

CARACO PHARMACEUTICAL LABORATORIES LTD  
Form 10-K  
May 14, 2007

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

FORM 10-K

(Mark one)

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

For the Fiscal Year ended March 31, 2007

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  
(State of Incorporation)

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

**1150 Elijah McCoy Drive, Detroit, MI 48202**

(Address of principal executive office)

**(313) 871-8400**

(Registrant's telephone number)

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

Title of Each Class to be so Registered	Name of Each Exchange On which Each Class is to be Registered
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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  No

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

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

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

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

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

Large Accelerated Filer  Accelerated Filer  Non-Accelerated Filer

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, 2006, the last day of the Registrant's most recently completed second quarter, as reported on the American Stock Exchange, was \$96,010,994.

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

As of May 11, 2007, there were 28,117,394 shares of common stock outstanding.

**Documents Incorporated By Reference:**

Incorporated by reference into Part III, Items 10-14 of this Form are portions of the registrant's Proxy Statement for the 2007 Annual Meeting of Shareholders to be held in September 2007, which will be filed with the Securities and Exchange Commission on or before July 29, 2007.

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**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. 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 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 ( Waxman-Hatch Act ) provides that generic drugs may enter the market after the approval of an Abbreviated New Drug Application ( ANDA ) and the expiration, invalidation or circumvention of any patents on the corresponding brand drug, or the end of any other market exclusivity periods related to the brand drug. Generic drugs are bioequivalent to their brand name counterparts. Accordingly, generic products provide a safe, effective and cost-efficient alternative to users of these brand products. Branded generic pharmaceutical products are generic products that are more responsive to the promotion efforts generally used to promote brand products. Growth in the generic pharmaceutical industry has been driven by the increased market acceptance of generic drugs, as well as the number of brand drugs for which patent terms and/or other market exclusivities have expired.

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

On January 27, 2005, the Board of Directors of the Company resolved to change the Company's fiscal year end from December 31 to March 31 commencing in 2005. This change was made in order to make the Company's fiscal year conform to the March 31 fiscal year of its parent company, Sun Pharmaceutical Industries, Limited ( Sun Pharma ). This Form 10-K covers the audited fiscal year, April 1, 2006 to March 31, 2007 ( Fiscal 2007 ), and comparative information for the Audited fiscal year, April 1, 2005 to March 31, 2006 ( Fiscal 2006 ) and with respect to the twelve month period, April 1, 2004 to March 31, 2005, which is unaudited ( Fiscal 2005 ). Additional information is provided with respect to the transition period (January 1, 2005 through March 31, 2005) which is audited (the Transition Period ). (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, 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 66% of the outstanding shares of the Company (approximately 75% including the convertible Series B Preferred Stock), (See "Current Status of the Corporation" and "Sun Pharmaceutical Industries Limited" below.). We currently have zero debt. Our cash flow from operations provides the working capital necessary to effectively manage the company.

## Current Status

During Fiscal 2007 we recorded net sales of \$117.0 million compared to \$82.8 million during Fiscal 2006. We have generated cash from operations of \$27.9 million as compared to \$8.9 million during the relevant periods. Cash was used primarily to augment working capital. We earned net income of \$26.9 million compared to a net loss of \$10.4 million during the relevant periods. This higher profit was primarily due to lower non-cash research and development expense (R&D) of \$11.8 million as compared to \$35.1 million during the relevant period and an increase in sales. This non-cash R&D expense relates to three products passing their bio-equivalency studies during Fiscal 2007 and the related value of the preferred stock issued to Sun Pharma Global, Inc., a wholly-owned subsidiary of Sun Pharma ("Sun Global"), pursuant to the Products Agreement (as defined below), as compared to nine products during Fiscal 2006. At March 31, 2007, we had stockholders' equity of \$95.2 million as compared to stockholders' equity of \$56.4 million at March 31, 2006. See "Part II Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations."

Pursuant to our products agreement with Sun Global, we have selected, through March 31, 2007, all of the 25 products to be transferred to us by Sun Global. Of these, 23 products have passed their bio-equivalency studies as of March 31, 2007. Sun Global has thereby earned 544,000 preferred shares for each such product. See "Sun Pharmaceutical Industries Limited" and "Part II Item 7. Future Outlook."

We filed 19 ANDAs with the FDA during Fiscal 2007, (Three products filed had multiple ANDAs). This brings our total number of ANDAs pending approval by the FDA to 29 (Including one tentative approval) or 21 products awaiting approval. We also submitted three other filings to the FDA for new strengths on existing ANDAs and for new sources on the Active Pharmaceutical Ingredients (API).

## 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 payor 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 33 prescription products in 66 strengths delivered in various package sizes. Our current products and their use for the indications are set forth in the table below:

Generic Name	Purpose
Metroprolol Tartrate	Hyper-Tension
Paromomycin Sulfate	Antibacterial
Salsalate	Decongestant
Choline Magnesium Trisalicylate	Arthritis/NSAID
Clonazepam	Seizure, Panic Disorders
Flurbiprofen	Arthritis/NSAID
Carbamazepine Chewable	Anti-convulsant
Carbamazepine IR	Anti-convulsant
Oxaprozin	Rheumatoid Disease
Metformin Hydrochloride	Diabetes
Tramadol Hydrochloride	Opiate Agonist/Analgesic
Tramadol Hydrochloride with Acetaminophen	Opiate Agonist/Analgesic
Meperidine Hydrochloride	Analgesic
Ticlopidine	Reduction of incidence of strokes
Tizanidine	Management of muscle tone associated with spasticity
Digoxin	Heart failure
Mirtazapine	Anti-depressant
Citalopram Hbr	Anti-depressant
Clozapine	Anti-psychotic
Midrin*	Vascular & Migraine Headache suppressant
Fluvoxamine	Anti-depressant
Meloxicam	Arthritis/NSAID
Baclofen	Skeletal Muscle Relaxant
Glipizide	Diabetes
Metformin Extended Release **	Diabetes
Zonisamide **	Anti-convulsant
Gabapentin Tablets **	Anti-convulsant
Gabapentin Capsules **	Anti-convulsant
Extended Phenytoin **	Anti-convulsant
Hydrochlorothiazide	Hyper-Tension
Nimodipine**	Cardiac, Channel Blocker
Zolpidem	Sedative hypnotic
Ondansetron Injectable**	Anti-Nausea

\* 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 53 ANDAs to the FDA for approval as of March 31, 2007, including 19 filed during Fiscal 2007, which includes three products with multiple ANDAs. Of these 53 ANDAs filed, the FDA has approved 24 through March 31, 2007. Accordingly, we have 29 pending ANDAs (including one tentative approval) or 21 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 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.

### **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.

Sun Pharma and its affiliates had loaned us approximately \$10 million since August 1997. As of December 2003, we had repaid all of such loans. Sun Pharma also assisted us by acting as guarantor in obtaining line of credit loans from ICICI Bank Limited, The Bank of Nova Scotia and Citibank FSB in the amounts of \$5.0 million, \$12.5 million and \$10.0 million, respectively, all of which have been terminated and repaid as of December 31, 2004.

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 receives 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 the 25 products, 23 of which have passed bio-equivalency studies as of March 31, 2007. See Part II Item 7. Management 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. They have established Research and Development Centers in Mumbai and Vadodara, India, where the development work for products is performed. In addition, 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. During Fiscal 2007, we purchased approximately \$38.8 million in raw materials and formulations from Sun Pharma and its subsidiaries, as compared to \$28.1 million during Fiscal 2006 and \$5.3 million during the Transition Period. We acquired \$0.8 million worth of machinery and equipment during Fiscal 2007 from Sun Pharma and its affiliates as compared to \$0.2 million during Fiscal 2006 and \$0.1 million during the Transition Period. Such machinery and equipment was sold to us at Sun Pharma's cost. 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.

On March 31, 2007, Sun Global converted 1,632,000 shares of Series B Preferred Stock into 1,632,000 shares of Common Stock. Sun Pharma's current beneficial ownership is 66%, (75% including its convertible Series B Preferred Stock).

During the Transition Period, SPARC Bioresearch Private Limited ( SPARC ), an affiliate of Sun Pharma, performed certain analytical studies required as part of the bio-equivalency process for two products. The Corporation incurred approximately \$172,000 of costs during the period for the studies performed by SPARC. No similar studies were performed by SPARC during Fiscal 2007, Fiscal 2006 or during the year ended December 31, 2004.

## 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 2007. The 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 such as Amerisource-Bergen Corporation, McKesson Corporation and/or Cardinal Health, which provide a service to supplement our indirect relationships with our customers or act as an intermediary to service the customers directly in lieu of direct shipments from our Company. Collectively, for Fiscal 2007 these wholesale accounts equated to 58% of our net sales. These net sales include sales for various customers of ours that have underlying direct contracts with our Company that are facilitated through our wholesale customers. During Fiscal 2006 shipments to these three large wholesale customers accounted for approximately

77% of gross sales. Balances due from these customers represented approximately 82% and 72% of gross accounts receivable as at March 31, 2007 and 2006 respectively. No other single customer accounted for more than 10% of net sales for Fiscal 2007 or Fiscal 2006.

As described above certain of the Corporation's customers purchase its products through designated wholesalers, who act as an intermediary distribution channel for the Corporation's products. One such customer, the Veterans Administration, an agency of the United States Government, entered into a sales contract with the Corporation effective August 5, 2002 to purchase a minimum of \$13.0 million of product per year over a one year base contract period that ended June 30, 2003. The contract has four one-year option periods, the last of which was exercised in August 2006. The agreement may be terminated by the purchaser without cause, and in such case; Caraco would only be entitled to a percentage of the contract price, plus reasonable charges that have resulted from the termination. The agreement further provides for certain penalty provisions if the Corporation is unable to meet its sales commitment.

**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 are not significantly different from those of the brand-name drug. Although we perform our own stability testing, bioequivalence is done through independent testing laboratories. The Company's research and development consists in conducting market research, 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 support the 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 2007, Fiscal 2006 and Fiscal 2005 as set forth below:

Fiscal 2007	\$22.4 million
Fiscal 2006	\$43.5 million
Fiscal 2005 (Unaudited)	\$33.4 million

The non-cash R&D Expense for the Fiscal 2007, Fiscal 2006 and Fiscal 2005 are set forth below:

Fiscal 2007	\$11.8 million
Fiscal 2006	\$35.1 million
Fiscal 2005 (Unaudited)	\$26.8 million

The non-cash technology transfer charges are for research and product development provided by Sun Global. The charges are based on the fair value of the preferred shares on the date the respective product formula passes the bio-equivalency studies. The fair value of such shares is based upon an independent valuation.

**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.

Following such inspections, the FDA may issue notices on Form 483 and Warning Letters that could cause a company to modify certain activities identified during the inspection. A Form 483 notice may be issued at the conclusion of an 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 adequately and promptly achieve correction may be expected to result in an enforcement action.

The FDA routinely performs inspection of pharmaceutical company facilities. The FDA completed an inspection of the Company's facility in June 2006. Observations were provided on FDA Form 483. The Company submitted a response to the observations to the FDA. The Company believes that we remain substantially cGMP compliant. We have since received approval from the FDA for four products previously submitted. 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. During Fiscal 2007, 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.

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. 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 Drug Enforcement Agency ("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 number 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**

On November 17, 2005, the Company entered into a one-year, \$10 million Credit Agreement with JP Morgan Chase Bank, N.A. Under the Credit Agreement, the lender may make loans and issue letters of credit to the Company for the Company'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 17, 2007. On November 16, 2006, this agreement was renewed through November 30, 2007. Borrowings are secured by the Company's receivables and inventory. Interest is payable based on a LIBOR Rate or an alternate base rate (determined by reference to the prime rate or the federal funds effective rate), as selected by the Company. The rate of interest is LIBOR plus 75 basis points or the bank's prime rate minus 100 basis points (effective rates of 6.1% and 7.25%, respectively at March 31, 2007.) The Credit Agreement requires that certain financial covenants be met on a quarterly basis. The Company is in compliance with these financial covenants at March 31, 2007. There are no outstanding borrowings under this Credit Agreement as of March 31, 2007.

#### **Employees**

We had a total of 446 and 272 full-time equivalent and contract employees at March 31, 2007 and 2006, 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.

#### **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 a 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 to accrue 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 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 hand on product that has already been sold to the customer. If a new competitor enters the marketplace and significantly lowers the price of any of its competing products, it is possible that we would make a decision to reduce the price of our product. As a result, we would be obligated to provide significant credits to our customers who are then holding inventories of such products, which could

reduce sales revenue and gross margin for the period the credit is provided. Like our competitors, we also give credits for chargebacks to wholesale customers that have contracts with us for their sales to chain drug retail, group purchasing organizations, or other retail customers.

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

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

The manufacture, use and sale of new products that are the subject of conflicting patent rights have been the subject of substantial litigation in the pharmaceutical industry. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. We may have to defend against charges that we violated patents or proprietary rights of third parties. Litigation may be costly and time-consuming, and could divert the attention of our management and technical personnel. If it is found that we infringe on the rights of others, we could lose our right to develop or manufacture products or could be required to pay monetary damages or royalties to license proprietary rights from third parties. An adverse determination in a judicial or administrative proceeding relating to patent infringement and/or product liability could prevent us from manufacturing and selling a product(s), which could negatively affect our financial condition and results of operations. Although we carry insurance, we believe that no reasonable amount of insurance can fully protect against all such risks because, among other things, of the potential liability inherent in the business of producing pharmaceuticals for human consumption. To the extent that a loss occurs, depending on the nature of the loss and the level of insurance coverage maintained, it could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

**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 our 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 Global and Sun Pharma to assist us in our research and development.**

Collectively Sun Global and Sun Pharma could determine that its own research and development takes precedent 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 further increase of our own capabilities. This gap could possibly cause future growth deficits until resolved.

