CARACO PHARMACEUTICAL LABORATORIES LTD
Form 10-K
June 10, 2008

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

FORM 10-K

(Mark one)

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

For the Fiscal Year ended March 31, 2008

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

Commission File No. 0-24676

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

Michigan	38-2505723
(State of Incorporation)	(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	American Stock Exchange

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 o No x

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 o No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark 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. o

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

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, 2007, the last day of the Registrant's most recently completed second quarter, as reported on the American Stock Exchange, was $145,417,915.

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 9, 2008, there were 32,561,194 shares of common stock outstanding.

Documents Incorporated By Reference:

Portions of the Proxy Statement for the 2008 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") i 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. 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, 2007 to March 31, 2008 ("Fiscal 2008"), and comparative information for the audited fiscal year, April 1, 2006 to March 31, 2007 ("Fiscal 2007"), and for the audited fiscal year, April 1, 2005 to March 31, 2006 ("Fiscal 2006"). Additional information is provided with respect to the transition period (January 1, 2005 through March 31, 2005), which is audited (the "Transition Period") and calendar years ended December 31, 2004 and 2003. (See Item 6 and Item 7 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 has been from Sun Pharma. Sun Pharma has contributed equity capital and has advanced us loans. In addition, among other things, Sun Pharma has 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 70% 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.). We currently have no bank debt. Our cash flow from operations provides the working capital necessary to effectively manage the Company.

Current Status

During Fiscal 2008 we recorded net sales of $350.4 million compared to $117.0 million during Fiscal 2007. We incurred $29.7 million in R&D expense during Fiscal 2008 as compared to $22.4 million during Fiscal 2007. This included $11.3 million during Fiscal 2008 in non-cash R&D expense, as compared to $11.8 million during Fiscal 2007. We generated cash from operations of $27.8 million during Fiscal 2008, as compared to $27.9 million during Fiscal 2007. We earned a net pre-tax income of $42.4 million and $26.9 million during the relevant periods. During Fiscal 2008, we provided an income tax provision of $7.0 million. There was no such provision or benefit for the corresponding period of Fiscal 2007. We earned net income of $35.4 million and $26.9 million during the relevant periods. This level of growth year over year may not be sustainable and is primarily due to the launch of two products during the third and fourth quarter of Fiscal 2008. At March 31, 2008, our inventory increased to $298.7 million from $31.9 million at March 31, 2007. This increase was to support our increased sales levels predominantly for products which we distribute on behalf of Sun Pharma (including the Paragraph IV products launched in the fourth quarter of the current year), and to a lesser extent, for our own manufactured products. At March 31, 2008, we had stockholders' equity of $142.8 million, as compared to stockholders' equity of $95.2 million at March 31, 2007. 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 have selected, through March 31, 2008, all of the 25 products to be transferred to us by Sun Global. All of these 25 products have 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 concludes 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 2008, we have received FDA approval for 12 ANDAs relating to 11 products. We filed eight ANDAs relating to seven products with the FDA during Fiscal 2008. Subsequent to the end of the fiscal year, we received approval for one ANDA relating to one product and filed one ANDA relating to one product This brings our total number of ANDAs pending approval by the FDA to 27 (including four tentative approvals) relating to 19 products.

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 52 prescription products in 114 strengths delivered in various package sizes. Our current products and their indicated usages are set forth in the table below:

Generic Name	Therapeutic Category
Allopurinol	Anti-gout
Amifostine for Injection **	Oncology Adjunct
Amlodipine Besylate Tablets**	Antihypertensive Drug / Beta Blocker
Atenolol	Antihypertensive Drug / Beta Blocker
Baclofen	Skeletal Muscle Releaxant
Carbamazepine Chewable	Anticonvulsant
Carbamazepine IR	Anticonvulsant
Carbidopa and Levodopa ER**	Parkinson Disease
Carisoprodol**	Muscle Releaxant
Carvedilol	Antihypertensive Drug/Beta Blocker
Cetirizine HCl Chewable Tablets	Antiallergic drug
Cetirizine HCl Tablets	Antiallergic drug
Choline Magnesium Trisalicylate	Nonsteroidal Antiinflammatory Agent
Citalopram HBr	Antidepressant
Clonazepam	Seizure, Panic Disorders
Clozapine	Antipsychotic
Digoxin	Cardiac Drug
Flurbiprofen	Nonsteroidal Antiinflammatory Agent
Fluvoxamine	Antidepressant
Gabapentin Capsules**	Anticonvulsant
Gabapentin Tablets**	Anticonvulsant
Glipizide	Antidiabetic
Glipizide/Metformin HCl Tablets	Antidiabetic
Hydrochlorothiazide	Antihypertensive
Meloxicam	Non Steroidal Anti-inflammatory Drug
Meperidine HCl	Narcotic, Analgesic
Metformin HCl	Antidiabetic
Metformin HCl Extended Release**	Antidiabetic
Methimazole Tablets USP	Antithyroid Agent
Metoprolol Tartrate	Antihypertensive Drug/Beta Blocker
Midrin*	Vascular & Migraine Headache suppressant
Mirtazapine	Antidepressant
Nimodipine**	Calcium Channel Blocker
Octreotide Acetate Injection**	Oncology Adjunct

