousing chain drugstores and managed care providers, throughout the U.S. and Puerto Rico.

As previously disclosed, on June 25, 2009, U.S. Marshals, at the request of the FDA, arrived and seized drug products manufactured in our Michigan facilities that the FDA stated in its complaint were adulterated. The seizure also included ingredients and in-process materials held at these same facilities. The estimated cost of such seized inventory as of March 31, 2010 was \$24.0 million. Caraco-owned products or licensed products distributed by Caraco that are manufactured outside of these facilities are not impacted, and distribution and marketing of these products continues. The Company has also transferred certain Caraco-owned products to additional manufacturing sites that would allow the Company to regain revenues from those products. The Company has filed with the FDA supplements to ANDAs, for its approval, for some of these transferred products.

Also as previously disclosed, the Company voluntarily entered into a Consent Decree with the FDA on September 29, 2009. As stipulated in the Consent Decree, the Company will attempt to have the seized inventory released. The Company believes that, except for the raw materials which were opened solely for the purpose of sampling, the estimated cost of which is \$8.1 million, all other seized inventory would be difficult to recondition. Accordingly, such inventory in the amount of \$15.9 million has been written off as of March 31, 2010. In accordance with the Consent Decree, the Company has 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 January 29, 2010, we received a letter from the FDA, seeking clarification on certain points. We submitted our response to the letter on March 24, 2010. Subsequent to our response, the FDA sent us a letter asking for additional information on April 7, 2010, to which we have submitted our response on June 3, 2010.

As a result of the FDA action, we have voluntarily ceased manufacturing operations and instituted, in two phases, indefinite layoffs of approximately 430 of our employees. The Company has subsequently started recalling some of these employees in conjunction with its efforts to restart its manufacturing activities. The Consent Decree provides a series of measures that, when satisfied, will permit the Company to resume manufacturing and distributing those products which are manufactured in its Michigan facilities. The Company has engaged a consulting firm which is

comprised of cGMP experts, in accordance with the Consent Decree, and 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.



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

We recorded net sales of \$233.7 million during Fiscal 2010 compared to \$337.2 million during Fiscal 2009. During Fiscal 2010, the sales of Caraco-owned products were \$22.3 million, as compared to \$111.8 million during Fiscal 2009, while the sales of distributed products during Fiscal 2010 were \$211.4 million, as compared to \$225.4 million during Fiscal 2009. We have generated cash from operations of \$5.7 million during Fiscal 2010 as compared to \$18.7 million during Fiscal 2009. We incurred a net pre-tax loss of \$13.2 million during Fiscal 2010, as compared to earning a net pre-tax income of \$29.5 million during Fiscal 2009. This reduction from last year was primarily due to write-off in the amount of \$15.9 million, relating to the inventory seized by the FDA, as disclosed above, and also due to the cessation of manufacturing at the Company's Michigan facilities, partially offset by non-recurring income earned during Fiscal 2010 in the amount of \$20.0 million as part of an asset purchase agreement arising out of a settlement agreement entered into by the Company. Such income is not expected to recur in future periods. At March 31, 2010, we had stockholders' equity of \$155.4 million as compared to stockholders' equity of \$163.8 million at March 31, 2009.

The following discussion of historical operating results compares Fiscal 2010 to Fiscal 2009 and Fiscal 2009 to Fiscal 2008.

#### Fiscal 2010 Compared to Fiscal 2009

**Net Sales.** Net sales for fiscal years 2010 and 2009 were \$233.7 million and \$337.2 million, respectively, reflecting a decrease of 31%. The decrease was primarily as a result of the adverse effect on sales of Caraco-owned products due to the actions of the FDA and the cessation of manufacturing, as disclosed above, and in part due to the negative impact of our voluntary recalls. Sales of distributed products were lower during Fiscal 2010 over Fiscal 2009 due to higher sales of Paragraph IV products during Fiscal 2009, particularly sales of certain Paragraph IV products which were launched by the Company during the fourth quarter of Fiscal 2008 under the distribution and sale agreement with Sun Pharma. These product sales may or may not be sustainable, as previously disclosed. The sales of distributed products were also lower due to price erosion on the products sold, partially offset by new product launches. Sales of one product (oxcarbazepine), launched under the marketing agreement during the third quarter of Fiscal 2008 were significantly higher during Fiscal 2009. This product was launched with 180 days shared exclusivity, which allowed its higher sales during the first quarter of Fiscal 2009. Subsequent to the end of the exclusivity period, which occurred during the first quarter of Fiscal 2009, the net realizations for this product have decreased significantly as several other competitors have entered the market for this generic product. Sales of Caraco-owned products during Fiscal 2010 were significantly lower than those in Fiscal 2009 as we have stopped marketing, effective June 25, 2009, all the products which were being manufactured out of our Michigan facilities on account of the FDA actions, as previously discussed, and in part due to the negative impact of our voluntary recalls of certain products. We did not distribute any digoxin during the period subsequent to the recall of digoxin that occurred on March 31, 2009. We also had a recall on various products on April 17, 2009, as previously disclosed. Net sales for distributed products during Fiscal 2010 were \$211.4 million compared to \$225.4 million for Fiscal 2009. Net sales for Caraco-owned products were \$22.3 million during Fiscal 2010 compared to \$111.8 million for Fiscal 2009. We were manufacturing and marketing all except two

of our approved products. However, as a result of action taken by the FDA, we have ceased manufacturing operations of the products which we manufacture at our facilities located in the state of Michigan. We continue to have sales of Caraco-owned products that are manufactured outside of the Company by other manufacturers including Sun Pharma. During Fiscal 2010 we have started selling two products which were acquired as part of an asset purchase agreement with Forest as previously disclosed.

During Fiscal 2010 sales of one product accounted for approximately 55% of net sales as compared to sales of three products accounting for approximately 57% of net sales for Fiscal 2009. See Note 1 to Financial Statements – Revenue Recognition for explanation of the determination of net sales.

**Gross Profit.** We incurred a gross loss of \$0.4 million in Fiscal 2010, as compared to earning a gross profit of \$67.8 million during Fiscal 2009. The gross loss incurred during Fiscal 2010 was, in large part, due to a write-off in the amount of \$15.9 million related to the inventory seized by the FDA, (See “Inventory” above), as well as lower sales of both distributed and Caraco-owned products. As disclosed above, due to the actions of the FDA, all shipments of products which were being manufactured at the Company’s Michigan facilities have ceased effective June 25, 2009, which has led to diminished sales of Caraco-owned products.

The gross profit margin as a percentage of net sales decreased to 0% in Fiscal 2010 from 20% in Fiscal 2009. As disclosed above, we have written-off inventory in the amount of \$15.9 million during Fiscal 2010 relating to the inventory seized by the FDA. Excluding the impact of such write-off, the gross profit margin in Fiscal 2010 was 7%, as compared to 20% for Fiscal 2009. The decrease in Fiscal 2010 was also due to the weight of increased sales of distributed products versus the sales of Caraco-owned products, which had an impact on the overall margins. The gross profit margin on distributed products was 9% for both Fiscal 2010 and Fiscal 2009. The gross profit margin for Caraco-owned products was (90%) for Fiscal 2010, as compared to 43% for Fiscal 2009. Excluding the impact of the inventory write-off, the gross profit margin in Fiscal 2010 was (19%). Caraco-owned product margins have decreased mainly due to impact of overhead absorption, having similar levels of direct overhead in the first quarter and decreased levels in the remainder of Fiscal 2010, with lower sales for Fiscal 2010, which contributed 41% to the decrease in gross profit margin. Price erosion on certain products and changes in the sales mix of the Caraco-owned products sold also contributed to the decrease. Also, we had initiated a recall of one product (digoxin) during the fourth quarter of Fiscal 2009. There were no sales of this product during Fiscal 2010. The loss of sales of this product also adversely affected the gross profit margins for Fiscal 2010. Further, as disclosed earlier, there were significantly low levels of sales of Caraco-owned products due to cessation of shipments of products which were being manufactured at the Company’s Michigan facilities. Also during Fiscal 2010, we wrote off certain non-seized inventories of approximately \$0.8 million respectively, partly relating to one DESI product which is being discontinued as stipulated in the Consent Decree, and partly related to products we purchased along with the brand, which have now become obsolete. The sales and related gross profits generated from the distribution and sale agreement dated January 29, 2008 and the marketing agreement dated January 19, 2007 are recognized under distributed products which we segregate from sales of Caraco-owned products and are accordingly disclosed in Note 13 of Notes to Financial statements under Segment Reporting.

**Selling, General and Administrative Expense.** Selling, general and administrative (“SG&A”) expenses during the relevant periods were \$22.8 million and \$16.4 million, representing an increase of 39%. SG&A expenses, as a percentage of net sales, increased to 10% in Fiscal 2010 as compared to 5% for Fiscal 2009. The higher SG&A percentage is partly due to the lower sales in the current year versus the previous year. Also the SG&A expenses were higher during Fiscal 2010 as the Company recorded additional expenses primarily related to legal and professional consultation fees pertaining to FDA issues.

**Research and Development Expenses.** Total R&D expenses incurred during Fiscal 2010 were \$10.1 million, as compared to \$22.5 million during Fiscal 2009. The R&D expenses during Fiscal 2010 were lower compared to those during Fiscal 2009 as we were reimbursed a certain amount relating to certain product litigation costs during the second quarter of Fiscal 2010, as part of a settlement agreement, as previously disclosed. Although R&D expenses have decreased in the current period due to the focus of the Company on remediating FDA concerns, they are likely to increase once the Company refocuses on new product filings and approvals with the FDA. We filed two ANDAs relating to two products with the FDA during Fiscal 2010 as compared to 10 products filed in 2009. This brings our total number of ANDAs pending approval by the FDA to 31 (including four tentative approvals) relating to 27

products. We also submitted 12 other various filings with the FDA including those related to new sources on the Active Pharmaceutical Ingredients (API) and alternative manufacturing sites.

**Non-Recurring Income.** We earned a one-time non-recurring income in the amount of \$20.0 million during Fiscal 2010 arising out of a product litigation settlement and an asset purchase agreement, as previously disclosed. There was no such income during Fiscal 2009 or Fiscal 2008, and the Company does not expect to earn such income in future periods.

**Net Other Income.** We earned net other income of \$0.1 million during Fiscal 2010 as compared to \$0.6 million during Fiscal 2009. The lower net other income was primarily due to interest expense incurred in relation to the Company's term loan with Charter One Bank and a loss on removal of certain assets during Fiscal 2010. During Fiscal 2010 an amount of \$0.3 million was also recorded under interest expense, relating to the fair value of the interest rate swap entered into by the Company to hedge the interest rate on the term loan with Charter One Bank.

**Income Taxes.** We provided an income tax benefit of \$4.5 million during Fiscal 2010, compared to income tax expense of \$8.9 million during Fiscal 2009. The benefit in the period is due to the future tax benefits of losses incurred. Also see discussion under "Income Taxes" above.

**Results of Operations.** We incurred a pre-tax loss of \$13.2 million during Fiscal 2010, as compared to earning pre-tax income of \$29.5 million during Fiscal 2009. We incurred a net loss of \$8.7 million in Fiscal 2010, as compared to earning net income of \$20.5 million during Fiscal 2009.

#### Fiscal 2009 Compared to Fiscal 2008

**Net Sales.** Net sales for fiscal years 2009 and 2008 were \$337.2 and \$350.4 million, respectively, reflecting a decrease of 4%. The decrease was primarily due to lower sales of our own manufactured products on account of our voluntary product recalls initiated during late Fiscal 2009 and the beginning of Fiscal 2010 and also due to price erosion on the products we sold. Sales of one product (oxcarbazepine), launched under the marketing agreement during the third quarter of Fiscal 2008 were significantly higher during Fiscal 2008. This product was launched with 180 days shared exclusivity, which allowed its higher sales during the period. Subsequent to the end of the exclusivity period, which occurred during the first quarter of Fiscal 2009, the net realizations for this product have decreased significantly as several other competitors have entered the market for this generic product. The sales of Paragraph IV products being marketed under the distribution and sales agreement were higher during Fiscal 2009 leading to little overall change in the sales of distributed products year over year. As previously disclosed, the sales of Paragraph IV products may not be sustainable at the same levels in the future. Net sales for distributed products during Fiscal 2009 were \$225.4 million compared to \$225.1 million for Fiscal 2008. Net sales for Caraco-owned products were \$111.8 million during Fiscal 2009 compared to \$125.3 million for Fiscal 2008. The lower sales were on account of price erosion and also due to product recalls which negatively impacted sales during the fourth quarter of Fiscal 2009. We initiated two recalls, one during the end of Fiscal 2009 for a specific product and the other at the beginning of Fiscal 2010 for certain lots of our products manufactured during a specific period, which together reduced Fiscal 2009 net sales of Caraco-owned products by \$4.2 million. Currently, we manufacture and market all except two of our approved products. Sales of three products accounted for approximately 57% of net sales for Fiscal 2009, compared to sales for two products accounting for approximately 55% of net sales for Fiscal 2008. See Note 1 to Financial Statements – Revenue Recognition for explanation of the determination of net sales.

**Gross Profit.** We earned a gross profit of \$67.8 million in Fiscal 2009, as compared to a gross profit of \$84.7 million during Fiscal 2008, reflecting a decrease of 20%. The decrease in gross profit was due to lower sales of our own manufactured products on account of product recalls, as previously stated, and also due to price erosion on both distributed and manufactured product sales.

The gross profit margin as a percentage of net sales decreased to 20% in Fiscal 2009 from 24% in Fiscal 2008. The decrease was primarily due to lower sales of our own manufactured products, recent product recalls initiated during late Fiscal 2009 and early Fiscal 2010, price erosion and sales mix on the products we sold. The gross profit margin on distributed products sold was 9% and 10% for Fiscal 2009 and Fiscal 2008, respectively. The decrease was primarily due to the weight of increased sales of Paragraph IV products, which earn lower margins as a percentage of sales versus the sale of other distributed products. The gross profit margin for Caraco-owned products was 43% for Fiscal 2009, as compared to 49% for Fiscal 2008. Caraco-owned product margins have decreased due to product recalls which had a negative impact of two percent, price erosion on certain products and sales mix of the Caraco-owned products sold. Overhead absorption also contributed to the lower gross profit margin based on maintaining the current level of direct overheads with lower sales in Fiscal 2009. The sales generated from the distribution and sale agreement dated January 29, 2008 and the marketing agreement dated January 19, 2007 are recognized under distributed products which we segregate from sales of manufactured products and are accordingly disclosed in Note 13 of Notes to Financial statements under Segment Reporting.

Selling, General and Administrative Expense. Selling, general and administrative expenses during the relevant periods were \$16.4 million and \$14.3 million, representing an increase of 15%. The increase was mainly due to higher distribution, marketing and administrative efforts relative to the increase in unit sales volumes, and also due to estimated costs associated with the product recalls as discussed above. SG&A expenses, as a percentage of net sales, was 5% for Fiscal 2009, as compared to 4% for Fiscal 2008.

