CARACO PHARMACEUTICAL LABORATORIES LTD
Form 10KSB
March 30, 2004

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

FORM 10-KSB

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2003

COMMISSION FILE NO. 0-24676

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

MICHIGAN	38-2505723
(State of Incorporation)	(I.R.S. Employer Identification No.)

1150 ELIJAH MCCOY DRIVE, DETROIT, MI 48202
(Address of principal executive office)

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

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE EXCHANGE ACT:

Title of Each Class to be so Registered	Name of Each Employee On which Each Class is to be Registered
Common Stock, No Par Value	American Stock Exchange

SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE EXCHANGE ACT: None.

INDICATE BY CHECK MARK WHETHER THE REGISTRANT (1) HAS FILED ALL REPORTS REQUIRED TO BE FILED BY SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 DURING THE PRECEDING 12 MONTHS (OR FOR SUCH SHORTER PERIOD THAT THE REGISTRANT WAS REQUIRED TO FILE SUCH REPORTS), AND (2) HAS BEEN SUBJECT TO SUCH FILING REQUIREMENTS FOR THE PAST 90 DAYS. Yes X No ___

INDICATE BY CHECK MARK IF DISCLOSURE OF DELINQUENT FILERS PURSUANT TO ITEM 405 OF REGULATION S-B 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-KSB OR ANY AMENDMENTS TO THIS FORM 10-KSB. [ ]

STATE ISSUER'S REVENUES FOR ITS MOST RECENT FISCAL YEAR: $45,498,400

THE AGGREGATE MARKET VALUE OF THE VOTING COMMON STOCK HELD BY NON-AFFILIATES,

BASED ON THE LAST SALE PRICE OF THE COMMON STOCK ON MARCH 25, 2004, AS REPORTED ON THE AMERICAN STOCK EXCHANGE, WAS $89,056,067.

INDICATE THE NUMBER OF SHARES OUTSTANDING OF EACH OF THE REGISTRANT'S CLASSES OF COMMON STOCK, AS OF THE LATEST PRACTICABLE DATE.

As of March 25, 2004, there were 24,577,828 Shares of Common Stock Outstanding

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of registrant's definitive 2004 Proxy Statement in connection with the Annual Meeting of Stockholders to be held in June 2004 ("2004 Proxy Statement") are incorporated by reference into Part III.

CARACO PHARMACEUTICAL LABORATORIES, LTD.
FORM 10-KSB

PART I

ITEM 1. DESCRIPTION OF BUSINESS

INTRODUCTION

Caraco Pharmaceutical Laboratories, Ltd. ("Caraco" which is also referred to as the "Company," the "Corporation," "we," "us" or "our") is a corporation organized under Michigan law in 1984, to engage in the business of developing, manufacturing and marketing generic drugs for the ethical or prescription and over-the-counter or non-prescription or "OTC" markets.

A generic drug is a pharmaceutical product, which is the chemical and therapeutic equivalent of a brand-name drug as to which the patent and/or market exclusivity has expired. Generics are well accepted for substitution of brand products as they sell at lower prices than the prices of the branded products and at their equivalence in quality and bioavailability.

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 Securities and Exchange Commission. You may read and copy any of the Company's SEC filings at the SEC's Public Reference Room at 450 5th Street, N.W., Washington, D.C., 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. Our principal Internet address is www.caraco.com. Our website provides a link to the SEC's website, through which our annual, quarterly and current reports, and amendments to those reports are available. We believe that these reports are made available as soon as reasonably practicable after we electronically file with or furnish them to the SEC.

OVERVIEW

Our 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"). From that date, until the second half of 2002, operations were funded from private placement offerings and loans. Since August 1997, such capital infusions and loans have primarily come from Sun Pharmaceutical Industries Limited, a specialty pharmaceutical corporation organized under the laws of India ("Sun Pharma"). In addition, among other things, Sun Pharma has acted as a guarantor on loans to Caraco, has supplied us with raw materials for certain of our products, helped us obtain machinery and

equipment to enhance our production capacities at competitive prices and transferred certain generic products to us. Sun Pharma's investment in and support of Caraco has resulted in, since the second quarter of 2002, Caraco achieving the sales necessary to support its operations. As of March 25, 2004, Sun Pharma beneficially owns approximately 63% of the outstanding shares of Caraco. See "Current Status" and "Sun Pharmaceutical Industries Limited."

CURRENT STATUS

We posted record net sales and four consecutive profitable quarters, and accomplished our first-ever profitable year. Net sales for 2003 were $45.5 million as compared to $22.4 million for 2002. We earned operating income of $12.4 million for 2003 as compared to $0.73 million for 2002. After interest costs, we earned net income of $11.2 million for 2003 as compared to a net loss of $2.2 million for 2002. Net cash generated from operating activities was $15.5 million for 2003 as compared to net cash used in operating activities of $0.8 million for 2002. At December 31, 2003, we had a stockholders' deficit of $5.0 million as compared to a deficit of $19.6 million at December 31, 2002. See "Part II - Item 6. Management's Discussion and Analysis of Financial Condition and Results of Operations."