Ondansetron Injection**	Oncology Adjunct
Ondansetron ODT**	Oncology Adjunct
Ondansetron Tablets**	Oncology Adjunct
Oxaprozin	Nonsteroidal Antiinflammatory Agent
Oxcarbazepine**	Anticonvulsant
Pantoprazole**	Anti-ulcerants
Paromomycin Sulfate	Antibiotic
Paroxetine	Antidepressant
Phentermine HCl Tablets	Anorectic
Phenytoin Sodium Extended Release Capsules**	Anticonvulsant
Salsalate	Nonsteroidal Antiinflammatory Agent
Ticlopidine	Platelet Aggregation Inhibitor
Tizanidine	Skeletal Muscle Relaxant
Torsemide **	Diruetic
Tramadol HCl and Acetaminophen Tablets	Opiate Agonist/Analgesic
Tramadol HCl Tablets	Opiate Agonist/Analgesic
Zolpidem	Sedatives & Hypnotics
Zonisamide**	Anticonvulsant

* Product marketed on behalf of Sun Pharmaceutical Industries, Inc., a wholly owned subsidiary of Sun Pharma

**Products marketed on behalf of Sun Pharma.

We have submitted 61 ANDAs to the FDA for approval as of March 31, 2008, including eight filed during Fiscal 2008, which includes one product with multiple ANDAs. Of these 61 ANDAs filed, the FDA has approved 34 through March 31, 2008. Subsequent to the end of the fiscal year, we received approval for one ANDA relating to one product and filed one ANDA relating to one product. Accordingly, we have 27 pending ANDAs (including four tentative approvals) relating to 19 products.

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. Recently, we have begun 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.

On November 21, 2002, we entered into a new products agreement with Sun Global. Under the agreement, 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 has established 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 18 active pharmaceutical ingredients from Sun Pharma and 34 active pharmaceutical ingredients from other third parties. Caraco currently purchases two 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 (see below). 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 2008, Fiscal 2007 and Fiscal 2006, we purchased approximately $498.5 million, $38.8 million and $28.1 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 $0.3 million worth of machinery and equipment during Fiscal 2008 from Sun Pharma and its affiliates as compared to $0.8 million and $0.2 million, respectively, during Fiscal 2007 and Fiscal 2006. Such machinery and equipment was sold to us at Sun Pharma’s cost. 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 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.

In Fiscal 2007, the Company entered into a three-year marketing agreement with Sun Pharma, which was reviewed and approved by the Independent Committee. Under the agreement, the Company purchases selected product formulations offered from 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.

In Fiscal 2008, the Company entered into a three-year distribution and sale agreement with Sun Pharma, which was reviewed and approved by the 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 Company markets and distributes the same as part of our 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 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 margin of 8% on such products, or such other percentages as shall be mutually agreed upon in the future. 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 marketing agreements were $225.1 million during Fiscal 2008 and $4.6 during Fiscal 2007.

During the fiscal years ended March 31, 2008 and March 31, 2007, Sun Global converted 4,352,000 shares and 1,632,000 shares of Series B Preferred Stock into 4,352,000 shares and 1,632,000 shares of Common Stock, respectively. As of March 31, 2008, Sun Pharma's current beneficial ownership is 70%, (76% including its convertible Series B Preferred Stock).

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.