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

We typically purchase the active pharmaceutical ingredient (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 in certain cases where we have listed only one supplier in our applications with the FDA, Additionally, we have received and submitted for FDA approval 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.

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. One such agreement is with the Veterans Administration. The Company entered into a sales contract with the Veterans Administration effective August 5, 2002 to purchase a minimum of \$13.0 million of product per year over a one year base contract period that ended June 30, 2003. The contract has four one-year option periods, the last of which was exercised in August 2006. Upon termination of this agreement, the Company must re-bid to renew this business. While we are hopeful that we will succeed in renewing this business, there can be no assurance that we will be successful.

**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 2007, the Company acquired a 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. We envision this acquisition will improve overall costs in packaging, bottling and increase our production. During Fiscal 2007 the Company acquired six acres of land directly adjacent to its existing manufacturing facility for \$0.3 million. We are contemplating the construction of a 125,000 sq. ft. facility on this site.

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 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 offices. The lease expires in 2009.

We have invested approximately \$6.0 million during Fiscal 2007 as compared to \$3.6 million during Fiscal 2006 and \$3.3 million during twelve months ending March 31, 2005 to upgrade our facilities and production. We have invested approximately \$0.6 million during the Transition Period as compared to \$1.3 million during the corresponding period of 2004. We invested \$4.0 million in the year 2004.

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 Pharmaceutical Industries, Ltd. ( Sun ) 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's ANDA, or will induce others to infringe by marketing and/or selling Sun's generic version of Clarinex® upon receiving FDA approval. Schering's complaint seeks an order from the Court which, among other things, directs the FDA not to approve Sun's ANDA any earlier than the claimed expiration date. The ANDA filed by Sun contains a Paragraph IV certification challenging the 274 patent. Sun believes that the 274 patent is invalid, unenforceable and/or will not be infringed by Sun's or Company's manufacture, use or sale of the product and both Sun 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.

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. The Company believes that, like its original patent, Ortho-McNeil's reissue patent is invalid and/or is not infringed by the Company's manufacture, use or sale of the product and the Company intends to vigorously defend this action. There is no assurance, however, that the Company will prevail in this action.

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 2007 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 2007, Fiscal 2006, the Transition Period and the year ended December 31, 2004, the high and low sales prices for each of the applicable quarters.

<b>Fiscal 2007</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 13.10	\$ 9.00
Second Quarter	\$ 11.99	\$ 8.15
Third Quarter	\$ 14.00	\$ 9.98
Fourth Quarter	\$ 14.99	\$ 10.50
<b>Fiscal 2006</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 8.97	\$ 7.06
Second Quarter	\$ 9.29	\$ 8.10
Third Quarter	\$ 9.81	\$ 7.50
Fourth Quarter	\$ 13.42	\$ 8.76
<b>2005</b>	<b>High</b>	<b>Low</b>
Transition Period	\$ 9.32	\$ 7.44
<b>2004</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 13.74	\$ 7.31
Second Quarter	\$ 11.94	\$ 9.40
Third Quarter	\$ 10.24	\$ 6.80
Fourth Quarter	\$ 10.00	\$ 6.82

As of May 11, 2007 there were 87 registered holders of our Common Stock.

During Fiscal 2007, 1,632,000 shares of preferred stock were converted into equal number of common stock and issued to Sun Pharma Global Inc

During Fiscal 2007, we issued to Sun Global 1,632,000 preferred shares in exchange for the transfer of three products. During Fiscal 2006, we issued to Sun Global 4,896,000 preferred shares in exchange for the transfer of nine products. During the Transition Period, we issued to Sun Global 1,632,000 preferred shares in exchange for the transfer of three products. During 2004, we issued to Sun Global 4,352,000 preferred shares in exchange for the transfer of eight products (of which 544,000 preferred shares were earned during 2003 for one product transfer) pursuant to our current products agreement.

Pursuant to various stock and option purchase agreements between Sun Pharma and three stockholders and their affiliates, Sun Pharma acquired in January and February, 2004, 3,452,291 shares of common stock and rights to acquire options for 1,679,066 shares of common stock. The shares were acquired for \$9.00 per share and the rights to the options were acquired for \$9.00 less the exercise price of each option.

During 2004, we issued 1,679,066 shares of common stock to Sun Pharma against exercise of stock options, which Sun Pharma had acquired from two former directors during the first quarter of 2004.

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, 2007 and 2006 and summary statements of operations data for the years ended March 31, 2007 and 2006, the three month period ended March 31, 2005 and the year ended December 31, 2004 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, 2005, December 31, 2004, and 2003 and the summary of the statements of operations for the years ended December 31, 2003, and 2002 are 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		Transition	Year ended		2002
	2007	2006	Period Ended March 31, 2005	2004	December 31, 2003	
Net sales	\$ 117,027	\$ 82,789	\$ 17,337	\$ 60,340	\$ 45,498	\$ 22,381
Cost of goods sold	59,243	41,873	7,879	24,441	19,507	12,047
Gross profit	57,784	40,916	9,457	35,899	25,991	10,334
Selling, general and administrative expenses	9,880	8,183	1,879	5,277	7,363	3,828
Research and development costs - affiliate non cash	11,761	35,055	10,200	24,397	3,103	3,887
Research and development costs - other	10,591	8,437	1,720	6,053	3,112	3,348
Operating income / (loss)	25,552	(10,759)	(4,342)	172	12,412	(730)
Other income / (expense)	1,306	336	21	(371)	(1,189)	(1,526)
Net Income / (Loss)	26,858	(10,423)	(4,322)	(199)	11,223	(2,256)
Net Income / (Loss) per share						
Basic	1.02	(0.39)	(0.16)	(0.01)	0.46	(0.10)
Diluted	0.72	(0.39)	(0.16)	(0.01)	0.44	(0.10)
Weighted Average Shares Outstanding:						
Basic	26,447	26,392	26,348	24,734	24,137	22,031
Diluted	37,255	26,392	26,348	24,734	25,482	22,031

## Financial Data (continued)

Balance Sheet Data	(In thousands)				
	As at March 31,			As at December 31,	
	2007	2006	2005	2004	2003
Current assets	\$ 95,439	\$ 62,282	\$ 32,938	\$ 24,857	\$ 18,918
Property, plant and equipment, net	19,030	14,960	12,897	12,546	9,506
Total assets	114,469	77,242	45,835	37,403	28,424
Current liabilities	19,276	20,864	14,149	11,627	20,008
Long term debt					13,395
Total liabilities	19,276	20,864	14,149	11,627	33,404
Stockholders' Equity (Deficit)	95,193	56,378	31,686	25,776	(4,980)
Working Capital (Deficiency)	76,163	41,418	18,789	13,230	(1,090)

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

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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 overhead components in 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, 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 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 of the change. 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 12-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 of the change. 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 2007 were \$316.6 million, as compared to \$200.4 million for Fiscal 2006. Chargebacks, returns, discounts and other customary customer deductions and other sales costs constituted approximately 63% for Fiscal 2007 compared to 59% for Fiscal 2006. Net sales for Fiscal 2007 were \$117.0 million, as compared to \$82.8 million for Fiscal 2006. The primary cause of increase in the sales diluters by almost 4% between the periods is the impact of price erosions for the products we sell and the corresponding impact of such price erosions on chargebacks.

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The following is a roll forward of the provisions for chargebacks, shelf stock adjustments, returns and allowances and estimated doubtful account allowances during Fiscal 2006 and Fiscal 2007.

(\$ in Thousands)

Fiscal 2006	Roll forward allowances at beginning of Fiscal 2006	Allowances charged to Gross Sales for Fiscal 2006		Credits taken by customers during Fiscal 2006	Balance at the end of Fiscal 2006
		Current Period	Prior Period		
Chargebacks & shelf stock adjustments	\$ 19,810	\$ 111,525	\$ -0-	\$ 119,868	\$ 11,467
Returns and other allowances	1,120	7,471	-0-	7,091	1,500
Doubtful Accounts	100	-0-	-0-	-0-	100

Fiscal 2007	Roll forward allowances at beginning of Fiscal 2007	Allowances charged to Gross Sales for Fiscal 2007		Credits taken by customers during Fiscal 2007	Balance at the end of Fiscal 2007
		Current Period	Prior Period		
Chargebacks & shelf stock adjustments	\$ 11,467	\$ 190,586	\$ -0-	\$ 169,415	\$ 32,638
Returns and other allowances	1,500	9,000	-0-	6,748	3,752
Doubtful Accounts	100	-0-	-0-	-0-	100

### Income Taxes

As part of the process of preparing our financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. We account for income taxes by the liability method. Under this method, deferred income taxes are recognized for tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end, based on enacted laws and statutory tax rates applicable for the differences that are expected to affect taxable income. In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. We have net deferred tax assets of \$7.5 million and \$20.1 million as at March 31, 2007 and March 31, 2006 respectively. Valuation allowances are provided based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. We have not recorded any net federal tax provision or benefit for the Fiscal 2007, Fiscal 2006, the Transition Period or for the year ended December 31, 2004. We have provided a valuation allowance for \$7.0 million as at March 31, 2007 and the full amount of our net deferred tax assets at March 31, 2006 since realization of any future benefit from deductible temporary differences and net operating loss (NOL) carryforwards cannot be sufficiently assured. During the year ended March 31, 2007, carryforwards of approximately \$26.8 million were used to offset taxable income. In addition, the Company determined that approximately \$13.1 million of previous NOLs were not available for utilization under the provisions of Internal Revenue Code Section 382. Accordingly, at March 31, 2007, we had federal net operating loss carryforwards of approximately \$18.7 million available to reduce taxable income, which will expire between 2008 and 2026.



## **Inventory**

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

## **FDA Compliance**

The FDA completed an inspection of the Company's facility in June 2006. Observations were provided on FDA Form 483. The Company submitted a response to the observations to the FDA. The Company believes that we remain substantially cGMP compliant. We have since received approval from the FDA for four products previously submitted. We continue to focus on improving the amount of support in both quality assurance and quality control in order to continually improve our performance and outcome in quality. This support is derived from the improvement of systems, training on risk management, improvement on our Corrective And Preventative Actions (CAPA) and cGMP, while adding the appropriate level of personnel to support our growth. During Fiscal 2007, in addition to our own internal audits we have retained outside companies to audit both our 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 the Company's future requirements and included follow up on the recommendations made by the FDA.

We remain extremely pro-active in regards to growing our business appropriately. Since April 2006, the analytical staff has been increased from 32 to approximately 64 employees, thereby enabling the laboratory to better cope with a significantly increased workload with improved timeliness, higher quality, and increased cGMP compliance. Several members of the lab staff attend supplemental professional training courses and conferences, which increases the laboratory's technical and cGMP proficiency. The lab facility has also undergone major upgrades, including a significant increase in working space to improve analyst efficiency and safety. Additional lab instruments and equipment have been purchased which will enable increased compliance with cGMP requirements, cut future costs by enabling in-house rather than contract analyses, and speed sample testing. Significant resources have also been spent to improve overall lab operations. Such expenditures demonstrate to the regulators, clients and shareholders that upper management is continually committed to adding quality individuals to the work force, providing the resources necessary to upgrade lab equipment and improve the effectiveness of lab operations and cGMP compliance.

## Overview of Fiscal 2007

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

Our Company effectively executed its operating plan during Fiscal 2007 and laid the ground work to support future growth. The organization continues to be strengthened to meet the demands of a competitive US generic pharmaceutical market.

We recorded net sales of \$117.0 million during Fiscal 2007 compared to \$82.8 million during Fiscal 2006. We have generated cash from operations of \$27.9 million during Fiscal 2007 as compared to \$8.9 million during Fiscal 2006. This cash was generated after funding our working capital requirements of \$12.8 million and \$17.5 million during the relevant periods. We earned a net income of \$26.9 million during Fiscal 2007 compared to a net loss of \$10.4 million during Fiscal 2006. The higher income was primarily due to higher sales and lower non-cash research and development expense (R&D) of \$11.8 million during Fiscal 2007 as compared to \$35.1 million during Fiscal 2006. This non-cash R&D expense relates to three products passing their bio-equivalency studies and related value of the preferred stock issued to Sun Global during Fiscal 2007 as compared to nine products during Fiscal 2006. At March 31, 2007, we had stockholders' equity of \$95.2 million as compared to stockholders' equity of \$56.4 million at March 31, 2006.

In January 2005, the Company changed its fiscal year end from December 31 to March 31 to better align our financial reporting with our parent company, Sun Pharma. The following discussion of historical operating results compares Fiscal 2007 to Fiscal 2006, Fiscal 2006 to Fiscal 2005. Results from Fiscal 2005 were derived from the Company's published quarterly results and are unaudited. Accordingly, this twelve month period is not disclosed in the accompanying financial statements. It is included in this discussion for comparative purposes only. For the previous calendar year ended December 31, 2004, the comparison is to the calendar year ended December 31, 2003. The discussion of historical operating results also includes and compares the three months ended March 31, 2006 to the Transition Period. Results from the three month period ended March 31, 2006 were derived from the Company's published quarterly results and are unaudited.