We received 2 Abbreviated New Drug Application ("ANDA") approvals in 2003. During the first quarter of 2004, we received approval for an additional strength for one product in our portfolio. See "Caraco's Products and Product Strategy" below.

In April 2003, we successfully modified our mortgage loan with the EDC, which had been in default since February 1999, with interest rates starting at 2.75% per annum and increasing to 5.16% per annum. Under the modification, the EDC retains a first mortgage on our property and a first lien on our furniture, fixtures and equipment and intellectual property, however, the EDC no longer retains a lien on our accounts receivable and inventory.

Pursuant to our products agreement with Sun Pharma Global, Inc. ("Sun Global"), a wholly-owned subsidiary of Sun Pharma, we have selected, through the first quarter of 2004, seven products out of the 25 products to be transferred to us by Sun Global. Of these, one product passed its bio-equivalency studies in the fourth quarter of 2003 and one product passed its bio-equivalency studies in February 2004. Under the products agreement, Sun Global has earned 544,000 preferred shares for each such product. See "Sun Pharmaceutical Industries Limited" and "Part II - Item 6. - Future Outlook."

During the first quarter of 2004, we filed two ANDAs with respect to the two above mentioned products transferred to us by Sun Global, with the FDA. This brings our total number of ANDAs pending approval by the FDA to four.

The FDA informed us and sixty-six other manufacturers and distributors of Guaifenesin to cease manufacturing Guaifenesin by May 23, 2003 and to cease all sales past November 2003. We have complied with the FDA's directive. During the year ended December 31, 2003, net sales for Guaifenesin was approximately $1.0 million.

We underwent inspections by the Food and Drug Administration ("FDA") in November 2002 and we were found to be in substantial compliance with current Good Manufacturing Practices ("cGMPs"). Although we did receive an FDA 483, a written list of observations, we do not believe the observations are material and we have taken appropriate remedial actions.

In August 2003, our common stock became listed on the American Stock

Exchange.

During the first quarter of 2004, we appointed three new independent directors to comply with the requirements of the Sarbanes-Oxley Act of 2002 and the regulations of the American Stock Exchange. The new independent directors replace the three independent directors who resigned in late 2003. The new independent directors are William C. Brooks, Timothy Manney and Georges Ugeux.

During the first quarter of 2004, Sun Pharma acquired 3,452,291 additional shares of common stock and 1,329,066 stock options from two former directors and a significant shareholder; thereby increasing its beneficial ownership from approximately 48% to 63%.

OVERVIEW OF THE GENERIC DRUG INDUSTRY

We believe that sales of generic drugs have increased in recent years because of a number of factors including (i) modification of state and federal laws to permit or require substitution of generic drugs by pharmacists; (ii) enactment of ANDA procedures for obtaining FDA approval to manufacture generic prescription drugs; (iii) changes in governmental and third-party payor health care reimbursement policies to encourage cost containment; (iv) increased acceptance of generic drugs by physicians, pharmacists and consumers; and (v) the number of formerly patented drugs which have become available to generic competition. Moreover, every year branded drugs with significant sales volumes come off patent.

CARACO'S PRODUCTS AND PRODUCT STRATEGY

Our present product portfolio includes 17 prescription products in 31 strengths in 70 package sizes. The products and their use for the indications are set forth in the table below:

GENERIC NAME	PURPOSE
Metroprolol Tartrate	Hyper-Tension
Miraphen PSE	Decongestant
Paromomycin Sulfate	Antibacterial
Salsalate	Decongestant
CMT	Arthritis/NSAID
Guai/DM	Decongestant
Clonazepam	Seizure, Panic Disorders
Flurbiprofen	Arthritis/NSAID
Carbamazepine	Epilepsy
Oxaprozin	Rheumatoid Disease
Metformin Hydrochloride	Diabetes
Tramadol Hydrochloride	Analgesic
Miraphen PE	Decongestant
Digoxin	Heart Failure
Meperidine Hydrochloride*	Analgesic
Ticlopidine	Reduction of incidence of Strokes
Tizanidine	Management of Muscle Tone associated with spasticity

* Expected to be marketed sometime in 2004.

We have submitted 17 ANDAs to the FDA for approval since August 1997, including 2 filed during the first quarter of 2004. Of these 17 ANDAs, the FDA approved 2 prior to 2000, 3 during 2001, 6 during 2002 and 2 during 2003.