**Research and Development Expenses.** Total R&D expenses were \$22.5 million for Fiscal 2009 and \$29.7 million for Fiscal 2008. In Fiscal 2009, all R&D expenses represented cash R&D expenses, while actual cash R&D expenses were \$18.4 million for Fiscal 2008. We incurred non-cash research and development expenses (technology transfer cost) of \$11.3 million for the 1,088,000 shares of preferred stock for two product transfers during Fiscal 2008. The final product was transferred to Caraco by Sun Global during the third quarter of Fiscal 2008, which concluded the obligations between the parties under the technology transfer agreement. Series B convertible preferred stock was issued to Sun Global under the products agreement between the Company and Sun Global in exchange for the technology of formulation products delivered by Sun Global to the Company. The resulting amount of R&D expense was charged to operations and was determined based upon the fair value of the preferred shares on the date the respective product formulas passed their bio-equivalency studies. The fair value of such shares was based upon a valuation performed by Donnelly Penman and Partners, an independent, third party valuation firm. The exchange of shares was prior to the initial ANDA submissions to the FDA. Cash R&D will continue to increase in an effort to develop additional products. The cash R&D expenses during Fiscal 2009 were higher compared to those during Fiscal 2008 primarily due to increased patent related expenses, increased R&D activity, and increases in other expenses in an effort to file additional products with the FDA. We filed 10 ANDAs relating to nine products with the FDA during Fiscal 2009 as compared to seven products filed in 2008. This brings our total number of ANDAs pending approval by the FDA to 29 (including four tentative approvals) relating to 25 products. We also submitted 10 other various filings with the FDA including those related to new sources on the Active Pharmaceutical Ingredients (API) and alternative manufacturing sites.

**Net Other Income.** We earned net other income of \$0.6 million during Fiscal 2009 as compared to \$1.7 million during Fiscal 2008. The decrease in other income was primarily due to reduction in interest rates as prevailing in the market during the corresponding periods.

**Income Taxes.** We recorded an income tax provision of \$8.9 million during Fiscal 2009, as compared to an income tax provision of \$7.0 million during Fiscal 2008. The income tax expense for Fiscal 2008 was lower due to reversals of valuation allowances, in the amount of \$7.0 million resulting from NOLs. As the Company continues to be profitable, and the fact that all of the net operating loss carryforwards have been utilized or are limited, the Company is expected to pay full income taxes on current profits. Also see discussion under "Income Taxes" above.

**Results of Operations.** We earned pre-tax income of \$29.5 million in Fiscal 2009, compared to pre-tax income of \$42.4 million in Fiscal 2008. The reduction in pre-tax income from last year was primarily due to lower gross profits resulting from price erosion of the products sold, the mix of distributed products sold and the provision for losses expected from the product recalls initiated during the end of Fiscal 2009 and early Fiscal 2010. Net income decreased to \$20.5 million during Fiscal 2009 from net income of \$35.4 million during the Fiscal 2008.

## Liquidity and Capital Resources

### Fiscal 2010 and Fiscal 2009

We generated cash from operations in the amount of \$5.7 million during Fiscal 2010, as compared to generating cash from operations of \$18.7 million during Fiscal 2009. The decrease in cash flows from operations was primarily due to lower net income and increases in accounts receivable and inventory balances, offset in part by an increase in accounts payable balances. Accounts receivable increased by \$79.6 million to \$94.7 million as of March 31, 2010, as compared to \$15.2 million at the end of Fiscal 2009. Accounts receivable is 154 days sales outstanding ("DSO") as of March 31, 2010 versus 27 days as of March 31, 2009. The higher level in DSO at March 31, 2010 is predominately due to outstanding balances from certain customers with whom we have entered into agreements which include extended payment terms, and accordingly, collections of the related accounts receivable balances from these sales will occur over an extended period. Further, the lower level in DSO at March 31, 2009 was temporary and is mainly due to the

timing of payments made by the wholesale customers. During Fiscal 2009 we received payments from our wholesale customers based upon the purchases they made on gross sales made. However, deductions for chargebacks were made in Fiscal 2010 related to these sales, and will continue to be made by these wholesale customers as they continue to sell to retail chain stores and managed care organizations with whom we have contractual pricing. The Company believes that it has provided adequate reserves for chargeback deductions which are likely to be taken by the wholesale customers in subsequent periods. Certain wholesale customers purchased quantities of a certain product based on their own forecast, to ensure an in-stock position for such product, as there were uncertainties related to the future availability of such product and continued shipments from the Company. Based on the respective fourth quarter cost of sales, which is most representative of current sales activity, inventory levels at March 31, 2010 and at March 31, 2009 were equivalent to 182 days on hand, and 160 days on hand. The inventory as of March 31, 2010 includes higher levels of inventory of Paragraph IV products to support anticipated sales in the near term period. At March 31, 2009 we had negligible stock of such product on hand. If the sale of the Paragraph IV products are not allowed by any regulatory authority and Sun Pharma does not file a timely appeal, we would have various rights to return the product to Sun Pharma. The accounts payable balance relating to Sun Pharma has also increased from \$43.9 million at March 31, 2009 to \$160.9 million at March 31, 2010 in line with increased levels of inventory relating to distributed products and accounts receivable balances. and extended payment terms for certain products.



During the first quarter of Fiscal 2010 the Company invested \$10.0 million in a bank certificate of deposit. The term of deposit is for twelve months and earns interest at a rate of 4.5% APY. If such deposit is withdrawn prior to maturity, the Company will earn interest at the applicable LIBOR rate as on the date of such withdrawal. The Company expended \$3.1 million during Fiscal 2010 in purchases of property, plant and equipment. During Fiscal 2009, the Company expended \$26.9 million, primarily to self fund the expansion of its primary facility located in Detroit, Michigan. Since the expansion of the aforementioned facility has been completed, the Company believes that capital expenditures will remain at much reduced levels from Fiscal 2009 in the upcoming periods.

As disclosed above the FDA actions and the Company's voluntary cessation of production at its Michigan facilities had a material adverse affect on our current operations and there may be a material adverse affect on our near term operations. The Company initiated a reduction in various expenses in an effort to bring its expenses in line with its current levels of sales and other activities. The sales of distributed products and certain Caraco-owned products made by other manufacturers will continue and will contribute to the ongoing cash flows. Also, the Company has recently entered into an agreement with Forest which, to date, has provided two additional products to the Company's product portfolio, and such products have begun generating incremental revenues under Caraco-owned product sales. We expect additional products will be added to our portfolio as a result of this agreement. The Company owns five products that are manufactured outside of the Company by other manufacturers including Sun Pharma and its affiliates. The Company has filed supplements to ANDAs for FDA approval, for the transfer of certain Caraco-owned products to regain revenues from these products. As of March 31, 2010, we have \$55 million in cash and another \$10 million in short-term investments, including the proceeds from a loan in the amount of \$15.3 million, currently classified as a short term liability. The Company believes that its cash flow from operations and cash balances will continue to support its ongoing business requirements. However, because of, among other things, decreased customer confidence resulting in lower sales, the uncertainty of resumption in manufacturing activities,,the uncertainty of future costs of FDA compliance and associated costs and the uncertainty of various litigation proceedings (see "Item,3. Legal Proceedings"), there can be no assurance of this belief.

At March 31, 2010, we had working capital of \$89.3 million, as compared to working capital of \$112.5 million at March 31, 2009.

During the fourth quarter of Fiscal 2009 the Company entered into a term loan of \$18 million with Charter One Bank. The loan is secured by a mortgage covering the Company's manufacturing facility and equipment located in Detroit, Michigan. The rate of interest is calculated as LIBOR plus an applicable margin thereto (based upon various leverage levels and current applicable rate is 50 basis points). The aggregate rate applicable to the Company as of March 31, 2010 was 1.2%. The principal loan payments and accrued interest are payable on a quarterly basis beginning July 2009. The principal is to be repaid in equal quarterly installments of \$900,000 for ten quarters through October 2011, and thereafter, if not renewed, the remaining balance of \$9 million is due in the subsequent quarter by January 2012. Subsequently, in October 2009 the terms of the loan were modified and we entered into an amended agreement. The amendment adds to the loan a one year line of credit note for \$15 million against which the Company can borrow funds for working capital purposes or can get letters of credit issued. Against this line of credit, the Bank has issued an Irrevocable Standby Letter of Credit in an amount of \$15 million, in favor of the United States of America, as required to be placed with the FDA in accordance with the Consent Decree, as disclosed above. The line of credit carries an interest rate of LIBOR plus 150 basis points, and if letters of credit are issued, the associated fees are 0.7% of such letters of credit on annualized basis. Also, there is an unused fee of 0.25% on an annualized basis to the extent the line remains idle. Both the line of credit and outstanding term loan are cross collateralized by all of the Company's fixed assets and cash deposit accounts held with Charter One Bank, equivalent to the amount of outstanding loans and the outstanding letter of credit. These cash deposits earn interest at prevailing rates applicable to such money market accounts. We are continuing discussions with Charter One Bank to allow the release of the cash collateral. Charter One Bank has temporarily suspended our required compliance with the covenants in the loan agreements relating to FDA enforcement actions, as previously disclosed, and has suspended testing of certain other compliance

requirements until October 9, 2010. On or before such date, we anticipate either entering into revised agreements or repaying the loan in full. Currently, as the loan is in technical default due to the FDA enforcement action, the entire outstanding balance has been classified as a short-term liability.

As required pursuant to the terms of the Loan Agreement, the Company has entered into an Interest Rate Swap Agreement with Charter One Bank to hedge the interest rate applicable on the loan. The notional amount for the swap is \$15.3 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 March 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 a provision to record the fair value of this swap agreement at March 31, 2010.

#### Fiscal 2009 and Fiscal 2008

We generated cash from operations in the amount of \$18.7 million during Fiscal 2009, as compared to generating cash from operations of \$27.8 million during Fiscal 2008. The decrease in cash flows from operations was primarily due to lower net income and a decrease in accounts payable, Sun Pharma balances offset, in part, by decreases in accounts receivable and inventory balances. Accounts payable, Sun Pharma decreased by \$344.4 million to \$43.9 million as of March 31, 2009, as compared to \$388.3 million as of March 31, 2008. Accounts receivable decreased by \$120.7 million to \$15.2 million as of March 31, 2009, as compared to \$135.9 million at March 31, 2008. Inventories decreased by \$219.2 million to \$79.5 million as of March 31, 2009, as compared to \$298.7 million at March 31, 2008. Based on the respective fourth quarter cost of sales, which is most representative of current sales activity, inventory levels at March 31, 2009 and at March 31, 2008 were equivalent to 160 days on hand, and 164 days on hand. We do not believe that the FDA Warning Letter dated October 31, 2008 and our voluntary recalls of certain products on March 31, 2009 and in April 2009 had a material impact on inventory balances at March 31, 2009. Accounts receivable is 27 days DSO as of March 31, 2009 versus 63 days as of March 31, 2008. The decrease in DSO is temporary and is mainly due to the timing of payments made by the wholesale customers. During the third quarter of Fiscal 2009, we received payments from our wholesale customers based upon the purchases they made on the gross sales during the previous quarter. However the deduction for chargebacks will be made by these wholesale customers as they continue to sell to retail chain stores and managed care organizations with whom we have contractual pricing. The Company believes that it has provided adequate reserves for chargeback deductions which are likely to be taken by the wholesale customers in subsequent periods. Certain wholesale customers purchased quantities of certain product based on their own forecast, to ensure an in-stock position for such product, as there were uncertainties related to the future availability of such product and continued shipments from the Company. The Company believes that its cash flows from operations will continue to support its ongoing business requirements.

The Company expended \$26.9 million during Fiscal 2009 in purchases of property, plant and equipment, primarily to self fund the expansion of its primary facility located in Detroit, Michigan. Capital expenditures incurred during Fiscal 2008 were \$5.1 million. Since the expansion of the aforementioned facility has been completed, the Company believes that capital expenditures will be at much reduced levels in the upcoming periods.

During the fourth quarter of Fiscal 2009 the Company entered into a term loan of \$18 million with Charter One Bank. The loan is secured by a mortgage covering the Company's manufacturing facility and equipment located in Detroit, Michigan. The proceeds from the loan are intended to fund any product or assist in any acquisition to fuel our future growth. The principal loan payments and accrued interest are payable on a quarterly basis beginning second quarter of Fiscal 2010. The principal is to be repaid in equal quarterly installments of \$0.9 million for ten quarters through October 2011, and thereafter, if not renewed, the remaining balance of \$9 million is due in January 2012. The Company expects that the term loan will be renewed, and the loan amortization is expected to be over 20 equal quarterly installments of \$0.9 million each.

At March 31, 2009, we had working capital of \$112.5 million compared to working capital of \$104.5 million at March 31, 2008. Additionally, we have available a \$10.0 million line of credit obtained through JP Morgan Chase Bank, N.A. Currently, the credit line has no outstanding balances.

The following tables present a summary of each of the four quarters of Fiscal 2010 and Fiscal 2009. The unaudited interim financial statements include all adjustments, consisting only of normal recurring adjustments, except for the following 1) product recalls initiated towards the end of the fourth quarter of Fiscal 2009 and the beginning of Fiscal 2010 which had a \$4.7 million impact on the fourth quarter of Fiscal 2009, 2) \$8.4 million and \$7.5 million recorded as reserves for inventory seized by the FDA in the first and second quarters of Fiscal 2010, respectively, and 3) \$20 million of non-recurring income recognized in the second quarter of Fiscal 2010 related to an asset purchase agreement, necessary for a fair statement of such information when read in conjunction with our audited financial statements and related notes. Our quarterly operating results have varied in the past, may continue to do so and are not necessarily indicative of results for any future period.

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Fiscal 2010 – April 1, 2009 to March 31, 2010 (unaudited)

(In thousands, except per share data)

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Net Sales	\$ 48,070	\$ 78,376	\$ 51,990	\$ 55,238
Gross (Loss) Profit	(3,610 )	(4,138 )	3,085	4,264
Operating (Loss) Income	(14,354 )	10,561	(5,072 )	(4,424 )
Net (Loss) Income	(9,423 )	6,669	(3,033 )	(2,873 )
Net (Loss) Income Per Share				
Basic	(0.25 )	0.17	(0.08 )	(0.07 )
Diluted	(0.25 )	0.16	(0.08 )	(0.07 )

Fiscal 2009 – April 1, 2008 to March 31, 2009 (unaudited)

(In thousands, except per share data)

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Net Sales	\$ 108,277	\$ 122,188	\$ 55,720	\$ 50,992
Gross Profit	23,583	22,002	15,901	6,308
Operating Income (Loss)	14,281	12,183	6,345	(3,960 )
Net Income (Loss)	9,440	8,424	5,085	(2,412 )
Net Income (Loss) Per Share				
Basic	0.29	0.25	0.15	(0.07 )
Diluted	0.23	0.21	0.13	(0.07 )

Contractual Obligations and Off Balance Sheet Transactions

The following table summarizes the Company's significant contractual obligations at March 31, 2010 (In millions)

Contractual Obligations	Total	Payment due by period			More than 5 years
		Less than 1 year	1-3 years	4-5 years	
Long-term Debt	\$ 15.3	\$ 15.3	-	-	-
Operating Leases	\$ 6.5	\$ 0.8	\$ 1.6	\$ 1.7	\$ 2.4
Milestone payments relating to various product development agreements	\$ 0.9	\$ 0.6	\$ 0.3	-	-



The events that would trigger the milestone payments relating to various product development agreements include signing the agreement, transfer of technology, passing the bio-equivalency study, completion of development batches, filing of the ANDA, approval of the ANDA, and commercial launch of the product. The determination of milestone payments assumes all of the conditions are satisfied and does not include profit-sharing, which cannot be estimated.

There are no other contractual obligations requiring disclosure.

#### Off Balance Sheet Transactions

None

#### Future Outlook

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

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

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

Currently, we have 31 ANDAs pending approval at the FDA (including four tentative approvals) relating to 27 products out of our Michigan facilities. We continue to expand and upgrade our facilities, and expand our customer base. Our internal efforts, combined with Sun Pharma in developing new products have also picked up momentum. We now have 17 products, that we market (including Caraco-owned products being manufactured by third parties and those distributed under various agreements with of Sun Pharma), whose market share is ranked third or higher against the same products of our generic competitors. We are focused on products that are currently in our portfolio and are yet to realize their full market potential. The total portfolio consists of 42 products.