## Fiscal 2007 Compared to Fiscal 2006

**Net Sales.** Net sales for the relevant periods of 2007 and 2006 were \$117.0 and \$82.8 million, reflecting an increase of over 41%. The increase is primarily due to the higher production of existing products; new product launches (primarily the sales of our generic equivalent of Ultracet®) and increased marketing of our products to new and existing customers. Currently, we manufacture and market all except two of the approved products. Sales of four products accounted for approximately 69% of net sales for Fiscal 2007 as compared to sales of three products accounting for approximately 70% of net sales for Fiscal 2006. See Note 1 to Financial Statements - Revenue Recognition for explanation of the determination of net sales.

**Gross Profit.** We earned a gross profit of \$57.8 million as compared to a gross profit of \$40.9 million during the relevant periods, reflecting an increase of 41% which is consistent with our growth in net sales. The increase in gross profit for the relevant periods is primarily due to higher sales, new product launches, an improved balance in the mix of customers or the class of trade and product selection being sold partially offset by price erosion during the year.

The gross profit margin remained constant at 49% during the relevant periods though the product and customer mix changed through out the year. The product mix included our manufactured products and also the distributed products being marketed and distributed pursuant to the Sun Pharma marketing agreement. The company also continued to experience increased competition, both domestic and foreign, resulting in erosion of prices and profit margins on certain products. We believe that as distributed sales increase our overall margin percentage could decrease depending on the weighted margin between our manufactured products and the distributed products.

The net sales for distributed products were \$4.6 million for Fiscal 2007. The gross profit margin on distributed products sold was 30%. The net sales for manufactured products were \$112.4 million for Fiscal 2007. The gross profit margin for manufactured products was 50%.

**Selling, General and Administrative Expense.** Selling, general and administrative expenses during the relevant

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periods were \$9.9 million and \$8.2 million, representing an increase of 21%. The selling, general and administrative expenses, as a percentage of net sales, have declined to 8% as compared to 10% during the relevant periods.

The increase in SG&A for Fiscal 2007 over Fiscal 2006 was primarily due to an increase in costs for additions to the management team and associated compensation and higher SG&A expenses associated with higher sales volumes.

**Research and Development Expenses.** Total R&D expenses for the relevant periods were \$22.4 million for Fiscal 2007 and \$43.5 million for Fiscal 2006. Actual cash research and development expenses were \$10.6 million for Fiscal 2007 and \$8.4 million for Fiscal 2006. We incurred non-cash research and development expenses (technology transfer cost) of \$11.8 million for the 1,632,000 shares of preferred stock for three product transfers as compared to \$35.1 million for the 4,896,000 shares of preferred stock for nine product transfers. The cash R&D expenses during Fiscal 2007 were higher compared to those during Fiscal 2006 due to increased internal R&D activity and initial milestone payments paid to third parties for initiating technology transfer of four products (see Future Outlook ). We filed 19 ANDAs with the FDA during Fiscal 2007, (Three products filed had multiple ANDAs). This brings our total number of ANDAs pending approval by the FDA to 29 (including one tentative approval) or 21 products. We also submitted three other filings to the FDA for new strengths on existing ANDAs and for new sources on the Active Pharmaceutical Ingredients (API)

**Net Other Income.** We earned net other income of \$1.3 million during Fiscal 2007 as compared to \$0.3 million during Fiscal 2006. The net interest income during the relevant periods were \$1.1 million and \$0.2 million respectively after incurring interest expense of twenty eight thousand dollars and four thousand dollars in respective periods. The higher income is reflective of our increase in cash balances during Fiscal 2007

**Results of Operations.** We earned a net income of \$26.9 million during Fiscal 2007 as compared to net loss of \$10.4 million during the Fiscal 2006. The higher results of operation are primarily due to higher volumes of sales and lower non-cash R&D expenses.

### Fiscal 2006 Compared to Fiscal 2005

	Year ended March 31,	
	2006 (Audited)	2005 (Unaudited)
	(in thousands, except per share data)	
<b>Statement of operations data</b>		
Net sales	\$ 82,789	\$ 64,116
Cost of goods sold	41,873	26,930
Gross profit	40,916	37,186
Selling, general and administrative expense	8,183	5,874
Research and development costs affiliate non cash	35,055	26,769
Research and development costs other	8,437	6,640
Operating loss	(10,759)	(2,097)
Other income (expense)	336	(181)
Net Loss	(10,423)	(2,278)
Net Loss per share		
Basic	(0.39)	(0.08)

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Diluted	(0.39)	(0.08)
Weighted Average Shares Outstanding:		
Basic	26,392	26,348
Diluted	26,392	26,348

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**Net Sales.** Net sales for the relevant periods of 2006 and 2005 were \$82.8 and \$64.1 million, reflecting an increase of over 29%. The increase is primarily due to the higher production, new product launches (primarily the sales of our generic equivalent of Ultracet® and increased marketing of our products to new and existing customers. Currently, we manufacture and market all except one of the approved products. Sales of three products accounted for approximately 70% and 77% of net sales for the relevant periods of 2006 and 2005, respectively. See Note 1 to Financial Statements Revenue Recognition for explanation of the determination of net sales.

**Gross Profit.** We earned a gross profit of \$40.9 million as compared to a gross profit of \$37.2 million during the relevant periods, reflecting an increase of 10%. The increase in gross profit for the relevant periods is primarily due to higher sales, new product launches, an improved balance in the mix of customers or the class of trade and product selection being sold partially offset by price erosion during the year.

The gross profit margin declined to 49% as compared to 58% during the relevant periods. The decrease was primarily the result of increased competition, both domestic and foreign, resulting in erosion of prices and profit margins.

**Selling, General and Administrative Expense.** Selling, general and administrative expense during the relevant periods were \$8.2 million and \$5.9 million, representing an increase of 39%. The selling, general and administrative expense have increased to 9.9% of net sales as compared to 9.2% of net sales during the relevant periods.

The increase in SG&A for Fiscal 2006 over Fiscal 2005 was due to an increase in regulatory costs for compliance with SEC regulations, including Sarbanes-Oxley requirements (\$0.4 million), primarily additions to management and associated compensation (\$0.7 million), higher taxes on property (\$0.2 million) and higher SG&A expenses associated with higher sales volumes as well as a one time charge (\$0.3 million) associated with our decision to forego an acquisition of real property in favor of alternate expansion opportunities.

**Research and Development Expenses.** Total R&D expenses for the relevant periods were \$43.5 million for Fiscal 2006 and \$33.4 million for Fiscal 2005. Cash research and development expenses were \$8.4 million for Fiscal 2006 and \$6.6 million during Fiscal 2005. We incurred non-cash research and development expenses (technology transfer cost) of \$35.1 million for the 4,896,000 shares of preferred stock for nine product transfers as compared to \$26.8 million for the 4,352,000 shares of preferred stock for eight product transfers. The substantially higher R&D expenses, both cash and non-cash, represent increased R&D activities.

**Interest Expense.** We incurred approximately four thousand dollars interest expense during Fiscal 2006 on a short term borrowing from JPMorgan Chase Bank See Note 2 to Financial Statements. Interest expense on loans from the EDC, ICICI Bank, the Bank of Nova Scotia and Citibank was \$0.2 million during Fiscal 2005. The decrease in the amount of interest is primarily due to paying off the entire loans due to the EDC, ICICI Bank, the Bank of Nova Scotia and CitiBank during Fiscal 2005.

**Results of Operations.** We incurred a net loss of \$10.4 million and \$2.3 million during the relevant periods. The lower results of operation are primarily due to higher non-cash R&D expenses and higher Cash R&D expenses.



**Three months ended March 31, 2006 compared with the Transition Period**

	2006 (Unaudited)	Transition Period (Audited)
	(in thousands, except per share data)	
<b>Statement of operations data</b>		
Net sales	\$ 24,701	\$ 17,337
Cost of goods sold	12,011	7,879
Gross profit	12,690	9,457
Selling, general and administrative expenses	2,481	1,879
Research and development costs affiliate non cash	14,008	10,200
Research and development costs other	2,925	1,720
Operating loss	(6,724)	(4,342)
Other income (expenses)	185	21
Net Loss	(6,539)	(4,322)
Net Loss per share		
Basic	(0.25)	(0.16)
Diluted	(0.25)	(0.16)
Weighted Average Shares Outstanding:		
Basic	26,392	26,348
Diluted	26,392	26,348

**Net Sales.** Net sales for the relevant periods of 2006 and 2005 were \$24.7 million and \$17.3 million, reflecting an increase of almost 43%. The increase is primarily due to the higher production, new product launches and increased marketing of our products to new and existing customers. Currently, we manufacture and market all except one of the approved products. See Part I, Item 1. Business Current Status above. Sales of four and three products accounted for approximately 76% and 77% of net sales for the relevant periods, respectively. See Note 1 to Financial Statements Revenue Recognition.

**Gross Profit.** We earned a gross profit of \$12.7 million as compared to a gross profit of \$9.5 million during the relevant periods, reflecting an increase of 34%. The improvement was primarily due to higher sales volumes during the three months ended March 31, 2006 compared to the Transition Period.

The gross profit margin declined to 51% as compared to 55% during the relevant periods. The decrease was primarily the result of increased competition, both domestic and foreign, resulting in erosion of prices and profit margins.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses during the relevant periods were \$2.5 million and \$1.9 million, representing an increase of 32%. The selling, general and administrative expenses have reduced to 9.4% of net sales compared to 10.8% of net sales during the relevant periods.

The increase in SG&A during the relevant periods has been due to an increase in regulatory costs for compliance with SEC regulations, including Sarbanes-Oxley requirements (\$0.1 million), primarily additions to management and associated compensation (\$0.2 million), and higher SG&A expenses associated with higher sales volumes.

**Research and Development Expenses.** Total R&D expenses for the relevant periods were \$16.9 million and \$11.9 million. Cash research and development expenses were \$3.0 million and \$1.7 million during the relevant periods. We incurred non-cash research and development expenses (technology transfer cost) of \$14.0 million for the 1,632,000 shares of preferred stock for three product transfers as compared to \$10.2 million for the 1,632,000 shares of preferred stock for three product transfers. The substantially higher R&D expenses, both cash and non-cash, represent increased R&D activities.

**Interest Expense.** Interest expense on loans from the JP Morgan Chase Bank was approximately four thousand dollars during the relevant period of 2006. There was no corresponding expense during the Transition Period.

**Results of Operations.** We incurred a net loss of \$6.5 million and \$4.3 million during the relevant periods. The lower results of operation are primarily due to higher non-cash R&D expenses.

**Year Ended December 31, 2004 Compared with Year Ended December 31, 2003**

**Net Sales.** Net sales for 2004 and 2003 were \$60.3 million and \$45.5 million, respectively, reflecting an increase of almost 33%. The increase is due to the higher production and marketing of our products to new and existing customers. Currently, we manufacture and market all except one of the approved products. See Part I, Item 1. Business Current Status above. Sales of two products accounted for approximately 74% and 87% of net sales in 2004 and 2003, respectively.

**Gross Profit.** We earned a gross profit of \$35.9 million for 2004 as compared to a gross profit of \$26.0 million for 2003, reflecting an increase of 38% over 2003. The improvement was primarily due to higher sales volumes with improved margins due to product mix in the current period as compared to the corresponding period of 2003 and ability to absorb operational overheads due to higher sales.

In addition to increased sales, the gross profit margin has marginally improved to 59% in 2004 as compared to 57% for 2003. The increase was primarily the result of:

Change in the product mix of sales.

Reduction in manufacturing costs due to increased batch sizes.

Further improved efficiency in the overall manufacturing process associated with higher utilization of plant capacity.

Utilization of newly installed larger and faster equipment to achieve economies of scale.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses for 2004 and 2003 were \$5.3 million and \$7.4 million, respectively, representing a decrease of 28%. Selling, general and administrative expenses have decreased to 9% of net sales for 2004 as compared to 16% of net sales for 2003.

The decrease in SG&A of approximately \$2.1 million in 2004 was primarily due to one time recording of variable compensation expense during 2003 on the extension of the term of two former directors stock options and severance compensation to a former CEO.

**Research and Development Expenses.** Total R&D expense for 2004 of \$30.5 million was substantially higher as compared to \$6.2 million during 2003. Cash research and development expenses of \$6.1 million for 2004 were higher by 97% when compared with \$3.1 million incurred for 2003. We incurred non-cash research and development expenses (technology transfer cost) of \$24.4 million for the 3,808,000 shares of preferred stock for seven product transfers during 2004 as compared to \$3.1 million for the 544,000 shares of preferred stock for one product transfer during 2003. The substantially higher R&D expenses, both cash and non-cash, represent increased R&D activities.

**Interest Expense.** Interest expense on loans from the EDC, Sun Pharma and its affiliates, ICICI Bank, the Bank of Nova Scotia and Citibank, was \$0.4 million and \$1.2 million for 2004 and 2003, respectively. The decrease in the amount of interest is primarily due to paying off the entire loans due to the EDC, ICICI Bank, the Bank of Nova Scotia and CitiBank during 2004 as well as Sun Pharma loans during 2003.

**Results of Operations.** We incurred a net loss of \$0.2 million for 2004 as compared to earning a net income of \$11.2 million for 2003. The significantly lower results of operation for 2004 as compared to 2003 are primarily due to higher non-cash R&D expenses.

**Liquidity and Capital Resources**

**Fiscal 2007 and Fiscal 2006**

We generated cash of \$27.9 million from operations as compared to \$8.9 million during the relevant periods. During the second quarter of Fiscal 2007, Caraco acquired a packaging facility for \$1.7 million. This 33,369 sq. ft. facility was previously owned and operated by our third party packager of our portfolio of products. We envision this acquisition will

improve overall costs in packaging, bottling and increase our production by adding additional packaging lines. During Fiscal 2007, Caraco acquired six acres of land directly adjacent to its existing manufacturing facility for \$0.3 million. We are contemplating the construction of a 125,000 sq. ft. facility on this site.