Accordingly, we have 4 pending ANDAs. Of the 17 ANDAs, Sun Pharma and Sun Global have transferred the technology for 14 of them to us. See "Sun Pharmaceutical Industries Limited."

Our strategy has been to analyze the marketplace and try to determine opportunities depending on a particular product's potential market and the number of competitors vying for that market.

HEXAL-PHARMA GMBH & CO., KG

Pursuant to an agreement between Caraco and Hexal-Pharma GmbH & Co., KG, a German pharmaceutical company and its United States affiliate (together, "Hexal") dated as of October 1, 1993, Hexal agreed to convey to us 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, we were required to pay Hexal (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 us. No options have yet been exercised.

Pursuant to the agreement, we received a formulation for one product, Metoprolol Tartrate, from Hexal in March 1995. However, we have determined that the formula provided to us by Hexal 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 us since 1997. Accordingly, since April 2003, we have discontinued to accrue royalties.

There is no assurance, however, that Hexal will not challenge our determination and make a claim that royalties are owed.

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.

Sun Pharma and its affiliates had loaned us approximately $10 million since August 1997. As of December 31, 2003, we have repaid all of such loans.

Sun Pharma has assisted us, by acting as guarantor, in obtaining line of credit loans from ICICI Bank Limited and The Bank of Nova Scotia in the amounts of $5.0 million and $12.5 million, respectively. Such lines are fully utilized as of December 31, 2003.

In August 1997, we entered into an agreement, whereby Sun Pharma was required to transfer to us the technology formula for 25 generic pharmaceutical products over a period of five years through August 2002. We exchanged 544,000 shares of our common stock for each technology transfer of an ANDA product (when a bio-equivalency studies was successfully completed) and 181,333 shares for each technology transfer of a DESI product. The products provided to us from Sun Pharma were selected by mutual agreement. Under such agreement, we conducted, at our expense, all tests including bio-equivalency studies. Pursuant to such agreement, Sun Pharma delivered to us the technology for 13 products. This agreement has expired and as noted below, we have entered into a new agreement, with Sun Global, an affiliate of Sun Pharma.

On November 21, 2002, we entered into a products agreement with Sun

Global. Under the agreement, which was approved by our independent directors, Sun Global has agreed to provide us with 25 new 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 such 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. In return for the technology transfer, Sun Global will receive 544,000 shares of a newly created preferred stock for each generic drug transferred when 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.

The products agreement was amended by the Independent Committee in the first quarter of 2004 to eliminate the provision requiring that the Independent Committee concur in the selection of each product, and provide instead, that each product satisfy certain objective criteria developed by management and approved by the Independent Committee. Pursuant to such objective criteria, we selected seven products during the first quarter of 2004 that we had been working on during 2003, but had not formally selected under the products agreement prior to its amendment. One of the seven products passed its bio-equivalency studies in December 2003 and one product passed its bio-equivalency studies in February 2004. Sun Global has thereby earned 544,000 preferred shares for each product. See Part II - Item 6. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Future Outlook."

Sun Pharma has established Research and Development Centers in Mumbai and Vadodara in India, where the development work for products is performed.

Sun Pharma supplies us with certain raw materials and formulations. In addition, Sun Pharma assists us in acquiring machinery and equipment to enhance our production capacities. During 2003, we purchased approximately

$10,270,000 in raw materials and formulations from Sun Pharma. We paid $510,000 to Sun Pharma, its cost, for machinery and equipment bought on our behalf.

Sun Pharma has also been providing us with qualified technical professionals.

During the first quarter of 2004, Sun Pharma acquired 3,452,291 additional shares of common stock and 1,329,066 stock options from two former directors and a significant shareholder, thereby increasing its beneficial ownership from approximately 48% to 63%.

MARKETING

Our marketing objective has been to create a distribution system to obtain access to a wide range of purchasers of generic pharmaceutical products. Internally, this requires a sales force. See "Sales and Customers" below. Externally, it requires forging relationships with wholesaler buyer groups,

distributors and mail order companies, among others.

Drug wholesalers, with an estimated 75% of the drug market, comprise a strategic link in the pharmacy distribution chain. They are used by drug manufacturers because they are a cost effective means of reaching thousands of drug purchasers and are used by most drug purchasers because they constitute a reasonably local, stocking source for hundreds or thousands of products from multiple manufacturers.

Our product line is now represented by the following major top drug wholesalers: McKesson Corporation, Amerisource - Bergen and Cardinal Health. Our products are now stocked by many other drug wholesalers, partly as a result of our arrangements, discussed below, with buying groups.

A large number of buying groups of retail pharmacists, hospitals, nursing homes and other regional or functionally similar categories of drug purchasers use their members' combined purchasing power to induce drug manufacturers or other vendors to submit bid prices at which their members may individually purchase products through designated wholesalers. As part of our ongoing marketing efforts, we are pursuing arrangements with additional wholesalers and expanding our sales network of buying groups.

