

CARACO PHARMACEUTICAL LABORATORIES LTD  
Form 10-K  
June 15, 2009

---

---

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

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, 2009

Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
**Commission File No. 001-31773**

**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)

**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
--	---

Common Stock, No Par Value	NYSE Amex
----------------------------	-----------

**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

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, 2008, the last day of the Registrant's most recently completed second quarter, as reported on the NYSE Amex Stock Exchange, was \$115,254,643.

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 10, 2009, there were 37,458,194 shares of common stock outstanding.

**Documents Incorporated By Reference:**

Portions of the Proxy Statement for the 2009 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.  
FORM 10-K**

**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, manufacturing, marketing and distributing generic and private-label pharmaceuticals to the nation’s largest wholesalers, distributors, warehousing and non-warehousing chain drugstores and managed care providers, throughout the U.S. 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.

On January 27, 2005, the Board of Directors of the Company resolved to change the Company’s fiscal year end from December 31 to March 31 commencing in 2005. This change was made in order to make the Company’s fiscal year conform to the March 31 fiscal year of its parent company, Sun Pharmaceutical Industries Limited (“Sun Pharma”). This Form 10-K covers the audited fiscal year, April 1, 2008 to March 31, 2009 (“Fiscal 2009”), and comparative information for the audited fiscal year, April 1, 2007 to March 31, 2008 (“Fiscal 2008”), and for the audited fiscal year, April 1, 2006 to March 31, 2007 (“Fiscal 2007”). Additional information is provided with respect to the audited fiscal year, April 1 2005 to March 31, 2006 and the transition period (January 1, 2005 through March 31, 2005), which is audited (the “Transition Period”) and the calendar year ended December 31, 2004. (See Item 6 below).

## 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 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 74% 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 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 continues to hold a \$10 million line of credit with JP Morgan Chase Bank, N.A. We believe our cash flow from operations provides the working capital necessary to effectively manage the Company.

## Current Status

During Fiscal 2009 we recorded net sales of \$337.2 million compared to \$350.4 million during Fiscal 2008. We incurred \$22.5 million in R&D expense during Fiscal 2009 as compared to \$29.7 million during Fiscal 2008. There were no non-cash R&D expenses incurred during Fiscal 2009, as compared to \$11.3 million during Fiscal 2008. We generated cash from operations of \$18.7 million during Fiscal 2009, as compared to \$27.8 million during Fiscal 2008. We earned a net pre-tax income of \$29.5 million and \$42.4 million during the relevant periods. During Fiscal 2009 and Fiscal 2008, we provided net income tax provisions of \$8.9 million and \$7.0 million, respectively. We earned net income of \$20.5 million and \$35.4 million for Fiscal 2009 and Fiscal 2008, respectively. The reduction in net pre-tax income from last year was primarily due to lower gross profits resulting from price erosion of the products sold, the weight of distributed products sold versus manufactured product sales and the provision for losses expected from product recalls. These recalls were initiated towards the end of Fiscal 2009 and the beginning of Fiscal 2010. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – FDA Compliance" below. At March 31, 2009, our inventory decreased to \$79.5 million from \$298.7 million at March 31, 2008. Inventory as of March 31, 2008 was higher to support our increased sales levels of then newly launched distributed products which we distribute on behalf of Sun Pharma (including the Paragraph IV products launched in the fourth quarter of Fiscal 2008). At March 31, 2009, we had stockholders' equity of \$163.8 million, as compared to stockholders' equity of \$142.8 million at March 31, 2008. 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."

During Fiscal 2009, we received FDA approval for eight ANDAs relating to three products. We filed 10 ANDAs relating to nine products with the FDA during Fiscal 2009. This brings our total number of ANDAs pending approval by the FDA to 29 (including four tentative approvals) relating to 25 products as of March 31, 2009. During Fiscal 2009 and subsequent thereto, the FDA inspected our 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 63 prescription products in 144 strengths delivered in various package sizes.

We have submitted 71 ANDAs to the FDA for approval as of March 31, 2009, including 10 filed during Fiscal 2009, which includes three products with multiple ANDAs. Of these 71 ANDAs filed, the FDA has approved 42 through March 31, 2009. Accordingly, we have 29 pending ANDAs (including four tentative approvals) relating to 25 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. 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 has 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 have 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 27 active pharmaceutical ingredients from Sun Pharma and 63 active pharmaceutical ingredients from other third parties. Caraco currently purchases three 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 may also provide manufacturing services on certain of our products when it is cost beneficial and will assist the Company in minimizing any capacity constraints at its manufacturing facilities. During Fiscal 2009, Fiscal 2008 and Fiscal 2007, we purchased approximately \$8.4 million, \$498.5 million and \$38.8 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. We acquired \$46 thousand worth of machinery and equipment during Fiscal 2009 from Sun Pharma and its affiliates as compared to \$0.3 million and \$0.8 million, respectively, during Fiscal 2008 and Fiscal 2007. Such machinery and equipment was sold to us at Sun Pharma’s cost. 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 2009 we have incurred \$0.3 million 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 is currently being marketed.

During Fiscal 2007, the Company entered into a three-year marketing agreement with Sun Pharma, which was reviewed and approved by the Board’s Independent Committee. Under the agreement, the Company purchases selected product formulations offered by Sun Pharma and markets and distributes the same as part of our 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 Company 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 product formulations which have been filed under Paragraph IV certification process with the FDA by Sun Pharma and offered for distribution. Paragraph IV certified ("Para IV") products may face litigation challenges with respect to claims of patent infringement. Under the agreement the Company shares in the sales opportunity and shares the litigation risk. The Company is indemnified by Sun Pharma of any risk beyond the percentage agreed to as its profit percentage thereby limiting the Company's exposure. Sun Pharma is not obligated to offer Caraco products under this agreement, however, Caraco has the exclusive right to market in the U.S., its territories and possessions, including Puerto Rico, any products offered by Sun Pharma and accepted by Caraco. The license granted with respect to a product terminates upon the end of 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 purchases selected Para IV products offered by Sun Pharma, and markets and distributes the same as part of our current product offerings in the U.S., its territories and possessions, including Puerto Rico, and currently receives a fixed margin of 8%, or such other percentages as shall be mutually agreed upon from time to time. Under the agreement, Sun Pharma and Caraco mutually indemnify each other, capped by the fixed margin percentage, with respect to damages from infringement.

Net sales from products selected under these agreements were \$225.4 million during Fiscal 2009, \$225.1 million during Fiscal 2008 and \$4.6 during Fiscal 2007.

During the fiscal years ended March 31, 2009 and March 31, 2008, Sun Global converted 4,896,000 shares and 4,352,000 shares of Series B Preferred Stock into 4,896,000 shares and 4,352,000 shares of Common Stock, respectively. As of March 31, 2009, Sun Pharma's current beneficial ownership is 74%, (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.

## **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 and reputation.

Generally, Caraco competes effectively with respect to each of these factors; however recent recalls 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**

The Company faced significant challenges in Fiscal 2009 relative to our production and compliance. This was

compounded by significant erosion on blockbuster products launched in Fiscal 2008 as previously disclosed. Our organization continues to be strengthened in all areas to meet the demands of a competitive U.S. generic pharmaceutical market, while providing additional support for our future growth, continual improvement of compliance and reducing costs where possible.

As is typical in the US retail sector, many of our customers are serviced through their designated wholesalers. For Fiscal 2009, the Company's three largest customers, Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health, accounted for approximately 9%, 16% and 20%, 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. This includes sales to the Veterans Administration, an agency of the United States Government. Our contracts with the Veterans Administration have expired, and due to the Company's recent product recalls and status with the FDA, the Veterans Administration has not renewed the contracts. 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. During Fiscal 2008 and Fiscal 2007, shipments to Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health, accounted for approximately 8%, 28% and 21%, respectively and 11%, 30% and 17%, respectively, of the Company's total net sales. Balances due from these customers represented approximately 47% and 66% of gross accounts receivable as at March 31, 2009 and 2008, respectively. No other single customer accounted for more than 10% of net sales for Fiscal 2009, Fiscal 2008 or Fiscal 2007.

### 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 2009, Fiscal 2008 and Fiscal 2007 as set forth below:

Fiscal 2009	\$22.5 million
Fiscal 2008	\$29.7 million
Fiscal 2007	\$22.4 million

The non-cash R&D Expense for Fiscal 2009, Fiscal 2008 and Fiscal 2007 are set forth below:

Fiscal 2009	\$ —
Fiscal 2008	\$11.3 million
Fiscal 2007	\$11.8 million

The non-cash technology transfer charges in Fiscal 2008 and Fiscal 2007 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 the submission of the ANDA to the FDA was approximately thirty days after the receipt of notice that the proposed drug product formula passes its bio-equivalency study and accelerated stability studies. An ANDA contains data related to a generic drug product which is submitted to the FDA for review and approval. The FDA must first determine the completeness of the filing and may deny the filing if it is incomplete. There are various reviews that are completed, including bio-equivalency, chemistry, manufacturing, and labeling. The bio-equivalency of a generic drug product is established by measuring the rate and level of active ingredient(s) in the bloodstream of healthy human subjects over a period of time. These pharmacokinetic parameters and results are compared with the innovator's drug product. The bio-equivalency results of the proposed generic drug product must meet pharmacokinetic standards set forth by the FDA. Accordingly, the generic version of a drug product must generally deliver the same amount of active ingredients into the bloodstream within the same timeframe as that of the innovator drug product. Following an indication that the generic drug product has passed its bio-equivalency study, the generic drug product will undergo reviews for chemistry, manufacturing and labeling. In each case, the FDA has an opportunity to raise questions or comments, or issue a deficiency letter. In the event that one or more deficiency letters are issued by the FDA, the submission of the ANDA may be halted or delayed as necessary to accommodate the correction of any such deficiencies and the completion of any additional reviews required. Minor deficiencies traditionally could delay the approval anywhere from 10 days to 90 days or more. Major deficiencies could stop the evaluation process. A restart of the FDA review process after a major deficiency could take up to as many as 180 days or more. Generally, any deficiencies we have experienced have been minor though at times approvals have faced considerable delays. Based on these delays, the economic benefit may not be realized at its highest potential as the delay could cause our approval to be behind our competition's approval of the same generic product.

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

In addition, we have reported the technology transfers as research and development expenses pursuant to FASB 2, "Accounting for Research and Development Costs." 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 current good manufacturing practices ("cGMP") regulations as well as provide substantial evidence of safety and efficacy of the drug product. Compliance with cGMPs 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, 2009.
- 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.

As previously disclosed, we currently manufacture several products that are regulated as Drug Efficacy Studies Implementation, or DESI products. These products do not require the submission of an ANDA or an NDA to the FDA. These products are, however, subject to cGMP compliance. Also, while products within this DESI classification require no prior approval from the FDA before marketing, they must comply with applicable FDA monographs, which specify, among other things, required ingredients, dosage levels, label contents and permitted uses. These monographs may be changed from time to time, in which case we might be required to change the formulation, packaging or labeling of any affected product. Changes to monographs normally have a delayed effective date, so while we may have to incur costs to comply with any such changes, disruption of distribution is not likely (but there is the possibility it can occur).

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 New Drug Application ("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." All 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.

#### **Line of Credit**

During the third quarter of Fiscal 2009, the Company renewed its one-year, \$10 million Credit Agreement with JP Morgan Chase Bank, N.A., which will expire on November 30, 2009. Under the Credit Agreement, the lender may make loans and issue letters of credit to the Company for working capital needs and general corporate purposes. Letters of credit, if issued, expire one year from their date of issuance, but no later than November 30, 2009. Borrowings are secured by the Company's receivables and inventory. Interest is payable based on a LIBOR Rate or an alternate base rate (determined by reference to the prime rate or the federal funds effective rate), as selected by the Company. The rate of interest is LIBOR plus 75 basis points, or the bank's prime rate minus 100 basis points (provided the prime rate is not less than the prevailing one month LIBOR Rate plus 250 basis points). The effective rates were 1.25% and 2.25%, respectively, at March 31, 2009. The Credit Agreement requires that certain financial covenants be met on a quarterly basis. The Company is in compliance with these financial covenants at March 31, 2009. There were no borrowings under this Credit Agreement at March 31, 2009.

#### **Term Loan**

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, MI. 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, 2009 was 2.01%. The principal loan payments and accrued interest are payable on a quarterly basis beginning July, 2009. The principal is to be repaid in equal quarterly installments of \$900,000 for ten quarters through October 2011, and thereafter, if not renewed, the remaining balance of \$9 million is due in January, 2012. The Company expects that the term loan will be renewed, and the loan amortization is expected to occur over 20 equal quarterly installments of \$900,000 each.

As required pursuant to the terms of the Loan Agreement, the Company has entered into an Interest Rate Swap Agreement with Charter One Bank to hedge the interest rate applicable on the loan. The notional amount for the swap is \$18 million which will amortize down as principal payments are made on the related debt. The annualized fixed rate of interest as it applies to this agreement is 2.41%. Thus as of March 31, 2009 the effective rate of interest to the Company for the term loan was 2.91% (2.41% swap rate plus applicable margin of 50 basis points). The fair value of the Swap Agreement at March 31, 2009 was not material.

#### **Employees**

We had a total of 667 and 662 full-time equivalent and contract employees at March 31, 2009 and 2008, 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."

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. The timing and cost of obtaining FDA approvals 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 by 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.

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**

**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, 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.

**We were issued a Warning Letter on October 31, 2008 from the FDA and are subject to follow-up cGMP inspections; the outcome of which may have a significant impact on our business, in particular new products awaiting approval from the FDA could be delayed or manufacturing product sales could be negatively impacted.**

We are 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 approval of new products.

**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 on 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 establish reserves we believe to be adequate that are based on our historical experience, actual chargebacks received, current chargeback rates and on hand inventory remaining at our wholesale customers, for the potential impact that these policies may have, 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.

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

The manufacture, use and sale of new products that are the subject of conflicting patent rights have been 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. 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. Although we carry 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. We market product formulations on behalf of Sun Pharma which have been filed under the Para IV certification process with the FDA. Para 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.



**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 Drug Enforcement Administration ("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 or the customer is acquired by a non-customer, 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, 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, these recalls have not been significant and have not had a 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 Condition and Results of Operations – FDA Compliance” with respect to disclosure of certain product recalls.

**An unaffiliated third party may make a claim for royalties which could have a material adverse effect on our results of operations.**

In 1993, we entered into a products agreement with an unaffiliated generic drug company (the “Non-Affiliate”). Under the agreement, two products were to be delivered to us in exchange for royalties and options. Pursuant to the agreement, we received a formulation for one product (the “Product”) from the Non-Affiliate. However, we have determined that the formula provided to us by the Non-Affiliate with respect to the Product is different than the formula submitted and approved by the FDA and marketed by us. Accordingly, since April 2003, we have discontinued the accrual of royalties. The Product has been one of our top selling products. There is no assurance that the Non-Affiliate will not challenge our determination and make a claim that those royalties and/or options are owed. If successful, such a claim could have a material adverse effect on our results of operations.