Caraco competes effectively with respect to each of these factors; however, price is 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

Our Company effectively executed its operating plan during Fiscal 2008. Our organization continues to be strengthened to meet the demands of a competitive US generic pharmaceutical market, while providing additional support for our future growth 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 2008, the Company's three largest customers, Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health, accounted for approximately 8%, 28% and 21%, respectively, of the Company's total net sales. The majority of these net sales include sales for various customers of ours that have underlying direct contracts with our Company that are facilitated through our wholesale customers. This includes sales to the Veterans Administration, an agency of the United States Government. During Fiscal 2007 and Fiscal 2006, shipments to Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health, accounted for approximately 11%, 30% and 17%, respectively and 8%, 38% and 14%, respectively, of the Company's total net sales. Balances due from these customers represented approximately 66% and 82% of gross accounts

receivable as at March 31, 2008 and 2007, respectively. No other single customer accounted for more than 10% of net sales for 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 not significantly different from those of the brand-name drug. We perform our own stability testing. Bioequivalence testing is done through independent testing laboratories. 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 coordinate development provided by Sun Pharma and continue 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 2008, Fiscal 2007 and Fiscal 2006 as set forth below:

Fiscal 2008	$29.7 million
Fiscal 2007	$22.4 million
Fiscal 2006	$43.5 million

The non-cash R&D Expense for the Fiscal 2008, Fiscal 2007 and Fiscal 2006 are set forth below:

Fiscal 2008	$11.3 million
Fiscal 2007	$11.8 million
Fiscal 2006	$35.1 million

The non-cash technology transfer charges are for research and product development provided by Sun Global. Series B convertible preferred stock was issued on an ongoing basis 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 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 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 concludes 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 passed 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 bioequivalency 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.

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.

The FDA recently concluded an inspection in February 2008. This specifically addressed a follow up to a voluntary class II recall the Company performed in January 2008 on one strength of its metformin products we currently market. The product recall announced by the FDA was limited to a single compression machine malfunction, and affected two lots. The Company chose to recall seven lots that were produced on that particular machine as an additional safeguard. The Company was issued a notice on Form 483. The Company has responded accordingly and we believe we remain substantially compliant. In May 2008 an investigation was initiated as part of a standard cGMP inspection and pre-approval inspection for three products. We continue to focus on improving the amount of support in both quality assurance and quality control in order to continually improve our performance in quality. 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 output and quality. During Fiscal 2008, in addition to our own internal audits we have retained outside companies to audit both the laboratory and manufacturing areas of our Company in order to improve and or maintain our systems of operation. These audits were based on a historical look back and offered improvements based on Caraco's future requirements.

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 have not submitted an NDA to date.

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 18 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 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

The Corporation has a one-year, $10 million Credit Agreement with JP Morgan Chase Bank, N.A., which expires November 30, 2008. Under the Credit Agreement, the lender may make loans and issue letters of credit to the Corporation for the Corporation's 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, 2008. 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 (effective rates of 3.45% and 4.25%, respectively, as at March 31, 2008.) The Credit Agreement requires that certain financial covenants be met on a quarterly basis. The Corporation is in compliance with these financial covenants as at March 31, 2008. There are no borrowings under this Credit Agreement at March 31, 2008.

Employees

We had a total of 662 and 446 full-time equivalent and contract employees at March 31, 2008 and 2007, 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 our permanent, full-time hourly employees. In September 2004, we successfully negotiated a four-year collective bargaining agreement with the union. This agreement sets forth the minimum wage increases which the union employees will receive in each of the next four years, and thereby giving us and the union employees, we believe, a measure of certainty and stability. The collective bargaining agreement with the union is set to expire in September 2008, whereupon the Corporation and the union expect to enter into a new agreement.

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.

Under these regulations, 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 an inspection, the FDA may issue notices on Form 483 and /or warning letters that could cause us to modify certain activities identified during the inspection. 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. Certain of our vendors that sell to us are also subject to similar regulation and periodic inspections.

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.

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.

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.

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 product that has already been sold to the customer, but are still in their hands. 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 products sales of these product 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 increase 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.

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, we currently 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 its 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.

The Facilities

Our entire property, plant, equipment and intellectual property are free of any mortgages, liens or similar restrictions. 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. 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 will occur on the acreage the Company acquired for $0.3 million directly adjacent to its existing manufacturing facility. Once completed, this will add approximately 140,000 square feet to our manufacturing facility and is expected to be operational by end of Fiscal 2009. In addition, the Company commenced use of its newly acquired packaging facility located in a suburb of Detroit, Michigan. During Fiscal 2007, the Company acquired this packaging facility for $1.7 million. This 33,369 sq. ft. facility was previously owned and operated by a third party packager of our portfolio of products. This acquisition has already improved our overall costs in packaging, bottling and increased our production.

During Fiscal 2008, we have 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 have 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 expires in March 2009 and includes an option to renew until 2011.

We also have leased an approximately 13,000 square foot office space for our administrative, sales and marketing and accounting staff. The lease expires in October 2008.

We have invested approximately $5.1 million during Fiscal 2008 as compared to $6.0 million during Fiscal 2007 and $3.6 million during Fiscal 2006 to upgrade our facilities and production.