Further, as part of our ongoing marketing efforts, we are pursuing arrangements to expand our business with our current distributors and a mail-order company.

Federal and state agencies purchase a large amount of generic pharmaceutical products. All of our products are now listed for purchase at prices bid by us in the Federal Supply Schedule, the Federal Bureau of Prisons Prime Vendor Program, the Veterans Administration Prime Vendor Program, the Department of Defense and by various state agencies.

SALES AND CUSTOMERS

Presently, we have a sales organization comprised of 8 persons. In time as new products are added to the existing product line, we plan to expand our customer sales effort through adding additional sales personnel and/or contracting with an independent sales and marketing firm.

Shipments to one wholesale customer accounted for approximately 61% and 65% of sales in 2003 and 2002, respectively. Balances due from this customer represented approximately 57% and 80% of gross accounts receivable at December 31, 2003 and 2002, respectively. No other single customer represented more than 10% of our net sales during the past two years.

As disclosed above under "Marketing," certain of our customers purchase our products through designated wholesale customers, such as Amerisource Bergen who act as an intermediary distribution channel for our products. For example, the Veterans Administration, which has entered into the sales contract discussed below, has selected Amerisource Bergen as its designated wholesaler.

We have entered into a sales contract with the Veterans Administration, an agency of the U.S. government. Our agreement with this customer is for the period of June 21, 2002 through June 20, 2003, with four 1-year option periods and is for the purchase of one product, Metformin Hydrochloride. The first option period was exercised. The agreement may be terminated by the purchaser without cause and in such case, we would only be entitled to a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges that have resulted from the

termination. The agreement provides that certain penalties would be incurred if we are unable to meet our sales commitment.

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.

An outline of research and development expenses incurred directly by Caraco for 2003 and 2002 follows ($ 000's):

	2003	2002
Salaries	719	678
Raw Materials/Supplies	439	165
Bio-equivalency Studies	179	594
Laboratory	559	505
Technology Transfer, non-cash	3,103	3,887
Other	1,217	1,407
TOTAL	6,216	7,236

The 2003 research and development expenses shown above include the non-cash cost, with respect to the one product transferred by Sun Global to Caraco, of $3,103,370 for 544,000 shares of our preferred stock, as compared to the 2002 non-cash cost with respect to the three products transferred by Sun Pharma to Caraco, of $3,887,423 for 1,632,000 shares of our common stock.

REGULATION

The research and development, manufacture 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 and the testing, manufacture, 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 Corporation time and resources in the areas of production and quality control.

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

New Drug Application ("NDA"). Generally, the NDA procedure is required for drugs with active ingredients and/or with a dosage form, dosage strength or delivery system of an active ingredient not previously approved by the FDA. We do not expect to submit an NDA in the foreseeable future.

Abbreviated New Drug Application ("ANDA"). The Waxman-Hatch 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. 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 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 bi-annually.

We underwent FDA inspections during March and April 2001 and November 2002 and on each occasion we were found to be in substantial compliance with cGMPs. We did receive FDA 483s but we do not believe the observations are material and we have taken appropriate remedial actions. We now have 4 ANDAs pending approval.

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.

We believe that we are in compliance with environmental laws.

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 market for generic drugs is highly competitive. There is intense competition in the generic drug industry in the United States, which is eroding price and profit margins. We compete with numerous pharmaceutical manufacturers, including both generic and brand-name manufacturers, many of which have been in business for a longer period of time than us, have a greater number of products in the market and have considerably greater financial, technical, research, manufacturing, marketing and other resources.

The principal competitive factor in the generic pharmaceutical market is the ability to be the first company, or among the first companies, to introduce a generic product after the related patent expires. Other competitive factors include price, quality, methods of distribution, reputation, customer service, including 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 a significant competitive factor, 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 hope to compete by selecting appropriate products, based on therapeutic segments, market sizes and number of competitors manufacturing the products, and by keeping our prices competitive and by providing reliability in the timely delivery, and in the quality, of our products.

EMPLOYEES

As of December 31, 2003 and 2002, we had a total of 200 and 190 employees, respectively, engaged in research and development, quality assurance, quality control, administration, sales and marketing, materials management, facility management and manufacturing 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 some of the employees of materials management, facility management and manufacturing and packaging departments.

PRODUCT LIABILITY AND INSURANCE

We currently have in force 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 2. DESCRIPTION OF PROPERTY.

EDC FINANCING

Pursuant to Section 108 of the Housing and Community Development Act of 1974, the EDC loaned us approximately $9.1 million in 1990 in accordance with a Development and Loan Agreement dated August 10, 1990. These funds were used to pay the direct costs of acquiring land and constructing thereon our pharmaceutical manufacturing facility and executive offices. See "Current Status," "Part II, Item 6. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Note 5 of Notes to Financial Statements."