Sun Pharma is involved in legal proceedings relating to a product (Pantoprazole sodium DR tablets), which we have been distributing under agreements with Sun Pharma. This product was launched at-risk as a Paragraph IV product. Considering recent developments with respect to the patent litigation relating to this product, the Company has currently put further shipments of this product on hold and will continually re-evaluate marketing the product. Sales of this product may resume at any time as market and other conditions permit. See “Item 3. Legal Proceedings” and “Item 1A. Risk Factors” for further information.



Although gross profit margins have come down due to the mix of distributed products' weight over Caraco-owned products, the inventory write-off and also due to negligible sales of Caraco-owned products, we believe we can be successful in marketing distributed products and our products that are manufactured by third parties. We have 14 new distributed products launched during Fiscal 2010 that Sun Pharma or its affiliates received approvals for from the FDA. We have also transferred certain Caraco-owned products to additional alternate manufacturing sites that would allow the Company to regain revenues from those products while Caraco completes the necessary remedial actions that would lead to resumption of its manufacturing operations. We intend to file with the FDA supplements to ANDAs, for its approval, in the next six months for these transferred products. Should the pricing pressures become more severe than anticipated; the result may be lower growth rates and gross margins. Management has worked, and will continue to work, diligently to counter the pricing pressures through increased sales volumes, improved market share on existing products, expansion of our customer base, improved productivity, and increased cost reductions.

The Company intends to decrease its internal development of new products. It will continue to develop products with third parties, including Alkaloida, an indirect subsidiary of Sun Pharma (see Item 1. Business - Sun Pharmaceutical Industries Limited). Our R&D expense should decline based on this provided that patent related expenses remain stable or decline. We believe that we will continue to have the cash and other means available to meet our working capital requirements, fund potential litigation expenses relating to Paragraph IV certification and finance further capital investments. The third party product development is a critical element in meeting expectations in the future.

We believe that Sun Pharma is a partner with a proven track record, and one that already has provided the Company with quality products. Moreover, Sun Pharma's increased beneficial ownership in the Company to approximately 75% (approximately 76% including the convertible Series B Preferred Stock), should, we believe, provide it with the vested interest to continue to help the Company succeed. Sun Pharma has previously provided the Company with capital, loans, guarantees of loans, personnel, raw materials and equipment, clinical research services which have significantly helped the Company to date. In addition to the Sun Pharma products agreement, we have implemented additional development strategies with various third parties, both domestically and abroad, that will complement the Sun Pharma's development pipeline and our own.

The FDA's action and the Company's voluntary actions have had, and are expected to continue to have, a material adverse effect on operations and operating results. At March 31, 2010, the Company had \$55 million in cash and \$10 million in short-term investments including the proceeds from a loan in the amount of \$15.3 million. The Company believes that its cash flow from operations and cash balances will continue to support its ongoing business requirements, however, because, among other things, of the uncertainty of future costs of FDA compliance and associated costs, there can be no assurance of this belief.

During Fiscal 2007, we entered into three definitive agreements with different companies to develop four additional ANDAs for Caraco and provide additional opportunities for the future development of products. These agreements contain, for three products, both milestone payments to be paid in cash and profit sharing based upon future sales for a defined period, and for one product only milestone payments in cash without any obligation to share profits in the future. During Fiscal 2008, we signed one definitive agreement for one additional product. However we have terminated an agreement earlier entered into with one company for two of these products. During Fiscal 2009, we entered into one agreement for one additional product. During Fiscal 2010, we entered into two agreements relating to two additional products. Subsequent to end of Fiscal 2010, we have terminated another agreement relating to one product. This brings the total number of products being developed by unaffiliated third party developers to five.

We anticipate additional development agreements will be entered into in order to eliminate gaps in our calendar of approvals from the FDA. As previously mentioned, in Fiscal 2007 we entered into a definitive agreement to market Sun Pharma ANDAs that are either approved or awaiting approval at the FDA. Accordingly, we continue to market a number of these products which are categorized as distributed products. This agreement has been further renewed in

January 2010, for a period of one year. In addition, on January 29, 2008, the Company executed a distribution and sale agreement with Sun Pharma. This agreement covers certain mutually agreed upon products that have been filed or will be filed with the FDA with a Paragraph IV certification. A Paragraph IV certification states that the filer believes that it either does not infringe the patent or believes that the patent is invalid. Paragraph IV certified products face litigation challenges with respect to claims of patent infringement. Sun Pharma is not obligated to offer Caraco products under this agreement, however, Caraco has the exclusive right to market in the U.S., its territories and possessions, including Puerto Rico, any products offered by Sun Pharma and accepted by Caraco. Under the agreement, the Company participates in the sales opportunity on the products, and also shares the litigation risks to a limited extent based on percentage. If such claims are successful, however, they could have a material adverse effect on the Company. We have been marketing three products under this agreement including Pantoprazole sodium DR tablets. See 'Item 3. Legal Proceedings.' These agreements should provide for an alternate stream of products that will complement our internal research and development and our outsourced development. From time to time significant product launches such as we incurred under the distribution and sale agreement for Paragraph IV products in Fiscal 2008 may occur that will add near term growth that may or may not be sustainable in future periods. Additionally we will continue to work with Sun Pharma in an effort to transfer future product technology on a cash basis similar to other third party developers and in the future we may provide services to Sun Pharma, its affiliates and other third party pharmaceutical manufacturers relating to distribution of certain products, on a fee for service basis in effort to expand our product offerings and remain competitive. In this connection, see Item I. Business - Sun Pharmaceutical Industries Limited, relating to our products agreement with Alkaloida, an indirect subsidiary of Sun Pharma. It is our belief that our infrastructure and relationships we have with our customers, can be utilized to optimize sales for our own products, as well as of other companies that are entering or are planning to enter the U.S. market but do not have the infrastructure required to compete effectively.

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

Management's goals for fiscal year ending March 31, 2011 include:

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

- Research possible development of brands for existing stream of products where such potential exists.
  - Increase focus on succession planning.
  - Increase management training and development.
  - Maintain balance in trade class.

#### Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

During Fiscal 2010, the Company had no material market risk exposure. The following describes our current loan arrangements and the interest rates associated therewith.

##### Loans Payable to Financial Institutions

During the fourth quarter of Fiscal 2009 the Company entered into a term loan of \$18 million with Charter One Bank. The loan is secured by a mortgage covering the Company's manufacturing facility and equipment located in Detroit, Michigan. The rate of interest is calculated as LIBOR plus an applicable margin thereto (based upon various leverage levels and current applicable rate is 50 basis points). The aggregate rate applicable to the Company as of March 31, 2010 was 1.2%. The principal loan payments and accrued interest are payable on a quarterly basis beginning July 2009. The principal is to be repaid in equal quarterly installments of \$900,000 for ten quarters through October 2011, and thereafter, if not renewed, the remaining balance of \$9 million is due in the subsequent quarter by January 2012. Subsequently, in October 2009 the terms of the loan were modified and we entered into an amended agreement. The amendment adds to the loan a one year line of credit note for \$15 million against which the Company can borrow funds for working capital purposes or can get letters of credit issued. Against this line of credit, the Bank has issued an Irrevocable Standby Letter of Credit in an amount of \$15 million, in favor of the United States of America, as required to be placed with the FDA in accordance with the Consent Decree, as disclosed above. The line of credit carries an interest rate of LIBOR plus 150 basis points, and if letters of credit are issued, the associated fees are 0.7% of such letters of credit on annualized basis. Also, there is an unused fee of 0.25% on an annualized basis to the extent the line remains idle. Both the line of credit and outstanding term loan are cross collateralized by all of the Company's fixed assets and cash deposit accounts held with Charter One Bank, equivalent to the amount of outstanding loans and outstanding letter of credit. These cash deposits earn interest at prevailing rates applicable to such money market accounts. We are continuing discussions with Charter One Bank to resolve its concerns and get the cash collateral released. Charter One Bank has temporarily suspended our required compliance with the covenants in the loan agreements relating to FDA enforcement actions, as previously disclosed, and has suspended certain other compliance requirements until October 9, 2010. On or before such date, we anticipate either entering into revised agreements or repaying the loan in full. Currently, as the loan is in technical default due to the FDA enforcement action, the entire outstanding balance has been classified as a short-term liability.

As required pursuant to the terms of the Loan Agreement, the Company has entered into an Interest Rate Swap Agreement with Charter One Bank to hedge the interest rate applicable on the loan. The notional amount for the swap is \$15.3 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 March 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 a provision to record the fair value of this swap agreement at March 31, 2010.

#### Item 8. Financial Statements and Supplementary Data

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Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. 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 our last fiscal quarter ended March 31, 2010 that materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting.

Management’s Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting for Caraco Pharmaceutical Laboratories Ltd. (the “Company”). We maintain internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America.

Because of its inherent limitations, any system of internal control over financial reporting, no matter how well designed, may not prevent or detect misstatements due to the possibility of collusion or improper override of controls, or that misstatements due to error or fraud may occur that are not detected. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management conducted an assessment of the effectiveness of the Company’s internal control over financial reporting as of March 31, 2010 using criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). This assessment included an evaluation of the design of the Company’s internal control over financial reporting and testing of the operational effectiveness of its internal control over financial reporting. Based on this assessment, management has concluded that the Company maintained effective internal control over financial reporting as of March 31, 2010, based upon the COSO framework criteria.

The Company’s internal control over financial reporting as of March 31, 2010 has been audited by Rehmann Robson P.C. our independent registered public accounting firm, as stated in their report which appears herein.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item is incorporated by reference to the information contained in our Proxy Statement for the 2010 Annual Meeting of Stockholders to be filed not later than 120 days after the Company's Fiscal year ended March 31, 2010.

Item 11. Executive Compensation.

The information required by this Item is incorporated by reference to the information contained in our Proxy Statement for the 2010 Annual Meeting of Stockholders to be filed not later than 120 days after the Company's Fiscal year ended March 31, 2010.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item is incorporated by reference to the information contained in our Proxy Statement for the 2010 Annual Meeting of Stockholders to be filed not later than 120 days after the Company's Fiscal year ended March 31, 2010.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item is incorporated by reference to the information contained in our Proxy Statement for the 2010 Annual Meeting of Stockholders to be filed not later than 120 days after the Company's Fiscal year ended March 31, 2010.

Item 14. Principal Accountant Fees and Services.

The information required by this Item is incorporated by reference to the information contained in our Proxy Statement for the 2010 Annual Meeting of Stockholders to be filed not later than 120 days after the Company's Fiscal year ended March 31, 2010.

## Part IV

## Item 15. Exhibits Financial Statement Schedules.

## (a) 1 Financial Statements

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## 2 Financial Statement Schedules

None

## 3 Exhibits. The exhibits filed in response to Item 601 of Regulation S-K are listed in the Exhibit Index, which is incorporated herein by reference.

## (b) Exhibits

The exhibits filed in response to Item 601 of Regulation S-K are listed in the Exhibit Index, which is incorporated herein by reference.

## (c) Other Schedules

None



SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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 on the 8th day of June, 2010.

CARACO PHARMACEUTICAL LABORATORIES, LTD.

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

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jitendra N. Doshi and / or Mukul Rathi, this 8th day of June, 2010, his true and lawful attorney(s)-in-fact and agent(s), with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any or all amendments to this report and to file the same, with all exhibits and schedules thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney(s)-in-fact and agent(s) full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney(s)-in-fact and agent(s), or their substitutes(s), may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons in the capacities and on the date indicated above.

/s/ Dilip S. Shanghvi Dilip S. Shanghvi	Chairman of the Board
/s/ Jitendra N. Doshi Jitendra N. Doshi	Director, Chief Executive Officer, Principal Executive Officer
/s/ Mukul Rathi Mukul Rathi	Interim Chief Financial Officer, Principal Accounting Officer
/s/ Gurpartap Singh Sachdeva Gurpartap Singh Sachdeva	Director
/s/ F. Folsom Bell F. Folsom Bell	Director
/s/ Sailesh T. Desai Sailesh T. Desai	Director
/s/ Timothy Manney Timothy Manney	Director
Madhava Reddy	Director
/s/ Sudhir V. Valia Sudhir V. Valia	Director

CARACO PHARMACEUTICAL LABORATORIES, LTD.  
(a subsidiary of Sun Pharmaceutical Industries Limited)

FINANCIAL STATEMENTS

AND

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

FOR THE YEARS ENDED MARCH 31, 2010, 2009 AND 2008

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CARACO PHARMACEUTICAL LABORATORIES, LTD.  
(a subsidiary of Sun Pharmaceutical Industries Limited)

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Stockholders and Board of Directors  
Caraco Pharmaceutical Laboratories, Ltd.  
Detroit, Michigan

We have audited the internal control over financial reporting of Caraco Pharmaceutical Laboratories, Ltd. (a Michigan corporation) (a subsidiary of Sun Pharmaceutical Industries Limited) (the “Corporation”) based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring organizations of the Treadway Commission (the “COSO criteria”). The Corporation’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management’s Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Corporation’s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A corporation’s internal control over financial reporting is a process designed by, or under the supervision of, the corporation’s principal executive and principal financial officers, or persons performing similar functions, and effected by the Corporation’s board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A corporation’s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the corporation; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Corporation are being made only in accordance with authorizations of management and directors of the Corporation; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition on the Corporation’s assets that could have a material effect on the financial statements.

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Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of internal control over financial reporting to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Corporation maintained, in all material respects, effective internal control over financial reporting as of March 31, 2010, based on the criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the financial statements as of and for the year ended March 31, 2010 of the Corporation and our report dated May 23, 2010 expressed an unqualified opinion on those financial statements.

/s/ Rehmann Robson P.C.

Troy, Michigan  
May 23, 2010

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REPORT OF INDEPENDENT REGISTERED  
PUBLIC ACCOUNTING FIRM

Stockholders and Board of Directors  
Caraco Pharmaceutical Laboratories, Ltd.  
Detroit, Michigan

We have audited the accompanying balance sheets of Caraco Pharmaceutical Laboratories, Ltd. (a Michigan corporation) (a subsidiary of Sun Pharmaceutical Industries Limited) (the "Corporation") as of March 31, 2010 and 2009 and the related statements of income, stockholders' equity and cash flows for the years ended March 31, 2010, 2009 and 2008. These financial statements are the responsibility of the Corporation's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statements presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Caraco Pharmaceutical Laboratories, Ltd. as of March 31, 2010 and 2009, and the results of its operations and its cash flows for the years ended March 31, 2010, 2009 and 2008 in conformity with accounting principles generally accepted in the United States of America.

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We have also audited, in accordance with the standards of Public Company Accounting Oversight Board (United States), the Corporation's internal control over financial reporting as of March 31, 2010, based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated May 23, 2010 expressed an unqualified opinion on the Corporation's internal control over financial reporting.

/s/ Rehmann Robson P.C.

Troy, Michigan  
May 23, 2010

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CARACO PHARMACEUTICAL LABORATORIES, LTD.  
(a subsidiary of Sun Pharmaceutical Industries Limited)

BALANCE SHEETS

ASSETS	March 31 2010	2009
Current assets		
Cash and cash equivalents	\$55,392,648	\$65,314,397
Short-term investments	10,000,000	-
Accounts receivable, net	94,736,759	15,181,197
Inventories	103,182,850	79,510,832
Prepaid expenses and deposits	6,556,346	6,259,989
Income tax receivable	1,602,621	3,180,953
Deferred income taxes	519,554	416,985
<b>Total current assets</b>	<b>271,990,778</b>	<b>169,864,353</b>
Property, plant and equipment		
Land	975,311	975,311
Buildings and improvements	29,157,542	28,148,447
Equipment	29,929,050	26,216,521
Furniture and fixtures	1,522,564	1,509,582
Construction in progress	286,250	2,708,137
<b>Total</b>	<b>61,870,717</b>	<b>59,557,998</b>
Less accumulated depreciation	18,627,773	14,734,961
<b>Net property, plant and equipment</b>	<b>43,242,944</b>	<b>44,823,037</b>
Intangible assets, net	1,285,992	1,383,048
Deferred income taxes	21,579,057	20,417,885
<b>Total assets</b>	<b>\$338,098,771</b>	<b>\$236,488,323</b>

The accompanying notes are an integral part of these financial statements.