**We manufacture our product line predominately from one FDA approved facility. There is a possibility that our production could be negatively impacted by a business disruption or closure of this facility.**

Although we have access to other facilities and have certain products that are manufactured at those facilities or in the process of filing these facilities as an alternate site, we primarily produce our products at our facility in Detroit, Michigan. We carry a limited amount of finished goods on hand and much of our inventory is either work in progress or is in bulk amounts. Should we experience an act of God that closes our facility, or production is stopped or a power outage continues for an inordinate period of time, it would impair our ability to produce and ship products to the market on a timely basis, 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.

**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 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.

During Fiscal 2008, the Company commenced construction on the expansion of its primary facility located in Detroit, Michigan. The expansion occurred on the acreage the Company acquired for \$0.3 million directly adjacent to its existing manufacturing facility. The expansion was completed during the fourth quarter of Fiscal 2009 and added approximately 140,000 square feet to our manufacturing facility. The expanded facility encompasses additional space required for manufacturing, quality control laboratories, raw material storage and administrative offices. It will also introduce additional automated equipment and process flow efficiencies in order to reduce long term costs associated with our production, while maintaining quality. The Detroit facility and the equipment therein are subject to a mortgage in connection with the \$18 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 feet. 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.

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 has not renewed 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 \$26.9 million during Fiscal 2009 as compared to \$5.1 million during Fiscal 2008 and \$6.0 million during Fiscal 2007 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 New Drug Applications (“NDAs”) and trademarks. These assets are recorded as intangible assets in the Company’s balance sheet at March 31, 2009. 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.

### **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 September 29, 2006, Schering Corporation (“Schering”) filed a complaint in the United States District Court for the District of New Jersey (“the New Jersey action”). A nearly identical complaint was filed on October 5, 2006, in the Eastern District of Michigan (“the Michigan action”). Both complaints allege, inter alia, that Sun Pharmaceutical Industries Ltd’s (“Sun”) filing of an ANDA seeking approval to market its generic version of Schering’s Clarinex® (desloratadine) drug product infringed Schering’s U.S. Patent No. 6,100,274 (“the ‘274 patent”), which expires July 7, 2019. Schering further alleges that the Company either directly infringed the ‘274 patent by aiding in the filing of Sun’s ANDA, or will induce others to infringe by marketing and/or selling Sun’s generic version of Clarinex® upon receiving FDA approval. Schering’s complaint seeks an order from the Court which, among other things, directs the FDA not to approve Sun’s ANDA any earlier than the claimed expiration date. On August 17, 2007, the New Jersey action was consolidated with other patent infringement cases filed by Schering against other ANDA filers for Schering’s Clarinex® drug product, while the Michigan action was stayed pending the outcome of the New Jersey action. The ANDA filed by Sun contains a Paragraph IV certification challenging the ‘274 patent. Sun believes that the ‘274 patent is invalid, unenforceable and/or will not be infringed by Sun’s or the Company’s manufacture, use or sale of the product. Sun further believes it is one of several first generics to file a Paragraph IV certification for this drug product. Sun and the Company reached an agreement with Schering dismissing this litigation without prejudice.

Schering filed an additional complaint in the District of New Jersey on November 14, 2008 alleging that Sun’s filing of an ANDA seeking approval to market its generic version of Schering’s Clarinex® drug product infringed Schering’s U.S. Patent No. 7,405,223 (“the ‘223 patent”), which issued on July 29, 2008 and expires January 7, 2020 (with pediatric exclusivity). Schering further alleges that the Company either directly infringed the ‘223 patent by aiding in the filing of Sun’s ANDA, or will induce others to infringe by marketing and/or selling Sun’s generic version of Clarinex® upon receiving FDA approval. Schering’s complaint seeks an order from the Court which, among other things, directs the FDA not to approve Sun’s ANDA any earlier than the claimed expiration date. On December 12, 2008 the ‘223 action was consolidated with another patent infringement case brought by Schering against Orgenus Pharma Inc. and Orchid Chemicals & Pharmaceuticals, Ltd. Sun believes that the ‘223 patent is invalid, unenforceable and/or will not be infringed by Sun’s or the Company’s manufacture, use or sale of the product.

On January 15, 2009, the Company, Sun, and Schering reached a settlement agreement as to all pending actions involving the ‘274 and ‘223 patents. The District of New Jersey subsequently entered orders dismissing Schering’s claims against Sun and the Company with respect to the ‘274 patent on February 13, 2009 and with respect to the ‘223 patent on March 16, 2009. The settlement agreement and proposed license agreement have been submitted to the United States Federal Trade Commission (“FTC”) and Department of Justice (“DOJ”) pursuant to Section 1112(a) of the Medicare Prescription Drug, Improvement, and Modernization Act.

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 viii statement with regard to the patent’s method claim. The Company believes that this Novo Nordisk patent is invalid and/or will not be infringed by the Company’s manufacture, use or sale of the product. The Company believes that it is the first to file an ANDA with a Paragraph IV certification for this drug product and it intends to defend this action vigorously to capitalize on the potential for obtaining 180 days exclusivity available for this product. The Company has filed motions for summary judgment of patent invalidity and non-infringement, both of which are pending. Caraco has also sought leave to supplement its answer and counterclaims to challenge a recent Orange Book use code amendment by Novo Nordisk in reference to Prandin®. Trial is scheduled for September 21, 2009.

As previously disclosed, on July 10, 2006, Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S (collectively, “Forest”) filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Company’s filing of an ANDA seeking approval to market its generic version of Forest’s Lexapro® (escitalopram oxalate) drug product infringed Forest’s Patent No. Re. 34,712, which is set to expire on September 13, 2011 based on a patent term extension (extended to March 14, 2012 based upon a six month pediatric exclusivity). Forest 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 Paragraph IV Certifications challenging Forest’s Patent Nos. Re. 34,712 (“the ‘712 patent”), as well as two other patents, the 6,916,941 (“the ‘941 patent”) and 7,420,069 (“the ‘069 patent”). The Company believes that it does not infringe any valid claims of the ‘712, ‘941 and ‘069 patents by the Company’s manufacture, use or sale of the product. Forest’s suit alleges only that Caraco infringes the ‘712 patent, which the Company intends to vigorously defend. Sun Pharmaceutical Industries Limited, the parent corporation of Caraco, is also a party to the case. Trial in the case, which was originally scheduled for April 2009, was adjourned through at least June 16, 2009. A new trial date has not been set.

Forest did not assert the ‘941 patent or ‘069 patent against Caraco. On February 20, 2007, Caraco brought a declaratory judgment action in the Eastern District of Michigan court against Forest seeking a declaration that its generic version of Lexapro® will not infringe the ‘941 patent. On April 13, 2007, Forest granted Caraco a covenant not to sue on the ‘941 patent, and the court, in May 2007, dismissed the case for lack of a controversy. Caraco filed a notice of appeal of that dismissal on June 8, 2007 before the U.S. Court of Appeals for the Federal Circuit. On April 1, 2008, the Federal Circuit granted Caraco’s appeal, holding that an actual case or controversy did exist and that Caraco should be allowed to maintain its declaratory judgment action regarding the ‘941 patent. Forest’s request for a rehearing of Caraco’s appeal *en banc* was denied. Forest filed a petition for a writ of certiorari to challenge this decision with the Supreme Court, which was also denied. On January 26, 2009, Caraco brought a similar declaratory judgment action in the Eastern District of Michigan court against Forest seeking a declaration that its generic version of Lexapro® will not infringe the ‘069 patent, a related patent newly obtained by Forest in September of 2008. The ‘941 and ‘069 cases are currently in discovery; both are expected to go to trial in late 2009.

As previously disclosed, on September 22, 2004, Ortho-McNeil Pharmaceutical, Inc. (“Ortho-McNeil”) filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Company’s filing of an ANDA seeking approval to market its generic version of Ortho-McNeil’s Ultracet® brand tramadol/acetaminophen drug product infringed Ortho-McNeil’s patent, which expires on September 6, 2011. Ortho-McNeil sought an order from the district court which, among other things, directed the FDA not to approve the Company’s ANDA any earlier than the claimed expiration date. The ANDA filed by the Company contains a Paragraph IV Certification challenging the Ortho-McNeil patent. The Company asserted that the Ortho-McNeil patent is invalid and/or will not be infringed by the Company’s manufacture, use or sale of the product. Since filing this action, Ortho-McNeil authorized a generic manufacturer to provide a generic version of Ortho-McNeil’s Ultracet® product while another manufacturer launched its approved generic at risk. On October 19, 2005, the Company’s motion for summary judgment was granted. On December 19, 2005, the FDA approved the manufacture, use and sale of the Company’s generic product. Ortho-McNeil filed an appeal of the finding of noninfringement by the district court with the United States Court of Appeals for the Federal Circuit. On January 19, 2007, the United States Court of Appeals for the Federal Circuit affirmed the lower court’s decision granting the Company’s motion for summary judgment.

Additionally, the United States Patent and Trademark Office approved Ortho-McNeil's request for a reissue patent. Although the district court had determined that the Company does not infringe Ortho-McNeil's original patent, on July 31, 2006, Ortho-McNeil filed a lawsuit against the Company in the United States District Court for the District of New Jersey, alleging that the Company's generic version of Ultracet® brand tramadol/acetaminophen drug product infringes its reissue patent. On September 26, 2006, the Company filed an answer denying, among other things, that its generic product infringes any valid claims of Ortho-McNeil's reissue patent. On December 10, 2007, the Company filed a motion for summary judgment that the asserted claims of the reissue patent were obvious and therefore invalid as a matter of law. This motion was granted by Judge Cavanaugh of the District of New Jersey on April 17, 2008. Final judgment has been granted. On August 25, 2008, Ortho-McNeil filed a notice of appeal with respect to that judgment with the United States Court of Appeals for the Federal Circuit. The appeal has been fully briefed and is scheduled for oral argument on July 7, 2009.

On February 24, 2009, MedImmune LLC filed a complaint against the Company and Sun in the United States District Court for the District of Maryland. The complaint alleges that Caraco has willfully infringed U.S. Patent Nos. 5,424,471 and 5,591,731 by offering to sell or selling a generic version of the drug Ethyol® in the United States. The complaint seeks trebled damages. The Company denies infringement and contends that the patents in suit are invalid and unenforceable. The Complaint is related to *MedImmune Oncology, Inc. v. Sun Pharmaceuticals Industries Ltd.*, 1:04-cv-02612-MJG, which is pending in the District of Maryland and involves the same patents. A trial in the related action is scheduled to begin September 30, 2009.

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 attorney's 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.

The Company is also involved in certain other legal proceedings from time to time incidental to normal business activities. While the outcome of any such proceedings cannot be accurately predicted, the Company does not believe the ultimate resolution of any existing matters would have a material adverse effect on its financial position or results of operations.

#### **Item 4. Submission of Matters to a Vote of Security Holders.**

We did not submit any matters to a vote of security holders in the fourth quarter of Fiscal 2009 through the solicitation of proxies or otherwise.

## **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 2009, Fiscal 2008 and Fiscal 2007, the high and low sales prices for each of the applicable quarters.

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

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

<b>Fiscal 2007</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 13.10	\$ 9.00
Second Quarter	\$ 11.99	\$ 8.15
Third Quarter	\$ 14.00	\$ 9.98
Fourth Quarter	\$ 14.99	\$ 10.50

As of June 10, 2009 there were 80 registered holders of our common stock.

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

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 and during Fiscal 2007, we issued to Sun Global 1,632,000 preferred shares in exchange for the transfer of three 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, 2009 and 2008 and summary statements of operations data for the years ended March 31, 2009, 2008 and 2007, 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, 2007, 2006 and 2005 and the summary of the statements of operations for the year ended March 31, 2006, the Transition period ended March 31, 2005 and year ended December 31, 2004 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	2009	Year ended March 31,			2006	Transition Period Ended March 31,	Year ended December 31,
		2008	2007	2005		2004	
Net sales	\$ 337,177	\$ 350,367	\$ 117,027	\$ 82,789	\$	17,337	\$ 60,340
Cost of goods sold	269,382	265,652	59,243	41,873		7,879	24,441
Gross profit	67,795	84,715	57,784	40,916		9,457	35,899
Selling, general and administrative expenses	16,418	14,322	9,880	8,183		1,879	5,277
Research and development costs – affiliate – (non cash)	—	11,321	11,761	35,055		10,200	24,397
Research and development costs – other	22,528	18,366	10,591	8,437		1,720	6,053
Operating income / (loss)	28,849	40,706	25,552	(10,759)		(4,342)	172
Other income / (expense), net	603	1,688	1,306	336		20	(371)
Income (loss) before income taxes	29,452	42,394	26,858	(10,423)		(4,322)	(199)
Income taxes	8,915	7,006	—	—		—	—
Net income / (loss)	20,537	35,388	26,858	(10,423)		(4,322)	(199)
Net income / (loss) per share							
Basic	0.60	1.19	1.02	(0.39)		(0.16)	(0.01)
Diluted	0.51	0.96	0.72	(0.39)		(0.16)	(0.01)
Weighted Average Shares Outstanding:							
Basic	34,227	29,657	26,447	26,392		26,348	24,734
Diluted	40,576	39,914	37,255	26,392		26,348	24,734

**Financial Data** (continued)

(In thousands)

Balance Sheet Data	As of March 31,				
	2009	2008	2007	2006	2005

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-K

Current assets	\$ 169,864	\$ 500,022	\$ 95,439	\$ 62,282	\$ 32,938
Property, plant and equipment, net	44,823	21,267	19,030	14,960	12,897
Intangible assets	1,383	—	—	—	—
Deferred income taxes	20,418	16,986	—	—	—
Total assets	236,488	538,275	114,469	77,242	45,835
Current liabilities	57,365	395,495	19,276	20,864	14,149
Working Capital	112,499	104,527	76,163	41,418	18,789
Long term debt	15,300	—	—	—	—
Total liabilities	72,665	395,495	19,276	20,864	14,149
Stockholders' Equity	163,823	142,780	95,193	56,378	31,686

23

**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, shipment of the goods has occurred, the selling price is fixed or determinable, and collectibility is reasonably probable. Our customers consist primarily of large pharmaceutical wholesalers who sell directly into the retail channel, chain drug stores, distributors, and managed care customers. Provisions for sales discounts, and estimates for chargebacks, rebates, and product returns are established as a reduction of product sales revenue at the time revenues are recognized, based on historical experience and current market trends adjusted to reflect known changes in the factors that impact these reserves. These revenue reductions are reflected as a direct reduction to accounts receivable through an allowance.

*Chargebacks*

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

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

1. The historical data of chargebacks as a percentage of sales, as well as actual chargeback reports received from our primary wholesaler customers.
2. Volume of all products sold to wholesaler customers and the average chargeback rates for the current quarter as compared to the previous quarter and compared to the last six month period.