We believe the existing facilities are suitable and adequate for our current level of operations and anticipated growth in the near future. We also believe that our facilities are adequately covered by insurance.

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. A nearly identical complaint was filed on October 5, 2006, in the Eastern District of Michigan. Both complaints allege, inter alia, that Sun Pharma's filing of ANDA 78-359 - seeking approval to market its generic version of Schering's Clarinex® drug product - infringed Schering's U.S. Patent No. 6,100,274 ("the '274 patent"), which expires July 7, 2019. Schering further alleges that Caraco Pharmaceutical Laboratories, Ltd. ("Company") either directly infringed the '274 patent by aiding in the filing of Sun Pharma's ANDA, or will induce others to infringe by

marketing and/or selling Sun Pharma'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 Pharma's ANDA any earlier than the claimed expiration date. The ANDA filed by Sun Pharma contains a Paragraph IV certification challenging the '274 patent. Sun Pharma believes that the '274 patent is invalid, unenforceable and/or will not be infringed by Sun Pharma's or Company's manufacture, use or sale of the product and both Sun Pharma and the Company intend to vigorously defend this action in order to capitalize on the potential 180 days of marketing exclusivity available for this product.

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® 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. 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.

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 (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 contained a Paragraph IV Certification challenging the Forest patent. The Company believes that the Forest patent is invalid and/or will not be infringed by the Company's manufacture, use or sale of the product and the Company intends to vigorously defend this action.

Prior to this action, Forest had filed two lawsuits against other manufacturers who sought to market a generic version of Lexapro®, one against Alphapharm Pty. Ltd. ("Alphapharm") and the other against IVAX Pharmaceuticals, Inc. ("IVAX") and CIPLA Ltd. ("CIPLA"). Forest settled the lawsuit with Alphapharm in October 2005, granting Alphapharm the exclusive right to distribute generic versions of Lexapro® for five years. Alphapharm's launch date is dependent on a number of factors but is set to be no later than two weeks before the claimed expiration of the Forest patent.

Forest proceeded in its action against IVAX and CIPLA. On July 13, 2006, Forest obtained an order from the United States District Court for the District of Delaware, holding that IVAX and CIPLA's proposed generic version of Lexapro® infringed the Forest patent and that the asserted claims of the Forest patent were valid and enforceable. On November 6, 2006, IVAX and CIPLA filed a notice to appeal the decision to the United States Court of Appeals for the Federal Circuit. The appeal is currently pending.

On August 23, 2006, Forest filed a motion to transfer its action against the Company to the United States District Court for the District of Delaware, where a similar action by Forest was pending. On November 15, 2006 the Court denied the motion and, accordingly, the litigation will proceed in the Eastern District of Michigan. In February of 2007, the Eastern District of Michigan court granted plaintiff's motion to stay the proceeding until June 20, 2007.

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 related '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 has indicated it plans to request a rehearing of Caraco's appeal *en banc*.

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 contained 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 has entered into a license agreement with another manufacturer which has launched its product generically while another manufacturer has launched its approved generic at risk. On October 19, 2005 the Company's motion for summary judgment was granted. On December 19, 2005, the FDA approved the manufacture, use and sale of the Company's generic product. Ortho-McNeil filed an appeal of the finding of non-infringement by the district court with the United States Court of Appeals for the Federal Circuit. On January 19, 2007, the United States Court of Appeals for the Federal Circuit affirmed the United States District Court for the Eastern District of Michigan decision granting the Company's motion for summary judgment. Additionally the United States Patent and Trademark Office has 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 reissue patent was 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. Ortho-McNeil has indicated it intends to appeal Judge Cavanaugh's ruling.

The Company is also involved in certain 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 2008 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 American Stock Exchange under the symbol "CPD." The following table sets forth for Fiscal 2008, Fiscal 2007 and Fiscal 2006, the high and low sales prices for each of the applicable quarters.

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

Fiscal 2007	**High**	**Low**
First Quarter	$ 13.10	$ 9.00
Second Quarter	$ 11.99	$ 8.15
Third Quarter	$ 14.00	$ 9.98
Fourth Quarter	$ 14.99	$ 10.50

Fiscal 2006	**High**	**Low**
First Quarter	$ 8.97	$ 7.06
Second Quarter	$ 9.29	$ 8.10
Third Quarter	$ 9.81	$ 7.50
Fourth Quarter	$ 13.42	$ 8.76

As of June 9, 2008 there were 84 registered holders of our common stock.