Accounts receivable increased by \$5.2 million to \$26.1 million as at the end of Fiscal 2007, as compared to \$20.9 million at the end of fiscal 2006. The increase in accounts receivable is primarily commensurate with the increase in sales. Our day's sales outstanding, (DSO), as at the end of Fiscal 2007 improved to 72 days from 76 days outstanding at the end of Fiscal 2006.

At March 31, 2007, we had working capital of \$76.2 million compared to a working capital of \$41.4 million at March 31, 2006. The working capital was significantly higher due to higher receivables and inventories at the end of March 2007 compared to that at March 31, 2006, and also due to reduction of current liabilities.

#### **Fiscal 2006 and Fiscal 2005**

We generated cash of \$8.9 million from operations as compared to cash of \$20.6 million during the relevant periods. The lower cash generation during Fiscal 2006 was primarily due to augmenting working capital. Cash generated from operations was used to finance our capital expenditures of \$3.6 million. Cash from operations during Fiscal 2005 was used to finance capital expenditure of \$3.3 million.

At March 31, 2006, we had working capital of \$41.4 million compared to a working capital of \$18.8 million at March 31, 2005. The working capital was significantly higher due to higher receivables and inventories at the end of March 2006 compared to that at March 31, 2005, partially offset by higher current liabilities.

#### **Three Months ended March 31, 2006 to the Transition Period**

We generated cash of \$4.3 million from operations as compared to cash of \$4.8 million during the relevant periods. In addition to augmenting working capital, the cash generated from operations was used to finance our capital expenditures of \$1.2 million and \$0.7 million during the relevant periods.

At March 31, 2006, we had working capital of \$41.4 million compared to a working capital of \$18.8 million at March 31, 2005. The working capital was significantly higher due to higher receivables and inventories at the end of March 2006 compared to that at March 31, 2005, partially offset by higher current liabilities.

#### **Years ended December 31, 2004 and 2003**

During 2004, we generated cash of \$22.0 million from operations as compared to cash of \$15.5 million during 2003. The higher cash generation during 2004 has been primarily due to higher sales volumes, better-cost absorption, an improved product mix, obtaining more competitive prices for raw materials and better utilization of new equipment to improve production and productivity.

In addition to paying down debt, the cash generated from operations for both 2004 and 2003 was used to finance our capital expenditures of \$4.0 million during 2004 and \$2.4 million during 2003.

During 2004, we repaid the entire balance of \$4.4 million due to ICICI Bank Limited and the \$6.4 million mortgage loan due to the Economic Development Corporation of the City of Detroit (the EDC), and repaid \$12.5 million due to the Bank of Nova Scotia. These payoffs were funded from internal cash flow and by utilizing a \$10.0 million credit line arranged with Citibank, FSB. We have also repaid the entire borrowing of \$10.0 million from Citibank during 2004. These repayments leave us debt-free (other than normal accounts payables and accruals) at December 31, 2004, and our entire property, plant, equipment and intellectual property free of any mortgages, liens or restrictions. In comparison, during 2003 we borrowed \$1.6 million from the Bank of Nova Scotia and repaid the entire Sun Pharma loans of \$9.7 million and the scheduled payments of \$1.2 million to the EDC and \$0.6 million to the ICICI Bank.

During 2004, we generated \$3.5 million from the exercise of stock options by Sun Pharma, our employees and one officer and director. During 2003, we generated \$0.9 million from the exercise of stock options by our employees and directors.

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At December 31, 2004, we had working capital of \$13.2 million compared to a negative working capital of \$1.1 million at December 31, 2003. The negative working capital as on December 31, 2003 was primarily due to classification of loans as current of \$8.8 million due to ICICI Bank and the Bank of Nova Scotia and \$1.1 million due to the EDC.

The available increased cash flow during 2004 was partly utilized to increase inventories, up from \$9.6 million in 2003 to \$17.1 million. These increased inventories served us well to satisfy increased sales requirement from \$45.5 million in 2003 to \$60.3 million in 2004. To meet customer demands in timely manner, it is essential to keep sufficient inventories at all levels including Finished goods stock. Therefore, if necessary the trend of increasing inventories will continue in 2005 to support increased sales.

The following tables present a summary of each of the four quarters of Fiscal 2007. The unaudited interim financial statements include all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of such information when read in conjunction with our audited financial statements and related notes. Our quarterly operating results have varied in the past, may continue to do so and are not necessarily indicative of results for any future period.

Fiscal 2007 April 1, 2006 to March 31, 2007 (unaudited)

(In thousands, except per share data)

	<u>Quarter 1</u>	<u>Quarter 2</u>	<u>Quarter 3</u>	<u>Quarter 4</u>
Net Sales	\$ 24,751	\$ 28,280	\$ 31,257	\$ 32,739
Net Profit	4,986	2,311	10,059	9,502
Earnings Per Share				
Basic	0.19	0.09	0.38	0.36
Diluted	0.13	0.06	0.26	0.25

### Contractual Obligations and Off Balance Sheet Transactions

#### Contractual Obligations

<u>Contractual Obligations</u>	<u>1-2 years</u>
Operating Leases	\$0.7 million
There are no other contractual obligations requiring disclosure.	

#### Off Balance Sheet Transactions

None

### Future Outlook

We believe the competitive environment we find ourselves in is conducive to our success. Due to our size and management structure, we believe that we are able to move swiftly and effectively. We are disciplined and have the aptitude to execute our plan. We believe we are substantially compliant with cGMP. We continue to invest in improved systems, training and personnel in quality assurance, quality control and manufacturing to improve our overall performance in quality.

Currently, we have 29 ANDAs pending approval at the FDA (including one tentative approval) or 21 products. We continue to expand and upgrade our facilities, attract and hire talented individuals and expand our customer base. Our internal

efforts, combined with Sun in developing new products have also picked up momentum and this should permit us to grow at the level of our guidance as provided below. We now have eight products, Metformin, Metoprolol, Tramadol, Salsalate, Tramadol with Acetaminophen, Clonazepam, Mirtazapine and Tizanidine, whose market share is ranked third or higher against the same products of our generic competitors. Based on current trends, we believe we will achieve 30% growth in sales for Fiscal 2008, compared to Fiscal 2007.

Although gross profit margins may come down over time due to price erosion, we are confident that our sales growth, expanding product portfolio and successful execution of our business plan will offset any long-term impact. However, should the pricing pressures become more severe than anticipated; the result may be lower growth rates and gross margins. Management has and will continue to work diligently to counter the pricing pressures through increased sales volumes, expansion of our customer base, improved productivity, and better cost absorption of operational overheads, cost reductions and increased development plans.

As previously disclosed, under the products agreement dated November 21, 2002 between Sun Global and the Company, Sun Global agreed to transfer the technology for 25 products to the Company over a five year period in exchange for 544,000 preferred shares (which are convertible on a one-to-one basis into common shares) per product. Since the date of the products agreement, the Company has selected all 25 products for development and 23 of these products have passed their respective bio-equivalency studies. There are two products that remain in our development pipeline that pertain to this agreement.

While the development of new products will increase our cash R&D expense and impact EPS, we expect that we will continue to have the cash and other means available to meet increased working capital requirements, fund potential Paragraph IV Certification litigation and finance further capital investments. Product development is critical in meeting expectations in the future.

The Company intends to aggressively move forward with the development of new products. We believe that Sun Pharma is a partner with a proven track record; and one that already has provided the Company with quality products. Moreover, Sun Pharma's increased beneficial ownership in the Company to approximately 66% (approximately 75% including the convertible Series B Preferred Stock), should, we believe, provide it with the vested interest to continue to help the Company succeed. Sun Pharma has previously provided the Company with capital, loans, guarantees of loans, personnel, raw materials and equipment, which have significantly helped the Company to date. In addition to the Sun products agreement, we have implemented additional development strategies with various third parties both domestically and abroad that will complement the Sun development pipeline.

During Fiscal 2007, the Company entered into three definitive agreements with different companies to develop four additional ANDAs for Caraco and provide additional opportunities for the future development of products. These agreements contain, for three products, both milestone payments to be paid in cash and profit sharing based upon future sales for a defined period, and for one product only milestone payments in cash without any obligation to share profits in the future.

We anticipate additional development agreements will be entered into in order to eliminate any future gaps in our calendar of approvals that we anticipate from the FDA. We expect these agreements to run parallel to our own product development. In order to improve the amount of filings during the Fiscal 2008, we continue to fortify our own research and development team by adding formulators and increasing the number of products we have in development internally. We filed 19 ANDAs in Fiscal 2007 or 11 products.

As previously mentioned, we have entered into a definitive agreement to market Sun Pharma ANDAs that are either approved or awaiting approval at the FDA. Accordingly, we have begun marketing a number of these products. This agreement will provide for an alternate stream of products that will complement our internal research and development, our outsourced development and our current technology agreement with Sun Pharma, providing four diverse paths of development, an increased product pipeline and potential revenue. These various paths mitigate the risk of each other, potentially allowing for an ongoing stream of approvals from the FDA.

Management's plans for Fiscal 2008 include:

Continued focus and improvement on FDA compliance.

Increased pace of research and development activities, with a view to increase the number of ANDA filings.

Continue to invest in equipment and facilities to expand capacity to meet requirements of projected short and long-term growth while improving quality.

Increased market share for certain existing products and recently introduced products

Enhanced customer reach and satisfaction.

Prompt introduction of new approved products to the market.

Achieving further operational efficiencies by attaining economies of scale and cost reduction per unit.

Increase the number of products, as well as anticipated volume increases for existing products, which, in turn, will improve manufacturing capacity utilization.

Consider alternative ways of increasing cash, such as marketing ANDAs owned by Sun Pharma.

Expand our relationships with financial institutions to fortify our credit position and borrowings as necessary.

Research alternate product development sources and product licenses such as in licensing authorized generics from brand innovator companies and acquisitions of ANDAs from competitor manufacturers both domestically and abroad.

Research possible development of brands for existing stream of products where such potential exists.

Increase focus on succession planning

Increase training in cGMP.

Increase management training and development.

Maintain balance in trade class.

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

The Company has no debt or other market risk securities or transactions in foreign exchange.

**Line of Credit**

On November 17, 2005, the Company entered into a one-year, \$10 million Credit Agreement with JP Morgan Chase Bank, N.A. Under the Credit Agreement, the lender may make loans and issue letters of credit to the Company for the Company'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 17, 2007. On November 16, 2006, this agreement was renewed through November 30, 2007. Borrowings are secured by the Company's receivables and inventory. Interest is payable based on a LIBOR Rate or an alternate base rate (determined by reference to the prime rate or the federal funds effective rate), as selected by the Company. The rate of interest is LIBOR plus 75 basis points or the bank's prime rate minus 100 basis points (effective rates of 6.1% and 7.25%, respectively at March 31, 2007.) The Credit Agreement requires that certain financial covenants be met on a quarterly basis. The Company is in compliance with these financial covenants at March 31, 2007. There are no outstanding borrowings under this Credit Agreement as of March 31, 2007.

**Item 8. Financial Statements and Supplementary Data****INDEX TO FINANCIAL STATEMENTS**

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

None.

**Item 9A. Controls and Procedures.**

a. The term "disclosure controls and procedures" is defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the Exchange Act). These rules refer to the controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is recorded, processed, summarized and reported within required time periods. Our Chief Executive Officer and our Chief Financial Officer have evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report (the "Evaluation Date"), and have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective in providing them with material information relating to the Company known to others within the Company which is required to be included in our periodic reports filed under the Exchange Act.

b. There has been no change in the Company's internal control over financial reporting that occurred during the fiscal quarter ended March 31, 2007 that materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

**Management's Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO").

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Based on our evaluation, management concluded that our internal control over financial reporting was effective as of March 31, 2007. Our management's assessment of the effectiveness of our internal control over financial reporting as of March 31, 2007 has been audited by Rehmann Robson, an independent registered public accounting firm, as stated in its Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting which appears on pages F-1 and F-2 below.



**Item 9B. Other Information.**

None.

### PART III

#### **Item 10. Directors, Executive Officers and Corporate Governance.**

The information with respect to directors and executive officers of the Company, the nomination of directors, the Company's Code of Ethics, compliance with Section 16(a) of the Exchange Act and the Company's audit committee are included under the sections Nominees For Directors Terms Expiring in 2008, Incumbent Directors Terms Expiring in 2006, Incumbent Directors Terms Expiring in 2007, Committees Meetings of Directors, Nomination of Directors, Executive Officers, Code of Business Conduct and Ethics, and Section 16(a) Beneficial Ownership Reporting Compliance in our 2007 Proxy Statement to be filed with the Securities and Exchange Commission on or before July 29, 2007, is incorporated herein by reference.

#### **Item 11. Executive Compensation.**

The information regarding executive compensation, director compensation, compensation committee interlocks and the compensation committee report are included under the sections Compensation of Executive Officers, Compensation of Directors, Compensation Committee Interlocks and Insider Participation and Compensation Committee Report in our 2007 Proxy Statement to be filed with the Securities and Exchange Commission on or before July 29, 2007, is incorporated herein by reference.

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

The information with respect to the security ownership of certain beneficial owners and management and with respect to equity compensation plans included under the sections Security Ownership of Certain Beneficial Owners, Security Ownership of Management and Directors and Equity Compensation Plan Information in our 2007 Proxy Statement to be filed with the Securities and Exchange Commission on or before July 29, 2007, is incorporated herein by reference.