3. The sales trends and future estimated prices of our products, wholesale acquisition cost (WAC), the contract prices with the retailers, chain stores, managed care organizations (end-users), and our wholesaler customer's contract prices.

4. We utilize remaining inventories on hand at our primary wholesaler customers at the end of the period in the calculation of our estimates.

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

#### *Shelf Stock Adjustments*

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

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

#### *Product returns and other allowances*

In the pharmaceutical industry, customers are normally granted the right to return product for credit if the product has not been used prior to its expiration date. Our return policy typically allows product returns for products within a twelve month window from six months prior to the expiration date and up to six months after the expiration date. We estimate the level of sale, what will ultimately be returned pursuant to our return policy, and record a related reserve at the time of sale. These amounts are deducted from our gross sales to determine our net revenues. Our estimates take into consideration historical returns of our products and our future expectations. We periodically review the reserves established for returns and adjust them based on actual experience, if necessary. The primary factors we consider in estimating our potential product returns include shelf life of expiration date of each product and historical levels of expired product returns. In case we become aware of any returns due to product related issues, such information from the customers is used to estimate an additional reserve. The amount of actual product return could be either higher or lower than the amounts we accrued. Changes in our estimates, if any, would be recorded in the income statement in the period the change is determined. If we over or under estimate the quantity of product which will ultimately be returned, there may be a material impact on our financial statements.

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

Customer rebates are estimated at every period end, based on direct or indirect purchases. If the purchases are direct, the rebates are recognized when products are purchased and a periodic credit is given. For indirect purchases, the rebates are recognized based on the terms with such customer. Medicaid rebates are estimated based on the historical data we receive from the public sector benefit providers, which is based on the final dispensing of our product by a pharmacy to a benefit plan participant.

#### *Doubtful Accounts*

Doubtful accounts are estimated based on the data available from external sources, including information on financial condition of customers. Also, a regular review of past due receivables is done on a quarterly basis to identify and make provision for such receivables not expected to be collected.

*Gross Sales and Related Allowances*

Our gross sales for Fiscal 2009 were \$648.1 million as compared to \$638.6 million for Fiscal 2008. Sales allowances, which include chargebacks, returns, discounts, other customary customer deductions and other sales costs, constituted approximately 48% for Fiscal 2009 as compared to 45% for Fiscal 2008. Net sales for Fiscal 2009 were \$337.2 million as compared to \$350.4 million for Fiscal 2008. The primary cause of the increased sales allowances by 3% for Fiscal 2009 is due to the impact of the increased difference between wholesale acquisition costs (WAC) and the contractual prices at which the wholesalers ship to our end use customers.

The following is a roll forward of the provisions for chargebacks, shelf stock adjustments, returns and allowances and estimated doubtful account allowances during Fiscal 2008 and Fiscal 2009.

(\$ 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		
<b>Fiscal 2008</b>					
Chargebacks, rebates & shelf stock adjustments	\$ 32,638	\$ 273,070	-0-	\$ 226,803	\$ 78,905
Returns and other allowances	3,752	15,168	-0-	13,647	5,273
Doubtful Accounts	100	346	-0-	328	118
<b>Fiscal 2009</b>					
Chargebacks, rebates & shelf stock adjustments	\$ 78,905	\$ 291,070	-0-	\$ 319,947	\$ 50,028
Returns and other allowances	5,273	19,870	-0-	18,588	6,555
Doubtful Accounts	118	231	-0-	271	78

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.

**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 \$20.8 million and \$17.3 million at March 31, 2009 and March 31, 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. We have recorded an income tax provision of \$8.9 million and \$7.0 million, respectively, for Fiscal 2009 and Fiscal 2008. The



income tax expense for Fiscal 2008 were lower due to reversals of valuation allowances in the amount of \$7.0 million, resulting from net operating loss carryforwards (“NOLs”). We have not provided for any valuation allowance as of March 31, 2009 or March 31, 2008. 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, 2009, we had federal NOLs of approximately \$2.3 million, which are restricted by limitations of Internal Revenue Code Section 382, available to reduce future taxable income. The NOLs will expire between 2010 and 2012.

The Company adopted FASB Interpretation 48, “Accounting for Uncertainty in Income Taxes” (“FIN 48”), at the beginning of Fiscal 2008. The Company, to date, has determined that no adjustments for unrecognized tax benefits are necessary as a result of the adoption of FIN 48.

The Company is subject to U.S. federal income tax as well as income tax in multiple state jurisdictions. The Company had not previously been the subject of an IRS examination. However, the IRS has initiated an examination of the Company’s tax return for the fiscal year ended March 31, 2007. The Company believes that it has complied with applicable IRS Codes and regulations, for the period under review. The Company’s federal statute of limitations on income tax has expired for years prior to 2003.

### **Inventory**

We value inventories at the lower of cost or market. We determine the cost of raw materials, work in process and finished goods using the specific identification cost method. We analyze our inventory levels quarterly and write down inventory that has become obsolete and inventory that has a cost basis in excess of its expected net realizable value. Expired inventory is disposed of and the related costs are written off. Materials acquired solely for R&D are written off in the year of acquisition. Inventory includes material purchased related to products for which the Company has filed ANDAs with the FDA, and the commercial launch of such products will commence once the approvals are received. The determination of whether or not inventory costs will be realizable requires estimates by management. A critical estimate in this determination is the estimate of the future expected inventory requirements, whereby we compare our internal sales forecasts to inventory on hand. Actual results may differ from those estimates and inventory write-offs may be required. We must also make estimates about the amount of manufacturing overhead to allocate to our finished goods and work in process inventories. Although the manufacturing process is generally similar for our products, we must make judgments as to the portion of costs to allocate to purchased product, work in process and finished goods, and such allocations can vary based upon the composition of these components and the fact that each product produced does not necessarily require the same amount of time or effort for the same production step. Accordingly, the assumptions we make can impact the value of reported inventories and cost of sales.

### **FDA Compliance**

During FY 2009, The FDA inspected both the Elijah McCoy manufacturing facility and the Farmington packaging facility. Forms FDA 483 were issued at the conclusion of both inspections detailing the FDA investigators’ observations. Responses to these observations were submitted to the FDA detailing the Company’s actions taken in response to the observations. On October 31, 2008, the Company received a warning letter from the Detroit District of the FDA. In this letter, the Agency reiterated some of the concerns detailed in the previous Form 483 issued as a result of our inspection that concluded in June 2008. These concerns included inadequate and untimely investigations by our quality control unit of certain incidents contrary to the Company’s standard operating procedures. The FDA also commented on our corrective action plans. The FDA added that failure to promptly correct the deficiencies may result in legal action without further notice, including, without limitation, seizure and injunction. It also noted that other federal agencies may take this warning letter into account when considering the award of contracts. Additionally, the FDA may withhold approval of requests for export certificates, or approval of pending new drug applications. We promptly responded to the warning letter on November 24, 2008 for the deficiencies noted and provided our corrective actions. The Detroit District acknowledged our response on December 22, 2008. It noted that our corrective actions would be evaluated during the FDA’s next scheduled inspection of our Detroit facility. On March 11, 2009 the FDA began an inspection as a follow-up to the October, 2008 warning letter. This inspection covered all the quality and production systems of the Company and concluded on May 12, 2009. The FDA investigators provided the Company with a list of their observations on FDA Form 483. Some of the observations were relative to the recent recalls and compliance, whereas others were focused on inventory controls. 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 a recall of certain product lots manufactured in our Detroit, MI facility, primarily to the

wholesale level. 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 has committed to provide a written response to these observations within approximately 30 days. We have not obtained FDA approvals of our ANDAs since the first quarter of Fiscal 2009. It is unlikely that we will receive any approvals for product out of our Detroit facility until the FDA reviews our remediation response and makes a determination of our status. Currently our status remains unchanged. We have changed our leadership in both manufacturing and quality control in order to better align these areas with our corporate goals and taken other steps, as stated below, to improve cGMP compliance.

Customer confidence could diminish based on the recent recalls and our status with the FDA. As previously disclosed it is possible that certain government contracts 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 them that were expiring. Once we have resolved our current issues with the FDA, we may regain this business when these contracts come up for renewal, which occurs on an annual basis.

We continue to focus on improving the amount of support in quality assurance, quality control, and manufacturing areas in order to continually improve the performance of our quality system. This support is derived from the improvement of systems, training on risk management and cGMP, while adding the appropriate level of personnel to support our growth. Additionally we have invested in more automation for improved quality and increase in output with less human intervention. During Fiscal 2008, and currently in Fiscal 2009, in addition to our own internal audits, we have retained outside companies to audit both the laboratory and manufacturing areas of our Company. The auditors are focusing in detail on compliance concerns noted in our most recent correspondence with the FDA. We also have, and will continue to, provide external training to our employees as a supplement to our internal training in order to improve or maintain our systems of operation. All audits are based on a historical look back and offer improvements based on Caraco's future requirements. The audits also included follow up on recommendations of best practices made by the FDA. We continue to gain effective support from Sun Pharma, in both quality systems and personnel, in the areas of quality and manufacturing. Further we have changed the leadership in both our quality and production areas in order to better align these areas with our corporate goals of compliance and quality. The new teams in these areas are affecting change as rapidly as required in order to provide continual improvement. We have focused our attention for continual improvement of our Corrective and Preventative Actions and cGMP, while adding the appropriate level of personnel to support our growth during Fiscal 2009 and we believe we are substantially cGMP compliant. The Company continues to look back historically for any issues or concerns to ensure we remain compliant. Our manufacturing personnel are going through more rigorous training at the time of hire, and continually thereafter, in order to maintain our compliance and quality.

We remain extremely pro-active in regards to growing our business appropriately. We continue to maintain the analytical staff, which consists of approximately 70 employees, thereby enabling the laboratory to better cope with an increased workload with improved timeliness, higher quality, and increased cGMP compliance. Several members of the lab staff attend supplemental professional training courses and conferences, which increases the laboratory's technical and cGMP proficiency. The lab facility has also undergone major upgrades, including a significant increase in working space to improve analyst efficiency and safety. Additional lab instruments and equipment have been purchased which will enable increased compliance with cGMP requirements, cut future costs by enabling in-house rather than contract analyses, and speed sample testing. Significant resources have also been spent to improve overall lab operations. Such expenditures demonstrate to the regulators, clients and shareholders that upper management is continually committed to adding quality individuals to the work force, providing the resources necessary to upgrade lab equipment and improve the effectiveness of lab operations and cGMP compliance. Our Quality control lab operations were not cited for any observations during the FDA's last inspection of our facility

## Overview of Fiscal 2009

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

The overall sales for our Company during Fiscal 2009 were slightly lower than the sales achieved in Fiscal 2008 primarily due to lower manufactured product sales, price erosion and recent recalls. We continued marketing of products distributed on behalf of Sun Pharma at the same levels as those in Fiscal 2008. The distribution and sale agreement, entered into during Fiscal 2008, for the distribution of Para IV products, which, together with sales under our marketing agreement with Sun Pharma, helped us maintain revenues for the distributed products at the same levels as Fiscal 2008. The Company enjoyed a higher level of sales of distributed products during the first two quarters of Fiscal 2009, primarily due to the strength of certain product launches during Fiscal 2008, which continued into Fiscal 2009. As disclosed previously this level of sales for these products may not be sustainable on an ongoing basis. Sales of manufactured products experienced a moderate decrease from prior year levels which accounted for moderate decrease in overall sales as compared to Fiscal 2008. In the fourth quarter of Fiscal 2009, our sales and gross profit were negatively impacted by lower sales of manufactured products. They were also affected by continued price erosion on the products we manufacture and also by the recall of certain shipments which took place during the end of Fiscal 2009 and also in the beginning of Fiscal 2010. As a result of the two recalls alone, our manufactured product sales were reduced by \$4.2 million. The negative impact to pre-tax income for the previously disclosed recalls, including related expenses, is \$4.7 million.

We recorded net sales of \$337.2 million during Fiscal 2009 compared to \$350.4 million during Fiscal 2008. We have generated cash from operations of \$18.7 million during Fiscal 2009 as compared to \$27.8 million during Fiscal 2008. This cash was generated after funding our working capital requirements of \$2.2 million and \$5.0 million during the relevant periods. We earned a net pre-tax income of \$29.5 million during Fiscal 2009 compared to a net pre-tax income of \$42.4 million during Fiscal 2008. The reduction in net 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. At March 31, 2009, we had stockholders' equity of \$163.8 million as compared to stockholders' equity of \$142.8 million at March 31, 2008.

In January 2005, the Company changed its fiscal year end from December 31 to March 31 to better align our financial reporting with our parent company, Sun Pharma. The following discussion of historical operating results compares Fiscal 2009 to Fiscal 2008 and Fiscal 2008 to Fiscal 2007.

### 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 Para 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 Para 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 manufactured 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 manufactured 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 Para IV products, which earn lower margins as a percentage of sales versus the sale of other distributed products. The gross profit margin for manufactured products was 43% for Fiscal 2009, as compared to 49% for Fiscal 2008. Manufactured 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 manufactured 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. We are hopeful that margins remain stable going forward as we manage, among other things, various factors such as changes in product sales mix, the balance of product sold to the various classes of trade, new product launches and continued price erosion. We can not determine the weight of distributed product sales versus manufactured product sales in any given period as it depends on our ability to gain market share on each product and is relative to when the FDA approves any given product in either category of product and the revenue potential of that product once it has been approved. 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.

#### **Fiscal 2008 Compared to Fiscal 2007**

**Net Sales.** Net sales for the relevant periods of 2008 and 2007 were \$350.4 and \$117.0 million, reflecting an increase of 199%. The increase was primarily due to sale of Para IV and other products being launched by the Company on behalf of Sun Pharma under the distribution and sale and marketing agreements we have with Sun Pharma. Currently, we manufacture and market all except three of our approved products. Excluding oxcarbazepine and pantoprazole sodium tablets, the sales mix amongst various products continues to be more diversified as the sales of three products accounted for 38% for Fiscal 2008 compared to sales of four products accounting for approximately 69% of net sales during Fiscal 2007. Overall, sales for two products (oxcarbazepine and pantoprazole sodium tablets) accounted for approximately 47% of net sales for Fiscal 2008 compared to sales of four products accounting for approximately 69% of net sales during Fiscal 2007. See Note 1 to Financial Statements – Revenue Recognition for explanation of the determination of net sales.

**Gross Profit.** We earned a gross profit of \$84.7 million as compared to a gross profit of \$57.8 million during the relevant periods, reflecting an increase of 47%. The increase in gross profit was due to higher sales, primarily of distributed products including new launches of Para IV products, under the agreements with Sun Pharma.