On March 1, 1994, the EDC Agreement was amended to extend the maturity date to July 1, 2002. On August 5, 1997, we restructured the loan from the EDC. We became in default of the restructured loan; however, from February 1999 to April 2003 we made $100,000 monthly payments to the EDC while we were negotiating another restructuring of the loan.

On April 23, 2003, the loan was again restructured, effective as of January 1, 2003. The loan has been extended for six years, with interest rates starting at 2.75% and increasing to 5.16%. Under the extension, the EDC retains a first mortgage on our property, and a first lien on our furniture, fixtures, equipment, ANDAs and intellectual property. The EDC has removed its first lien on our accounts receivable and inventory. In addition to other covenants, we agreed that we will not redeem any of our outstanding shares, pay any dividends with respect to our outstanding common stock or preferred shares or merge or consolidate with any other corporation or other entity without the prior written consent of the EDC. However, the EDC has eliminated the prior restriction on capital investment in excess of $2 million by permitting us, so long as we are not in default of any of our obligations, to purchase new capital and sell the existing capital equipment so long as a result of such transactions, the book value of our assets is not reduced below the balance as of December 31, 2002 and the proceeds of any such sales are retained by us.

THE FACILITIES

Our approximately 70,000 square foot facility, which was designed and constructed to our specifications and completed in 1994, contains our production, packaging, research and corporate office. It is on a four-acre site. The manufacturing 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.

We also have leased an approximately 55,000 square foot facility for storage of inventory and office space. The lease expires in 2007 and includes an option to renew until 2008.

We have invested approximately $2.4 million in 2003 and $1.6 million in

2002 to upgrade our facilities.

We believe the existing facilities are suitable and adequate for our current level of operations. We also believe that our facility is adequately covered by insurance.

ITEM 3. LEGAL PROCEEDINGS.

Except for the following, we are not a party to any litigation, which, individually or in the aggregate, is believed to be material to our business:

As previously disclosed, on February 12, 2003, C. Arnold Curry filed a complaint in the Wayne County Circuit Court alleging breach of a written employment agreement. Mr. Curry is seeking 175,000 shares of our common stock (35,000 shares for each of the first five ANDAs approved by the FDA). We, and plaintiff, have each filed a motion for summary judgment. No trial date has been scheduled. We intend to vigorously defend ourselves against these claims, which we believe have no merit.

As previously disclosed, we were named as one of two defendants and as one of several defendants in two separate product liability suits, involving Miraphen, which contains phenylopropanolame (PPA), one in federal court in Pennsylvania and another in state court in New Jersey, respectively. These lawsuits seek damages generally for personal injury as well as punitive damages under a variety of liability theories including strict products liability, breach of warranty and negligence. The plaintiff in the federal lawsuit stipulated to a dismissal of the lawsuit and the case was formally dismissed by the federal court in December 2003. Since we believe that the other lawsuit has not been appropriately served on the Company, we are treating the matter as if we are not an active party. If we are deemed to be an active party, we believe we have substantial defenses to the claims and we will vigorously defend the lawsuit.

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 the fiscal year through the solicitation of proxies or otherwise.

PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

Since August 2003, our common stock has been listed on the American Stock Exchange, under the symbol "CPD." Prior to August 2003, our common stock was quoted on the OTC Bulletin Board under the symbol "CARA." The following table sets forth, in U.S. dollars and cents, for 2003, the high and low sales prices for each of the calendar quarters, and for 2002, the high and low bid prices. The quotations for the high and low bid prices reflect inter-dealer prices, without retail mark up, mark down or commissions and may not represent actual transactions.

2002	HIGH	LOW

First Quarter	$4.96	$1.10
Second Quarter	$3.73	$2.25
Third Quarter	$3.07	$1.73
Fourth Quarter	$2.77	$1.72

2003	HIGH	LOW
First Quarter	$3.98	$2.65
Second Quarter	$6.63	$2.40
Third Quarter	$12.20	$6.47
Fourth Quarter	$11.90	$6.77

As of March 16, 2004 there were 119 registered holders of our Common Stock.

During 2002, we issued 635,000 shares of common stock for cash of $1,692,000 pursuant to a private placement to accredited investors. All of the shares were issued pursuant to exemptions from registration under Section 4(2), 4(16) and Regulation D under the Securities Act of 1933.

During 2003, Sun Global earned 544,000 preferred shares in exchange for the transfer of one product pursuant to our current products agreement with Sun Global. During 2002, we issued 1,632,000 shares of common stock to Sun Global in exchange for the transfer of 3 products pursuant to the then existing products agreement between Sun Pharma and us. See "Part I. Sun Pharmaceutical Industries Limited." All issued shares of common stock to Sun Pharma are issued pursuant to exemptions from registration under Section 4(2), Section 4(6) and Regulation D under the Securities Act of 1933.