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

The information with respect to certain relationships and related transactions and director independence are included under the sections Transactions of Directors, Executive Officers and Certain Beneficial Owners of Caraco in our 2007 Proxy Statement to be filed with the Securities and Exchange Commission on or before July 29, 2007, is incorporated herein by reference.

#### **Item 14. Principal Accountant Fees and Services.**

The information under the caption Relationship with Independent Auditors Audit and Non-Audit Fees in our 2007 Proxy Statement to be filed with the Securities and Exchange Commission on or before July 29, 2007, is incorporated herein by reference.

**Part IV**

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

- (a) 1 Financial Statements

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- 2 Financial Statement Schedules

None

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

- (b) Exhibits

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

- (c) Other Schedules

None

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on the 14th day of May, 2007.

CARACO PHARMACEUTICAL LABORATORIES, LTD.

/s/ Daniel H. Movens

\_\_\_\_\_  
Daniel H. Movens  
Chief Executive Officer



**POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Daniel H. Movens and / or Mukul Rathi, this 14<sup>th</sup> day of May, 2007, his true and lawful attorney(s)-in-fact and agent(s), with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any or all amendments to this report and to file the same, with all exhibits and schedules thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney(s)-in-fact and agent(s) full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney(s)-in-fact and agent(s), or their substitutes(s), may lawfully do or cause to be done by virtue hereof.

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

<u>/s/ Dilip S. Shanghvi</u>	Chairman of the Board
Dilip S. Shanghvi	
<u>/s/ Daniel H. Movens</u>	Director, Chief Executive Officer, Principal Executive Officer
Daniel H. Movens	
<u>/s/ Mukul Rathi</u>	Interim Chief Financial Officer, Principal Accounting Officer
Mukul Rathi	
<u>/s/ Jitendra N. Doshi</u>	Director
Jitendra N. Doshi	
<u>/s/ John D. Crissman</u>	Director
John D. Crissman	
<u>/s/ Sailesh T. Desai</u>	Director
Sailesh T. Desai	
<u>/s/ Timothy Manney</u>	Director
Timothy Manney	
<u>/s/ Madhava Reddy</u>	Director
Madhava Reddy	
<u>/s/ Georges Ugeux</u>	Director
Georges Ugeux	
<u>/s/ Sudhir V. Valia</u>	Director
Sudhir V. Valia	

***CARACO PHARMACEUTICAL LABORATORIES, LTD.***

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(a subsidiary of Sun Pharmaceutical Industries Limited)  
***FINANCIAL STATEMENTS***

***AND***

***REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM***

***FOR THE YEARS ENDED MARCH 31, 2007 AND 2006,  
THE THREE MONTHS ENDED MARCH 31, 2005 AND  
THE YEAR ENDED DECEMBER 31, 2004***

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

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

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

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting that **Caraco Pharmaceutical Laboratories, Ltd.** (a Michigan corporation) (a subsidiary of Sun Pharmaceutical Industries Limited) (the Corporation) maintained effective internal control over financial reporting as of March 31, 2007, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Corporation's internal control over financial reporting based on our audit.

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

A corporation's internal control over financial reporting is a process designed by, or under the supervision of, the corporation's principal executive and principal financial officers, or persons performing similar functions, and effected by the corporation's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A corporation's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the corporation; (2) provide reasonable assurance that transactions are recorded as



necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that the Corporation maintained effective internal control over financial reporting as of March 31, 2007, is fairly stated, in all material respects, based on the COSO criteria. Also in our opinion, the Corporation maintained, in all material respects, effective internal control over financial reporting as of March 31, 2007, based on the COSO criteria.

We have also audited, in accordance with the standards of the *Public Company Accounting Oversight Board (United States)*, the financial statements as of and for the year ended March 31, 2007 of the Corporation and our report dated May 14, 2007 expressed an unqualified opinion on those financial statements.

/s/ Rehmann Robson

Troy, Michigan  
May 14, 2007.

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited the accompanying balance sheets of *Caraco Pharmaceutical Laboratories, Ltd.* (a Michigan corporation) (a subsidiary of Sun Pharmaceutical Industries Limited) (the Corporation) as of March 31, 2007 and 2006 and the related statements of operations, stockholders equity (deficit) and cash flows for the years ended March 31, 2007 and 2006, the three months ended March 31, 2005 and for the year ended December 31, 2004. These financial statements are the responsibility of the Corporation's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Caraco Pharmaceutical Laboratories, Ltd. as of March 31, 2007 and 2006, and the results of its operations and its cash flows for the years ended March 31, 2007 and 2006, the three months ended March 31, 2005, and for the year ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America.

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We have also audited, in accordance with the standards of the *Public Company Accounting Oversight Board (United States)*, the effectiveness of the Corporation's internal control over financial reporting as of March 31, 2007, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated May 14, 2007 expressed an unqualified opinion on management's assessment of the effectiveness of the Corporation's internal control over financial reporting and an unqualified opinion on the effectiveness of the Corporation's internal control over financial reporting.

/s/ Rehmann Robson

Troy, Michigan

May 14, 2007

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

**BALANCE SHEETS**

	March 31	
	2007	2006
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 33,897,622	\$ 11,924,245
Accounts receivable, net	26,125,146	20,859,099
Inventories	31,943,297	26,965,690
Prepaid expenses and deposits	3,473,340	2,532,561
	<b>95,439,405</b>	<b>62,281,595</b>
<b>Property, plant and equipment</b>		
Land	975,311	197,305
Buildings and improvements	12,448,221	10,790,703
Equipment	15,292,499	12,040,688
Furniture and fixtures	992,013	681,705
	29,708,044	23,710,401
Total	29,708,044	23,710,401
Less accumulated depreciation	10,678,157	8,749,997
	<b>19,029,887</b>	<b>14,960,404</b>
<b>Net property, plant and equipment</b>	<b>19,029,887</b>	<b>14,960,404</b>
<b>Total assets</b>	<b>\$ 114,469,292</b>	<b>\$ 77,241,999</b>

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

**LIABILITIES AND STOCKHOLDERS EQUITY**

	<b>March 31</b>	
	<b>2007</b>	<b>2006</b>
<b>Current liabilities</b>		
Accounts payable, trade	\$ 3,350,024	\$ 3,696,265
Accounts payable, Sun Pharma	12,143,157	14,678,085
Accrued expenses	3,782,702	2,489,398
<b>Total liabilities (all current)</b>	<b>19,275,883</b>	<b>20,863,748</b>
<b>Commitments and contingencies (Notes 9, 11 and 12)</b>		
<b>Stockholders equity (Note 7)</b>		
Series B convertible preferred stock, no par value; issued and outstanding 10,880,000 shares at March 31, 2007 and 2006.	73,585,520	72,755,770
Common stock, no par value; authorized 50,000,000 shares, issued and outstanding 28,102,394 shares (March 31, 2007) and 26,421,994 shares (March 31, 2006)	55,970,097	44,988,597
Additional paid-in capital	2,864,522	2,718,735
Accumulated deficit	(37,226,730)	(64,084,851)
<b>Total stockholders equity</b>	<b>95,193,409</b>	<b>56,378,251</b>
<b>Total liabilities and stockholders equity</b>	<b>\$ 114,469,292</b>	<b>\$ 77,241,999</b>

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

**STATEMENTS OF OPERATIONS**

	Year Ended March 31, 2007	Year Ended March 31, 2006	Three Months Ended March 31, 2005	Year Ended December 31, 2004
Net sales	\$ 117,027,016	\$ 82,788,918	\$ 17,336,500	\$ 60,340,309
Cost of goods sold (Notes 1 and 4)	59,242,858	41,872,834	7,879,425	24,441,569
<b>Gross profit</b>	<b>57,784,158</b>	<b>40,916,084</b>	<b>9,457,075</b>	<b>35,898,740</b>
Selling, general and administrative expenses	9,880,674	8,182,718	1,879,480	5,276,755
Research and development costs - affiliate (Note 7)	11,761,280	35,055,360	10,200,000	24,397,040
Research and development costs - other	10,590,643	8,437,338	1,719,865	6,053,334
<b>Operating income (loss)</b>	<b>25,551,561</b>	<b>(10,759,332)</b>	<b>(4,342,270)</b>	<b>171,611</b>
<b>Other income (expense)</b>				
Interest income	1,081,208	233,385	16,385	40,316
Interest expense	(28,194)	(3,740)		(407,330)
Loss on sale of equipment	(5,106)			(10,636)
Other income	258,652	106,375	4,172	6,671
<b>Other income (expense) - net</b>	<b>1,306,560</b>	<b>336,020</b>	<b>20,557</b>	<b>(370,979)</b>
<b>Net income (loss)</b>	<b>\$ 26,858,121</b>	<b>\$ (10,423,312)</b>	<b>\$ (4,321,713)</b>	<b>\$ (199,368)</b>
<b>Net income (loss) per share</b>				
Basic	\$ 1.02	\$ (0.39)	\$ (0.16)	\$ (0.01)
Diluted	\$ 0.72	\$ (0.39)	\$ (0.16)	\$ (0.01)

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

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

**STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)**

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
<b>Balances at January 1, 2004</b>		\$	24,577,828	\$ 41,442,311	\$ 2,718,735	\$ (49,140,458)	\$ (4,979,412)
Issuance of preferred stock to affiliate in exchange for product technology transfers	4,352,000	27,500,410					27,500,410
Common stock options exercised			1,756,866	3,453,946			3,453,946
Net loss						(199,368)	(199,368)
<b>Balances at December 31, 2004</b>	4,352,000	27,500,410	26,334,694	44,896,257	2,718,735	(49,339,826)	25,775,576
Issuance of preferred stock to affiliate in exchange for product technology transfers	1,632,000	10,200,000					10,200,000
Common stock options exercised			25,600	31,730			31,730
Net loss						(4,321,713)	(4,321,713)
<b>Balances at March 31, 2005</b>	5,984,000	37,700,410	26,360,294	44,927,987	2,718,735	(53,661,539)	31,685,593
Issuance of preferred stock to affiliate in exchange for product technology transfers	4,896,000	35,055,360					35,055,360
Common stock options exercised			61,700	60,610			60,610
Net loss						(10,423,312)	(10,423,312)
<b>Balances at March 31, 2006</b>	10,880,000	\$ 72,755,770	26,421,994	\$ 44,988,597	\$ 2,718,735	\$ (64,084,851)	\$ 56,378,251
Issuance of preferred stock to affiliate in exchange for product technology transfers	1,632,000	11,761,280					11,761,280
Conversion of preferred stock into common stock	(1,632,000)	(10,931,530)	1,632,000	10,931,530			
Common stock options exercised			48,400	49,970			49,970
Stock option expense					145,787		145,787
Net Income						26,858,121	26,858,121
<b>Balances at March 31, 2007</b>	10,880,000	\$ 73,585,520	28,102,394	\$ 55,970,097	\$ 2,864,522	\$ (37,226,730)	\$ 95,193,409

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

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

**STATEMENTS OF CASH FLOWS**

	<u>Year Ended March 31, 2007</u>	<u>Year Ended March 31, 2006</u>	<u>Three Months Ended March 31, 2005</u>	<u>Year Ended December 31, 2004</u>
<b>Cash flows from operating activities</b>				
Net Income (loss)	\$ 26,858,121	\$ (10,423,312)	\$ (4,321,713)	\$ (199,368)
Adjustments to reconcile net income (loss) to net cash provided by operating activities				
Depreciation	1,931,423	1,552,578	306,626	932,419
Capital stock issued or to be issued to affiliate in exchange for product formula	11,761,280	35,055,360	10,200,000	24,397,040
Loss on sale of property, plant and equipment	5,106			10,636
Stock option expense	145,787			
Changes in operating assets and liabilities which (used) provided cash				
Accounts receivable	(5,266,047)	(14,122,321)	(2,133,911)	(64,393)
Inventories	(4,977,607)	(8,497,997)	(1,333,882)	(7,523,001)
Prepaid expenses and deposits	(940,778)	(1,426,943)	(441,807)	(140,430)
Accounts payable	(2,881,171)	6,156,792	2,300,793	4,690,789
Accrued expenses	1,293,307	557,954	220,793	(64,548)
<b>Net cash provided by operating activities</b>	<b>27,929,421</b>	<b>8,852,111</b>	<b>4,796,899</b>	<b>22,039,144</b>
<b>Cash flows for investing activities</b>				
Purchases of property, plant and equipment	(6,006,014)	(3,615,901)	(657,673)	(3,982,413)
<b>Net cash used in investing activities</b>	<b>(6,006,014)</b>	<b>(3,615,901)</b>	<b>(657,673)</b>	<b>(3,982,413)</b>
<b>Cash flows from financing activities</b>				
Proceeds from loans payable to financial institutions	5,000,000	1,500,000		10,000,000
Repayments of loans payable to financial institutions	(5,000,000)	(1,500,000)		(26,875,000)
Repayments of EDC loan				(6,385,490)
Proceeds from issuance of common stock	49,970	60,610	31,730	3,453,946
<b>Net cash provided by (used in) financing activities</b>	<b>49,970</b>	<b>60,610</b>	<b>31,730</b>	<b>(19,806,544)</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>21,973,377</b>	<b>5,296,820</b>	<b>4,170,956</b>	<b>(1,749,813)</b>
Cash and cash equivalents, beginning of year / period	11,924,245	6,627,425	2,456,469	4,206,282
<b>Cash and cash equivalents, end of year / period</b>	<b>\$ 33,897,622</b>	<b>\$ 11,924,245</b>	<b>\$ 6,627,425</b>	<b>\$ 2,456,469</b>

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



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

**NOTES TO FINANCIAL STATEMENTS**

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**1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Organization and Nature of Business*

Caraco Pharmaceutical Laboratories, Ltd. ( Caraco or the Corporation ), based in Detroit, Michigan, develops, manufactures and markets generic, prescription and over-the-counter pharmaceuticals in the United States. The process of developing a line of proprietary drugs requires approvals by the Food and Drug Administration (FDA) of Abbreviated New Drug Applications (ANDA). The Corporation's present product portfolio consists of 33 products in various strengths and package sizes. The Corporation's drugs relate to a variety of therapeutic segments including the central nervous system, cardiology, pain management and diabetes.