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LIABILITIES AND STOCKHOLDERS' EQUITY	March 31 2010	2009
Current liabilities		
Accounts payable, trade	\$4,342,502	\$7,979,341
Accounts payable, Sun Pharma	160,913,483	43,928,166
Accrued expenses	2,156,921	2,757,361
Long term debt, current portion	15,300,000	2,700,000
Total current liabilities	182,712,906	57,364,868
Long term debt	-	15,300,000
Total liabilities	182,712,906	72,664,868
Commitments and contingencies (Notes 9, 11 and 12)	-	-
Stockholders' equity (Note 7)		
Series B convertible preferred stock, no par value; issued and outstanding 1,088,000 and 2,720,000 shares at March 31, 2010 and 2009, respectively	11,320,640	23,081,920
Common stock, no par value; authorized 50,000,000 shares, issued and outstanding 39,094,194 and 37,458,194 shares at March 31, 2010 and 2009, respectively	130,330,615	118,569,335
Additional paid-in capital	3,696,288	3,474,246
Retained earnings	10,038,322	18,697,954
Total stockholders' equity	155,385,865	163,823,455
Total liabilities and stockholders' equity	\$338,098,771	\$236,488,323

The accompanying notes are an integral part of these financial statements.

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CARACO PHARMACEUTICAL LABORATORIES, LTD.  
(a subsidiary of Sun Pharmaceutical Industries Limited)

STATEMENTS OF OPERATIONS

	Year Ended March 31, 2010	Year Ended March 31, 2009	Year Ended March 31, 2008
Net sales	\$233,673,688	\$337,177,482	\$350,366,689
Cost of goods sold (Notes 1 and 4)	234,072,916	269,382,927	265,651,539
Gross (loss) profit	(399,228 )	67,794,555	84,715,150
Selling, general and administrative expenses	22,768,338	16,417,971	14,322,140
Research and development costs - affiliate (Note 7)	-	-	11,320,640
Research and development costs - other	10,121,009	22,527,504	18,366,306
Non-recurring income	(20,000,000 )	-	-
Operating (loss) income	(13,288,575 )	28,849,080	40,706,064
Other income (expense)			
Interest income	947,046	631,151	1,832,409
Interest expense	(867,074 )	(28,294 )	-
Loss on sale of equipment	(84,174 )	-	(144,551 )
Other income	119,003	-	-
Other income - net	114,801	602,857	1,687,858
(Loss) income before income taxes	(13,173,774 )	29,451,937	42,393,922
Income tax (benefit) expense	(4,514,142 )	8,915,358	7,005,817
Net (loss) income	\$(8,659,632 )	\$20,536,579	\$35,388,105
Net (loss) income per share			
Basic	\$(0.22 )	\$0.60	\$1.19
Diluted	\$(0.22 )	\$0.51	\$0.89

The accompanying notes are an integral part of these financial statements.

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CARACO PHARMACEUTICAL LABORATORIES, LTD.  
(a subsidiary of Sun Pharmaceutical Industries Limited)

STATEMENTS OF STOCKHOLDERS' EQUITY

	Preferred Stock		Common Stock		Additional	Retained	Total
	Shares	Amount	Shares	Amount	Paid-in Capital	Earnings / Accumulated Deficit	Stockholders' Equity
Balances at April 1, 2007	10,880,000	\$73,585,520	28,102,394	\$55,970,097	\$2,864,522	\$(37,226,730)	\$95,193,409
Issuance of preferred stock to affiliate in exchange for product technology transfers	1,088,000	11,320,640	-	-	-	-	11,320,640
Conversion of preferred stock into common stock	(4,352,000 )	(26,768,880)	4,352,000	26,768,880	-	-	-
Common stock options exercised	-	-	36,700	119,810	-	-	119,810
Common stock issued to former director and officer	-	-	15,000	115,950	-	-	115,950
Common stock option expense	-	-	-	-	284,649	-	284,649
Common stock grants	-	-	45,000	357,750	-	-	357,750
Net income	-	-	-	-	-	35,388,105	35,388,105
Balances at March 31, 2008	7,616,000	58,137,280	32,551,094	83,332,487	3,149,171	(1,838,625 )	142,780,313

Conversion of preferred stock into common stock	(4,896,000 )	(35,055,360)	4,896,000	35,055,360	-	-	-
Common stock options exercised	-	-	1,000	11,250	-	-	11,250
Common stock option expense	-	-	-	-	325,075	-	325,075
Common stock grants	-	-	10,100	170,238	-	-	170,238
Net income	-	-	-	-	-	20,536,579	20,536,579
Balances at March 31, 2009	2,720,000	23,081,920	37,458,194	118,569,335	3,474,246	18,697,954	163,823,455
Conversion of preferred stock into common stock	(1,632,000 )	(11,761,280)	1,632,000	11,761,280	-	-	-
Common stock option expense	-	-	-	-	222,042	-	222,042
Net loss	-	-	-	-	-	(8,659,632 )	(8,659,632 )
Balances at March 31, 2010	1,088,000	\$11,320,640	39,090,194	\$130,330,615	\$3,696,288	\$10,038,322	\$155,385,865

The accompanying notes are an integral part of these financial statements.

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CARACO PHARMACEUTICAL LABORATORIES, LTD.  
(a subsidiary of Sun Pharmaceutical Industries Limited)

STATEMENTS OF CASH FLOWS

	Year Ended March 31, 2010	Year Ended March 31, 2009	Year Ended March 31, 2008
Cash flows from operating activities			
Net (loss) income	\$(8,659,632 )	\$20,536,579	\$35,388,105
Adjustments to reconcile net (loss) income to net cash provided by operating activities			
Depreciation	4,498,446	3,369,721	2,508,931
Capital stock issued or to be issued to affiliate in exchange for product formula	-	-	11,320,640
Loss on sale of equipment	84,174	-	144,551
Common stock option expense	222,042	325,075	284,649
Common stock grants	-	170,238	357,750
Common stock issued to former officer & director	-	-	115,950
Deferred income tax benefit	(1,263,741 )	(3,487,195 )	(17,347,675 )
Changes in operating assets and liabilities which (used) provided cash			
Accounts receivable	(79,555,562 )	120,745,831	(109,801,881)
Inventories	(23,672,018 )	219,154,848	(266,722,382)
Prepaid expenses and deposits	1,281,975	(1,279,623 )	(4,687,979 )
Accounts payable	113,348,477	(341,160,358)	377,574,685
Accrued expenses	(600,439 )	472,851	(1,498,192 )
Income taxes payable	-	(142,494 )	142,494
Net cash provided by operating activities	5,683,722	18,705,473	27,779,646
Cash flows for investing activities			
Purchases of property, plant and equipment	(3,077,021 )	(26,852,537 )	(5,094,031 )
Proceeds from sale of equipment	171,550	-	203,004
Purchase of short-term investments	(10,000,000 )	-	-
Purchases of intangibles	-	(1,455,840 )	-
Net cash used in investing activities	(12,905,471 )	(28,308,377 )	(4,891,027 )
Cash flows from financing activities			
Proceeds from loans payable to financial institution	-	18,000,000	-
Repayments of loans payable to financial institution	(2,700,000 )	-	-
Proceeds from issuance of common stock	-	11,250	119,810
Net cash (used in) provided by financing activities	(2,700,000 )	18,011,250	119,810
Net (decrease) increase in cash and cash equivalents	(9,921,749 )	8,408,346	23,008,429
Cash and cash equivalents, beginning of year	65,314,397	56,906,051	33,897,622
Cash and cash equivalents, end of year	\$55,392,648	\$65,314,397	\$56,906,051

The accompanying notes are an integral part of these financial statements.

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1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization and Nature of Business

Caraco Pharmaceutical Laboratories, Ltd. (“Caraco” or the “Corporation” or the “Company”), based in Detroit, Michigan, develops, licences, manufactures and markets generic, prescription and over-the-counter pharmaceuticals in the United States. The process of developing a line of proprietary drugs requires approvals by the Food and Drug Administration (“FDA”) of Abbreviated New Drug Applications (“ANDAs”). The Corporation's present product portfolio includes 42 prescription products, in 93 strengths, in various package sizes. This represents products the Company distributes for Sun Pharmaceutical Industries Limited, a specialty pharmaceutical corporation organized under the laws of India (“Sun Pharma”) and Caraco-owned products (those products for which Caraco owns the ANDAs) manufactured by Sun Pharma and other third parties. This does not include those Caraco-owned products for which the Company has temporarily ceased manufacturing and marketing, due to the enforcement actions of the FDA. The products are intended to treat a variety of disorders including but not limited to the following: hypertension, arthritis, epilepsy, diabetes, depression and pain management.

The Corporation’s manufacturing facility and executive offices were constructed in 1991, pursuant to a \$9.1 million loan from the Economic Development Corporation of the City of Detroit (the “EDC”). During 2009, the Corporation completed the expansion of the facility adjacent to its existing facility which has provided additional space required for manufacturing, quality control laboratories, raw material storage and administrative offices. Since August 1997, capital infusions had primarily come from Sun Pharma. Among other things, Sun Pharma had in the past, acted as a guarantor on loans to Caraco, has and continues to supply the Corporation with raw materials for certain products, assists in obtaining machinery and equipment to enhance production capacities at competitive prices, and has transferred certain technology formulas for generic products. As of March 31, 2010, Sun Pharma beneficially owns approximately 75% (76% including its holdings of convertible Series B Convertible Preferred stock) of the outstanding common shares of Caraco.

On June 25, 2009, U.S. Marshals, at the request of the FDA, arrived and seized drug products manufactured in our Michigan facilities that the FDA stated in its complaint were adulterated.. The seizure also included ingredients and in-process materials held at these same facilities. The estimated cost of such seized inventory as of March 31, 2010 was \$24.0 million. Caraco-owned products (those products for which Caraco owns the ANDAs) or licensed products distributed by Caraco that are manufactured outside of these facilities are not impacted and distribution and marketing of these products continues. The Company has also transferred certain Caraco-owned products to additional manufacturing sites that would allow the Company to regain revenues from those products. The Company has filed with the FDA supplements to ANDAs, for its approval, for some of these transferred products.



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The Company voluntarily entered into a Consent Decree of Condemnation, Forfeiture and Permanent Injunction (“Consent Decree”) with the FDA on September 29, 2009. As stipulated in the Consent Decree, the Company will attempt to have the seized inventory released. The Company believes that, except for the raw materials which were opened solely for the purpose of sampling, the estimated cost of which is \$8.1 million, all other seized inventory would be difficult to recondition. Accordingly, such inventory in the amount of \$15.9 million has been written off as of March 31, 2010. In accordance with the Consent Decree, the Company has 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 January 29, 2010, the Company received a letter from the FDA, seeking clarification on certain points. The Company submitted its response to the letter on March 24, 2010. Subsequent to the Company’s response the FDA sent a letter to the Company asking for additional information on April 7, 2010, to which the Company has submitted its response on June 3, 2010.

As a result of the FDA action, the Company has voluntarily ceased manufacturing operations and instituted, in two phases, indefinite layoffs of approximately 430 of its employees. The Company has subsequently started recalling some of these employees in conjunction with its efforts to restart its manufacturing activities. The Consent Decree provides a series of measures that, when satisfied, will permit the Company to resume manufacturing and distributing those products which are manufactured in its Michigan facilities. The Company has engaged a consulting firm which is comprised of current good manufacturing practice (“cGMP”) experts, in accordance with the Consent Decree, and has submitted a work plan to the FDA in October 2009 for remedial actions leading to resumption of its manufacturing operations. The FDA, after seeking certain additional clarifications and asking for certain modifications, has approved the work plan on March 17, 2010. The Company is in the process of implementing the corrective actions and remedial measures as stipulated in the work plan.

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

During Fiscal 2010, the Company formed a wholly-owned subsidiary, Caraco Pharma, Inc. To date, this subsidiary has not entered into any financial transactions.

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Sun Pharmaceutical Industries Limited

Pursuant to a stock purchase agreement, a Mumbai, India based specialty pharmaceutical manufacturing company, Sun Pharma made an initial investment of \$7.5 million for the purchase of 5.3 million common shares of Caraco in 1997.

In August 1997, Caraco entered into an agreement, whereby Sun Pharma was required to transfer the technology formulas for 25 generic pharmaceutical products over a five-year period in exchange for 544,000 shares of Caraco common stock for each technology transfer of an ANDA product (when bio-equivalency studies were successfully completed) and 181,333 common shares for each technology transfer of a Drug Efficacy Study Implementation (“DESI”) product. The products provided to the Corporation from Sun Pharma were selected by mutual agreement. Under such agreement, Caraco conducted, at its own expense, all tests including bio-equivalency studies. Pursuant to such agreement through 2002, Sun Pharma delivered the technology formula for 13 products. This agreement expired on November 21, 2002, and the Corporation entered into a new technology transfer agreement with Sun Global, Inc. (“Sun Global”), an affiliate of Sun Pharma.

Under the agreement, which was approved by the Corporation’s independent directors, Sun Global agreed to provide the formulations for 25 new generic drugs over a five-year period. Caraco’s rights to the products are limited to the United States and its territories or possessions, including Puerto Rico. Sun Global retains rights to the products in all other territories. The products are selected by mutual agreement. Under this agreement, Caraco conducts at its own expense all tests, including bio-equivalency studies. The Corporation also markets the products consistent with its customary practices. In return for the technology transfer, Sun Global receives 544,000 shares of Series B Convertible Preferred Stock for each generic drug transferred when such drug has passed its bio-equivalency studies.

The products agreement was amended by the Independent Committee, comprised of the three independent directors, in the first quarter of 2004 to eliminate the provision requiring that the Independent Committee concur in the selection of each product, and provides instead that each product satisfy certain objective criteria developed by management and approved by the Independent Committee. Pursuant to such objective criteria, all 25 of the products under this agreement had been selected, and all 25 products had passed their respective bio-equivalency studies as of March 31, 2008.

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

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

Sun Pharma operates research and development centers in Mumbai and Vadodara in India, where the development work for products is performed.

Sun Pharma and its subsidiaries supply the Corporation with certain raw materials (Note 4) and formulations, assist in acquiring machinery and equipment to enhance production capacities, and have provided qualified technical professionals who work as Caraco employees. Also, five of the eight directors of Caraco are, or were, affiliated with Sun Pharma.

Further, Sun Pharma and its affiliates may use Caraco as a contract manufacturer and/or distributor of their products. In December 2004 and January 2005, Caraco entered into agreements for two such products, of which one was being marketed until Caraco ceased all manufacturing operations at its Michigan facility due to actions taken by the FDA as discussed above

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 further renewed for a period of one year in January 2010. Under the agreement, the Corporation purchases selected product formulations offered by Sun Pharma and markets and distributes the same as part of the current product offerings in the U.S., its territories and possessions, including Puerto Rico. Sun Pharma is not obligated to offer Caraco products under this agreement, however, Caraco has the exclusive right to market in the U.S., its territories and possessions, including Puerto Rico, any products offered by Sun Pharma and accepted by Caraco.