During Fiscal 2008 and 2007, 4,352,000 and 1,632,000 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. During Fiscal 2007, we issued to Sun Global 1,632,000 preferred shares in exchange for the transfer of three products and during Fiscal 2006, we issued to Sun Global 4,896,000 preferred shares in exchange for the transfer of nine products. As of March 31, 2008, all 25 of the products under this agreement have been selected and all of these 25 products have passed their respective bio-equivalency studies. The final product was transferred to Caraco during the third quarter of Fiscal 2008, which concludes 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 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, 2008 and 2007 and summary statements of operations data for the years ended March 31, 2008, 2007 and 2006, 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, 2006, 2005 and December 31, 2004 and the summary of the statements of operations for the Transition period ended March 31, 2005 and years ended December 31, 2004 and 2003 is derived from the audited financial statements of the Company which are not included herein and have been previously filed with the SEC.

Financial Data

(In thousands, except per share data)

Statements of operations data	Year ended March 31, 2008	2007	2006	Transition Period Ended March 31, 2005	Year ended December 31, 2004	2003
Net sales	$ 350,367	$ 117,027	$ 82,789	$ 17,337	$ 60,340	$ 45,498
Cost of goods sold	265,652	59,243	41,873	7,879	24,441	19,507
Gross profit	84,715	57,784	40,916	9,457	35,899	25,991
Selling, general and administrative expenses	14,322	9,880	8,183	1,879	5,277	7,363
Research and development costs – affiliate – non cash	11,321	11,761	35,055	10,200	24,397	3,103
Research and development costs – other	18,366	10,591	8,437	1,720	6,053	3,112
Operating income / (loss)	40,706	25,552	(10,759)	(4,342)	172	12,412
Other income / (expense)	1,688	1,306	336	20	(371)	(1,189)
Income (loss) before income taxes	42,394	26,858	(10,423)	(4,322)	(199)	11,223
Income tax expense	7,006	—	—	—	—	—
Net Income / (Loss)	35,388	26,858	(10,423)	(4,322)	(199)	11,223
Net Income / (Loss) per share						
Basic	1.19	1.02	(0.39)	(0.16)	(0.01)	0.46
Diluted	0.89	0.72	(0.39)	(0.16)	(0.01)	0.44

Weighted Average Shares Outstanding:						
Basic	29,657	26,447	26,392	26,348	24,734	24,137
Diluted	39,914	37,255	26,392	26,348	24,734	25,482

Financial Data (continued)

(In thousands)

Balance Sheet Data	As of March 31, 2008	2007	2006	2005	As of December 31, 2004
Current assets	$ 500,022	$ 95,439	$ 62,282	$ 32,938	$ 24,857
Property, plant and equipment, net	21,267	19,030	14,960	12,897	12,546
Deferred income taxes	16,986	—	—	—	—
Total assets	538,275	114,469	77,242	45,835	37,403
Current liabilities	395,495	19,276	20,864	14,149	11,627
Long term debt	—	—	—	—	—
Total liabilities	395,495	19,276	20,864	14,149	11,627
Stockholders' Equity	142,780	95,193	56,378	31,686	25,776
Working Capital	104,527	76,163	41,418	18,789	13,230

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 Reserves

Our gross sales for Fiscal 2008 were $638.6 million as compared to $316.6 million for Fiscal 2007. Sales allowances, which include chargebacks, returns, discounts, other customary customer deductions and other sales costs, constituted approximately 45% for Fiscal 2008 as compared to 63% for Fiscal 2007. Net sales for Fiscal 2008 were $350.4 million as compared to $117.0 million for Fiscal 2007. The primary cause of the lower sales allowances by almost 18% for Fiscal 2008 is due to the impact of the gross sales versus the net sales on two products (oxcarbazepine and pantoprazole tablets) reflecting lesser discounts between the gross sales and the net sales calculation than the rest of our product line. Sales on this product were a significant portion of our overall sales for the year. Excluding these two products, sales allowances for Fiscal 2008 were 59% as compared to 63% for Fiscal 2007. The lower discount percentage was also due to changes on our wholesale acquisition price (WAC) on various products during the current year to date combined with the change in the mix of customers and products we sell.

The following is a roll forward of the provisions for chargebacks, shelf stock adjustments, returns and allowances and estimated doubtful account allowances during Fiscal 2007 and Fiscal 2008.

(In thousands)

	Balances at beginning of period	Allowances charged to Gross Sales		Credits taken by customers	Balance at the end of period
		Current Period	Prior Period		
Fiscal 2007					
Chargebacks, rebates & shelf stock adjustments	$ 11,467	$ 190,586	-0-	$ 169,415	$ 32,638
Returns and other allowances	1,500	9,000	-0-	6,748	