The Corporation's manufacturing facility and executive offices were constructed in 1991, pursuant to a \$9.1 million loan from the Economic Development Corporation of the City of Detroit (the EDC ). Since August 1997, capital infusions and loans have primarily come from Sun Pharmaceutical Industries Limited, a specialty pharmaceutical corporation organized under the laws of India ( Sun Pharma ). Among other things, Sun Pharma has acted as a guarantor on loans to Caraco, has supplied the Corporation with raw materials for certain products, assisted in obtaining machinery and equipment to enhance production capacities at competitive prices, and has transferred certain generic products. As of March 31, 2007, Sun Pharma beneficially owns approximately 66% (75% including its convertible Series B Preferred stock) of the outstanding common shares of Caraco.

*Sun Pharmaceutical Industries Limited*

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

Sun Pharma and its affiliates have loaned the Corporation approximately \$10 million since August 1997. As of December 31, 2003, all such loans had been repaid. Sun Pharma has also assisted the Corporation, by acting as guarantor, in obtaining line of credit loans from ICICI Bank Limited, The Bank of Nova Scotia and Citibank FSB in the amounts of \$5.0 million, \$12.5 million and \$10.0 million, respectively, all of which have been repaid and terminated as of December 31, 2004.

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**NOTES TO FINANCIAL STATEMENTS**

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

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

The products agreement was amended by the Independent Committee, comprised of the three independent directors, in the first quarter of 2004 to eliminate the provision requiring that the Independent Committee concur in the selection of each product, and provides instead that each product satisfy certain objective criteria developed by management and approved by the Independent Committee. Pursuant to such objective criteria, all 25 of the products under this agreement have been selected, 23 of which passed bio-equivalency studies through March 31, 2007.

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

Sun Pharma and its subsidiaries supply the Corporation with certain raw materials (Note 4) and formulations, assist in acquiring machinery and equipment to enhance production capacities, and provide qualified technical professionals who work as Caraco employees.

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

**NOTES TO FINANCIAL STATEMENTS**

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

In Fiscal 2007, the Corporation entered into a three-year marketing agreement with Sun Pharma, which was reviewed and approved by the Board's Independent Committee. Under the agreement, the Corporation purchases selected products offered by Sun Pharma and markets and distributes the same as part of the current product offerings in the U.S., its territories and possessions, including Puerto Rico. During Fiscal 2007 the Corporation made net sales of \$4.6 million of the marketed products.

During the three month period ended March 31, 2005 SPARC Bioresearch Private Limited ( SPARC ), an affiliate of Sun Pharma, performed certain analytical studies required as part of the bio-equivalency process for two products. The Corporation incurred approximately \$172,000 of costs during this period for the studies performed by SPARC. No similar studies were performed by SPARC during the years ended March 31, 2007 and 2006 and December 31, 2004.

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

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 Pharma exercised these stock options during the fourth quarter of 2004.

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

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

**NOTES TO FINANCIAL STATEMENTS**

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***Operations***

The Corporation recorded net sales of \$117.0 million for the year ended March 31, 2007 ( Fiscal 2007 ) and generated cash from operations of \$27.9 million during Fiscal 2007. This cash was generated after funding working capital requirements of \$12.8 million. The Corporation earned a net income of \$26.9 million during Fiscal 2007. The income was primarily due to increased sales and lower non-cash research and development expense (R&D) of \$11.8 million recorded during Fiscal 2007, compared to \$35.1 million during Fiscal 2006. This non-cash R&D expense relates to three products passing their bio-equivalency studies and the related value of the preferred stock issued to Sun Global during this period. At March 31, 2007, the Corporation had stockholders' equity of \$95.2 million.

Management's plans for Fiscal 2008 include:

Continued focus and improvement on FDA compliance.

Increased pace of research and development activities, with a view to increase the number of ANDA filings.

Continue to invest in equipment and facilities to expand capacity to meet requirements of projected short and long-term growth while improving quality.

Increased market share for certain existing products and recently introduced products

Enhanced customer reach and satisfaction.

Prompt introduction of new approved products to the market.

Achieving further operational efficiencies by attaining economies of scale and cost reduction per unit.

Increase the number of products, as well as anticipated volume increases for existing products, which, in turn, will improve manufacturing capacity utilization.

Consider alternative ways of increasing cash, such as marketing ANDAs owned by Sun Pharma.

Expand our relationships with financial institutions to fortify our credit position and borrowings as necessary.

Research alternate product development sources and product licenses such as in licensing authorized generics from brand innovator companies and acquisitions of ANDAs from competitor manufacturers both domestically and abroad.

Research possible development of brands for existing stream of products where such potential exists.

**CARACO PHARMACEUTICAL LABORATORIES, LTD.**  
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**NOTES TO FINANCIAL STATEMENTS**

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Increase focus on succession planning

Increase training in cGMP.

Increase management training and development.

Maintain balance in trade class.

***Use of Estimates***

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates. Significant estimates include, but are not limited to, provisions for estimated customer returns, discounts, rebates and other price adjustments, including customer chargebacks (see Revenue Recognition , below), valuation allowances for deferred tax assets, and valuation of overhead components in inventory.

***Cash and Cash Equivalents***

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

***Revenue Recognition***

Revenue from product sales, net of estimated provisions, is recognized when there is persuasive evidence that an arrangement exists, shipment of the goods has occurred, the selling price is fixed or determinable, and collectibility is reasonably probable. The Corporation's customers consist primarily of large pharmaceutical wholesalers who sell directly into the retail channel, chain drug stores, distributors, and managed care customers. Provisions for sales discounts, and estimates for chargebacks, rebates, and product returns are established as a reduction of product sales revenue at the time

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**NOTES TO FINANCIAL STATEMENTS**

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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.

*Allowances for Sales Adjustments*

Chargebacks

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

The Corporation considers the following factors in the determination of the estimates of chargebacks.

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

Such estimated amounts, in addition to certain other deductions, are deducted from the Corporation's gross sales to determine net revenues. The amount of actual chargebacks

**CARACO PHARMACEUTICAL LABORATORIES, LTD.**  
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**NOTES TO FINANCIAL STATEMENTS**

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claimed could be either higher or lower than the amounts accrued. Changes in estimates, if any, would be recorded in the income statement in the period of the change. If the Corporation materially over or under estimates the amount that will ultimately be charged back to it by its wholesale customers, there could be a material impact on the Corporation's financial statements. Approximately 90% and 88% of the total allowance for trade receivables at March 31, 2007 and 2006, respectively, has been established to provide for estimated chargebacks and rebates (see Note 3).

Shelf Stock Adjustments

Shelf stock adjustments are credits issued to customers to reflect decreases in the selling prices of products. These credits are customary in the industry and are intended to reduce the customers' inventory cost to better reflect current market prices. The decision to grant a shelf stock adjustment to a customer following a price decrease is at the Corporation's 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 products based on historical experience and input from customers, and levels of inventory held by customers at the date of the pricing adjustments.

Product Returns and Other Allowances

In the pharmaceutical industry, customers are normally granted the right to return product for credit if the product has not been used prior to its expiration date. The Corporation's return policy typically allows product returns for products within a 12-month window from six months prior to the expiration date and up to six months after the expiration date. The Corporation estimates the level of sales, which will ultimately be returned pursuant to its return policy, and records a related reserve at the time of sale. These amounts are deducted from its gross sales to determine net revenues. These estimates take into consideration historical returns of the products and the Corporation's future expectations. The Corporation periodically reviews the reserves established for returns and adjusts them based on actual experience, as necessary. The primary factors considered in estimating its potential product returns include shelf life of expiration date of each product and historical levels of expired product returns. If the Corporation becomes aware of any returns due to product related issues, this information is used to estimate an additional reserve. The amount of actual product return could be either higher or lower than the amounts reserved. Changes in these estimates, if any, would be

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**NOTES TO FINANCIAL STATEMENTS**

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recorded in the income statement in the period of the change. If the Corporation over or under estimates the quantity of product that will ultimately be returned, there may be a material impact to its financial statements.

Discounts (trade and prompt payment discounts) are reserved for at the end of every reporting period based on the gross sales made to the customers during the period and based on their terms of trade. The Corporation reviews its contracts with its customers in addition to historical data and percentages to estimate the reserve for estimated discounts.

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

***Doubtful Accounts***

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

***Accounts Receivable***

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

***Inventories***

Inventories, which consist of raw materials, goods in transit and finished goods, as well as work-in-process, are stated at the lower of cost, determined using the



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specific identification method, or market. The Corporation analyzes its inventory levels quarterly and writes down any inventory that has become obsolete and inventory that has a cost basis in excess of its expected net realizable value. Expired inventory is disposed of and the related costs are written off. Materials acquired for research and development on products yet to be launched are written off in the year of acquisition. The determination of whether or not inventory costs will be realizable requires estimates by management. A critical estimate in this determination is the estimate of the future expected inventory requirements, whereby the Corporation compares its internal sales forecasts to inventory on hand. Actual results may differ from those estimates and inventory write-offs may be required. The Corporation must also make estimates about the amount of manufacturing overhead to allocate to its finished goods and work in process inventories. Although the manufacturing process is generally similar for its products, the Corporation must make judgments as to the portion of costs to allocate to purchased product, work in process and finished goods, and such allocations can vary based upon the composition of these components and the fact that each product produced does not necessarily require the same amount of time or effort for the same production step. Accordingly, the assumptions made can impact the value of reported inventories and cost of sales.

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

Net income (loss) per share is computed using the weighted average number of common shares outstanding during each period and considers a dual presentation and reconciliation of basic and diluted per share amounts. Diluted reflects the potential dilution of all common stock equivalents.

At March 31, 2006 and 2005 and at December 31, 2004 options to purchase 341,400, 357,000 and 381,600 common shares respectively, 10,880,000, 5,984,000 and 4,352,000 shares of convertible preferred stock, respectively and 45,000 shares of common stock granted to the Corporation's Chief Executive Officer during 2006 (Note 7) were excluded from the computation of earnings per share because they would have an antidilutive effect on net loss per share.

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

	Year Ended March 31 2007	Year Ended March 31 2006	Three Months Ended March 31 2005	Year Ended December 31 2004
<b>Numerator:</b>				
Net income (loss) available for common stockholders	\$ 26,858,121	\$ (10,423,312)	\$ (4,321,713)	\$ (199,368)
<b>Denominator:</b>				
Weighted average shares outstanding, basic	26,447,312	26,392,054	26,348,347	24,734,282
Incremental shares from assumed conversion of -				
- preferred stock	10,464,175			
- common stock options	343,293			
Weighted average shares outstanding, diluted	37,254,780	26,392,054	26,348,347	24,734,282
<b>Net income (loss) per common share</b>				
Basic	\$ 1.02	\$ (0.39)	\$ (0.16)	\$ (0.01)
Diluted	\$ 0.72	\$ (0.39)	\$ (0.16)	\$ (0.01)

***Property, Plant and Equipment and Depreciation***

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

***Federal Income Taxes***

Deferred income tax assets and liabilities are determined based on the difference between the financial statement and federal income tax basis of assets and liabilities as measured by the estimated tax rates that will be in effect when these differences reverse. Deferred income taxes result principally from the Corporation's net operating loss carryforwards.

***Research and Development Costs***

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Series B convertible preferred stock (Note 7) is 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

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to the Corporation. The resulting amount of research and development expense is charged to operations and is determined based on the fair value of the preferred shares on the date the respective product formula passes its bio-equivalency studies. The fair value of such shares is based upon an independent valuation.

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

***Fair Values of Financial Instruments***

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

***Recent Accounting Pronouncements***

In February 2006, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 155 *Accounting for Certain Hybrid Financial Instruments-An amendment of FASB Statements No. 133 and 140* . This statement requires evaluation of all interests in securitized financial assets to determine whether they represent either freestanding derivatives or contain embedded derivatives. These interests were previously exempted from such evaluation. SFAS No. 155 permits any hybrid instrument, such as an interest in securitized financial assets containing an embedded derivative, to be accounted at fair value as opposed to bifurcating and accounting for the embedded derivative separate from the host instrument. This Statement also eliminates restrictions on a qualifying special purpose entity's ability to hold passive derivative financial instruments pertaining to beneficial interests that are, or contain, a derivative financial instrument. The Corporation will adopt this statement in the first quarter of Fiscal 2008, and does not expect the adoption to have a material impact on the Corporation's financial position or results of operations. This statement is effective for fiscal years beginning after September 15, 2006.

In June 2006, the FASB issued Interpretation No. 48 *Accounting for Uncertainty in Income Taxes - An interpretation of FASB Statement no. 109* ( FIN 48 ). This interpretation provides a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. The Corporation will adopt this Interpretation in the first quarter of fiscal 2008. The cumulative effects, if any, of applying FIN 48 will be recorded as an adjustment to retained earnings. The Corporation is currently assessing the impact of this Interpretation on its financial position and results of operations.