The gross profit margin decreased to 24% in Fiscal 2008 from 49% in Fiscal 2007. The decrease was primarily due to the weight of increased sales of distributed products versus the sale of manufactured products which had an impact on the overall margins. Net sales for distributed products during Fiscal 2008 were \$225.1 million compared to \$4.6 million for Fiscal 2007. The gross profit margin on other than Para IV distributed products sold was 14% and 30% for Fiscal 2008 and Fiscal 2007, respectively. Net sales for manufactured products were \$125.3 million during Fiscal 2008 compared to \$112.4 million for Fiscal 2007. The gross profit margin for manufactured products was 49% for Fiscal 2008, as compared to 50% for Fiscal 2007. Manufactured product margins have remained fairly stable and are slightly lower, primarily due to overall erosion in sales prices partially offset by sales of our product mix. As anticipated, the distribution margins, as a percentage of sales, were in the mid-teens excluding Para IV distributed products. We can not determine the weight of distributed product sales versus manufactured product sales in any given period as it depends on our ability to gain market share on each product and is relative to when the FDA approves any given product in either category of product and the revenue potential of that product once it has been approved. The sales generated from both of 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 manufactured sales 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 \$14.3 million and \$9.9 million, representing an increase of 44%. The increase was mainly due to higher marketing and administrative efforts relative to the increase in sales. SG&A expenses, as a percentage of net sales improved to 4% for Fiscal 2008, as compared to 8% for Fiscal 2007.

**Research and Development Expenses.** Total R&D expenses were \$29.7 million for Fiscal 2008 and \$22.4 million for Fiscal 2007. Actual cash research and development expenses were \$18.4 million for Fiscal 2008 and \$10.6 million for Fiscal 2007. 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 as compared to \$11.8 million for the 1,632,000 shares of preferred stock for three product transfers during Fiscal 2007. The cash R&D expenses during Fiscal 2008 were higher compared to those during Fiscal 2007 primarily due to increased patent related expenses, increased R&D activity, including milestone payments for outside development and increases in other expenses in an effort to file additional products with the FDA. We filed eight ANDAs relating to seven products with the FDA during Fiscal 2008. As of March 31, 2008, this brought our total number of ANDAs pending approval by the FDA to 27 (including four tentative approvals) relating to 19 products. We also submitted five other filings to the FDA for new strengths on existing ANDAs and for new sources on the Active Pharmaceutical Ingredients (API).



**Net Other Income.** We earned net other income of \$1.7 million during Fiscal 2008 as compared to \$1.3 million during Fiscal 2007. The net interest income during the relevant periods were \$1.8 million and \$1.1 million, respectively, after incurring interest expense of zero dollars and twenty-eight thousand dollars in the respective periods. The higher interest income was reflective of our increase in cash balances during Fiscal 2008.

**Income Taxes.** We recorded an income tax provision of \$7.0 million during Fiscal 2008. There was no such provision or benefit recorded for Fiscal 2007. 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 income taxes on current profits. Also see discussion under "Income Taxes" above.

**Results of Operations.** We earned pre-tax income of \$42.4 million in Fiscal 2008, compared to pre-tax income of \$26.9 million in Fiscal 2007. Net income increased to \$35.4 million during Fiscal 2008 from net income of \$26.9 million during the Fiscal 2007. The improvement in results of operations was primarily due to the increase in sales volume during Fiscal 2008 over Fiscal 2007.

## Liquidity and Capital Resources

### 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. As of March 31, 2009, inventory levels are equivalent to 140 days sales on hand, as compared to 142 days on hand as of March 31, 2008. Accounts receivable is 27 days sales outstanding ("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.

**Fiscal 2008 and Fiscal 2007**

We generated cash from operations of \$27.8 million during Fiscal 2008, compared to \$27.9 million in Fiscal 2007. Accounts receivable increased to \$135.9 million at March 31, 2008 from \$26.1 million at March 31, 2007 due to higher net sales in the fourth quarter this year, compared to the same period last year. Accounts receivable is 63 days sales outstanding (DSO) as of March 31, 2008 versus 72 days outstanding at the end of Fiscal 2007. There has been cash outflow due to payment of federal income taxes of \$24.2 million as a result of a change in the Company's tax position (see discussion under "Income Taxes" above). Inventory levels for Fiscal 2008 are equivalent to 142 days sales on hand as compared to 88 days for the relative period of Fiscal 2007. The inventory as of March 31, 2008, includes a build up for Para IV products launched in the last quarter of Fiscal 2008. If the sale of the product is 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. Excluding the inventory for these products, inventory levels were equivalent to 94 days sales as compared to 88 days for the relative period of Fiscal 2007.

At March 31, 2008, we had working capital of \$104.5 million compared to working capital of \$76.2 million at March 31, 2007. The increase in working capital in Fiscal 2008 is due to an increase in accounts receivable, an increase in inventory balances resulting from higher sales volumes and a build up of inventory for Para IV products recently launched, and an increase in prepaids due to an increase in a contractual deposit with a certain customer, partially offset by higher accounts payable balances related to the higher inventory levels. We believe inventory, though considerably higher than previous periods, will generate future revenues or are returnable. Additionally, we have available a \$10.0 million line of credit obtained through JP Morgan Chase Bank, N.A. which would allow us flexibility in expansion efforts to increase our capacity over the next few years.

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-K

The following tables present a summary of each of the four quarters of Fiscal 2009 and Fiscal 2008. The unaudited interim financial statements include all adjustments, consisting only of normal recurring adjustments, except for the 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, 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.

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
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)

Fiscal 2008 – April 1, 2007 to March 31, 2008 (unaudited)

(In thousands, except per share data)

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Net Sales	\$ 35,400	\$ 41,355	\$ 81,860	\$ 191,752
Gross Profit	15,868	18,016	23,285	27,546
Net Income	8,515	4,621	10,773	11,479
Net Income Per Share				
Basic	0.30	0.16	0.37	0.37
Diluted	0.22	0.12	0.28	0.28

**Contractual Obligations and Off Balance Sheet Transactions**

The following table summarizes the Company's significant contractual obligations at March 31, 2009

(In millions)

Contractual Obligations	Total	Payment due by period			
		Less than 1 year	1-3 years	4-5 years	More than 5 years

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-K

Long-term Debt	\$ 18.0	\$ 2.7	\$ 15.3	—	—
Operating Leases	\$ 7.3	\$ 0.8	\$ 1.6	\$ 1.6	\$ 3.3
Milestone payments relating to various product development agreements	\$ 0.7	\$ 0.3	\$ 0.4	—	—

34

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, 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**

Though Fiscal 2009 has seen several challenges in manufacturing and compliance, we believe that the steps that we have taken will provide for a better outcome going forward. We have hired experienced people in these areas to correct such areas where we may be deficient. Further, we have third party consultants that are providing guidance on remediation for such improvements. Sun Pharma has provided assistance and guidance from its own corporate quality group. It also continues to provide improvements for our quality systems. We believe the Company's future performance in these areas will be capable of supporting our efforts in providing a quality product on time to satisfy our customers' needs. Though near term sales of manufactured products may face some challenges, we believe we are effecting the changes required to improve our performance on manufactured product sales on a long term basis. We will continue to compete effectively in the market we serve. Due to our size and management structure, we believe that we will execute our plan effectively, on a long term basis. We are disciplined and have the aptitude to execute our plan. Though we have made considerable improvements in our quality systems, we still have improvements to implement and measure as part of our continual improvement process. With this in mind, we believe we are substantially compliant with cGMP. We continue to invest in improved systems, equipment, training and personnel in quality assurance, quality control and manufacturing to improve our overall performance in quality. We have added considerable amount of infrastructure in quality and expect that we will continue to add additional infrastructure in manufacturing.

The expansion of our facilities should provide the capacity we need to supply our customers effectively. Our training and succession planning is being enhanced to support our growth and predict future operational efficiencies. We are working with local universities and technical schools in order to provide the proper talented employees required to perform in a highly regulated business. We anticipate improved productivity as our staff continues to increase their experience in their respective positions. Our platform is poised for growth. We have the capacity, infrastructure and capability to perform well in the industry. The personnel that we have added have improved the competency level which should improve the performance of our manufacturing and quality areas. Our distribution and marketing capability continues to offer its standard of excellence to maximize our market share.

Currently, we have 29 ANDAs pending approval at the FDA (including four tentative approvals) or 25 products. We continue to upgrade our facilities, attract and hire talented individuals and expand our customer base. Based on our own development pipeline and the current agreements we have with Sun Pharma along with other third party developers, we believe we will continue to perform well in our industry. Though we remain hopeful, the uncertainty of the timelines associated with new approvals based on our status with the FDA limits our view on our growth in the near term. Since FDA approvals are a significant part of any generic pharmaceutical company's growth we have determined that we will not provide any further guidance related to our top line growth. We remain confident that our reporting of our basic fundamental performance over the course of Fiscal 2010 will provide sufficient disclosure to our shareholders and others. The recent voluntary recalls previously disclosed, have had a negative impact on the Company's performance and may continue to have a negative impact in the near term. We remain confident that our implementation of corrective actions in compliance and quality will ultimately let us gain back our momentum of sales growth that we have enjoyed over the last several years. We have a successful marketing platform and also have Sun Pharma's product line to complement our manufacturing products business.

We now have twenty-two products, that we market (including our own manufactured products and those distributed on behalf of Sun Pharma), whose market share is ranked third or higher against the same products of our generic competitors. Based on our own development pipeline and the current agreements we have with Sun Pharma along with other third party developers we believe we will continue to perform well and achieve considerable growth in sales for Fiscal 2010, as compared to Fiscal 2009.

Although gross profit margins may come down over time due to price erosion, we remain confident that our sales growth, expanding product portfolio and successful execution of our business plan will offset any long-term impact. However, should the pricing pressures become more severe than anticipated, the result may be lower growth rates and gross margins. Management has and will continue to work diligently to counter the pricing pressures through increased sales volumes, expansion of our customer base, improved productivity, and better cost absorption of operational overheads, cost reductions and increased development plans. The balance of sales between distributed products and manufactured products remains an unknown and is based on the amount of approvals in each segment and also the timing of those approvals. Subsequently the margin percentage may come down due to a heavier weight of distributed product sales. The Company will manage itself accordingly so that we have the proper level of personnel to operate and support the manufactured products sales. Additional overheads are not generally required to support the distribution product sales. Though there are some additional expenses to distribute these products we do not add personnel to support these sales.

We intend to aggressively move forward with the development of new products. While the development of new products will increase our cash R&D expense and impact EPS, we believe that we will continue to have the cash and other means available to meet increased working capital requirements, fund potential litigation expenses relating to Paragraph IV certification and finance further capital investments. 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 74% (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, 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.

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

We anticipate additional development agreements will be entered into should we define any future gaps in our calendar of approvals that we anticipate from the FDA. We expect these agreements to run parallel to our own internal product development. In order to improve the amount of filings during Fiscal 2009, we continued to fortify our own research and development team by increasing the number of products we have in development internally. We filed ten ANDAs in Fiscal 2009, covering nine products, whereas we filed seven products in Fiscal 2008.

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 have begun marketing a number of these products which are categorized as distributed products. In addition, on January 29, 2008, the Company executed a distribution and sale agreement with Sun Pharma. This agreement covers certain mutually agreed upon products that have been filed or will be filed with the FDA with a Paragraph IV certification. A Paragraph IV certification states that the filer believes that it either does not infringe the patent or believes that the patent is invalid. Paragraph IV certified products face litigation challenges with respect to claims of patent infringement. Sun Pharma is not obligated to offer Caraco products under this agreement, however, Caraco has the exclusive right to market in the U.S., its territories and possessions, including Puerto Rico, any products offered by Sun Pharma and accepted by Caraco. Under the agreement, the Company participates in the sales opportunity on the products,

and also shares the litigation risks to a limited extent based on percentage. If such claims are successful, however, they could have a material adverse effect on the Company. We are marketing two products under this agreement including Pantoprazole sodium DR tablets. While increased distributed products may lower our overall gross profit margins, we do not have any of the associated costs other than routine marketing costs including freight, carrying costs, and actual purchase price. These agreements should provide for an alternate stream of products that will complement our internal research and development and our outsourced development. From time to time significant product launches such as we incurred under the distribution and sale agreement for Para IV products in Fiscal 2008 may occur that will add near term growth that may or may not be sustainable in future periods. Additionally we will continue to work with Sun Pharma in effort to transfer product technology on a cash basis similar to other third party developers. In addition 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.

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 plans for Fiscal 2010 include:

- Continue to focus and improve on FDA compliance.
- Continue to invest in equipment to improve quality.
- Improve management of manufacturing with a focus on quality.
- Increase cGMP training to accommodate growing staff and compliance.
- Increase research and development activities, with a view to increase the number of ANDA filings.
- Look for potential acquisitions that either complement or are synergistic to our current business model.
- Increased market share for certain existing products and recently introduced products.
- Enhanced customer reach and satisfaction.
- 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.
- Leverage distribution and marketing to market other third party products through in-licensing and marketing.
- Expand our relationships with financial institutions to fortify our credit position and borrowings for potential acquisitions of any products or companies.
- 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 2009, the Company had no material market risk exposure. The following describes our current loan arrangements and the interest rates associated therewith.



**Line of Credit**

During the third quarter of Fiscal 2009, the Corporation renewed its one-year, \$10 million Credit Agreement with JP Morgan Chase Bank, N.A., which will expire on November 30, 2009. Under the Credit Agreement, the lender may make loans and issue letters of credit to the Corporation for working capital needs and general corporate purposes. Letters of credit, if issued, expire one year from their date of issuance, but no later than November 30, 2009. Borrowings are secured by the Corporation's receivables and inventory. Interest is payable based on a LIBOR Rate or an alternate base rate (determined by reference to the prime rate or the federal funds effective rate), as selected by the Corporation. The rate of interest is LIBOR plus 75 basis points, or the bank's prime rate minus 100 basis points (provided the prime rate is not less than the prevailing one month LIBOR Rate plus 250 basis points). The effective rates were 1.25% and 2.25%, respectively, at March 31, 2009. The Credit Agreement requires that certain financial covenants be met on a quarterly basis. The Corporation is in compliance with these financial covenants at March 31, 2009. There were no borrowings under this Credit Agreement at March 31, 2009.

**Term Loan**

During the fourth quarter of Fiscal 2009 the Company entered into a term loan of \$18 million with Charter One Bank. Understanding today's cost of money and the difficulty in the borrowing climate at the time we believed that it was prudent to take this loan to fortify our cash position to allow flexibility should product acquisitions come available. 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, 2009 was 2.01%. The principal loan payments and accrued interest are payable on a quarterly basis beginning July, 2009. The principal is to be repaid in equal quarterly installments of \$900,000 for ten quarters through October 2011, and thereafter, if not renewed, the remaining balance of \$9 million is due in January, 2012. The Company expects that the term loan will be renewed, and the loan amortization is expected to occur over 20 equal quarterly installments of \$900,000 each.