During the fiscal year ended March 31, 2008 ("Fiscal 2008"), the Corporation entered into a three-year distribution and sale agreement with Sun Pharma, which was reviewed and approved by the Board's Independent Committee. Under this agreement the Company purchases selected formulations which have been filed under Paragraph IV certification process with the FDA by Sun Pharma and offered for distribution. Paragraph IV certified ("Paragraph IV") products may face litigation challenges with respect to claims of patent infringement. Under the agreement the Company shares in the sales opportunity and shares the litigation risk. The Company is indemnified by Sun Pharma of any risk beyond the percentage agreed to as its profit percentage thereby limiting the Company's exposure. Sun Pharma is not obligated to offer Caraco products under this agreement, however, Caraco has the exclusive right to market in the U.S., its territories and possessions, including Puerto Rico, any products offered by Sun Pharma and accepted by Caraco. The Company markets and distributes the same as part of its current product offerings in the U.S., its territories and possessions, including Puerto Rico. The license granted with respect to a product terminates upon the end of an exclusivity period of 180 days or a non-appealable court decision, or until a third generic manufacturer launches the product, whichever is later, or until a settlement is reached, at which time the product will become part of the standard Caraco-Sun Pharma marketing agreement disclosed above. The Company currently receives a 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.

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During the fiscal years ended March 31, 2010 (“Fiscal 2010”), March 31, 2009 (“Fiscal 2009”) and Fiscal 2008, the Corporation made net sales of \$211.4 million, \$225.4 million and \$225.1 million of the marketed products under aforesaid agreements, respectively.

The Corporation also paid approximately \$8 thousand, \$46 thousand and \$0.3 million for the years ended March 31, 2010, 2009 and 2008, respectively, to Sun Pharma and its subsidiaries for the purchase of various parts and machinery needed for operations. During Fiscal 2010 the Corporation made an equipment sale of approximately \$0.2 million to Sun Pharma and its subsidiaries.

The Corporation has also obtained technical and scientific services, including bio-equivalency studies, from the Clinical Research Organization operated by Sun Pharma. The product, on which the Company decides to work with Sun Pharma, is determined on a case by case basis as mutually agreed upon by both companies. During Fiscal 2010 and Fiscal 2009, the Corporation incurred \$1.5 million and \$0.3 million, respectively, related to these services. No fees for these services were incurred during Fiscal 2008.

While management has a basis to reasonably believe that Sun Pharma's substantial investment in Caraco provides Sun Pharma with sufficient economic incentive to continue to assist Caraco in developing its business and Sun Pharma has supported Caraco's operations in the past, however there can be no assurance that such support will, in fact, continue, or that the current terms and conditions will remain the same in the future.

In addition to its substantial relationship with and dependence on Sun Pharma as described above, the Corporation is subject to certain risks associated with companies in the generic pharmaceutical industry. Profitable operations are dependent on the Corporation's ability to market its products at reasonable profit margins. In addition to maintaining profitable operations, the ongoing success of the Corporation will depend, in part, on its continuing ability to attract and retain key employees, obtain timely approvals of its ANDAs, and develop new products (see “Operations”, below).

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### Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make 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 (see “Revenue Recognition”, below), valuation of inventories and deferred tax assets.

### Cash and Cash Equivalents

Cash and cash equivalents consist of demand deposits in banks, cash on hand and all highly liquid investments purchased with an original maturity of three months or less. The Corporation invests its excess cash primarily in deposits with major banks and in other high quality short-term liquid money market investments. During the normal course of business, the Corporation may maintain cash on deposit in excess of federally insured limits with financial institutions. The Corporation maintains a policy of making investments only with institutions with at least an investment grade credit rating.

### Short-Term Investments

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

### Revenue Recognition

Revenue from product sales, both Caraco-owned and distributed products, 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, the selling price is fixed or determinable, and collectibility is reasonably probable. The Corporation's 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 sales chargebacks, customer 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 allowances. These revenue reductions are reflected as a direct reduction to accounts receivable through a sales allowance account.

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



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Allowances for Sales Adjustments

Chargebacks

Chargebacks represent the Corporation's most significant provision against gross accounts receivable and related reduction to gross sales revenue. Chargebacks are retroactive credits given to wholesale customers that represent the difference between the lower price they sell (contractual price) to retail, chain stores, and managed care organizations and what the Corporation charges the wholesaler. The Corporation estimates chargebacks at the time of sale for their wholesale customers. The Corporation is currently unable to specifically determine whether the amounts provided in specific prior periods for chargeback allowances have been over or understated. Wholesaler customers who submit chargebacks to the Corporation do not reference a specific invoice that the chargeback is related to when the chargeback is submitted to the Corporation. Thus, the Corporation cannot determine the specific period to which the wholesaler's chargeback relates.

The Corporation considers the following factors in the determination of the estimates of sales chargebacks:

1. The historical data of chargebacks as a percentage of sales, as well as actual chargeback reports received from 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 products, wholesale acquisition cost (WAC), the contract prices with the retailers, chain stores, managed care organizations (end-users), and wholesaler customer's contract prices.
4. The Corporation utilizes data on remaining inventories on hand at primary wholesaler customers at the end of each reporting period in the calculation of estimates.

Such estimated amounts, in addition to certain other allowances, are deducted from the Corporation's gross sales to determine net revenues. The amount of actual chargebacks claimed could be either higher or lower than the amounts accrued. Changes in estimates, if any, would be recorded in the income statement in the period the change is determined. If the Corporation materially over or under estimates the amount that will ultimately be charged back to it by its wholesale customers, there could be a material impact on the Corporation's financial statements. Approximately 90% and 88% of the total allowance for trade receivables at March 31, 2010 and 2009, respectively, has been established to provide for estimated sales chargebacks, and customer rebates. (see Note 3).



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Shelf Stock Adjustments

Shelf stock adjustments are credits issued to customers to reflect decreases in the selling prices of products. These credits are customary in the industry and are intended to reduce the customers' inventory cost to better reflect current market prices. The decision to grant a shelf stock adjustment to a customer following a price decrease is made at the Corporation's discretion.

Factors considered when recording an allowance for shelf stock adjustments include estimated launch dates of competing products based on market intelligence, estimated decline in market price of products based on historical experience and input from customers, and levels of inventory held by customers at the date of the pricing adjustments.

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. The Corporation's return policy typically allows product returns for products within a 12-month window from six months prior to the expiration date and up to six months after the expiration date. The Corporation estimates the level of sales that will ultimately be returned, pursuant to its return policy, and records a related allowance at the time of sale. These amounts are deducted from its gross sales to determine net revenues. These estimates take into consideration historical returns of the products and the Corporation's future expectations. The Corporation periodically reviews the allowances established for returns and adjusts them based on actual experience, as necessary. The primary factors considered in estimating its potential product returns include shelf life of expiration date of each product and historical levels of expired product returns. If the Corporation becomes aware of any returns due to product quality related issues, this information is used to estimate an additional allowance. The Corporation provides for allowance related to returns resulting from product recalls, in the period that such recalls occur. The amount of actual product return could be either higher or lower than the amounts provided. Changes in these estimates, if any, would be recorded in the income statement in the period the change is determined. If the Corporation over or under estimates the quantity of product that will ultimately be returned, there may be a material impact to its financial statements.

Sales discounts (trade and prompt payment discounts) are provided for 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. The Corporation reviews its contracts with its customers in addition to historical data and percentages to estimate the reserve for estimated discounts.

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Customer rebates are estimated at the end of every reporting period, based on direct or indirect purchases. If the purchases are direct (purchases made by end use customers directly from the Company), the rebates are recognized when products are purchased and a periodic credit is given. For indirect purchases (purchases by end use customers through wholesale customers), the rebates are recognized based on the terms with such customer. Medicaid rebates are estimated based on the historical data the Corporation receives from the public sector benefit providers, which is based on the final dispensing of the products by a pharmacy to a benefit plan participant.

### Doubtful Accounts

Doubtful accounts are estimated based on the data available from external sources, including information obtained related to the financial condition of customers. Delinquent accounts are reviewed by management on a quarterly basis, to identify and record allowances, as considered necessary, for accounts receivable not expected to be recoverable.

### Accounts Receivable

The Corporation sells its products using customary trade terms; the resulting accounts receivable are unsecured. Accounts receivable are stated at the amount management expects to collect from outstanding balances. The Corporation provides for probable uncollectible amounts through a charge to earnings and a credit to a valuation allowance based on management's assessment of the current status of individual accounts. Balances that are still outstanding after the Corporation has attempted reasonable collection efforts are written off through a charge to the valuation allowance and a credit to trade accounts receivable.

### Inventories

Inventories, which consist of raw materials, goods in transit and finished goods, as well as work-in-process, are stated at the lower of cost, determined using the specific identification method, or market. The Corporation analyzes its inventory levels quarterly and writes down any inventory that has become obsolete and inventory that has a cost basis in excess of its expected net realizable value. Expired inventory is disposed of and the related costs are written off. Materials acquired for research and development on products yet to be launched are written off in the year of acquisition. Inventory includes material purchased related to products for which the Corporation has filed ANDAs with the FDA, and the commercial launch of such products will commence once the approvals are received. The determination of whether or not inventory costs will be realizable requires estimates by management. A critical estimate in this determination is the estimate of the future expected inventory requirements, whereby the Corporation compares its internal sales forecasts to inventory on hand. Actual results may differ from those estimates and inventory write-offs may be required. The Corporation must also make estimates about the amount of manufacturing overhead to allocate to its finished goods and work in process inventories. Although the manufacturing process is generally similar for its products, the Corporation 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 made can impact the value of reported inventories and cost of sales.

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## Net (Loss) Income Per Share

Net (loss) income per share is computed using the weighted average number of common shares outstanding during each year 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 following table sets forth the computation of basic and diluted net (loss) income per common share:

	Year Ended March 31, 2010	Year Ended March 31, 2009	Year Ended March 31, 2008
Numerator:			
Net (loss) income available for common stockholders	\$ (8,659,632 )	\$ 20,536,579	\$ 35,388,105
Denominator:			
Weighted average shares outstanding, basic	38,613,262	34,227,335	29,656,624
Incremental shares from assumed conversion of -			
- preferred stock	-	5,949,721	9,916,852
- common stock options	-	398,665	340,278
Weighted average shares outstanding, diluted	38,613,262	40,575,721	39,913,754
Net (loss) income per common share			
Basic	\$ (0.22 )	\$ 0.60	\$ 1.19
Diluted	\$ (0.22 )	\$ 0.51	\$ 0.89

## Property, Plant and Equipment and Depreciation

Property, plant and equipment is carried at cost less accumulated depreciation. Land is carried at cost. Construction in process is carried at cost until such time the associated asset(s) is placed into service. Depreciation is computed using the straight-line method over the estimated useful lives of the related assets, which range from 3 to 40 years. Major improvements and renewals are capitalized while ordinary maintenance and repairs are expensed. Management annually reviews these assets for impairment and believes the carrying value of these assets will be recovered through cash flows from operations.

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Income Taxes

Deferred income tax assets and liabilities are determined based on the difference between the financial statement and federal income tax basis of assets and liabilities as measured by the estimated tax rates that will be in effect when these differences reverse. Deferred income taxes result principally from the Corporation's intangibles related to technology transfer costs and net operating loss carryforwards. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is the tax payable or refundable for the year plus or minus the change during the year in deferred tax assets and liabilities.

Research and Development Costs

Series B convertible preferred stock was issued to Sun Pharma and its affiliates under the Products Agreement between the Corporation and Sun Global in exchange for the technology of formulation products delivered by Sun Global to the Corporation. Such Products Agreement has been completed with the last technology transfer occurring during the third quarter of Fiscal 2008. Accordingly, no further non-cash research and development expense is expected to 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.

The Corporation was responsible for submission of these transferred formulations for FDA approval. In the Company's experience, generally, the submission of an ANDA to the FDA is approximately thirty days after the receipt of notice that the proposed drug product formula passes its bio-equivalency study and accelerated stability studies. An ANDA contains data related to a generic drug product which is submitted to the FDA for review and approval. The FDA must first determine the completeness of the filing and may deny the filing if it is incomplete. There are various reviews that are completed, including bio-equivalency, chemistry, manufacturing, and labeling. The bio-equivalency of a generic drug product is established by measuring the rate and level of active ingredient(s) in the bloodstream of healthy human subjects over a period of time. These pharmacokinetic parameters and results are compared with the innovator's drug product. The bio-equivalency results of the proposed generic drug product must meet pharmacokinetic standards set forth by the FDA. Accordingly, the generic version of a drug product must generally deliver the same amount of active ingredient(s) into the bloodstream within the same timeframe as that of the innovator drug product. Following an indication that the generic drug product has passed its bio-equivalency study, the generic drug product will undergo reviews for chemistry, manufacturing and labeling. In each case, the FDA has an opportunity to raise questions or comments, or issue a deficiency letter. In the event that one or more deficiency letters are issued by the FDA, the submission of the ANDA may be halted or delayed as necessary to accommodate the correction of any such deficiencies and the completion of any additional reviews required. Minor deficiencies traditionally could delay the approval anywhere from 10 days to 90 days or more. Major deficiencies could stop the evaluation process. A restart of the FDA review process after a major deficiency could take up to as many as 180 days or more. Generally, any deficiencies the Company has 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.

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Based on the definition and characteristics of an asset, the Company did not capitalize the technology formulas transferred, as the probability of the future economic benefit to be derived from such formulations was considered uncertain at the time of technology transfer.

In addition, the Company has reported the technology transfers as research and development expenses pursuant to Accounting Standards Codification (“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.

Intangible Assets

The Company had made a cash payment in the first quarter of Fiscal 2009 in the amount of \$1,100,000 for the purchase of certain assets which included brand products, associated New Drug Applications (“NDAs”) and trademarks. These assets are recorded as intangible assets in the Company’s balance sheet at March 31, 2010. Additionally during the second quarter of Fiscal 2009, the Company paid \$356,000 in cash towards product and establishment fees for these products. The total gross carrying amount for these assets is \$1,456,000 as of March 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. During Fiscal 2010 and Fiscal 2009, the Company recorded amortization expense in the amount of \$97,000 and \$73,000, respectively, and estimates that an additional \$97,000 of related amortization expense will be recorded in each of the Company’s next five fiscal years. The Company annually reviews these assets to determine whether the carrying values have been impaired.

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Interest Rate Risk Management Strategies and Objectives.

The Company assesses interest rate cash flow risk by attempting to identify and monitor changes in interest rate exposures that may adversely impact expected future cash flows. The variable rate loans payable described in Note 5 exposes the Company to variability in interest rate payments due to changes in interest rates. If interest rates increase, interest expense increases. Conversely, if interest rates decrease, interest expense also decreases. Management believes it is prudent to limit the variability of the entire portion of the interest payments on this loan. To meet this objective the Company entered into an interest rate swap agreement, effective March 13, 2009. This interest rate swap changes the variable-rate cash flow exposure on the loan to fixed-rate cash flows. Under this swap agreement, the Company pays interest quarterly at a fixed annual rate of 2.41% on the notional amount related to the variable rate loans payable outstanding as of March 31, 2010 and 2009. Also the Company receives quarterly interest at a variable annual rate equal to LIBOR on the notional amount. The termination of this derivative financial instrument is no later than March 17, 2014.

The Company does not enter into derivative instruments for any purpose other than economically hedging its interest rate risk associated with variable loan. That is, the Company employs derivatives solely for risk management reasons and does not enter into derivative instruments for trading or speculative purposes.

The use of the interest rate swap affects the Company's financial position by the recognition of the fair value of the swap on its balance sheet. The corresponding changes in fair value of the swap between periods introduces volatility in the Company's reported results of operations. The Company's cash flows are more predictable since the swap, in effect, converts the variable rate debt service payments to fixed payments.

The interest rate swap agreement is reported on the accompanying March 31, 2010 balance sheet based on the interest rate swap's fair value at that date. The change in the fair value of the liability to record the position associated with the change in the swap's fair value is recognized as interest expense in the statement of operations.