During 2003 and 2002, certain of our non-employee directors were issued 31,000 and 36,000 shares of common stock, respectively, for attending board and committee meetings. The shares of common stock were issued pursuant to exemptions from registration under Section 4(2), Section 4(6) and Regulation D under the Securities Act of 1933.

DIVIDEND POLICY

We never have 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, contractual restrictions and other factors deemed relevant by our Board of Directors. No dividend may be declared without the consent of the EDC.

ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

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

OVERVIEW

2003 was a milestone year. We earned record revenues of $45.5 million and net income of $11.2 million, our first full year of profitability. Net cash generated from operating activities was a record $15.5 million.

FDA COMPLIANCE AND PRODUCT APPROVALS

During 2001 and 2002, the FDA conducted inspections of our facility. During these inspections, we were found to be substantially in compliance with the cGMP regulations. While the FDA did issue us an FDA 483 list of observations after each inspection, we do not believe they are material and we have taken appropriate remedial actions. We have submitted 17 ANDAs to the FDA for approval since August 1997, including 2 filed during the first quarter of 2004. Of these, 13 have been approved and four are pending approval.

YEAR ENDED DECEMBER 31, 2003 COMPARED WITH YEAR ENDED DECEMBER 31, 2002

NET SALES. Net sales for 2003 and 2002 were $45.5 million and $22.4 million, respectively, reflecting an increase of almost 103%. The increase is due to the higher production and marketing of our products. 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 87% and 78% of sales in 2003 and 2002, respectively.

Net sales have also improved for the following reasons:

- We have been successful in obtaining larger sales contracts in 2002 with an agency of the U.S. government (in June 2002) and with one large mail order company (during 2002) so that we have benefited from sales pursuant to such contracts for all of 2003 as compared to part of 2002.

- With our larger base of products, we have been able to attract both new customers, and larger orders.

GROSS PROFIT. We earned a gross profit of $26.0 million for 2003 as compared to a gross profit of $10.3 million for 2002, reflecting an increase of 151% over 2002. 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 2002 and ability to absorb operational overheads due to higher sales.

As a result of increased sales, the gross profit margin has also improved when comparing the gross profit margins for 2003 and 2002. Gross profit margin for 2003 was 57% as compared to 46% for 2002. The increases were the result of:

- Changes in sales mix to higher profit margin products.

- 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 economics of scale.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES. Selling, general and administrative expenses for 2003 and 2002 were $7.4 million and $3.8 million, respectively, representing an increase of 92%. Selling, general and administrative expenses have decreased to 16.1% of net sales for 2003 as compared to 17.0% of net sales for 2002.

The increase in SG&A of approximately $3.6 million in 2003 was primarily due to recording of variable compensation expense on the extension of the term of two former directors' stock options and severance compensation to a former CEO ($2.2 million).

RESEARCH AND DEVELOPMENT EXPENSES. Total R&D expense for 2003 was $6.2 million as compared to $7.4 million during 2002, lower by almost 14%. Cash research and development expenses of $3.1 million for 2003 were lower by 8% when compared with $3.3 million incurred for 2002. We incurred non-cash research and development expenses (technology transfer cost) of $3.1 million for the 544,000 shares of preferred stock earned by Sun Global for 1 product transfer during 2003 as compared to $3.9 million for the 1,632,000 shares of common stock issued to Sun Global for 3 product transfers made to us during 2002. The major reason for the reduced cash research and development expenses was the lower new product development during 2003

INTEREST EXPENSE. Interest expense on loans from the EDC, Sun Pharma and its affiliates, ICICI Bank and the Bank of Nova Scotia, was $1.2 million and $1.5 million for 2003 and 2002, respectively. The decrease in the amount of interest is primarily due to paying off the Sun Pharma loans during the second and third quarters of 2003.

RESULTS OF OPERATIONS. We earned net income of $11.2 million for 2003 as compared to incurring a net loss of $2.3 million for 2002. The significantly higher income for 2003 as compared to 2002 is primarily due to higher sales volumes, better-cost absorption, an improved product mix and obtaining more competitive prices for raw materials. In comparison, the net sales in 2002 were inadequate to absorb all expenses including interest cost and non-cash technology transfer cost. Also, the higher utilization of new equipment installed helped to improve production volumes and productivity.

LIQUIDITY AND CAPITAL RESOURCES

During 2003, we generated cash of $15.5 million from operations as compared to using cash in operations of $0.8 million during 2002. The higher cash generation during 2003 has been primarily due to higher sales and improved cost absorptions in the operations.