As required per the terms of the Loan Agreement, the Company has entered into an Interest Rate Swap Agreement with Charter One Bank to hedge the interest rate applicable on the loan. The notional amount for the swap is \$18 million which will amortize down as principal payments are made on the related debt. The annualized fixed rate of interest as it applies to this agreement is 2.41%. Thus as of March 31, 2009 the effective rate of interest to the Company for the term loan was 2.91% (2.41% swap rate plus applicable margin of 50 basis points). This loan will assist us in potential product acquisitions and or contribute to facilitating any other acquisition. We believe that our operations will provide the cash flow necessary to run our day to day business.

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

**INDEX TO FINANCIAL STATEMENTS**

	<b>Page</b>
1. Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting	F-1 & F-2
2. Report of Independent Registered Public Accounting Firm	F-3 & F-4
3. Financial Statements:	
Balance Sheets as of March 31, 2009 and 2008	F-5 & F-6
Statements of Operations for the years ended March 31, 2009, 2008 and 2007	F-7
Statements of Stockholders' Equity for the years ended March 31, 2009, 2008 and 2007	F-8
Statements of Cash Flows for the years ended March 31, 2009, 2008 and 2007	F-9
Notes to Financial Statements	F-10 to F-39



**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 the fiscal year ended March 31, 2009 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, 2009 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, 2009, based upon the COSO framework criteria.

The Company’s internal control over financial reporting as of March 31, 2009 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 2009 Annual Meeting of Stockholders to be filed not later than 120 days after the Company's Fiscal year ended March 31, 2009.

**Item 11. Executive Compensation.**

The information required by this Item is incorporated by reference to the information contained in our Proxy Statement for the 2009 Annual Meeting of Stockholders to be filed not later than 120 days after the Company's Fiscal year ended March 31, 2009.

**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 2009 Annual Meeting of Stockholders to be filed not later than 120 days after the Company's Fiscal year ended March 31, 2009.

**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 2009 Annual Meeting of Stockholders to be filed not later than 120 days after the Company's Fiscal year ended March 31, 2009.

**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 2009 Annual Meeting of Stockholders to be filed not later than 120 days after the Company's Fiscal year ended March 31, 2009.

**Part IV**

**Item 15. Exhibits Financial Statement Schedules.**

- (a) 1 Financial Statements

**Page**

1.	Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting	F-1 & F-2
2.	Report of Independent Registered Public Accounting Firm	F-3 & F-4
3.	Financial Statements:	
	Balance Sheets as of March 31, 2009 and 2008	F-5 & F-6
	Statements of Operations for the years ended March 31, 2009, 2008 and 2007	F-7
	Statements of Stockholders' Equity for the years ended March 31, 2009, 2008 and 2007	F-8
	Statements of Cash Flows for the years ended March 31, 2009, 2008 and 2007	F-9



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 10<sup>th</sup> day of June, 2009.

CARACO PHARMACEUTICAL LABORATORIES, LTD.

/s/ Daniel H. Movens

Daniel H. Movens  
Chief Executive Officer

41

---

**POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Daniel H. Movens and / or Mukul Rathi, this 10th day of June, 2009, 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	Chairman of the Board
Dilip S. Shanghvi	
/s/ Daniel H. Movens	Director, Chief Executive Officer, Principal Executive Officer
Daniel H. Movens	
/s/ Mukul Rathi	Interim Chief Financial Officer, Principal Accounting Officer
Mukul Rathi	
/s/ Gurpartap Singh Sachdeva	Director
Gurpartap Singh Sachdeva	
/s/ John D. Crissman	Director
John D. Crissman	
/s/ Sailesh T. Desai	Director
Sailesh T. Desai	
/s/ Timothy Manney	Director
Timothy Manney	
	Director
Madhava Reddy	
/s/ Georges Ugeux	Director
Georges Ugeux	
/s/ 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, 2009, 2008 AND 2007***

---

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

**INDEX TO FINANCIAL STATEMENTS**

<b><u>Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting</u></b>	F-1 - 2
<b><u>Report of Independent Registered Public Accounting Firm</u></b>	F-3 - 4
<b>Financial Statements as of March 31, 2009 and 2008, and for the Years Ended March 31, 2009, 2008 and 2007</b>	
<u>Balance Sheets</u>	F-5 - 6
<u>Statements of Operations</u>	F-7
<u>Statements of Stockholders' Equity</u>	F-8
<u>Statements of Cash Flows</u>	F-9
<u>Notes to Financial Statements</u>	F-10 – F-39

\* \* \* \* \*

---

**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.

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, 2009, 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, 2009 of the Corporation and our report dated May 29, 2009 expressed an unqualified opinion on those financial statements.

/s/ Rehmann Robson P.C.

Troy, Michigan  
May 29, 2009

F-2

---

**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, 2009 and 2008 and the related statements of income, stockholders' equity and cash flows for the years ended March 31, 2009, 2008 and 2007. 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, 2009 and 2008, and the results of its operations and its cash flows for the years ended March 31, 2009, 2008 and 2007 in conformity with accounting principles generally accepted in the United States of America.

F-3

---

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, 2009, 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 29, 2009 expressed an unqualified opinion on the Corporation's internal control over financial reporting.

/s/ Rehmann Robson P.C.

Troy, Michigan

May 29, 2009

F-4

---

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

	<b>March 31</b>	
	<b>2009</b>	<b>2008</b>
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 65,314,397	\$ 56,906,051
Accounts receivable, net	15,181,197	135,927,027
Inventories	79,510,832	298,665,680
Prepaid expenses and deposits	9,440,942	8,161,319
Deferred income taxes	416,985	361,707
<b>Total current assets</b>	<b>169,864,353</b>	<b>500,021,784</b>
<b>Property, plant and equipment</b>		
Land	975,311	975,311
Buildings and improvements	28,148,447	13,102,557
Equipment	26,216,521	17,046,501
Furniture and fixtures	1,509,582	1,175,403
Construction in progress	2,708,137	405,689
<b>Total</b>	<b>59,557,998</b>	<b>32,705,461</b>
Less accumulated depreciation	14,734,961	11,438,027
<b>Net property, plant and equipment</b>	<b>44,823,037</b>	<b>21,267,434</b>
Intangible assets, net	1,383,048	—
Deferred income taxes	20,417,885	16,985,968
<b>Total assets</b>	<b>\$ 236,488,323</b>	<b>\$ 538,275,186</b>

	March 31	
	2009	2008
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable, trade	\$ 7,979,341	\$ 4,781,739
Accounts payable, Sun Pharma	43,928,166	388,286,127
Accrued expenses	2,757,361	2,284,513
Income taxes payable	—	142,494
Long term debt, current portion	2,700,000	—
<b>Total current liabilities</b>	<b>57,364,868</b>	<b>395,494,873</b>
Long term debt	15,300,000	—
<b>Total liabilities</b>	<b>72,664,868</b>	<b>395,494,873</b>
<b>Commitments and contingencies (Notes 9, 11 and 12)</b>		
<b>Stockholders' equity</b>		
Series B convertible preferred stock, no par value; issued and outstanding 2,720,000 and 7,616,000 shares at March 31, 2009 and 2008, respectively	23,081,920	58,137,280
Common stock, no par value; authorized 50,000,000 shares, issued and outstanding 37,458,194 and 32,551,094 shares at March 31, 2009 and 2008, respectively	118,569,335	83,332,487
Additional paid-in capital	3,474,246	3,149,171
Retained earnings (accumulated deficit)	18,697,954	(1,838,625)
<b>Total stockholders' equity</b>	<b>163,823,455</b>	<b>142,780,313</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 236,488,323</b>	<b>\$ 538,275,186</b>



**CARACO PHARMACEUTICAL LABORATORIES, LTD.****(a subsidiary of Sun Pharmaceutical Industries Limited)****STATEMENTS OF INCOME**

	<b>Year Ended March 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
Net sales	\$ 337,177,482	\$ 350,366,689	\$ 117,027,016
Cost of goods sold (Notes 1 and 4)	269,382,927	265,651,539	59,242,858
<b>Gross profit</b>	<b>67,794,555</b>	<b>84,715,150</b>	<b>57,784,158</b>
Selling, general and administrative expenses	16,417,971	14,322,140	9,880,674
Research and development costs - affiliate (Note 7)	—	11,320,640	11,761,280
Research and development costs - other	22,527,504	18,366,306	10,590,643
<b>Operating income</b>	<b>28,849,080</b>	<b>40,706,064</b>	<b>25,551,561</b>
<b>Other income (expense)</b>			
Interest income	631,151	1,832,409	1,081,208
Interest expense	(28,294)	—	(28,194)
Loss on sale of equipment	—	(144,551)	(5,106)
Other income	—	—	258,652
<b>Other income - net</b>	<b>602,857</b>	<b>1,687,858</b>	<b>1,306,560</b>
<b>Income before income taxes</b>	<b>29,451,937</b>	<b>42,393,922</b>	<b>26,858,121</b>
Income taxes	8,915,358	7,005,817	—
<b>Net income</b>	<b>\$ 20,536,579</b>	<b>\$ 35,388,105</b>	<b>\$ 26,858,121</b>
<b>Net income per share</b>			
Basic	\$ 0.60	\$ 1.19	\$ 1.02

Diluted	\$	0.51	\$	0.89	\$	0.72
---------	----	------	----	------	----	------

F-7

---

**CARACO PHARMACEUTICAL LABORATORIES, LTD.****(a subsidiary of Sun Pharmaceutical Industries Limited)****STATEMENTS OF STOCKHOLDERS' EQUITY**

	Preferred Stock		Common Stock		Additional Paid-in Capital	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
<b>Balances at April 1, 2006</b>	<b>10,880,000</b>	<b>\$ 72,755,770</b>	<b>26,421,994</b>	<b>\$ 44,988,597</b>	<b>\$ 2,718,735</b>	<b>\$ (64,084,851)</b>	<b>\$ 56,378,251</b>
Issuance of preferred stock to affiliate in exchange for product technology transfers	1,632,000	11,761,280	—	—	—	—	11,761,280
Conversion of preferred stock into common stock	(1,632,000)	(10,931,530)	1,632,000	10,931,530	—	—	—
Common stock options exercised	—	—	48,400	49,970	—	—	49,970
Common stock option expense	—	—	—	—	145,787	—	145,787
Net income	—	—	—	—	—	26,858,121	26,858,121
<b>Balances at March 31, 2007</b>	<b>10,880,000</b>	<b>73,585,520</b>	<b>28,102,394</b>	<b>55,970,097</b>	<b>2,864,522</b>	<b>(37,226,730)</b>	<b>95,193,409</b>
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
<b>Balances at March 31, 2008</b>	<b>7,616,000</b>	<b>58,137,280</b>	<b>32,551,094</b>	<b>83,332,487</b>	<b>3,149,171</b>	<b>(1,838,625)</b>	<b>142,780,313</b>
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
<b>Balances at March 31, 2009</b>	<b>2,720,000</b>	<b>\$ 23,081,920</b>	<b>37,458,194</b>	<b>\$ 118,569,335</b>	<b>\$ 3,474,246</b>	<b>\$ 18,697,954</b>	<b>\$ 163,823,455</b>



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

	<b>Year Ended March 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
<b>Cash flows from operating activities</b>			
Net income	\$ 20,536,579	\$ 35,388,105	\$ 26,858,121
Adjustments to reconcile net income to net cash provided by operating activities			
Depreciation	3,369,721	2,508,931	1,931,423
Capital stock issued or to be issued to affiliate in exchange for product formula	—	11,320,640	11,761,280
Loss on sale of equipment	—	144,551	5,106
Common stock option expense	325,075	284,649	145,787
Common stock grants	170,238	357,750	—
Common stock issued to former officer & director	—	115,950	—
Deferred income tax benefit	(3,487,195)	(17,347,675)	—
Changes in operating assets and liabilities which (used) provided cash			
Accounts receivable	120,745,831	(109,801,881)	(5,266,047)
Inventories	219,154,848	(266,722,382)	(4,977,607)
Prepaid expenses and deposits	(1,279,623)	(4,687,979)	(940,778)
Accounts payable	(341,160,358)	377,574,685	(2,881,171)
Accrued expenses	472,851	(1,498,192)	1,293,307
Income taxes payable	(142,494)	142,494	—
<b>Net cash provided by operating activities</b>	<b>18,705,473</b>	<b>27,779,646</b>	<b>27,929,421</b>
<b>Cash flows for investing activities</b>			
Purchases of property, plant and equipment	(26,852,537)	(5,094,031)	(6,006,014)
Proceeds from sale of equipment	—	203,004	—
Purchases of intangibles	(1,455,840)	—	—
<b>Net cash used in investing activities</b>	<b>(28,308,377)</b>	<b>(4,891,027)</b>	<b>(6,006,014)</b>
<b>Cash flows from financing activities</b>			
Proceeds from loans payable to financial institutions	18,000,000	—	5,000,000
Repayments of loans payable to financial institutions	—	—	(5,000,000)
Proceeds from issuance of common stock	11,250	119,810	49,970
<b>Net cash provided by financing activities</b>	<b>18,011,250</b>	<b>119,810</b>	<b>49,970</b>

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-K

<b>Net increase in cash and cash equivalents</b>	<b>8,408,346</b>	<b>23,008,429</b>	<b>21,973,377</b>
Cash and cash equivalents, beginning of year	56,906,051	33,897,622	11,924,245
<b>Cash and cash equivalents, end of year</b>	<b>\$ 65,314,397</b>	<b>\$ 56,906,051</b>	<b>\$ 33,897,622</b>

F-9

---

**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, 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 consists of 63 products in various strengths and package sizes. The Corporation’s drugs relate to a variety of therapeutic segments including the central nervous system, cardiology, pain management and diabetes.

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 Pharmaceutical Industries Limited, a specialty pharmaceutical corporation organized under the laws of India (“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, 2009, Sun Pharma beneficially owns approximately 74% (76% including its holdings of convertible Series B Convertible Preferred stock) of the outstanding common shares of Caraco.

*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.

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

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

During the fiscal year ended March 31, 2007 ("Fiscal 2007"), the Corporation entered into a three-year marketing agreement with Sun Pharma, which was reviewed and approved by the Board's Independent Committee. Under the agreement, the Corporation purchases selected product formulations offered by Sun Pharma and markets and distributes the same as part of the current product offerings in the U.S., its territories and possessions, including Puerto Rico. Sun Pharma is not obligated to offer Caraco products under this agreement, however, Caraco has the exclusive right to market in the U.S., its territories and possessions, including Puerto Rico, any products offered by Sun Pharma and accepted by Caraco.