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In September 2006, the FASB issued SFAS No. 157 *Fair Value Measurements*. This Statement replaces multiple existing definitions of fair value with a single definition, establishes a consistent framework for measuring fair value, and expands financial statement disclosures regarding fair value measurements. This Statement applies only to fair value measurements that are already required or permitted by other accounting standards and does not require any new fair value measurements. SFAS No. 157 is effective for fiscal years beginning subsequent to November 15, 2007. The Corporation will be required to adopt SFAS No. 157 for the first quarter of Fiscal 2009.

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, including an amendment of FASB Statement No. 115 ( *SFAS 159* ). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. SFAS 159 does not affect any existing accounting literature that requires certain assets and liabilities to be carried at fair value. SFAS 159 is effective for fiscal years beginning after November 15, 2007. Management currently does not expect adoption of SFAS 159 will have a material effect on the Corporation's financial position or results of operations. The Corporation plans to adopt SFAS for the first quarter of Fiscal 2009.

**2. SUPPLEMENTAL CASH FLOWS INFORMATION**

***Non-Cash Financing Activities***

As described in Notes 1 and 7, pursuant to the technology transfer agreement with an affiliate of the Corporation's parent, Caraco, on an ongoing basis, finances the acquisition of research and development costs in exchange for the issuance of preferred stock to its parent. Preferred stock earned or issued to affiliates had fair values of \$11,761,280 and \$35,055,360 for the years ended March 31, 2007 and 2006, respectively, \$10,200,000 for the three month period ended March 31, 2005, and \$24,397,040 for the year ended December 31, 2004. In March 2007, the Corporation issued 1,632,000 shares of its common stock to Sun Pharma Global Inc. in exchange for 1,632,000 preferred shares at a value of \$10,931,530.

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***Other Cash Flows Information***

Cash paid for interest was approximately \$28,000, \$4,000 and \$407,000 for the years ended March 31, 2007 and 2006, and December 31, 2004, respectively. No cash was paid for interest for the three month period ended March 31, 2005.

**3. ACCOUNTS RECEIVABLE, NET OF ALLOWANCES FOR SALES ADJUSTMENTS AND DOUBTFUL ACCOUNTS (NOTE 1)**

Accounts receivable and related allowances are summarized as follows:

	March 31	
	2007	2006
Accounts receivable - gross	\$ 62,615,146	\$ 33,926,099
Allowances:		
Chargebacks & Rebates	32,638,000	11,467,000
Sales returns and allowances	3,752,000	1,500,000
Doubtful accounts	100,000	100,000
Total allowances	36,490,000	13,067,000
Accounts receivable, net of allowances	\$ 26,125,146	\$ 20,859,099

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

	Total Allowances
<b>Balance at December 31, 2003</b>	<b>\$ 16,043,000</b>
Additions charged to net sales	67,670,000
Deductions allowed to customers	(65,578,000)
<b>Balance at December 31, 2004</b>	<b>18,135,000</b>
Additions charged to net sales	21,712,000
Deductions allowed to customers	(18,817,000)
<b>Balance at March 31, 2005</b>	<b>21,130,000</b>
Additions charged to net sales	118,996,000
Deductions allowed to customers	(126,959,000)

<b>Balance at March 31, 2006</b>	<b>13,067,000</b>
Additions charged to net sales	199,586,000
Deductions allowed to customers	(176,163,000)
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<b>Balance at March 31, 2007</b>	<b>\$ 36,490,000</b>
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**NOTES TO FINANCIAL STATEMENTS**

**4. INVENTORIES**

Inventories consist of the following amounts:

	March 31	
	2007	2006
Raw materials	\$ 10,443,715	\$ 9,735,502
Goods in transit	4,972,668	5,974,600
Work in process	3,717,911	3,283,911
Finished goods	12,809,003	7,971,677
	\$ 31,943,297	\$ 26,965,690

The principal components used in the Corporation's business are active and inactive pharmaceutical ingredients and certain packaging materials. Some of these components are purchased from single sources; however, the majority of the components have an alternate source of supply. Because the FDA approval process requires manufacturers to specify their proposed supplier of components in their applications, FDA approval of a new supplier would be required if components were no longer available from the specified suppliers.

During the years ended March 31, 2007 and 2006, the three months ended March 31, 2005, and during the year ended December 31, 2004, the Corporation purchased inventory components of approximately \$38.8 million, \$28.1 million, \$5.3 million, and \$16.7 million, respectively, from Sun Pharma.

**5. DEBT**

***Loans Payable to Financial Institutions***

During 2004, the Corporation obtained a \$10,000,000 line-of-credit with Citibank, N.A. that incurred interest at the London Interbank Offered Rate (LIBOR) plus 125 basis points. Borrowings on the line-of-credit were available to Caraco only when secured by



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an irrevocable standby letter-of-credit from Sun Pharma. Such a letter was provided by Sun Pharma during 2004. The letter had expired as of December 31, 2004, and the line was terminated on March 15, 2005.

On November 17, 2005, the Corporation entered into a one-year, \$10 million Credit Agreement with JP Morgan Chase Bank, N.A. 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 17, 2007. On November 16, 2006, this agreement was renewed through November 30, 2007. 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 6.1% and 7.25%, respectively at March 31, 2007.) The Credit Agreement requires that certain financial covenants be met on a quarterly basis. There are no borrowings under this Credit Agreement at March 31, 2007.

**6. INCOME TAXES**

The Corporation's deferred income taxes result principally from its net operating loss carryforwards (NOLs) and payment of alternative minimum tax. At March 31, 2007 a net deferred income tax asset of approximately \$7.5 million (computed using a 34% tax rate) relating to these temporary differences exists. Based on the Corporation's prior operating results and operating characteristics, full utilization of this deferred tax asset to offset future taxable income is not reasonably assured. Accordingly, Caraco has recorded a valuation allowance of \$7.0 million at March 31, 2007 (\$20.1 million March 31, 2006), to offset the net deferred tax asset, resulting in a net deferred tax asset of \$0.5 million recognized at March 31, 2007. No net deferred tax asset or liability was recognized at March 31, 2006. The valuation allowance has decreased by approximately \$13.1 million for the year ended March 31, 2007 and increased by approximately \$3.7 million for the year ended March 31, 2006, \$2.0 million for the three month period ended March 31, 2005, \$0.4 million in 2004.

During the year ended March 31, 2007, NOL carryforwards of approximately \$26.8 million were used to offset taxable income. In addition, the Corporation determined that approximately \$13.1 million of previous NOLs have been lost under the provisions of Internal Revenue Code Section 382. Accordingly, at March 31, 2007, NOL

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carryforwards of approximately \$18.7 million, which expire between 2007 and 2026, are available to offset future federal taxable income, if any.

**7. STOCKHOLDERS EQUITY (DEFICIT)**

*Common Stock*

During 2003, the Corporation's shareholders approved the authorization of an additional 20,000,000 shares of common stock. The Corporation filed an amendment to its articles of incorporation to effect this change in Fiscal 2007.

The Corporation granted 45,000 shares of common stock on May 2, 2005 to its Chief Executive Officer, which vest at a rate of 15,000 shares on each anniversary date until they are fully vested on May 2, 2008. The Corporation has recorded compensation expense of approximately \$119,000 and \$109,000 related to the portion of the stock grant that vested during Fiscal 2007 and 2006, respectively.

*Preferred Stock*

In November 2002, in connection with the new technology transfer agreement established with Sun Global (Note 1), the Corporation designated the Series B Convertible Preferred Stock. The Series B preferred shares are non-redeemable and have no par value. In addition, the Series B Convertible Preferred Stock has no voting or dividend rights or liquidation preference other than priority liquidation based on their values on the dates they were earned, and can be converted after three years from the issuance date (or immediately upon a change in control) into one share of common stock, subject to a conversion adjustment (Note 1). While such preferred shares are outstanding, Caraco cannot, without the consent of the holders of a majority of the outstanding shares of the preferred stock, amend or repeal its articles of incorporation or bylaws if such action would adversely affect the rights of the preferred stock. In addition, without such consent, capital stock having any preference or priority superior to the preferred stock may not be issued. As of March 31, 2007, the Corporation has issued 12,512,000 shares of the Series B Convertible Preferred stock to Sun Pharma in exchange for twenty-three product transfers. Such shares have been cumulatively valued at \$84,517,050 as of March 31, 2007. On March 31, 2007, 1,632,000 shares of the preferred stock were converted into an equal number of shares of Corporation's common stock at a value of \$10,931,530.

**8. COMMON STOCK OPTIONS**

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**Common Stock Option Plans**

As of March 31, 2007, the Corporation maintains one stock option plan, the 1999 Equity Participation Plan (the 1999 Plan ) (all options under the 1993 plan were exercised during 2003), under which the Corporation may grant options to employees and non-employee-directors for the purchase of up to 3,000,000 shares of common stock. The exercise price of options granted may not be less than the fair value of the common stock on the date of grant. Options granted under this plan generally vest in annual installments, from the date of grant, over a three and five-year period, and expire within six years from the date of the grant. Activity with respect to these options is summarized as follows:

	Year Ended March 31, 2007		Year Ended March 31, 2006		Three Months Ended March 31, 2005		Year Ended December 31, 2004	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding, beginning of year / period	141,400	3.93	160,500	1.68	181,600	\$ 1.41	277,000	\$ 1.00
Granted	74,000	9.78	46,000	8.39	4,500	9.60	9,000	9.60
Exercised	(48,400)	1.03	(61,700)	0.98	(25,600)	1.24	(80,400)	1.08
Terminated	(1,100)	8.83	(3,400)	9.30			(24,000)	0.80
Outstanding, end of year / period	165,900	\$ 7.36	141,400	\$ 3.93	160,500	\$ 1.67	181,600	\$ 1.41
Options exercisable, end of year	61,233	\$ 3.95	71,720	\$ 1.32	79,418	\$ 1.50	49,800	\$ 1.02

Options at March 31, 2007:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Shares	Remaining Contractual Life *	Exercise Price *	Shares	Exercise Price *
\$0.68 to \$1.00	36,900	0.2	\$ 0.76	36,900	\$ 0.76
\$7.01 to \$8.00	1,500	4.0	7.90	1,000	7.90
\$8.01 to \$9.00	50,500	4.2	8.41	16,333	8.42
\$9.01 to \$10.00	61,000	5.0	9.31	6,000	9.53
\$10.01 to \$13.00	16,000	5.5	11.71	1,000	11.01

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Total	<u>165,900</u>	<u>3.7</u>	<u>\$ 7.36</u>	<u>61,233</u>	<u>\$ 3.95</u>
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\* Weighted average

The estimated fair value as of the date options were granted during the year ended March 31, 2007, is estimated on the date of the grant using the Black Scholes option-pricing model and is based upon the following assumptions:

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**Year ended  
March 31, 2007**

Weighted average estimated fair value per share of options granted during the period \$ 9.78

Assumptions

Common stock price volatility	36.50%
Risk free rate of return	4.74%
Expected option term (in years)	3

*Other Common Stock Option Agreements*

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

	Year Ended March 31, 2007		Year Ended March 31, 2006		Three Months Ended March 31, 2005		Year Ended December 31, 2004	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding, beginning of period	200,000	\$ 3.50	200,000	\$ 3.50	200,000	\$ 3.50	1,876,666	\$ 2.01
Exercised							(1,676,666)	2.01
Outstanding, end of period	200,000	\$ 3.50	200,000	\$ 3.50	200,000	\$ 3.50	200,000	\$ 3.50
Options exercisable, end of period	200,000	\$ 3.50	200,000	\$ 3.50	200,000	\$ 3.50	200,000	\$ 3.50

Options at March 31, 2007:

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

On April 1, 2006, the Corporation adopted Statement of Financial Accounting Standards ( SFAS ) No. 123 (Revised 2004), *Share-Based Payment* (Statement No. 123 (R) ), which requires employee share-based compensation to be accounted for under the fair value method and requires the use of an option pricing model for estimating the fair value

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of stock options at the date of grant. Previously, the Corporation accounted for stock options under the intrinsic value method prescribed by Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, and provided the required pro forma disclosures prescribed by SFAS No. 123, *Accounting for Stock-Based Compensation*, (Statement No. 123), as amended. Since the exercise price of options equaled the market price of the stock on the date of grant, the stock options had no intrinsic value and, therefore, no expense was recognized for stock options by the Corporation prior to the beginning of fiscal 2007.

The Corporation elected to adopt Statement No. 123 (R) using the modified prospective method, which requires compensation expense to be recorded for all unvested share-based awards beginning in the first quarter of adoption.

For the year ended March 31, 2007, the Corporation has recognized expense amounting to \$145,787 related to share-based compensation. As of March 31, 2007 total unrecognized compensation cost related to stock options granted was \$250,732. The unrecognized stock option compensation cost is expected to be recognized over a period of approximately 3 to 5 years.

The Corporation estimates the fair value of stock options granted using the Black-Scholes option-pricing model, which requires the Corporation to estimate the expected term of the stock option grants and expected future stock price volatility over the term. The term represents the expected period of time the Corporation believes the options will be outstanding based on historical information. Estimates of expected future stock price volatility are based on historical volatility of the Corporation's common stock. The Corporation calculates the historical volatility as the standard deviation of the differences in the natural logarithms of the weekly stock closing price, adjusted for dividends and stock splits.

Options to purchase 74,000, 46,000, 4,500 and 9,000 shares of common stock were granted for the years ended March 31, 2007 and 2006, the three month period ended March 31, 2005 and the year ended December 31, 2004, respectively, to the independent directors, officers and employees of the Corporation. No options were granted during 2003.

The Corporation granted options to purchase 40,000 shares of common stock each on June 11, 2006 and May 2, 2005 respectively, to its Chief Executive Officer, which vest at a rate of 1/3rd on each anniversary date until they are fully vested on June 11, 2009 and May 2, 2008, respectively.