In addition to paying down debt, the cash generated from operations was used to finance our capital expenditures of $2.4 million during 2003. The capital expenditure in 2002 of $1.6 million was financed out of the private placement of our stock and higher borrowings from Sun Pharma and Bank of Nova Scotia.

Although we borrowed $1.6 million from the Bank of Nova Scotia during the first quarter of 2003, the higher cash inflow from operations during the remaining three quarters of 2003 allowed us to repay all of the Sun Pharma loans of $10 million in addition to the scheduled payments to the EDC of $1.2 million and the first installment of $0.6 million to the ICICI Bank. In comparison, during 2002 we borrowed $2.3 million to fund our operations, capital expenditures and debt redemption to the EDC.

During 2003, we generated $0.9 million from exercise of stock options by our employees and directors. There were no similar exercises during 2002. During 2002, we offered our stock in a private placement, which generated $1.7 million. No private placement offering was made during 2003.

At December 31, 2003, we had negative working capital of $1.1 million

compared to a negative working capital of $1.6 million at December 31, 2002.

FUTURE OUTLOOK

We have experienced difficult times in the past. However, because we have been substantially compliant with cGMPs since 2001, have received approvals of eleven ANDAs during the last three years, have expanded and upgraded our facilities and have expanded our customer base, management feels that our future outlook is brighter.

Although management expects an increase in sales and improvement in cash flow during 2004, we expect pricing pressures, which resulted in lower gross margins in the fourth quarter of 2003, to continue in 2004 due to increased competition. However, we still expect to meet our previously stated guidance of 20-25% revenue growth in 2004.

As disclosed, under the products agreement dated November 21, 2002, between Sun Global and the Company, Sun Global has 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, seven products have been selected for development by the Company and two of these products have passed their respective bio-equivalency studies (one in December 2003 and one in February 2004). If some or all of the remaining five products pass their bio-equivalency studies in 2004, the fair value of the preferred shares earned by Sun Global in exchange for such products could cause our non-cash research and development expenses to increase to an amount which would significantly decrease profit or create a loss.

While the development of new products will increase our non-cash R&D expense and will impact EPS, the cash will be available, among other things, to repay loans and reduce interest burden, meet increased working capital requirements and finance capital investments. This in turn will strengthen our balance sheet and build value for our shareholders. During the first quarter of 2004, we have repaid the entire balance of the ICICI Bank loan of $4.4 million out of the cash generated. With a view to augment working capital requirements in the short-term and to reduce interest expense by paying off higher interest-bearing loans, the Corporation began negotiations to secure a $10 million line of credit with a financial institution. Management expects the line of credit to be approved sometime in 2004.

The Company will continue to aggressively move forward on the development of the products ("Products") presented and to be presented for consideration by Sun Global pursuant to the products agreement. We believe that receiving products from Sun Global, which products, it is believed, will be originated by Sun Pharma, provides us with a partner with a proven track record; one that already has provided us with quality products. Moreover, Sun Pharma's increased beneficial ownership in us, to approximately 63% of our outstanding shares, should, we believe, provide it with the incentive to continue to help us succeed. Sun Pharma has already provided us with millions of dollars in capital, loans, and guarantees of loans, and with personnel, raw materials and equipment, which have significantly helped us to date.

Management's plans for the remainder of 2004 include:

(a) Continued focus on FDA compliance.

(b) Continued research and development activities.

(c) Continued expenditures for capital investment including equipment and expansion of capacity.

(d) Increased market share for certain existing products and recently introduced new products and enhanced customer reach and satisfaction.

(e) Prompt introduction of new approved products to the market.

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

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

(h) Considering alternative ways of increasing cash flow including developing, manufacturing and marketing ANDAs owned by Sun Pharma.

(i) Locating and utilizing facilities of contract-manufacturers to enhance production and therefore sales.

(j) Raising of additional lines of credit to support increasing working capital requirements.

(k) Further reducing debt, if adequately supported by positive cash flows.

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: (i) that the information is of a preliminary nature and may be subject to further adjustment; (ii) not obtaining FDA approval for new products or delays in receiving FDA approvals; (iii) governmental restrictions on the sale of certain products; (iv) dependence on key personnel; (v) development by competitors of new or superior products or cheaper products or new technology for the production of products or the entry into the market of new competitors; (vi) market and customer acceptance and demand for new pharmaceutical products; (vii) availability of raw materials in a timely manner, at competitive prices, and in required quantities; (viii) timing and success of product development and launch; (ix) integrity and reliability of the Company's data; (x) lack of success in attaining full compliance with regard to regulatory and cGMP compliance; (xi) experiencing difficulty in managing our recent rapid growth and anticipated future growth; (xii) dependence on limited

customer base; (xiii) occasional credits to certain customers reflecting price reductions on products previously sold to them and still available as shelf-stock; (xiv) possibility of an incorrect estimate of charge-backs and the impact of such an incorrect estimate on net sales, gross profit and net income; (xv) dependence on few products generating majority of sales; (xvi) product liability claims for which the Company may be inadequately insured; and (xvii) other risks identified in this report and identified from time to time in our reports and registration statements filed with the Securities and Exchange Commission. 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.