During the fiscal year ended March 31, 2008 ("Fiscal 2008"), the Corporation entered into a three-year distribution and sale agreement with Sun Pharma, which was reviewed and approved by the Board's Independent Committee. Under this agreement the



Company purchases selected formulations which have been filed under Paragraph IV certification process with the FDA by Sun Pharma and offered for distribution. Paragraph IV certified ("Para IV") products may face litigation challenges with respect to claims of patent infringement. Under the agreement the Company shares in the sales opportunity and shares the litigation risk. The Company is indemnified by Sun Pharma of any risk beyond the percentage agreed to as its profit percentage thereby limiting the Company's exposure. Sun Pharma is not obligated to offer Caraco products under this agreement, however, Caraco has the exclusive right to market in the U.S., its territories and possessions, including Puerto Rico, any products offered by Sun Pharma and accepted by Caraco. The Company markets and distributes the same as part of its current product offerings in the U.S., its territories and possessions, including Puerto Rico. The license granted with respect to a product terminates upon the end of an exclusivity period of 180 days or a non-appealable court decision, or until a third generic manufacturer launches the product, whichever is later, or until a settlement is reached, at which time the product will become part of the standard Caraco-Sun Pharma marketing agreement disclosed above. The Company currently receives a fixed gross profit margin of 8%, or such other percentages as shall be mutually agreed upon. Under the agreement, Sun Pharma and Caraco mutually indemnify each other capped by the fixed margin percentage with respect to damages from infringement.

During the fiscal year ended March 31, 2009 ("Fiscal 2009"), Fiscal 2008 and Fiscal 2007, the Corporation made net sales of \$225.4 million, \$225.1 million and \$4.6 million of the marketed products under aforesaid agreements, respectively.

The Corporation also paid approximately \$46 thousand, \$0.3 million and \$0.8 million for the years ended March 31, 2009, 2008 and 2007, respectively, to Sun Pharma and its associates for the purchase of various parts and machinery needed for operations.

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 2009, the Corporation incurred \$0.3 million related to these services. No fees for these services were incurred during Fiscal 2008 and Fiscal 2007.

While management has a basis to reasonably believe that Sun Pharma's substantial investment in Caraco provides Sun Pharma with sufficient economic incentive to continue to assist Caraco in developing its business, and Sun Pharma has expressed its intent to continue to support Caraco's operations in the near term, as it has done in the past, there can be no assurance that such support will, in fact, continue, 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).

#### *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) and valuation of inventories.

#### *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.

#### *Revenue Recognition*

Revenue from product sales, both manufactured and distributed, net of estimated provisions, is recognized when there is persuasive evidence that an arrangement exists, shipment of the goods has occurred, the selling price is fixed or determinable, and collectibility is reasonably probable. 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.

#### *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 88% and 94% of the total allowance for trade receivables at March 31, 2009 and 2008, respectively, has been established to provide for estimated sales chargebacks and customer rebates (see Note 3).

#### 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, which 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 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.

Customer rebates are estimated at the end of every reporting period, based on direct or indirect purchases. If the purchases are direct, the rebates are recognized when products are purchased and a periodic credit is given. For indirect purchases, the rebates are recognized based on the terms with such customer. Medicaid rebates are estimated based on the historical data 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.

***Net Income (Loss) Per Share***

Net income (loss) 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.

## Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-K

The following table sets forth the computation of basic and diluted net income (loss) per common share:

	Year Ended March 31 2009	Year Ended March 31 2008	Year Ended March 31 2007
<b>Numerator:</b>			
Net income available for common stockholders	\$ 20,536,579	\$ 35,388,105	\$ 26,858,121
<b>Denominator:</b>			
Weighted average shares outstanding, basic	34,227,335	29,656,624	26,447,312
Incremental shares from assumed conversion of -			
- preferred stock	5,949,721	9,916,852	10,464,175
- common stock options	398,665	340,278	343,293
 Weighted average shares outstanding, diluted	 40,575,721	 39,913,754	 37,254,780
<b>Net income per common share</b>			
Basic	\$ 0.60	\$ 1.19	\$ 1.02
Diluted	\$ 0.51	\$ 0.89	\$ 0.72

### ***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.

### ***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.

*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.

Based on the definition and characteristics of an asset, set forth in paragraphs 25 and 26 of Statement of Financial Accounting Concepts No. 6 issued by the Financial Accounting Standards Board ("FASB"), the Company did not capitalize the technology formulas

transferred, as the probability of the future economic benefit to be derived from such formulations was considered uncertain at the time of technology transfer.

In addition, the Company has reported the technology transfers as research and development expenses pursuant to Statement of Financial Accounting Standards ("SFAS") No. 2, "Accounting for the Research and Development Costs." 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 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, 2009. Additionally during the second quarter of Fiscal 2009, the Company paid \$356,000 in cash towards product and establishment fees for these products. The total gross carrying amount for these assets is \$1,456,000 as of March 31, 2009. These intangible assets are being amortized equally over a period of 15 years, the period during which the Company expects to receive economic benefits from these intangible assets. During Fiscal 2009, the Company recorded \$73,000 in amortization expense, and estimates that an additional \$97,000 of related amortization expense will be recorded in each of the Company's next five fiscal years.

#### ***Financial Instrument***

The Company utilizes interest rate swap agreements with a bank to fix interest rates on the Company's term loan which reduces exposure to interest rate fluctuations. The interest rate swap changes the variable-rate cash flow exposure on the long-term debt obligations to fixed-rate cash flows by entering into a receive-variable, pay-fixed interest rate swap. Under the interest rate swap, the Company receives variable-rate payments and makes fixed interest rate payments, thereby creating fixed-rate long-term debt. The Company does not use any other types of derivative financial instruments to hedge such exposures, nor does it use derivatives for speculative purposes. The Company assesses interest rate cash flow risk by continually identifying and monitoring changes in interest rate exposures that may adversely impact expected future cash flows and by evaluating hedging opportunities. The notional value of the interest rate swap agreement in place at March 31, 2009 covers the Company's term loan in the amount of \$18 million. The



expiration of this swap agreement is consistent with the underlying debt instrument. Interest is settled quarterly. The Company has not elected hedge accounting with respect to this swap agreement, and accordingly, changes in fair value of the swap agreement will be reported in the Income Statement. The fair value of this swap agreement at March 31, 2009 was not material..

***Fair Value Measurements***

In September 2006, the FASB issued SFAS No. 157, “Fair Value Measurements” (“SFAS 157”). SFAS 157 defines fair value, establishes a framework for measuring fair value within generally accepted accounting principles and expands required disclosures about fair value measurements. SFAS 157 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions. In November 2007, the FASB provided a one year deferral for the implementation of SFAS 157 for non-financial assets and liabilities. The Company adopted SFAS 157 on April 1, 2008, as required. The adoption of SFAS 157 did not have any impact on the Company’s reported financial condition or results of operations.

In February 2007, the FASB issued SFAS No. 159, “The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB Statement No. 115” (“SFAS 159”). SFAS 159 permits companies to measure many financial instruments and certain other items at fair value at specified election dates. The Company adopted SFAS 159 on April 1, 2008. The adoption of SFAS 159 did not have any impact on the Company’s reported financial condition or results of operations.

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

***Recent Accounting Pronouncements***

In December 2007, the FASB issued SFAS No. 160, “Noncontrolling Interests in Consolidated Financial Statements” (“SFAS 160”). SFAS 160 re-characterizes minority interests in consolidated subsidiaries as non-controlling interests and requires the classification of minority interests as a component of equity. Under SFAS 160, a change in control will be measured at fair value, with any gain or loss recognized in earnings. The effective date for SFAS 160 is for annual periods beginning on or after December 15, 2008 (the Corporation’s Fiscal 2010) and are not expected to have a material impact on the Corporation’s financial statements. Early adoption and retroactive application is not permitted.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "Business Combinations" ("SFAS 141R") which replaces SFAS No. 141, "Business Combinations" ("SFAS 141"). SFAS 141R establishes principles and requirements for recognizing and measuring identifiable assets and goodwill acquired, liabilities assumed and any non-controlling interest in a business combination at their fair value at acquisition date. SFAS 141R provides updated guidance and makes significant amendments to previous guidance in SFAS 141 and other standards including the treatment of acquisition related costs, business combinations achieved in stages (referred to as a step acquisition), the treatment of gains from a bargain purchase, the recognition of contingencies in business combinations, the treatment of IPR&D in a business combination as well as the treatment of recognizable deferred tax benefits. SFAS 141R is effective for financial statements issued for fiscal years beginning after December 15, 2008 (the Corporation's Fiscal 2010) and are not expected to have a material impact on the Corporation's financial statements. Early adoption is prohibited.

In February, 2008, the FASB issued FSP No. 157-2, "Effective Date of FASB Statement No. 157," which delays for one year the effective date of FASB Statement No. 157, "Fair Value Measurements," for nonfinancial assets and nonfinancial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). The delay is intended to allow additional time to consider the effect of various implementation issues that have arisen, or that may arise, from the application of SFAS 157, which became effective for fiscal years beginning after November 15, 2007 (and for interim periods within those years). The requirements of FSP No. 157-2 will be effective for the Corporation's Fiscal 2010 and are not expected to have a material impact on the Corporation's financial statements.

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133" ("SFAS 161"). This statement is intended to improve transparency in financial reporting by requiring enhanced disclosures of an entity's derivative instruments and hedging activities and their effects on the entity's financial position, financial performance and cash flows. SFAS 161 applies to all derivative instruments within the scope of SFAS 133, "Accounting for Derivative Instruments and Hedging Activities". The effective date for SFAS 161 is fiscal years and interim periods beginning after November 15, 2008 (the Corporation's Fiscal 2010), with early application encouraged. The Corporation is currently reviewing SFAS 161 and does not expect its adoption to have a material impact on the Company's financial statements.

In April 2008, the FASB issued FSP No. 142-3, "Determination of the Useful Life of Intangible Assets." This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"). The objective of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141(R), and other U.S. generally accepted accounting principles. This FSP applies to all intangible assets,

whether acquired in a business combination or otherwise and shall be effective for financial statements issued for fiscal years beginning after December 15, 2008, (the Corporation's Fiscal 2010) and interim periods within those fiscal years and applied prospectively to intangible assets acquired after the effective date. Early adoption is not permitted. The requirements of this FSP are not expected to have a material impact on the Company's 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, \$11,320,640 and \$11,761,280 for the years ended March 31, 2009, 2008 and 2007, respectively. During Fiscal 2009 and Fiscal 2008, the Corporation issued 4,896,000 and 4,352,000 shares of its common stock to Sun Pharma Global Inc. in exchange for 4,896,000 and 4,352,000 preferred shares, valued at \$35,055,360 and \$26,768,880, respectively.

### *Other Cash Flows Information*

There was no cash paid for interest during Fiscal 2009 and Fiscal 2008, while approximately \$28,000 was paid for interest during Fiscal 2007. During Fiscal 2009 and Fiscal 2008, the Company paid approximately \$15,600,000 and \$24,210,000, respectively, of federal income taxes. No such payments were made in Fiscal 2007.

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

Accounts receivable and related allowances are summarized as follows:

	March 31,	
	2009	2008
Accounts receivable - gross	\$ 71,842,197	\$ 220,223,027
Allowances:		
Chargebacks and rebates	50,028,000	78,905,000
Sales returns and allowances	6,555,000	5,273,000
Doubtful accounts	78,000	118,000
Total allowances	56,661,000	84,296,000
Accounts receivable, net of allowances	\$ 15,181,197	\$ 135,927,027

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

	Total Allowances
<b>Balance at March 31, 2007</b>	<b>\$ 36,490,000</b>
Additions charged to net sales	288,584,000
Deductions allowed to customers	(240,778,000)
<b>Balance at March 31, 2008</b>	<b>\$ 84,296,000</b>
Additions charged to net sales	311,171,000
Deductions allowed to customers	(338,806,000)
<b>Balance at March 31, 2009</b>	<b>\$ 56,661,000</b>

#### 4. INVENTORIES

Inventories consist of the following amounts:

	March 31	
	2009	2008
Raw materials	\$ 17,954,511	\$ 9,803,735
Goods in transit	29,236,869	46,002,600
Work in process	9,279,009	7,308,480
Finished goods (Manufactured)	9,749,721	7,953,293
Finished goods (Distributed)	13,290,722	227,597,572
<b>Total inventories</b>	<b>\$ 79,510,832</b>	<b>\$ 298,665,680</b>

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, 2009 includes materials purchased in the amount of \$2,875,885 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, 2009, 2008 and 2007, the Corporation purchased inventory components of approximately \$8.4 million, \$498.5 million and \$38.8 million, respectively, from Sun Pharma. (Also see Note 11).

## 5. DEBT

### *Loans Payable to Financial Institutions*

During the third quarter of Fiscal 2009, the Corporation renewed its one-year, \$10 million Credit Agreement with JP Morgan Chase Bank, N.A., which will expire on November 30, 2009. Under the Credit Agreement, the lender may make loans and issue letters of credit to the Corporation for working capital needs and general corporate purposes. Letters of credit, if issued, expire one year from their date of issuance, but no later than November 30, 2009. Borrowings are secured by the Corporation's receivables and inventory. Interest is payable based on a LIBOR Rate or an alternate base rate (determined by reference to the prime rate or the federal funds effective rate), as selected by the Corporation. The rate of interest is LIBOR plus 75 basis points, or the bank's prime rate minus 100 basis points (provided the prime rate is not less than the prevailing one month LIBOR Rate plus 250 basis points). The effective rates were 1.25% and 2.25%, respectively, at March 31, 2009. The Credit Agreement requires that certain financial covenants be met on a quarterly basis. There were no borrowings under this Credit Agreement at March 31, 2009.

During the fourth quarter of Fiscal 2009 the Company entered into a term loan of \$18 million with RBS Citizens, N.A. d/b/a Charter One Bank ("Charter One Bank"). The loan is secured by a mortgage covering the Company's manufacturing facility and equipment located in Detroit, Michigan. The rate of interest is calculated as LIBOR plus an applicable margin thereto (based upon various leverage levels and current applicable rate is 50 basis points). The aggregate rate applicable to the Company as of March 31, 2009 was 2.01%. The principal loan payments and accrued interest are payable on a quarterly basis beginning July 2009. The principal is to be repaid in equal quarterly installments of \$900,000 for ten quarters through October 2011, and thereafter, if not renewed, the remaining balance of \$9 million is due in January 2012. The Company expects that the term loan will be renewed, and the loan amortization is expected to occur over 20 equal quarterly installments of \$900,000 each.

The following is a schedule of annual future payments of debt installments:

<u>Fiscal Year</u>	<u>Amount</u>
2010	\$ 2,700,000
2011	3,600,000
2012	11,700,000
	\$ 18,000,000

As required pursuant to the terms of the Loan Agreement, the Company has entered into an Interest Rate Swap Agreement with Charter One Bank to hedge the interest rate applicable on the loan. The notional amount for the swap is \$18 million which will amortize down as principal payments are made on the related debt. The annualized fixed rate of interest as it applies to this agreement is 2.41%. Thus as of March 31, 2009 the effective rate of interest to the Company for the term loan was 2.91% (2.41% swap rate plus applicable margin of 50 basis points). The fair value of this swap agreement at March 31, 2009 was not material.