Fair Value of Interest Rate SWAP.

The Company utilizes fair value measurements to record fair value adjustments to its interest rate swap to determine fair value disclosures. The Company's interest rate swap is recorded at fair value on a recurring basis.

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Fair Value Hierarchy

Fair Value Measurement standards in accounting established a framework for measuring fair value. That framework provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of fair value hierarchy are described as follows:

Level 1: Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active market that the Company has the ability to access.

Level 2: Inputs to the valuation methodology include:

- Quoted prices for similar assets or liabilities in active markets;
- Quoted prices for identical or similar assets or liabilities in inactive markets;
- Inputs other than quoted prices that are observable for the asset or liability; and

• Inputs that are derived principally from or corroborated by observable market data by correlation or other means.

Level 3: If the asset or liability has specified (contractual) term, the level 2 input must be observable for substantially the full term of the asset or liability. Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

An asset or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Valuation techniques used need to maximize the use of observable inputs and minimize the use of unobservable inputs.

Following is the description of the valuation methodologies and key inputs used to measure the interest rate swap recorded at fair value, as well as a description of the method. The description includes an indication of the level of the fair value hierarchy in which the assets or liabilities are classified.

The Company's interest rate swap is recorded at fair value on a recurring basis. The fair value of the interest rate swap is based on a valuation model which considers current interest rates and the present values of future fixed cash flows combined with expected floating cash flows determined by references to forward rates considering the spot market and construction of a yield curve using observable market data. As such, the Company classifies its interest rate swap as a Level 2 valuation.

The following table sets forth by level, within the fair value hierarchy, the recorded amount of derivative instruments measured at fair value on a recurring basis as of March 31, 2010.

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	Liability at Fair Value..			Total
	Level 1	Level 2	Level 3	
Interest rate swap	\$ –	\$ 331,000	\$ –	\$ 331,000

## Fair Value Measurements

The carrying values of cash and cash equivalents, short-term investments, accounts receivable, and accounts payable approximate their fair values due to the short-term maturities of these financial instruments.

## Recent Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board (“FASB”) issued SFAS No. 168, “FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles - a replacement of Financial Statement No. 162”, which was primarily codified into ASC Topic 105 — “Generally Accepted Accounting Principles.” This standard identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of non-governmental entities that are presented in conformity with GAAP. This statement is effective for financial statements issued for interim and annual periods ending after September 15, 2009. Accordingly, the Company adopted this standard effective with its quarterly report ended September 30, 2009. The adoption of this standard has changed how we reference various elements of GAAP when preparing our financial statement disclosures, but had no impact on the Company’s consolidated financial statements.

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

## 2. SUPPLEMENTAL CASH FLOWS INFORMATION

## Non-Cash Financing Activities

As described in Notes 1 and 7, pursuant to the technology transfer agreement with an affiliate of the Corporation’s parent, Caraco, in the past, financed the acquisition of research and development costs in exchange for the issuance of preferred stock to its parent. Preferred stock earned or issued to affiliates had fair values of \$0, \$0 and \$11,320,640 for the years ended March 31, 2010, 2009 and 2008, respectively. During Fiscal 2010, Fiscal 2009 and Fiscal 2008 the Corporation issued 1,632,000, 4,896,000 and 4,352,000 shares of its common stock to Sun Pharma Global Inc. in conversion of 1,632,000, 4,896,000 and 4,352,000 preferred shares, valued at \$11,761,280, \$35,055,360 and \$26,768,880, respectively.



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## Other Cash Flows Information

The Company paid approximately \$445,000 for interest during Fiscal 2010, while there was no cash paid for interest during Fiscal 2009 and Fiscal 2008. During Fiscal 2010, the Company received federal income tax refunds in the amount of \$4,892,000, while the Company paid approximately \$15,600,000 and \$24,210,000 during Fiscal 2009 and Fiscal 2008, respectively, of federal income taxes.

## 3. ACCOUNTS RECEIVABLE, NET OF ALLOWANCES FOR SALES ADJUSTMENTS AND DOUBTFUL ACCOUNTS

Accounts receivable and related allowances are summarized as follows:

	March 31,	
	2010	2009
Accounts receivable - gross	\$ 167,142,759	\$ 71,842,197
Allowances:		
Chargebacks and rebates	64,808,000	50,028,000
Sales returns and discounts	7,467,000	6,555,000
Doubtful accounts	131,000	78,000
Total allowances	72,406,000	56,661,000
Accounts receivable, net of allowances	\$ 94,736,759	\$ 15,181,197

A summary of the activity in accounts receivable allowances is as follows:

	Total Allowances
Balance at March 31, 2008	\$ 84,296,000
Additions charged to net sales	311,171,000
Deductions allowed to customers	(338,806,000)
Balance at March 31, 2009	\$ 56,661,000
Additions charged to net sales	219,214,000
Deductions allowed to customers	(203,469,000)
Balance at March 31, 2010	\$ 72,406,000

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## 4. INVENTORIES

Inventories consist of the following amounts:

	March 31	
	2010	2009
Raw materials	\$ 14,545,370	\$ 17,954,511
Goods in transit (Distributed)	28,406,006	29,236,869
Work in process	--	9,279,009
Finished goods (Caraco-owned)	4,460,252	9,749,721
Finished goods (Distributed)	55,771,222	13,290,722
Total inventories	\$ 103,182,850	\$ 79,510,832

The principal components used in the Corporation's business are active and inactive pharmaceutical ingredients and certain packaging materials. Some of these components are purchased from single sources; however, the majority of the components have an alternate source of supply available. Because the FDA approval process requires manufacturers to specify their proposed supplier of components in their applications, FDA approval of a new supplier would be required if components were no longer available from the specified suppliers. Also, a major component of the Company's inventory includes purchase of finished goods for distribution under various marketing agreements. Total inventories at March 31, 2010 and March 31, 2009 includes materials purchased in the amount of \$2,249,878 and \$2,875,885, respectively, related to products for which the Company has filed ANDAs with the FDA, and the commercial launch of such products will commence once the approvals are received.

During the years ended March 31, 2010, March 31, 2009 and March 31, 2008, the Corporation made net purchases of inventory components, consisting of raw materials and finished goods, of approximately \$241.7 million, \$8.4 million and \$498.5 million, respectively, from Sun Pharma. (Also see Note 11).

As disclosed above, on June 25, 2009, certain drug products manufactured, work in process, and ingredients held, at the Company's Michigan facilities were seized at the direction of the FDA. The estimated cost of such seized inventory as of March 31, 2010 was \$24.0 million. The Company has voluntarily entered into a Consent Decree and is in the process of getting the material released. The Company believes that, except for the raw materials which were opened solely for the purpose of sampling, the estimated value of which is \$8.1 million, all other seized inventory would be difficult to recondition. Accordingly, such inventory in the amount of \$15.9 million has been written off as of March 31, 2010 which consists of work in process relating to those materials which are in various stages of production within our manufacturing facilities, all finished goods and those raw material ingredients which are partially consumed in process. In accordance with the Consent Decree, the Company has 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 January 29, 2010, the Company received a letter from the FDA, seeking clarification on certain points. The Company submitted its response to the letter on March 24, 2010. Subsequent to the Company's response the FDA sent a letter to the Company asking for additional information on April 7, 2010, to which the Company has submitted its response on June 3, 2010. The Company believes that it will be able to use the inventory of raw materials which were opened solely for sampling purposes, however, in the event the Company is unable to recondition or recover all of such inventory, the Company will adjust the value of its inventory accordingly in future periods, which would result in a negative impact on the future operating results of the Company

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## 5. DEBT

## Loans Payable to Financial Institution

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 March 31, 2010 was 1.2%. The principal loan payments and accrued interest are payable on a quarterly basis beginning July 2009. The principal is to be repaid in equal quarterly installments of \$900,000 for ten quarters through October 2011, and thereafter, if not renewed, the remaining balance of \$9 million is due in the subsequent quarter by January 2012. Subsequently, in October 2009 the terms of the loan were modified and we entered into an amended agreement. The amendment adds to the loan a one year line of credit note for \$15 million against which the Company can borrow funds for working capital purposes or can get letters of credit issued. Against this line of credit, the Bank has issued an Irrevocable Standby Letter of Credit in an amount of \$15 million, in favor of the United States of America, as required to be placed with the FDA in accordance with the Consent Decree, as disclosed above. The line of credit carries an interest rate of LIBOR plus 150 basis points, and if letters of credit are issued, the associated fees are 0.7% of such letters of credit on annualized basis. Also, there is an unused fee of 0.25% on an annualized basis to the extent the line remains idle. Both the line of credit and outstanding term loan are cross collateralized by all of the Company’s fixed assets and cash deposit accounts held with Charter One Bank equivalent to the amount of outstanding loans and outstanding letter of credit. These cash deposits earn interest at prevailing rates applicable to such money market accounts. The Company is continuing discussions with Charter One Bank to allow the release of the cash collateral. Charter One Bank has temporarily suspended the required compliance with the covenants in the loan agreements relating to FDA enforcement actions, and has suspended certain other compliance requirements until October 9, 2010. On or before such date, the Company anticipates either entering into revised agreements or repaying the loan in full.

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

As required pursuant to the terms of the Loan Agreement, the Company has entered into an Interest Rate Swap Agreement with Charter One Bank to hedge the interest rate applicable on the loan. The notional amount for the swap is \$15.3 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 March 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 a provision of \$331,000 to record the fair value of this swap agreement at March 31, 2010, with such amount included in Interest expense and Accrued Expenses.

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## 6. INCOME TAXES

The provision (benefit) for income taxes for the fiscal years ended March 31, 2010, March 31, 2009 and March 31, 2008 consist of the following:

	2010	March 31, 2009	2008
Currently payable (refundable)	\$ (3,250,401)	\$ 12,402,553	\$ 24,353,492
Deferred benefit	(1,263,741)	(3,487,195)	(17,347,675)
Total	\$ (4,514,142)	\$ 8,915,358	\$ 7,005,817

The provision (benefit) for income taxes is different from that which would be obtained by applying the statutory federal income tax rate to net (loss) income before income taxes. The items causing the difference for the fiscal years ended March 31 are as follows:

	2010	2009	2008
Provision for income taxes at federal statutory rate	\$ (4,610,821)	\$ 10,308,528	\$ 14,837,872
Change in valuation allowance	-	-	(6,962,422)
Permanent items and other	96,679	(1,393,170)	(869,633)
Income tax (benefit) expense	\$ (4,514,142)	\$ 8,915,358	\$ 7,005,817

Deferred taxes consist of the following:

	March 31, 2010	March 31, 2009
Deferred tax assets:		
Net operating loss carryforwards	\$ 797,631	\$ 797,631
Intangibles	24,079,523	26,458,255
Other	519,554	417,136
Total deferred tax assets	\$ 25,396,708	\$ 27,673,022
Deferred tax liabilities:		
Intangibles	\$ -	\$ 6,180,987
Depreciation	3,298,097	657,165
Total deferred tax liabilities	\$ 3,298,097	\$ 6,838,152
Net deferred tax assets	\$ 22,098,611	\$ 20,834,870

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The Company had net deferred tax assets of \$22.1 million and \$20.8 million at March 31, 2010 and March 31, 2009, respectively. The Company has recorded an income tax benefit of \$4.5 million during Fiscal 2010, and recorded income tax expense of \$8.9 million and \$7.0 million during Fiscal 2009 and Fiscal 2008, respectively. Valuation allowances are provided when based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company has not provided for any valuation allowance as of March 31, 2010, March 31, 2009 or March 31, 2008. Based upon the level of projected future taxable incomes over the periods in which 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 March 31, 2010, the Company had federal net operating loss carryforwards (“NOLs”) of approximately \$2.3 million, which are restricted by limitations of Internal Revenue Code Section 382, available to reduce taxable income and will expire between Fiscal 2011 and Fiscal 2012.

The Company adopted the provisions of ASC 740 (“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 March 31, 2010.

The Company is subject to U.S. federal income tax as well as income tax in certain state jurisdictions. The IRS had initiated an examination of the Company’s tax return for the fiscal year ended March 31, 2007. The examination has been completed and the IRS has notified the Company that no adjustments are required to be made to the tax return filed for the period under review. The Company’s federal statute of limitations has expired for years prior to 2006.

7. STOCKHOLDERS' EQUITY

Common Stock

The Corporation granted 45,000 shares of common stock on May 2, 2005 to its then Chief Executive Officer, which vested at a rate of 15,000 shares on each anniversary date until they became fully vested on May 2, 2008. The Corporation recorded compensation expense of approximately \$10,000 and \$119,000 related to the portion of the stock grant that vested during Fiscal 2009 and Fiscal 2008, respectively. During Fiscal 2009 the Corporation granted 10,000 shares of common stock to its then Chief Executive Officer, which vested on May 2, 2008. During Fiscal 2009, the Corporation recorded compensation expense of \$169,900 relating to this stock grant.

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There were no common stock issuances to Directors or employees during Fiscal 2010. The Company issued 1,000 shares of common stock to its employees upon exercise of their stock options during Fiscal 2009.

Preferred Stock

In November 2002, in connection with the new technology transfer agreement established with Sun Global (Note 1), the Corporation designated the Series B Convertible Preferred Stock. The Series B preferred shares are non-redeemable and have no par value. In addition, the Series B Convertible Preferred Stock has no voting or dividend rights or liquidation preference other than priority liquidation based on their values on the dates they were earned, and can be converted after three years from the issuance date (or immediately upon a change in control) into one share of common stock, subject to a conversion adjustment (Note 1). While such preferred shares are outstanding, Caraco cannot, without the consent of the holders of a majority of the outstanding shares of the preferred stock, amend or repeal its articles of incorporation or bylaws if such action would adversely affect the rights of the preferred stock. In addition, without such consent, capital stock having any preference or priority superior to the preferred stock may not be issued. As of March 31, 2010, the Corporation has issued 13,600,000 shares of the Series B Convertible Preferred stock to Sun Pharma in exchange for twenty-five product transfers. Such shares have been cumulatively valued at \$95,837,690 as of March 31, 2010. During Fiscal 2010, 1,632,000 shares of the preferred stock were converted into an equal number of shares of Corporation's common stock at a value of \$11,761,280, while during Fiscal 2009, 4,896,000 shares of preferred stock were converted into an equal number of shares of the Corporation's common stock at a value of \$35,055,360 and during Fiscal 2008, 4,352,000 shares of preferred stock were converted into an equal number of shares of the Corporation's common stock at a value of \$26,768,880. As of March 31, 2010, all 25 of the products under the technology transfer agreement had been selected and all of these 25 products had passed bio-equivalency studies; the final product being transferred to Caraco during the third quarter of Fiscal 2008, which concluded the obligations between the parties under this agreement.