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***Strategic Alliance Stock Options Agreement***

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

**9. LEASES (INCLUDING RELATED PARTY)**

The Corporation entered into two non-cancelable operating leases during 2000 with Sun Pharma to lease production machinery. The leases each required quarterly rental payments of \$4,245 and expired during 2005.

The Corporation entered into a non-cancelable operating lease with an unrelated party during 2002 to lease additional warehouse space. This lease was subsequently modified during 2003 in lieu of a new non-cancelable operating lease for additional space at this warehouse. The lease was again modified during 2006 to change the term from 42 months to 66 months. The new lease requires monthly payments that increase from \$15,458 to \$18,623 over the term of the lease that expires in 2009 with an option to renew for an additional year.

The Corporation entered into a non-cancelable operating lease with an unrelated party on March 13, 2006 to obtain additional space for its executives and administrative staffs. The lease was subsequently modified during 2006 in lieu of a new non-cancelable operating lease for additional office space. The lease commences in May 2006 and requires monthly payments that increase from \$13,458 to \$14,387 over the term of the lease that expires in 2008.

Net rental expense on these operating leases was \$314,917 and \$224,569 for the years ended March 31, 2007 and 2006, respectively, \$64,896 for the three months ended March 31, 2005 and \$181,129 for the year ended December 31, 2004.

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The following is a schedule of annual future minimum lease payments required under the operating leases with remaining non-cancelable lease terms in excess of one year as of March 31, 2007:

<u>Year</u>	<u>Amount</u>
2008	\$ 379,442
2009	323,720

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The Corporation also paid approximately \$0.8 million and \$0.2 million for the years ended March 31, 2007 and 2006, respectively, \$0.1 million for the three month period ended March 31, 2005, and \$0.6 million during the year ended December 31, 2004 to Sun Pharma and its associates for the purchase of various parts and machinery needed for operations.

**10. RETIREMENT PLAN**

The Corporation maintains a deferred compensation plan qualified under Section 401(k) of the Internal Revenue Code. Under this plan, eligible employees are permitted to contribute up to the maximum allowable amount determined by the Internal Revenue Code. The Corporation may make discretionary matching and profit sharing contributions under the provisions of the plan. The Corporation made contributions in the amount of \$72,876 for the year ended March 31, 2007. The Corporation made no discretionary contributions during the year ended March 31, 2006, the three months ended March 31, 2005, or for the year ended December 31, 2004.

**11. CONCENTRATIONS AND COMMITMENTS**

*Major Customers*

Shipments to three wholesalers accounted for approximately 58% of net revenue for the year ended March 31, 2007. Shipments to three wholesalers accounted for approximately 74% of gross revenue for the year ended March 31, 2006, 60% of gross revenue for the three months ended March 31, 2005 and 79% of gross revenue for the year ended December 31, 2004 respectively. Balances due from these customers represented approximately 82% and 72% of gross accounts receivable at March 31, 2007 and 2006, respectively.

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The loss of any of these customers could have a materially adverse effect on short-term operating results.

***Major Products***

Shipments of four products and three products accounted for approximately 69% of net revenue for the year ended March 31, 2007 and 70% of net revenue for the year ended March 31, 2006, respectively. Shipments of three products accounted for approximately 74% of gross revenue for the three months ended March 31, 2005 and 80% of gross revenue for the year ended December 31, 2004.

Approximately 79% and 84% of raw material purchases for the years ended March 31, 2007 and 2006 respectively, 84% for the three months ended March 31, 2005 and 75% for the year ended December 31, 2004 were made from Sun Pharma. The Corporation, however, believes that other sources of raw materials are available.

***Product Sales Commitment***

Certain of the Corporation's customers purchase their products through designated wholesalers, who act as an intermediary distribution channel for the Corporation's products. One such customer, the Veterans Administration, an agency of the United States Government, entered into a sales contract with the Corporation effective August 5, 2002 to purchase approximately \$13,000,000 of product per year over a one year base contract period that ended June 30, 2003. The contract has four one-year option periods, the last of which was exercised in August 2006. The agreement may be terminated by the purchaser without cause and in such case, Caraco would only be entitled to a percentage of the contract price, plus reasonable charges that have resulted from the termination. The agreement further provides for certain penalty provisions if the Corporation is unable to meet its sales commitment.

***Labor Contract***

The majority of the Corporation's hourly work force is covered by a collective bargaining agreement that expires in September 2008.

**12. OTHER MATTERS**

***Employment Contracts***

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

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**NOTES TO FINANCIAL STATEMENTS**

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

***Litigation***

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 Pharmaceutical Industries, Ltd. ( Sun ) 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's ANDA, or will induce others to infringe by marketing and/or selling Sun's generic version of Clarinex® upon receiving FDA approval. Schering's complaint seeks an order from the Court which, among other things, directs the FDA not to approve Sun's ANDA any earlier than the claimed expiration date. The ANDA filed by Sun contains a Paragraph IV Certification challenging the 274 patent. Sun believes that the 274 patent is invalid, unenforceable and/or will not be infringed by Sun's or Company's manufacture, use or sale of the product and both Sun 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.

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.

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**NOTES TO FINANCIAL STATEMENTS**

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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 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-

**CARACO PHARMACEUTICAL LABORATORIES, LTD.**  
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**NOTES TO FINANCIAL STATEMENTS**

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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. The Company believes that, like its original patent, Ortho-McNeil's reissue patent is invalid and/or is not infringed by the Company's manufacture, use or sale of the product and the Company intends to vigorously defend this action. There is no assurance, however, that the Company will prevail in this action.

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.

***Product Liability and Insurance***

The Corporation currently maintains general and product liability insurance, with coverage limits of \$10 million per incident and in the aggregate. The Corporation's insurance policies provide coverage on a claim made basis and are subject to annual renewal. Such insurance may not be available in the future on acceptable terms or at all.

**CARACO PHARMACEUTICAL LABORATORIES, LTD.**  
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**NOTES TO FINANCIAL STATEMENTS**

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There can be no assurance that the coverage limits of such policies will be adequate to cover the Corporation's liabilities, should they occur.

***Royalty Accrual***

Pursuant to the Strategic Alliance Stock Options Agreement (Note 8), Caraco received the formulation for one product, Metoprolol Tartrate, in March 1995. However, Caraco has determined that the formula provided to it with respect to Metoprolol Tartrate is different than the formula submitted in an ANDA to the FDA in 1995, approved by the FDA in 1996 and manufactured and introduced by Caraco since 1997. The Corporation has accrued royalties of approximately \$1 million, which is included with accrued expenses in the accompanying balance sheets at March 31, 2007 and 2006, and since April 2003, has discontinued to accrue royalties related to this agreement.

***Product Development***

The Corporation during the year ended March 31, 2007, entered into three definitive agreements with different companies to develop four products. These agreements contain, for three products both milestone payments to be paid in cash and profit sharing based upon future sales for a defined period, and for one product only milestone payments in cash without any obligation to share profits in the future.

**13. SEGMENT INFORMATION**

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

SFAS No. 131, *Disclosures About Segments of an Enterprise and Related Information* establishes standards for reporting of financial information about operating segments in annual financial statements. The Corporation considers its business to be a single segment entity, as its revenues are solely attributable to its generic drug product line.

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**CARACO PHARMACEUTICAL LABORATORIES, LTD.**  
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**NOTES TO FINANCIAL STATEMENTS**

For informational purposes, the Corporation's sales, grouped by therapeutic categories, for the years ended March 31, 2007 and March 31, 2006 the three months ended March 31, 2005 and the year ended December 31, 2004 are as follows:

Therapeutic Category	Year Ended March 31 2007	Year Ended March 31 2006	Three Months Ended March 31 2005	Year Ended December 31 2004
Antianxiety Drug	\$ 4,035,902	\$ 2,890,213	\$ 631,670	\$ 2,119,276
Antibiotic	506,592	652,055	132,624	549,261
Anticonvulsant	4,293,332	232,669	45,578	204,003
Antidepressant	14,053,823	8,010,744	507,480	957,557
Antidiabetic	30,056,770	32,110,625	7,362,962	30,842,081
Antihypertensive Drug/Beta Blocker	19,751,939	16,788,820	4,178,650	14,257,386
Antipsychotic	3,530,898	2,167,911	484,780	1,293,620
Cardiac	2,446,608	1,239,431	514,139	1,344,603
Decongestants	62,814	116,257	316,524	358,059
Hormonal Replacement Therapy			295,172	
Nonsteroidal Antiinflammatory Agent	2,886,593	2,101,804	544,983	1,719,487
Opiate Agonist/Analgesic	31,257,560	14,082,000	1,887,640	5,121,809
Platelet Aggregation Inhibitor	206,185	147,856	24,571	80,730
Skeletal Muscle Relaxant	2,902,770	1,150,073	201,673	1,492,437
Vascular and Migraine Headache Suppressant	1,035,230	1,098,460	208,054	
<b>Net Sales</b>	<b>\$ 117,027,016</b>	<b>\$ 82,788,918</b>	<b>\$ 17,336,500</b>	<b>\$ 60,340,309</b>

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**EXHIBIT INDEX**

- 3.01 Registrant s Amended and Restated Articles of Incorporation, as amended. (1)
- 3.02 Certificate of Amendment to the Articles of Incorporation filed February 13, 1997. (2)
- 3.03 Certificate of Amendment to the Articles of Incorporation filed February 10, 2000. (3)
- 3.04 Certificate of Determination of Rights, Privileges and Preferences Series B Preferred Stock. (4)
- 3.05 Registrant s Amended and Restated Bylaws. (5)
- 10.01 Agreement, dated as of October 1, 1993, among Registrant and Non-Affiliate (6)
- 10.02 Employment Agreement, dated October 22, 1993, of Robert Kurkiewicz. (6)
- 10.03 Stock Purchase Agreement by and between Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries, Ltd. dated as of April 23, 1997. (7)
- 10.04 Products Agreement by and between Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries, Ltd. dated as of April 23, 1997. (7)
- 10.05 Registration Rights Agreement dated as April 1997. (7)
- 10.06 Amendment to Employment Agreement of Robert Kurkiewicz dated as of April 1, 1997. (8)
- 10.07 1999 Equity Participation Plan. (9)
- 10.08 Renewal to Employment Agreement of Robert Kurkiewicz dated as of January 1, 1999. (3)
- 10.09 Third Amendment to Employment Agreement of Robert Kurkiewicz dated August 30, 2002. (3)
- 10.10 Agreement between Caraco and Sun Pharma Global, Inc. dated November 21, 2002. (4)
- 10.11 Sales contract with government vendor. (4)
- 10.12 Employment Agreement of Mr. Singh (5)
- 10.13 Employment Agreement of Mr. Movens (10)
- 10.14 Confidentiality and Non-Competition Agreement of Dan Movens (10)
- 10.15 Summary of Fiscal 2006 Executive Officer Salaries (11)
- 10.16 Credit Agreement with JPMorgan Chase Bank, N.A. (12)
- 10.17 Security Agreement with JPMorgan Chase Bank, N.A. (12)
- 10.18 Form of Grant of Employee Stock Option (13)
- 10.19 Marketing Agreement between Caraco and Sun Pharmaceutical Industries, Limited (14)
- 21 Subsidiaries of the Registrant (+)
- 23.01 Consent of Registered Independent Public Accountants (+)



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

- 24.1 Power of Attorney (included on signature page) (+)
- 31.1 Certificate of Chief Executive Officer (+)
- 31.2 Certificate of Chief Financial Officer (+)
- 32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (+)

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+ Filed herewith

- (1) Incorporated by reference from Exhibits to Registrant's Form 10-KSB filed on or about March 30, 1995 as Commission File no. 0-24676.
- (2) Incorporated by reference from Exhibits to Registrant's Form 10-KSB filed on or about March 31, 1997, as Commission File No. 0-24676.
- (3) Incorporated by reference from Exhibits to Pre-Effective Amendment No. 1 to Form SB-2 filed on September 4, 2002 as Commission File No. 333-91968.
- (4) Incorporated by reference from Exhibits to Registrant's Form 10-KSB filed on or about March 31, 2003, Commission File No. 0-24676.
- (5) Incorporated by reference from Exhibit to Registrant's Form 10-K filed on or about March 15, 2005, Commission File No. 0-24676.
- (6) Incorporated by reference from Exhibits to Registrant's Registration Statement on Form SB-2, as amended, filed on November 5, 1993 as Commission File No. 33-71398C.
- (7) Incorporated by reference from Exhibits to Registrant's Form 10-QSB filed on November 14, 1997 as Commission File No. 0-24676.
- (8) Incorporated by reference from Exhibits to Registrant's Form 10-KSB filed on or about March 31, 1998, as Commission File No. 0-24676.
- (9) Incorporated by reference from Appendix A to Registrant's Proxy Statement dated April 28, 1999 as Commission File No. 0-24676.
- (10) Incorporated by reference from Exhibits to Registrant's Form 10-K/A filed on or about May 2, 2005, Commission File No. 0-24676.
- (11) Incorporated by reference from Exhibits to Registrant's Form 8-K filed on or about August 25, 2005. Commission File No. 0-24676
- (12) Incorporated by reference from Exhibits to Registrant's Form 10-Q filed on or about January 26, 2006. Commission File No. 0-24676
- (13) Incorporated by reference from Exhibits to Registrant's Form 10-K filed on or about June 14, 2006. Commission File No. 0-24676
- (14) Incorporated by reference from Exhibits to Registrant's Form 8-K filed on or about January 19, 2007. Commission File No. 0-24676