**6. INCOME TAXES**

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

	March 31,		
	2009	2008	2007
Current	\$ 12,402,553	\$ 24,353,492	\$ 538,059
Deferred benefit	(3,487,195)	(17,347,675)	(538,059)
<b>Total</b>	<b>\$ 8,915,358</b>	<b>\$ 7,005,817</b>	<b>\$ —</b>

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

	2009	2008	2007
Provision for income taxes at statutory rates	\$ 10,308,528	\$ 14,837,872	\$ 9,131,761
Change in valuation allowance	—	(6,962,422)	(8,642,636)
Permanent items	(557,849)	107,174	9,905
Other	(835,321)	(976,807)	(499,030)
<b>Income tax expense</b>	<b>\$ 8,915,358</b>	<b>\$ 7,005,817</b>	<b>\$ —</b>

Deferred taxes consist of the following:

	March 31, 2009	March 31, 2008
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ 797,631	\$ 1,063,509
Intangibles	26,458,255	28,865,403

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-K

Other		417,136		361,706
Total deferred tax assets	\$	27,673,022	\$	30,290,618
Deferred tax liabilities:				
Intangibles	\$	6,180,987	\$	12,361,975
Depreciation		657,165		580,968
Total deferred tax liabilities	\$	6,838,152	\$	12,942,943
Net deferred tax assets	\$	20,834,870	\$	17,347,675

F-25



The Company had net deferred tax assets of \$20.8 million and \$17.3 million at March 31, 2009 and March 31, 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 recorded an income tax provision of \$8.9 million and \$7.0 million during Fiscal 2009 and Fiscal 2008, respectively. No such provision or benefit was recorded for Fiscal 2007 due to the reversal of valuation allowances previously offsetting deferred tax assets. The Company has not provided for any valuation allowance as of 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, 2009, 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 2010 and Fiscal 2012.

The Company adopted FASB Interpretation 48, Accounting for Uncertainty in Income Taxes ("FIN 48"), at the beginning of Fiscal 2008. The Company had determined that no adjustments for unrecognized tax benefits were necessary as a result of the adoption of FIN 48. There are no unrecognized tax benefits present at March 31, 2009.

The Company is subject to U.S. federal income tax as well as income tax in certain state jurisdictions. The Company had not previously been a subject of an IRS examination however the IRS has recently initiated an examination of the Company's tax return for the fiscal year ended March 31, 2007. The Company believes that it has complied with applicable IRS Codes and regulations, for the period under review. The Company's federal statute of limitations has expired for years prior to 2003.

In July 2007, the State of Michigan signed into law the Michigan Business Tax Act ("MBTA"), replacing the Michigan Single Business Tax with a business income tax and a modified gross receipts tax. This new tax took effect January 1, 2008, and because the MBTA is based or derived from income-based measures, the provisions of SFAS No. 109, Accounting for Income Taxes, apply as of the enactment date. The law, as amended, established a deduction to the business income tax base if temporary differences associated with certain assets results in a net deferred tax liability as of December 31, 2007 (the year of enactment of this new tax). This deduction has a carryforward period to at least tax year 2029. This new tax had an immaterial effect on the results of operations.

## **7. STOCKHOLDERS' EQUITY**

### ***Common Stock***

The Corporation granted 45,000 shares of common stock on May 2, 2005 to its 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, \$119,000 and \$119,000 related to the portion of the stock grant that vested during Fiscal 2009, Fiscal 2008 and Fiscal 2007, respectively. During Fiscal 2009 the Corporation granted 10,000 shares of common stock to its Chief Executive Officer, which vested on May 2, 2008. The Corporation recorded compensation expense of \$169,900 relating to this stock grant.

### ***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, 2009, 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, 2009. During Fiscal 2009, 4,896,000 shares of the preferred stock were converted into an equal number of shares of Corporation's common stock at a value of \$35,055,360, while 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, 2009, 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, 2009, 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 replaces 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

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-K

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:

	Year Ended March 31, 2009		Year Ended March 31, 2008		Year Ended March 31 2007	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding, beginning of year	161,000	\$ 10.83	165,900	\$ 7.36	141,400	\$ 3.93
Granted	86,500	14.20	52,000	14.31	74,000	9.78
Exercised	(1,000)	11.25	(36,700)	3.26	(48,400)	1.03
Terminated	(19,500)	14.34	(20,200)	4.80	(1,100)	8.83
Outstanding, end of year	227,000	\$ 11.81	161,000	\$ 10.83	165,900	\$ 7.36
Options exercisable, end of year	102,000	\$ 9.84	52,000	\$ 8.93	61,233	\$ 3.95

Options at March 31, 2009:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Shares	Remaining Contractual Life *	Exercise Price *	Shares	Exercise Price *
\$4.01 to \$5.00	4,500	5.9	\$ 4.08	—	\$ —
\$5.01 to \$7.00	4,500	5.8	5.31	—	—
\$7.01 to \$8.00	4,500	4.4	7.61	1,500	7.90
\$8.01 to \$9.00	47,000	2.2	8.38	46,000	8.38
\$9.01 to \$10.00	46,000	3.1	9.35	31,667	9.35
\$10.01 to \$13.00	9,500	3.5	12.17	6,500	12.14
\$13.01 to \$18.00	111,000	4.9	15.00	16,333	14.19
Total	227,000	3.7	\$ 11.81	102,000	\$ 9.84

\*Weighted average

The estimated fair value as of the date options were granted during the fiscal years ended March 31, 2009, March 31, 2008 and March 31, 2007 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, 2009	Year ended March 31, 2008	Year ended March 31, 2007
	\$ 4.78	\$ 7.15	\$ 4.08

## Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-K

Weighted average estimated fair value per share of options granted during the period

### Assumptions

Common stock price volatility	39.6%	39.9%	36.5%
Risk free rate of return	3.0%	4.6%	4.7%
Expected option term (in years)	4	4	6
Average dividend yield	0%	0%	0%

F-28

---

*Other Common Stock Option Agreements*

The Corporation had issued other stock options outside of the 1999 Plan and 2008 Plan. These stock options have been issued with various vesting schedules and expired at various dates through October 2006. Activity with respect to these options is summarized as follows:

	Year Ended March 31, 2009		Year Ended March 31, 2008		Year Ended March 31, 2007	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding, beginning of period	200,000	\$ 3.50	200,000	\$ 3.50	200,000	\$ 3.50
Exercised	—	—	—	—	—	—
Outstanding, end of period	200,000	\$ 3.50	200,000	\$ 3.50	200,000	\$ 3.50
Options exercisable, end of period	200,000	\$ 3.50	200,000	\$ 3.50	200,000	\$ 3.50

Options at March 31, 2009:

Options Outstanding and Exercisable			
Range of Exercise Prices	Shares	Remaining Contractual Life	Exercise Price
\$3.01 to \$4.00	200,000	—	\$ 3.50

The Corporation accounts for its stock-based compensation plans in accordance with Statement of Financial Accounting Standards (“SFAS”) No. 123 (Revised 2004), “Share-Based Payment” (Statement No. 123 (R)), which requires employee share-based compensation to be accounted for under the fair value method and requires the use of an option pricing model for estimating the fair value of stock options at the date of grant.

The 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, 2009, the Corporation has recognized expense amounting to \$325,075 related to common stock options, as compared to \$284,649 for the year ended March 31, 2008 and \$145,787 for the year ended March 31, 2007. As of March 31, 2009, total unrecognized compensation cost related to common stock options granted was \$509,048. The unrecognized stock option compensation cost is expected to be recognized over a period of approximately 3 to 5 years.

Options to purchase 86,500, 52,000 and 74,000 shares of common stock were granted for the years ended March 31, 2009, 2008 and 2007, respectively, to the independent directors, and certain officers and employees of the Corporation.

The Corporation granted options to purchase 40,000 shares of common stock each on August 9, 2007 and June 11, 2006, respectively, to its Chief Executive Officer, which vest at a rate of 1/3<sup>rd</sup> on each anniversary date until they are fully vested on August 9, 2010 and June 11, 2009, respectively. Additionally, the Company recorded an expense of \$169,900 related to a stock grant of 10,000 common shares issued to the CEO on May 2, 2008 as part of his employment agreement, which vested immediately upon issuance.

#### ***Strategic Alliance Stock Options Agreement***

Pursuant to an agreement between the Corporation and an unaffiliated large generic pharmaceutical corporation, dated October 1, 1993, the Corporation was to receive the formulations, technology, manufacturing processes and know-how, and other relevant information, and to pay for the bio-equivalency studies required for the preparation of ANDAs for two products. Pursuant to the agreement, the Corporation was required to pay (i) a Sign-Up Option to purchase 100,000 shares of Common Stock at \$3.50 per share; and (ii) a Product Option to purchase shares at an exercise price of \$3.50 per share. These options may be exercised and payment for shares may be made only out of royalties and any interest earned on the royalties while held by the Corporation. No options have yet been exercised (See Note 12).

### **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.

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 \$1,156,874, \$524,271 and \$314,917 for the years ended March 31, 2009, 2008 and 2007, 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, 2009:

Fiscal Year	Amount
2010	\$ 789,533
2011	789,533
2012	789,533
2013	793,536
2014	837,591
Thereafter through 2018	3,280,565
	\$ 7,280,291

#### 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 \$172,675, \$152,483 and \$72,876 for the years ended March 31, 2009, 2008 and 2007, respectively.

#### 11. CONCENTRATIONS AND COMMITMENTS

##### *Major Customers*

Shipments to three wholesalers, Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health, accounted for approximately 45% of net revenues for the year ended March 31, 2009. The approximate percentage of net revenues attributable to each of these wholesalers is 9%, 16% and 20%, respectively. Shipments to Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health accounted for approximately 57% and 58% of net revenues for the years ended March 31, 2008 and 2007, respectively, or 8%, 28% and 21% for Fiscal 2008 and 11%, 30% and 17% for Fiscal 2007, respectively. Balances due from these customers represented approximately 47% and 66% of gross accounts receivable at March 31, 2009 and 2008, 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. This includes sales to the Veterans Administration, an agency of the United States Government. The Company's contracts with the Veterans Administration have expired,

and due to the Company's recent product recalls and status with the FDA, the Veterans Administration has not renewed the contracts. 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. No other single customer accounted for more than 10% of net sales for Fiscal 2009 or Fiscal 2008. The loss of any of these customers could have a materially adverse effect on short-term operating results.

***Major Products***

Shipments of three products, accounted for 57% of net revenue for the year ended March 31, 2009. Two products and four products accounted for approximately 55% of net revenue for the year ended March 31, 2008 and 69% of net revenue for the year ended March 31, 2007, respectively.

Approximately 69%, 66% and 79% of raw material purchases for the years ended March 31, 2009, 2008 and 2007, respectively, were made from Sun Pharma. The Corporation, however, believes that other sources of raw materials are available. The Corporation currently purchases 27 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 and the union expect to enter into a new agreement.

**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.



As previously disclosed, on September 29, 2006, Schering Corporation (“Schering”) filed a complaint in the United States District Court for the District of New Jersey (“the New Jersey action”). A nearly identical complaint was filed on October 5, 2006, in the Eastern District of Michigan (“the Michigan action”). Both complaints allege, inter alia, that Sun Pharmaceutical Industries Ltd’s (“Sun”) filing of an ANDA seeking approval to market its generic version of Schering’s Clarinex® (desloratadine) drug product infringed Schering’s U.S. Patent No. 6,100,274 (“the ‘274 patent”), which expires July 7, 2019. Schering further alleges that the Company either directly infringed the ‘274 patent by aiding in the filing of Sun’s ANDA, or will induce others to infringe by marketing and/or selling Sun’s generic version of Clarinex® upon receiving FDA approval. Schering’s complaint seeks an order from the Court which, among other things, directs the FDA not to approve Sun’s ANDA any earlier than the claimed expiration date. On August 17, 2007, the New Jersey action was consolidated with other patent infringement cases filed by Schering against other ANDA filers for Schering’s Clarinex® drug product, while the Michigan action was stayed pending the outcome of the New Jersey action. The ANDA filed by Sun contains a Paragraph IV certification challenging the ‘274 patent. Sun believes that the ‘274 patent is invalid, unenforceable and/or will not be infringed by Sun’s or the Company’s manufacture, use or sale of the product. Sun further believes it is one of several first generics to file a Paragraph IV certification for this drug product. Sun and the Company reached an agreement with Schering dismissing this litigation without prejudice.

Schering filed an additional complaint in the District of New Jersey on November 14, 2008 alleging that Sun’s filing of an ANDA seeking approval to market its generic version of Schering’s Clarinex® drug product infringed Schering’s U.S. Patent No. 7,405,223 (“the ‘223 patent”), which issued on July 29, 2008 and expires January 7, 2020 (with pediatric exclusivity). Schering further alleges that the Company either directly infringed the ‘223 patent by aiding in the filing of Sun’s ANDA, or will induce others to infringe by marketing and/or selling Sun’s generic version of Clarinex® upon receiving FDA approval. Schering’s complaint seeks an order from the Court which, among other things, directs the FDA not to approve Sun’s ANDA any earlier than the claimed expiration date. On December 12, 2008 the ‘223 action was consolidated with another patent infringement case brought by Schering against Orgenus Pharma Inc. and Orchid Chemicals & Pharmaceuticals, Ltd. Sun believes that the ‘223 patent is invalid, unenforceable and/or will not be infringed by Sun’s or the Company’s manufacture, use or sale of the product.

On January 15, 2009, the Company, Sun, and Schering reached a settlement agreement as to all pending actions involving the ‘274 and ‘223 patents. The District of New Jersey subsequently entered orders dismissing Schering’s claims against Sun and the Company with respect to the ‘274 patent on February 13, 2009 and with respect to the ‘223 patent on March 16, 2009. The settlement agreement and proposed license agreement have been submitted to the United States Federal Trade Commission (“FTC”) and Department of Justice (“DOJ”) pursuant to Section 1112(a) of the Medicare Prescription Drug, Improvement, and Modernization Act.

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 viii statement with regard to the patent’s method claim. The Company believes that this Novo Nordisk patent is invalid and/or will not be infringed by the Company’s manufacture, use or sale of the product. The Company believes that it is the first to file an ANDA with a Paragraph IV certification for this drug product and it intends to defend this action vigorously to capitalize on the potential for obtaining 180 days exclusivity available for this product. The Company has filed motions for summary judgment of patent invalidity and non-infringement, both of which are pending. Caraco has also sought leave to supplement its answer and counterclaims to challenge a recent Orange Book use code amendment by Novo Nordisk in reference to Prandin®. Trial is scheduled for September 21, 2009.