8. COMMON STOCK OPTIONS

Common Stock Option Plans

As of March 31, 2010, the Corporation maintains one common stock option plan, the 2008 Equity Participation Plan (the "2008 Plan"). This plan was adopted and approved by shareholders at the Annual Meeting of Shareholders held in September 2008. The 2008 Plan replaced the 1999 Equity Participation Plan (the "1999 Plan"). Under the 2008 Plan, the Corporation may grant options to employees and non-employee-directors for the purchase of up to 1,000,000 shares of common stock. The exercise price of options granted may not be less than the fair value of the common stock on the date of grant. Options granted under this plan generally vest in annual installments, from the date of grant, over a three and five-year period, and expire within six years from the date of the grant. Activity with respect to options under these plans is summarized as follows:

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	Year Ended March 31, 2010		Year Ended March 31, 2009		Year Ended March 31, 2008	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding, beginning of year	227,000	\$ 11.81	161,000	\$ 10.83	165,900	\$ 7.36
Granted	13,500	3.77	86,500	14.20	52,000	14.31
Exercised	-	-	(1,000 )	11.25	(36,700 )	3.26
Terminated	(150,000 )	10.74	(19,500 )	14.34	(20,200 )	4.80
Outstanding, end of year	90,500	\$ 12.39	227,000	\$ 11.81	161,000	\$ 10.83
Options exercisable, end of year	36,500	\$ 12.88	102,000	\$ 9.84	52,000	\$ 8.93

Options at March 31, 2010:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Shares	Remaining Contractual Life *	Exercise Price *	Shares	Exercise Price *
\$3.01 to \$5.00	13,500	5.3	\$ 3.83	\$ 1,500	4.08
\$5.01 to \$7.00	3,000	4.9	5.27	1,000	5.27
\$7.01 to \$8.00	4,500	3.4	7.61	1,500	12.88
\$8.01 to \$9.00	2,000	1.8	8.76	2,000	8.76
\$9.01 to \$10.00	6,000	1.1	9.19	6,000	9.19
\$10.01 to \$13.00	6,000	2.6	12.45	6,000	12.45
\$13.01 to \$18.00	55,500	4.3	15.72	18,500	15.78
Total	90,500	4.0	\$ 12.39	36,500	\$ 12.88

\*Weighted average

The estimated fair value as of the date options were granted during the fiscal years ended March 31, 2010, March 31, 2009 and March 31, 2008 was estimated on the date of the grant using the Black Scholes option-pricing model and is based upon the following assumptions:

	Year ended March 31, 2010	Year ended March 31, 2009	Year ended March 31, 2008
Weighted average estimated fair value per share of options granted during the period	\$ 2.04	\$ 4.78	\$ 7.15
Assumptions			
Common stock price volatility	71.2 %	39.6 %	39.9 %

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Risk free rate of return	2.0	%	3.0	%	4.6	%
Expected option term (in years)	4		4		4	
Average dividend yield	0	%	0	%	0	%

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The Corporation accounts for its stock-based compensation plans in accordance with 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 Corporation estimates the fair value of stock options granted using the Black-Scholes option-pricing model, which requires the Corporation 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 Corporation believes the options will be outstanding based on historical information. Estimates of expected future stock price volatility are based on historical volatility of the Corporation's common stock. The Corporation 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 year ended March 31, 2010, the Corporation has recognized expense amounting to \$222,042 related to common stock options, as compared to \$325,075 for the year ended March 31, 2009 and \$284,649 for the year ended March 31, 2008. As of March 31, 2010, total unrecognized compensation cost related to common stock options granted was \$206,884. The unrecognized stock option compensation cost is expected to be recognized over a period of approximately 3 to 5 years.

Options to purchase 13,500, 86,500 and 52,000 shares of common stock were granted for the years ended March 31, 2010, 2009 and 2008, respectively, to the independent directors, and certain officers and employees of the Corporation.

The Corporation had granted options to purchase 40,000 shares of common stock each on August 9, 2007 and June 11, 2006, respectively, to its then Chief Executive Officer, which were scheduled to vest at a rate of 1/3rd on each anniversary date until they were fully vested on August 9, 2010 and June 11, 2009, respectively. As of March 31, 2010 these options have expired as he did not exercise the options within the stipulated period subsequent to his resignation. Additionally, the Company recorded an expense of \$169,900 related to a stock grant of 10,000 common shares issued to its then CEO on May 2, 2008 as part of his employment agreement, which vested immediately upon issuance.

9. LEASES

The Corporation entered into a non-cancelable operating lease with an unrelated party during 2002 to lease additional warehouse space. This lease was subsequently modified during 2003 in lieu of a new non-cancelable operating lease for additional space at this warehouse. The lease was again modified during 2006 to change the term from 42 months to 66 months. The new lease required monthly payments that increased from \$15,458 to \$18,623 over the term of the lease that expired in Fiscal 2009. The Company did not renew the lease.

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The Corporation entered into a non-cancelable operating lease with an unrelated party on March 13, 2006 to obtain additional space for its executives and administrative staff. The lease was subsequently modified during 2006 in lieu of a new non-cancelable operating lease for additional office space. The lease commenced in May 2006 and required monthly payments that increased from \$13,458 to \$14,387 over the term of the lease that expired in Fiscal 2009. The Company did not renew this lease.

The Corporation entered into a non-cancelable operating lease with an unrelated party during Fiscal 2008 to lease additional warehouse space. The lease requires monthly payments that increase from \$64,078 to \$68,083 over the term of the lease that expires in 2018, with an option to renew for an additional period of five years.

Net rental expense on these operating leases was \$819,462, \$1,156,874 and \$524,271 for the years ended March 31, 2010, 2009 and 2008, respectively.

The following is a schedule of annual future minimum lease payments required under the operating leases with remaining non-cancelable lease terms in excess of one year as of March 31, 2010:

Fiscal Year	Amount
2011	\$ 789,533
2012	789,533
2013	793,538
2014	837,593
2015	837,593
Thereafter through	
2018	2,442,976
	\$ 6,490,766

## 10. RETIREMENT PLAN

The Corporation maintains a deferred compensation plan qualified under Section 401(k) of the Internal Revenue Code. Under this plan, eligible employees are permitted to contribute up to the maximum allowable amount determined by the Internal Revenue Code. The Corporation may make discretionary matching and profit sharing contributions under the provisions of the plan. The Corporation made contributions in the amount of \$122,156, \$172,675 and \$152,483 for the years ended March 31, 2010, 2009 and 2008, respectively.

## 11. CONCENTRATIONS AND COMMITMENTS

## Major Customers

Shipments to three wholesalers, Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health, accounted for approximately 33% of net revenues for the year ended March 31, 2010. The approximate percentage of net revenues attributable to each of these wholesalers is 13%, 8% and 12%, respectively. Shipments to Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health accounted for approximately 45% and 57% of net revenues for the years ended March 31, 2009 and 2008, respectively, or 9%, 16% and 20% for Fiscal 2009 and 8%, 28% and 21% for Fiscal 2008, respectively. Balances due from these customers represented approximately 53% and 47% of gross accounts receivable at March 31, 2010 and 2009, respectively. As is typical in the US retail sector, many of Corporation's customers are serviced through their designated wholesalers. Of the net sales made to wholesalers, the majority of these include sales for various customers of the Corporation that have underlying direct contracts with the Company that are facilitated through such wholesale customers. During Fiscal 2010, sales to CVS Caremark Corporation accounted for approximately 37% of the Company's net sales. The sales to CVS Caremark

Corporation have increased as the Company entered into a new contract with it towards the end of Fiscal 2009. The sales contracts for CVS Caremark Corporation includes special payment terms, and accordingly, collections of the related accounts receivable balances from these sales are expected to occur over an extended period. Balance due from CVS Caremark Corporation represented approximately 30% of gross accounts receivable as at March 31, 2010. No other single customer accounted for more than 10% of net sales for Fiscal 2010, Fiscal 2009 or Fiscal 2008. The loss of any of these customers could have a materially adverse effect on short-term operating results.

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Major Products

Shipments of one product, accounted for 55% of net revenue for the year ended March 31, 2010. Three products and two products accounted for approximately 57% of net revenue for the year ended March 31, 2009 and 55% of net revenue for the year ended March 31, 2008, respectively.

Approximately 61%, 69% and 66% of raw material purchases for the years ended March 31, 2010, 2009 and 2008, respectively, were made from Sun Pharma. The Corporation, however, believes that other sources of raw materials are available. The Corporation currently purchases 28 active pharmaceutical ingredients from Sun Pharma and 63 from other third parties.

Labor Contract

A union represents substantially all of the Company's permanent, full-time and regular part-time hourly employees. In September 2008, the Company successfully negotiated a new four-year collective bargaining agreement with the union. This agreement sets forth minimum wage increases and growth opportunities which the union employees will be eligible for in each of the next four years, thereby giving the Company and the union employees, the Company believes, a measure of certainty and stability. The collective bargaining agreement with the union is set to expire in September 2012, whereupon the Corporation expects to enter into a new agreement with the union.

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12. OTHER MATTERS

Employment Contracts

The Corporation has employment agreements with three of its executive officers that provide for fixed annual salaries and at least a six-month continuance including insurance benefits and immediate vesting of common stock options upon termination without cause.

Litigation

While it is not possible to determine with any degree of certainty the ultimate outcome of the following legal proceedings, the Company believes that it has meritorious defenses with respect to the claims asserted against it and intends to vigorously defend its position. An adverse outcome in any of these proceedings could have a material adverse effect on the Company's financial position and results of operations.

On June 9, 2005, Novo Nordisk A/S and Novo Nordisk, Inc. ("Novo Nordisk") filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Company's filing of an ANDA seeking approval to market its generic version of Novo Nordisk's Prandin® (repaglinide) drug product infringed Novo Nordisk's U.S. Patent No. 6,677,358. Novo Nordisk seeks an order from the Court which, among other things, directs the FDA not to approve the Company's ANDA any earlier than the claimed expiration date. The ANDA filed by the Company contains a Paragraph IV certification challenging the Novo Nordisk patent as well as a section viii statement with regard to the patent's method claim. The Company believes that this Novo Nordisk patent is invalid, unenforceable and/or will not be infringed by the Company's manufacture, use or sale of the product. The Company believes that it is the first to file an ANDA with a Paragraph IV certification for this drug product and it intends to defend this action vigorously to capitalize on the potential for obtaining 180 days exclusivity available for this product. The Company filed a supplemental answer and counterclaim challenging Novo Nordisk's recent Orange Book use code amendment by Novo Nordisk in reference to Prandin®. On September 25, 2009, the District Court entered an injunction requiring Novo Nordisk to correct its amended use code description for Prandin® on the ground that it does not accurately characterize the referenced method patent. Novo Nordisk then appealed that injunction. On October 14, 2009, the parties entered into a stipulation regarding the appeal. On October 27, 2009, the United States Court of Appeals for the Federal Circuit entered an Order staying the use code injunction during the appeal. Under the stipulation, if the Company were to prevail on the use code injunction appeal, Novo Nordisk would stipulate to non-infringement based on Caraco's proposed section viii split-certification. If Novo Nordisk prevails on the use code injunction appeal, the parties will proceed to trial on patent validity and unenforceability. On April 14, 2010, the Court of Appeals reversed the decision of the District Court. Subsequently, on May 14, 2010, the Company filed a petition for rehearing en banc the Federal Circuit. The trial regarding the validity and unenforceability of the patent began on June 1, 2010.

On September 22, 2004, Ortho-McNeil Pharmaceutical, Inc. ("Ortho-McNeil") filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Company's filing of an ANDA seeking approval to market its generic version of Ortho-McNeil's Ultracet® brand tramadol/acetaminophen drug product infringed Ortho-McNeil's patent, which expires on September 6, 2011. Ortho-McNeil sought an order from the district court which, among other things, directed the FDA not to approve the Company's ANDA any earlier than the claimed expiration date. The ANDA filed by the Company contains a Paragraph IV Certification challenging the Ortho-McNeil patent. The Company asserted that the Ortho-McNeil patent is invalid and/or will not be infringed by the Company's manufacture, use or sale of the product. Since filing this action, Ortho-McNeil authorized a generic manufacturer to provide a generic version of Ortho-McNeil's Ultracet® product while another manufacturer launched its approved generic at risk. On October 19, 2005, the Company's motion for summary judgment was granted. On December 19, 2005, the FDA approved the manufacture, use and sale of the Company's generic product. Ortho-McNeil filed an appeal of the finding of non-infringement by the district court with the United States Court of

Appeals for the Federal Circuit. On January 19, 2007, the United States Court of Appeals for the Federal Circuit affirmed the lower court's decision granting the Company's motion for summary judgment.

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Additionally, the United States Patent and Trademark Office approved Ortho-McNeil's request for a reissue patent. Although the district court had determined that the Company does not infringe Ortho-McNeil's original patent, on July 31, 2006, Ortho-McNeil filed a lawsuit against the Company in the United States District Court for the District of New Jersey, alleging that the Company's generic version of Ultracet® brand tramadol/acetaminophen drug product infringes its reissue patent. On September 26, 2006, the Company filed an answer denying, among other things, that its generic product infringes any valid claims of Ortho-McNeil's reissue patent. On December 10, 2007, the Company filed a motion for summary judgment that the asserted claims of the reissue patent were obvious and therefore invalid as a matter of law. This motion was granted by Judge Cavanaugh of the United States District for New Jersey on April 17, 2008. Final judgment has been granted. On August 25, 2008, Ortho-McNeil filed a notice of appeal with respect to that judgment with the United States Court of Appeals for the Federal Circuit. The appeal was fully briefed and was argued on July 7, 2009. On August 26, 2009, the Court of Appeals reversed a portion of the previously decided summary judgment. Although the Court did find that a portion of the patent was not valid, the Court remanded the litigation back to the lower court for further proceedings. Caraco subsequently filed a combined petition for a panel rehearing and a rehearing en banc. That combined petition was denied, and the case has been remanded back to the Court for further proceedings.

On May 5, 2009, Wyeth filed a complaint against the Company and Sun Pharma in the United States District Court for the Eastern District of Michigan. The complaint alleges that the package insert for Sun Pharma's product that is distributed by the Company and which is a generic version of Wyeth's Protonix® (pantoprazole) pharmaceutical product contains false and misleading statements regarding the active ingredient of that product in violation of federal and state laws. The complaint requests damages, injunctive relief and attorneys' fees and costs. The Company and Sun Pharma believe that they have not engaged in any improper conduct and intend to vigorously contest these allegations. On July 6, 2009, the Company and Sun Pharma filed a Motion to Dismiss the Complaint for Failure to State a Claim upon Which Relief May Be Granted. Plaintiff's brief in response to the Company's and Sun Pharma's Motion to Dismiss was filed on July 30, 2009. Caraco and Sun Pharma filed a reply memorandum of law in support of its Motion to Dismiss on August 13, 2009. On March 2, 2010, the Court dismissed Wyeth's complaint, but without prejudice. On March 31, 2010, Wyeth filed a Notice of Appeal with United States District Court for the Sixth Circuit.

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

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



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

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

On July 10, 2006, Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S (collectively, "Forest") filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Company's filing of an ANDA seeking approval to market its generic version of Forest's Lexapro® (escitalopram oxalate) drug product infringed Forest's Patent No. Re. 34,712 (the "'712 patent"). The ANDA contains Paragraph IV Certifications challenging the '712 patent, as well as two other Forest-owned patents, the 6,916,941 ("the '941 patent") and 7,420,069 ("the '069 patent"). Forest did not assert the '941 patent or '069 patent, so the Company brought declaratory judgment actions seeking a declaration that it did not infringe those patents. The Company vigorously litigated all three cases.

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

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

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2. Forest has reimbursed the Company for a portion of its attorney's fees related to this litigation, which has been recorded as a reduction to Research & Development\_Costs\_in Fiscal 2010.
3. Pursuant to the APA, the Company is taking over the commercialization and sale of several products from Forest's Inwood business and received compensation payment from Forest in connection with certain products that were not transferred through its Inwood business. Caraco has paid Forest an advance against royalties and will pay royalties on net sales of the products which have been taken over from Forest's Inwood business.

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

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

On September 29, 2009, Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc. ("Taro") filed suit against Caraco and Sun Pharma and certain of its affiliates in the United States District Court for the Southern District of New York. The complaint, as it pertains to Caraco, alleges misappropriation and misuse of trade secrets, unfair competition, and tortious interference with business relationships, fraud and unjust enrichment. The claims against Caraco arise out of Caraco's purported access to information from Taro as a part of the due diligence conducted for Sun Pharma's tender offer for Taro Pharmaceuticals Industries Ltd. On December 18, 2009, the Defendants filed a Motion to dismiss the complaint. That motion has been fully briefed by the parties and is pending before the Court.