As previously disclosed, on July 10, 2006, Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S (collectively, “Forest”) filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Company’s filing of an ANDA seeking approval to market its generic version of Forest’s Lexapro® (escitalopram oxalate) drug product infringed Forest’s Patent No. Re. 34,712, which is set to expire on September 13, 2011 based on a patent term extension (extended to March 14, 2012 based upon a six month pediatric exclusivity). Forest 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 Paragraph IV Certifications challenging Forest’s Patent Nos. Re. 34,712 (“the ‘712 patent”), as well as two other patents, the 6,916,941 (“the ‘941 patent”) and 7,420,069 (“the ‘069 patent”). The Company believes that it does not infringe any valid claims of the ‘712, ‘941 and ‘069 patents by the Company’s manufacture, use or sale of the product. Forest’s suit alleges only that Caraco infringes the ‘712 patent, which the Company intends to vigorously defend. Sun Pharmaceutical Industries Limited, the parent corporation of Caraco, is also a party to the case. Trial in the case, which was originally scheduled for April 2009, was adjourned through at least June 16, 2009. A new trial date has not been set.

Forest did not assert the ‘941 patent or ‘069 patent against Caraco. On February 20, 2007, Caraco brought a declaratory judgment action in the Eastern District of Michigan court against Forest seeking a declaration that its generic version of Lexapro® will not infringe the ‘941 patent. On April 13, 2007, Forest granted Caraco a covenant not to sue on the ‘941 patent, and the court, in May 2007, dismissed the case for lack of a controversy. Caraco filed a notice of appeal of that dismissal on June 8, 2007 before the U.S. Court of Appeals for the Federal Circuit. On April 1, 2008, the Federal Circuit granted Caraco’s appeal, holding that an actual case or controversy did exist and that Caraco should be

allowed to maintain its declaratory judgment action regarding the '941 patent. Forest's request for a rehearing of Caraco's appeal *en banc* was denied. Forest filed a petition for a writ of certiorari to challenge this decision with the Supreme Court, which was also denied. On January 26, 2009, Caraco brought a similar declaratory judgment action in the Eastern District of Michigan court against Forest seeking a declaration that its generic version of Lexapro® will not infringe the '069 patent, a related patent newly obtained by Forest in September of 2008. The '941 and '069 cases are currently in discovery; both are expected to go to trial in late 2009.

As previously disclosed, on September 22, 2004, Ortho-McNeil Pharmaceutical, Inc. ("Ortho-McNeil") filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Company's filing of an ANDA seeking approval to market its generic version of Ortho-McNeil's Ultracet® brand tramadol/acetaminophen drug product infringed Ortho-McNeil's patent, which expires on September 6, 2011. Ortho-McNeil sought an order from the district court which, among other things, directed the FDA not to approve the Company's ANDA any earlier than the claimed expiration date. The ANDA filed by the Company contains a Paragraph IV Certification challenging the Ortho-McNeil patent. The Company asserted that the Ortho-McNeil patent is invalid and/or will not be infringed by the Company's manufacture, use or sale of the product. Since filing this action, Ortho-McNeil authorized a generic manufacturer to provide a generic version of Ortho-McNeil's Ultracet® product while another manufacturer launched its approved generic at risk. On October 19, 2005, the Company's motion for summary judgment was granted. On December 19, 2005, the FDA approved the manufacture, use and sale of the Company's generic product. Ortho-McNeil filed an appeal of the finding of noninfringement by the district court with the United States Court of Appeals for the Federal Circuit. On January 19, 2007, the United States Court of Appeals for the Federal Circuit affirmed the lower court's decision granting the Company's motion for summary judgment.

Additionally, the United States Patent and Trademark Office approved Ortho-McNeil's request for a reissue patent. Although the district court had determined that the Company does not infringe Ortho-McNeil's original patent, on July 31, 2006, Ortho-McNeil filed a lawsuit against the Company in the United States District Court for the District of New Jersey, alleging that the Company's generic version of Ultracet® brand tramadol/acetaminophen drug product infringes its reissue patent. On September 26, 2006, the Company filed an answer denying, among other things, that its generic product infringes any valid claims of Ortho-McNeil's reissue patent. On December 10, 2007, the Company filed a motion for summary judgment that the asserted claims of the reissue patent were obvious and therefore invalid as a matter of law. This motion was granted by Judge Cavanaugh of the District of New Jersey on April 17, 2008. Final judgment has been granted. On August 25, 2008, Ortho-McNeil filed a notice of appeal with respect to that judgment with the United States Court of Appeals for the Federal Circuit. The appeal has been fully briefed and is scheduled for oral argument on July 7, 2009.

On February 24, 2009, MedImmune LLC filed a complaint against the Company and Sun in the United States District Court for the District of Maryland. The complaint alleges

that Caraco has willfully infringed U.S. Patent Nos. 5,424,471 and 5,591,731 by offering to sell or selling a generic version of the drug Ethyol® in the United States. The complaint seeks trebled damages. The Company denies infringement and contends that the patents in suit are invalid and unenforceable. The Complaint is related to *MedImmune Oncology, Inc. v. Sun Pharmaceuticals Industries Ltd.*, 1:04-cv-02612-MJG, which is pending in the District of Maryland and involves the same patents. A trial in the related action is scheduled to begin September 30, 2009.

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 attorney's 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.

The Company is also involved in certain other legal proceedings from time to time incidental to normal business activities. While the outcome of any such proceedings cannot be accurately predicted, the Company does not believe the ultimate resolution of any existing matters would have a material adverse effect on its financial position or results of operations.

#### ***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.

#### ***Royalty Accrual***

Pursuant to the Strategic Alliance Stock Options Agreement (See Note 8), Caraco received the formulation for one product, Metoprolol Tartrate, in March 1995. However, Caraco has determined that the formula provided to it with respect to Metoprolol Tartrate is different than the formula submitted in an ANDA to the FDA in 1995, approved by the FDA in 1996 and manufactured and introduced by Caraco since 1997. The Corporation has accrued royalties of approximately \$1 million, which is included with accrued expenses in the accompanying balance sheets at March 31, 2009 and 2008, and since April 2003, has discontinued to accrue royalties related to this agreement.

***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 two definitive agreements for two additional products. These agreements contain for one product, 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. 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 subsequent to end of Fiscal 2009, the Company entered into one more agreement relating to one additional product. This brings the total number of products being developed by unaffiliated third party developers to six. 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 \$83,000, \$200,000 and \$161,000 in milestone payments were made in Fiscal 2009, Fiscal 2008 and Fiscal 2007, respectively. Collectively, as of March 31, 2009, future milestone payments, assuming all of the conditions are satisfied and not including profit-sharing which cannot be estimated, will amount to approximately \$680,000 spread over a period of more than three years.

***Regulatory Matters***

During Fiscal 2009, the FDA inspected the Company's manufacturing facility located in Detroit, Michigan and issued a warning letter related to deficiencies noted during their inspection. The FDA has indicated that failure to promptly correct these deficiencies may result in enforcement action or withholding of approvals for pending new drug applications. The Company responded to the warning letter for the deficiencies noted and provided its corrective actions. Subsequently the FDA commenced a follow-up inspection which has since been concluded. Observations were provided to the Company on Form 483. The Company has committed to provide a formal response to the FDA within the stipulated period. Further, the Company voluntarily initiated two recalls, reducing pre-tax income by approximately \$4.7 million, that were initiated with the knowledge of the FDA as a precautionary measure in conjunction with the ongoing inspections.

**13. SEGMENT INFORMATION**

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

F-37

---

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-K

Category	Year Ended March 31, 2009		Year Ended March 31, 2008		Year Ended March 31, 2007	
	Sales	Gross Profit	Sales	Gross Profit	Sales	Gross Profit
Manufactured Products	\$ 111,754,209	\$ 48,132,508	\$ 125,251,055	\$ 61,342,641	\$ 112,467,447	\$ 56,426,473
Distributed Products	225,423,273	19,662,047	225,115,634	23,372,509	4,559,569	1,357,685
Total	\$ 337,177,482	\$ 67,794,555	\$ 350,366,689	\$ 84,715,150	\$ 117,027,016	\$ 57,784,158

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.

F-38

Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-K

The Corporation's net sales, grouped by therapeutic categories, for the years ended March 31, 2009, 2008 and March 31, 2007 are as follows:

Therapeutic Category	Net Sales Year Ended March 31, 2009	Net Sales Year Ended March 31, 2008	Net sales Year Ended March 31, 2007
Analgesic	\$ 344,920	\$ —	—
Anorectic	1,757,126	266,230	—
Antiallergic Drugs	2,076,743	2,194,004	—
Antianxiety Drug	3,733,838	4,563,207	4,035,902
Antibiotic	424,934	417,941	506,592
Anticonvulsant	43,013,058	73,850,445	4,293,332
Antidepressant	13,781,861	16,294,454	14,053,823
Antidiabetic	20,162,183	23,394,110	30,056,770
Antiemetic	10,978	—	—
Anti-gout	803,505	132,687	—
Antihypertensive Drug/Beta Blocker	20,271,051	22,700,396	19,751,939
Antipsychotic	7,465,342	5,936,243	3,530,898
Antithyroid Agents	735,277	1,568	—
Antitussive	89,451	—	—
Anti Ulcerants	149,583,614	134,735,991	—
Bisphosphonate Derivative	148,843	—	—
Calcium Channel Blocker	9,174,500	7,709,527	—
Cardiac	6,844,618	2,893,926	2,446,608
Decongestants	—	—	62,814
Narcotic Analgesics	156,586	165,860	—
Nonsteroidal Antiinflammatory Agent	4,437,107	3,154,862	2,886,593
Opiate Agonist/Analgesic	28,652,439	38,567,526	31,257,560
Oncology Adjunct	16,839,293	3,816,026	—
Parkinson's Disease	1,110,877	4,227	—
Platelet Aggregation Inhibitor	164,013	211,345	206,185
Sedatives & Hypnotics	883,799	1,642,383	—
Skeletal Muscle Relaxant	3,232,998	3,935,676	2,902,770
Vascular and Migraine Headache Suppressant	1,278,528	3,778,055	1,035,230
<b>Net Sales</b>	<b>\$ 337,177,482</b>	<b>\$ 350,366,689</b>	<b>\$ 117,027,016</b>

\* \* \*

F-39

**EXHIBIT INDEX**

- 3.01 Registrant's Amended and Restated Articles of Incorporation, as amended. (1)
- 3.02 Certificate of Amendment to the Articles of Incorporation filed February 13, 1997. (2)
- 3.03 Certificate of Amendment to the Articles of Incorporation filed February 10, 2000. (3)
- 3.04 Certificate of Determination of Rights, Privileges and Preferences Series B Preferred Stock. (4)
- 3.05 Registrant's Amended and Restated Bylaws. (5)
- 3.06 Certificate of Amendment to Articles of Incorporation filed December 28, 2006 (17)
- 10.01 Agreement, dated as of October 1, 1993, among Registrant and Non-Affiliate (6)
- 10.02 Employment Agreement, dated October 22, 1993, of Robert Kurkiewicz. (6)
- 10.03 Stock Purchase Agreement by and between Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries Limited dated as of April 23, 1997. (7)
- 10.04 Products Agreement by and between Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries Limited dated as of April 23, 1997. (7)
- 10.05 Registration Rights Agreement dated as April 1997. (7)
- 10.06 Amendment to Employment Agreement of Robert Kurkiewicz dated as of April 1, 1997. (8)
- 10.07 1999 Equity Participation Plan. (9)
- 10.08 Renewal to Employment Agreement of Robert Kurkiewicz dated as of January 1, 1999. (3)
- 10.09 Third Amendment to Employment Agreement of Robert Kurkiewicz dated August 30, 2002. (3)
- 10.10 Agreement between Caraco and Sun Pharma Global, Inc. dated November 21, 2002. (4)
- 10.11 Sales contract with government vendor. (4)
- 10.12 Employment Agreement of Mr. Singh (5)
- 10.13 Employment Agreement of Mr. Movens (10)
- 10.14 Confidentiality and Non-Competition Agreement of Dan Movens (10)
- 10.15 Credit Agreement with JPMorgan Chase Bank, N.A. (12)
- 10.16 Form of Grant of Employee Stock Option (13)
- 10.17 Marketing Agreement between Caraco and Sun Pharmaceutical Industries Limited (14)



- 10.18 Form of Stock Option Agreement – Daniel H. Movens (15)
  - 10.19 Form of Restricted Stock Agreement – Daniel H. Movens (15)
-

## Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-K

- 10.20 Distribution and Sale Agreement between Caraco and Sun Pharmaceutical Industries Limited. (16)
- 10.21 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. (18)
- 10.22 2008 Equity Participation Plan (19)
- 10.23 Loan Agreement with RBS Citizens N.A. (+)
- 21 Subsidiaries of the Registrant (+)
- 23.01 Consent of Independent Registered Public Accounting Firm (+)
- 24.1 Power of Attorney (included on signature page) (+)
- 31.1 Certificate of Chief Executive Officer (+)
- 31.2 Certificate of Chief Financial Officer (+)
- 32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (+)

+ Filed herewith

- (1) Incorporated by reference from Exhibits to Registrant's Form 10-KSB filed on or about March 30, 1995.
- (2) Incorporated by reference from Exhibits to Registrant's Form 10-KSB filed on or about March 31, 1997.
- (3) 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.
- (4) Incorporated by reference from Exhibits to Registrant's Form 10-KSB filed on or about March 31, 2003,.
- (5) Incorporated by reference from Exhibit to Registrant's Form 10-K filed on or about March 15, 2005,.
- (6) 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.
- (7) Incorporated by reference from Exhibits to Registrant's Form 10-QSB filed on November 14, 1997 as.
- (8) Incorporated by reference from Exhibits to Registrant's Form 10-KSB filed on or about March 31, 1998, as.
- (9) Incorporated by reference from Appendix A to Registrant's Proxy Statement dated April 28, 1999 as.
- (10) Incorporated by reference from Exhibits to Registrant's Form 10-K/A filed on or about May 2, 2005,.
- (11) Incorporated by reference from Exhibits to Registrant's Form 8-K filed on or about August 25, 2005.



Edgar Filing: CARACO PHARMACEUTICAL LABORATORIES LTD - Form 10-K

- (12) Incorporated by reference from Exhibits to Registrant's Form 10-Q filed on or about January 26, 2006.
  - (13) Incorporated by reference from Exhibits to Registrant's Form 10-K filed on or about June 14, 2006.
  - (14) Incorporated by reference from Exhibits to Registrant's Form 8-K/A filed on or about November 5, 2007.
  - (15) Incorporated by reference from Exhibits to Registrant's Form 10-Q filed on or about October 25, 2007.
  - (16) Incorporated by reference from Exhibits to Registrant's Form 8-K filed on or about January 31, 2008.
  - (17) Incorporated by reference from Exhibits to Registrant's For S-8 filed on April 7, 2009.
  - (18) Incorporated by reference from Exhibits to Registrant's Form 10-K filed on June 10, 2008.
  - (19) Incorporated by reference from Exhibits to Registrant's Proxy Statement filed on July 29, 2008.
-