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

The Company is also currently involved, and from time to time becomes involved, in certain other legal proceedings relating to the conduct of its business, including those pertaining to product liability, contract and employment claims. With respect to employee claims the Company is currently involved in three employment lawsuits, involving multiple plaintiffs. The Company carries employment practices liability insurance. Additionally, the Company does not believe these claims constitute material litigation matters. With respect to product liability claims, we are currently involved in a total of 10 cases, 9 of which involve products alleged to have been manufactured by the Company. The Company carries product liability insurance in an amount it believes is sufficient for its needs. The Company is also a defendant in one product liability case, where it is alleged that the Company distributed a product manufactured by another party. In that instance, the Company is contractually indemnified by the product manufacturer. While the outcome of any of such proceedings cannot be accurately predicted, the Company does not believe that the ultimate resolution of any of these existing proceedings will have a material adverse effect on the Company's financial condition or liquidity.

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Product Liability and Insurance

The Corporation currently maintains general and product liability insurance, with coverage limits of \$10 million per incident and in the aggregate. The Corporation's insurance policies provide coverage on a claim made basis and are subject to annual renewal. Such insurance may not be available in the future on acceptable terms or at all. There can be no assurance that the coverage limits of such policies will be adequate to cover the Corporation's liabilities, should they occur.

Product Development

The Corporation, during the year ended March 31, 2007, entered into three definitive agreements with different companies to develop four products. These agreements contain, for three products, both milestone payments to be paid in cash and profit sharing based upon future sales for a defined period, and for one product, only milestone payments in cash without any obligation to share profits in the future. During Fiscal 2008, the Corporation signed one definitive agreement for one additional product. This agreement contains both milestone payments to be paid in cash and profit sharing based upon future sales for a defined period. However, the Company terminated an agreement earlier entered into with one company for two of these products. During Fiscal 2009, the Company entered into one agreement for one additional product, and during Fiscal 2010, the Company entered into two more agreements relating to two additional products. Subsequent to end of Fiscal 2010, the Company has terminated another agreement relating to one product. This brings the total number of products being developed by unaffiliated third party developers to five. The events that would trigger these payments include signing the agreement, transfer of technology, passing the bio-equivalency study, filing the ANDA, approval of the ANDA, and commercial launch of the product. Approximately \$450,000, \$83,000 and \$200,000 in milestone payments were made in Fiscal 2010, Fiscal 2009 and Fiscal 2008, respectively. Collectively, as of March 31, 2010, future milestone payments, assuming all of the conditions are satisfied and not including profit-sharing which cannot be estimated, will amount to approximately \$900,000 spread over a period of more than three years.

During Fiscal 2010 the Corporation entered into an asset purchase agreement arising out of a settlement agreement with Forest. Pursuant to the Asset Purchase Agreement, the Company is taking over the commercialization and sale of several products from Forest's Inwood business and received compensation payment from Forest in connection with its Inwood business. Caraco has paid Forest an advance against royalties and will pay royalties on net sales of these products. The Company has started selling two products which were acquired as part of an asset purchase agreement

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## Regulatory Matters

On October 31, 2008, the Company received a warning letter from the Detroit District of the FDA for its manufacturing facility in Detroit, Michigan. In this letter, the Agency reiterated some of the concerns detailed in the previous Forms 483 issued as a result of previous inspections. The Company responded to the warning letter on November 24, 2008 for the deficiencies noted and provided its corrective actions. The Detroit District acknowledged the response on December 22, 2008. It noted that the Company's corrective actions would be evaluated during the FDA's next scheduled inspection of the Company's Detroit, Michigan facility. 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. Some of the observations were relative to the recent recalls and compliance, whereas others were focused on inventory controls. The FDA's inspection found unresolved violations of current Good Manufacturing Practice (cGMP) requirements as previously disclosed in our last SEC filing on Form 10-K filed June 15, 2009. On March 31, 2009, the Company recalled all tablets of Digoxin, USP, 0.125 mg, and Digoxin, USP, 0.25 mg, distributed prior to March 31, 2009 to the consumer level. As a precautionary measure, in April 2009, the Company initiated recalls of certain product lots manufactured in its Detroit, Michigan facility, primarily to the retail and wholesale levels. The total sales revenue, related to these recalls, the Company believes, is approximately \$4.2 million. These recalls were voluntarily initiated by the Company with the knowledge of the FDA. The recalls were made as a precautionary measure. The Company provided a written response to these observations on June 19, 2009. On June 25, 2009, U.S. Marshals, at the request of the FDA, seized drug products manufactured in the Company's Michigan facilities. The seizure also included ingredients held at these same facilities as well as work in process. Products distributed by Caraco that are manufactured outside of these facilities are not impacted. In its complaint relating to its seizure, the FDA stated, among other things, that the May 12, 2009 inspection and the Company's written response thereto revealed continuing significant cGMP violations. The FDA also stated that the drug products are adulterated in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and/or holding do not conform to and are not operated and administered in conformity with cGMP requirements. As a result of the FDA action, the Company has voluntarily ceased manufacturing operations and instituted an indefinite reduction in our workforce of approximately 430 employees in two phases. The Company has subsequently started recalling some of these employees in conjunction with its efforts to restart its manufacturing activities. This FDA action has resulted and will result in a material adverse effect on the Company's current and near term operations.

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

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Under terms of the Consent Decree, Caraco's cessation of manufacturing operations will continue until it receives written notification from independent experts and the FDA that it is in compliance with the Consent Decree and regulations and can resume operations. Caraco-owned products or licensed products distributed by Caraco that are manufactured outside of these facilities are not impacted, and distribution and marketing of these products continues. There is no assurance that the steps taken will be successful or result in resolution of the FDA complaint. The Company is also not able, at this time, to estimate the cost of these actions. We intend to continue to work with the FDA to resolve its concerns as effectively and expeditiously as possible.

The Company has not received FDA approvals for any of its ANDAs since the first quarter of Fiscal 2009. It is unlikely that it will receive any approvals for product out of its Michigan facilities until the FDA reviews its remediation response and makes a determination of the Company's status. The Company had submitted a remediation work plan, approved by its consultants, to the FDA in October 2009. Some additional details and clarifications to the work plan were submitted to the FDA in response to their letters, seeking such clarifications. The FDA after reviewing the responses informed the Company in its letter dated March 17, 2010, that it has approved the work plan. Remediation activities are ongoing with the full knowledge of the cGMP experts. In accordance with the Consent Decree, the Company has 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 January 29, 2010, we received a letter from the FDA, seeking clarification on certain points. We submitted our response to the letter on March 24, 2010. Subsequent to our response, the FDA sent us a letter asking for additional information on April 7, 2010, to which we have submitted our response on June 3, 2010.

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

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## 13. SEGMENT INFORMATION

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

Category	Year Ended March 31, 2010		Year Ended March 31, 2009		Year Ended March 31, 2008	
	Sales	Gross (Loss) Profit	Sales	Gross Profit	Sales	Gross Profit
Caraco-owned Products	\$22,315,139	\$(20,115,245)	\$111,754,209	\$48,132,508	\$125,251,055	\$61,342,641
Distributed Products	211,358,549	19,716,017	225,423,273	19,662,047	225,115,634	23,372,509
Total	\$233,673,688	\$(399,228)	\$337,177,482	\$67,794,555	\$350,366,689	\$84,715,150

The Corporation is primarily in the business of manufacturing, developing, selling and distributing various therapeutic classes of solid oral dosage of generic pharmaceuticals. There are no separate management teams or individuals assigned to a product or products or therapeutic classes of products, no separate allocation of funds or resources to distinct product or products or therapeutic classes or products, and the performance of any individual product or products or therapeutic classes of products is not separately assessed. The Corporation's revenues are solely based on the receipt of customers' orders.

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The Corporation's net sales, grouped by therapeutic categories, for the years ended March 31, 2010, March 31, 2009 and March 31, 2008 are as follows:

Therapeutic Category	Net Sales Year Ended March 31, 2010	Net Sales Year Ended March 31, 2009	Net Sales Year Ended March 31, 2008
Analgesic	\$ 1,130,084	\$ 1,623,448	\$ 3,778,055
Anorectic	299,116	1,757,126	266,230
Anti-allergic drug	264,609	2,076,743	2,194,004
Anti-anxiety / anti-depressant	1,782,480	17,536,769	20,980,411
Anti-biotic	-	424,934	417,941
Anti-convulsant	30,317,689	43,013,058	73,850,445
Anti-diabetic	13,822,365	20,162,183	23,394,110
Antidote	5,995,947	11,874,949	2,538,897
Antihistamine	203,947	10,978	-
Anti-hyperlipidemic	277,111	-	-
Anti-hypertensive, beta blocker, calcium channel blocker, cardiac drug	13,360,641	36,269,099	33,181,097
Anti-neoplastic	9,289,177	-	-
Anti-psychotic	1,231,197	7,465,343	5,936,243
Anti-thyroid agent	366,783	735,277	1,568
Anti-tussive / opiod	648,099	89,451	-
Bisphosphonate derivative	1,771,187	148,843	-
Bronchodilator	1,211,292	-	-
Cholinergic	226,068	-	-
Gastrointestinal agent, emesis, receptor antagonist anti-emetic	130,139,355	150,052,832	134,830,934
Migraine relief	1,421,624	-	-
Musculo-skeletal	93,425	803,505	132,687
Narcotic analgesic	2,115,354	156,586	165,860
Neuromuscular blocking agent	5,771,192	-	-
Nonsteroidal anti-androgen	130,110	-	-
Nonsteroidal anti-inflammatory agent	1,265,170	4,437,108	3,154,862
Oncology adjunct	3,172,388	4,495,126	1,182,188
Opiate agonist/analgesic	2,085,418	28,652,439	38,567,526
Ophthalmic-nonsteroidal anti-inflammatory	28,169	-	-
Parkinson's disease	4,396,932	1,110,877	4,227
Platelet aggregation inhibitor	35,617	164,011	211,345
Prevents angina	270,032	-	-
Sedatives & hypnotics	164,407	883,799	1,642,383
Skeletal muscle relaxant	386,703	3,232,998	3,935,676
<b>Net Sales</b>	<b>\$ 233,673,688</b>	<b>\$ 337,177,482</b>	<b>\$ 350,366,689</b>

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EXHIBIT INDEX

2.01*	Asset Purchase Agreement by and between Caraco and Forest Laboratories, Ltd. dated July 10, 2009, and as amended on September 8, 2009, September 11, 2009 and September 22, 2009 (1)
3.01	Registrant's Articles of Incorporation as of October 26, 2009 (1)
3.02	Registrant's Bylaws as of October 26, 2009 (1)
3.03	Certificate of Determination of Rights, Privileges and Preferences Series B Preferred Stock (2)
10.01	Employment Agreement, dated October 22, 1993, of Robert Kurkiewicz (3)
10.02	Stock Purchase Agreement by and between Caraco and Sun Pharmaceutical Industries Limited dated as of April 23, 1997 (4)
10.03	Products Agreement by and between Caraco and Sun Pharmaceutical Industries Limited dated as of April 23, 1997 (4)
10.04	Registration Rights Agreement dated as April 1997 (4)
10.05	Amendment to Employment Agreement of Robert Kurkiewicz dated as of April 1, 1997 (5)
10.06	1999 Equity Participation Plan (6)
10.07	Renewal to Employment Agreement of Robert Kurkiewicz dated as of January 1, 1999 (7)
10.08	Third Amendment to Employment Agreement of Robert Kurkiewicz dated August 30, 2002 (7)
10.09	Agreement between Caraco and Sun Pharma Global, Inc. dated November 21, 2002 (2)
10.10	Sales contract with government vendor (2)
10.11	Employment Agreement of Mr. Singh (8)
10.12	Employment Agreement of Mr. Doshi (1)
10.13	Credit Agreement with JPMorgan Chase Bank, N.A. (9)
10.14	Marketing Agreement between Caraco and Sun Pharmaceutical Industries Limited (10)
10.15	Distribution and Sale Agreement between Caraco and Sun Pharmaceutical Industries Limited (11)

- 10.16 Summary of Oral Agreements between Caraco and Sun Pharmaceutical Industries Limited with respect to certain raw materials and formulations and the acquisition of machinery and equipment (12)
- 10.17 2008 Equity Participation Plan (13)
- 10.18 Loan Agreement with RBS Citizens N.A. (14)
- 10.19\* Settlement Agreement by and between Forest Laboratories, Inc., H. Lundbeck A/S, Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries Ltd., dated July 10, 2009 (1)
- 10.20 Separation Agreement and Release of All Claims between Daniel Movens and Caraco Pharmaceutical Laboratories, Ltd., dated July 28, 2009 (1)

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10.21	Employment Agreement of Jitendra N. Doshi, dated July 28, 2009 (1)
10.22	Technology Transfer Agreement with Alkaloida Chemical Company ZRT dated July 10, 2009 (1)
10.23	Indemnification Agreement with F. Folsom Bell dated September 14, 2009 (1)
10.24	Form of Grant of Independent Director Stock Option (1)
10.25	Form of Grant of Employee Stock Option (1)
10.26	First Amendment to Loan Agreement with RBS Citizens, N.A. dated as of August 11, 2009 (1)
10.27	Second Amendment to Loan Agreement with RBS Citizens, N.A. dated as of October 9, 2009 (1)
10.28	First Amendment to Agreement between Caraco and Sun Pharmaceutical Industries limited dated January 15, 2010 (15)
10.29	Certificate of Suspension of Loan Covenants between Caraco and RBS Citizens, N.A. (d/b/a Charter One) dated February 26, 2010 (16)
<u>21</u>	Subsidiaries of the Registrant (+)
<u>23.01</u>	Consent of Independent Registered Public Accounting Firm (+)
24.1	Power of Attorney (included on signature page) (+)
<u>31.1</u>	Certificate of Chief Executive Officer (+)
<u>31.2</u>	Certificate of Chief Financial Officer (+)
<u>32.1</u>	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (+)

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\* Confidential treatment was granted for portions of this exhibit

+ Filed herewith

- (1) Incorporated by reference from Exhibits to Registrant's Form 10-Q filed on November 9, 2009
- (2) Incorporated by reference from Exhibits to Registrant's Form 10-KSB filed on March 31, 2003
- (3) Incorporated by reference from Exhibits to Registrant's Registration Statement on Form SB-2, as amended, filed on November 5, 1993 as Commission File No. 33-71398C

- (4) Incorporated by reference from Exhibits to Registrant's Form 10-QSB filed on November 14, 1997
- (5) Incorporated by reference from Exhibits to Registrant's Form 10-KSB filed on March 31, 1998
- (6) Incorporated by reference from Appendix A to Registrant's Proxy Statement dated April 28, 1999
- (7) Incorporated by reference from Exhibits to Pre-Effective Amendment No. 1 to Form SB-2 filed on September 4, 2002 as Commission File No. 333-91968
- (8) Incorporated by reference from Exhibit to Registrant's Form 10-K filed on March 15, 2005
- (9) Incorporated by reference from Exhibits to Registrant's Form 10-Q filed on January 26, 2006
- (10) Incorporated by reference from Exhibits to Registrant's Form 8-K/A filed on November 5, 2007
- (11) Incorporated by reference from Exhibits to Registrant's Form 8-K filed on or about January 31, 2008
- (12) Incorporated by reference from Exhibits to Registrant's Form 10-K filed on June 10, 2008
- (13) Incorporated by reference from Exhibits to Registrant's Proxy Statement filed on July 29, 2008
- (14) Incorporated by reference from Exhibits to Registrant's Form 10-K filed on June 15, 2009
- (15) Incorporated by reference from Exhibits to Registrant's Form 8-K filed on January 21, 2010
- (16) Incorporated by reference from Exhibits to Registrant's Form 8-K filed on March 4, 2010