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ITEM 7. FINANCIAL STATEMENTS

INDEX TO FINANCIAL STATEMENTS

ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 8A. 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, who is also our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report (the "Evaluation Date"), and has concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective in providing him 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 quarter ended December 31, 2003 that materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART III

ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS OF THE REGISTRANT.

The information with respect to directors and executive officers of the Corporation, the Corporation's Code of Ethics, and compliance with Section 16(a) of the Exchange Act is included in the Corporation's definitive Proxy Statement under the sections "Nominees For Directors' Terms Expiring in 2006," "Incumbent Directors' Terms Expiring in 2005," "Incumbent Directors' Terms Expiring in 2004," "Committees and Meetings of Directors," "Executive Officers," "Code of Ethics," and "Section 16(a) Beneficial Ownership Reporting Compliance," which are incorporated herein by reference.

ITEM 10. EXECUTIVE COMPENSATION.

The information regarding executive compensation is included in the Corporation's definitive 2004 Proxy Statement under the section "Compensation of Executive Officers" and "Compensation of Directors," which is incorporated herein by reference.

ITEM 11. 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 is included in the Corporation's definitive 2004 Proxy Statement under the sections "Security Ownership of Certain Beneficial Owners" and "Security Ownership of Management and Directors," and "Equity Compensation Plan Information" which are incorporated herein by reference.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

The information with respect to certain relationships and related transactions are included in the Corporation's definitive 2004 Proxy Statement under the Section "Transactions of Directors, Executive Officers and Certain Beneficial Owners of Caraco," which is incorporated herein by reference.

ITEM 13. EXHIBITS AND REPORTS ON FORM 8-K.

(a) Exhibits

3.01	Registrant's Amended and Restated Articles of Incorporation, as amended. (2)
3.02	Certificate of Amendment to the Articles of Incorporation filed February 13, 1997. (4)
3.03	Certificate of Amendment to the Articles of Incorporation filed February 10, 2000. (11)
3.04	Certificate of Determination of Rights, Privileges and Preferences Series B Preferred Stock. (12)
3.05	Registrant's Amended and Restated Bylaws. (6)

3.06	Amendment to Amended and Restated Bylaws dated May 2002. (10)
3.07	Amendment to Amended and Restated Bylaws dated November 2002. (12)
3.08	Amendment to Amended and Restated Bylaws dated November 2003 (+)
10.01	Development and Loan Agreement, dated August 10, 1990, between Registrant and The Economic Development Corporation of the City of Detroit; First Amendment thereto, dated December 3, 1990; Second Amendment thereto, dated April 2, 1993; and supplemental letter, dated October 26, 1993 and agreement. (1)
10.02	Amended and Restated Section 108 Guaranty Agreement, dated as of August 10, 1990, of C. Arnold Curry and Cara Jean Curry in favor of the Economic Development Corporation of the City of Detroit. (1)
10.03	Registrant's Amended and Restated Purchase Money Promissory Note, dated as of August 10, 1990, in the principal amount of $157,500, to the order of the Economic Development Corporation of the City of Detroit. (1)

10.04	Registrant's Amended and Restated Section 108 Note, dated August 10, 1990 in the principal amount of $9,000,000, payable to The Economic Development Corporation of the City of Detroit. (1)
10.05	Amended and Restated Purchase Money Mortgage, dated as of August 10, 1990, between Registrant as mortgagor and The Economic Development Corporation of the City of Detroit. (1)
10.06	Agreement, dated as of October 1, 1993, among Registrant, Hexal-Pharma GmbH & Co., KG, and Hexal Pharmaceuticals, Inc. (1)
10.07	Form of 1993 Stock Option Plan. (1)
10.08	Employment Agreement, dated October 22, 1993, with Robert Kurkiewicz. (1)
10.09	Secured Promissory Note dated December 23, 1996 with Sun Pharma Global, Inc. (4)
10.10	Security Agreement dated December 23, 1996 with Sun Pharma Global Inc. (4)
10.11	Stock Purchase Agreement by and between Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries, Ltd. dated as of April 23, 1997. (5)
10.12	Products Agreement by and between Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries, Ltd. dated as of April 23, 1997. (5)
10.13	Registration Rights Agreement dated as April 1997. (5)
10.14	Second Note and Mortgage Modification Agreement. (6)

10.15	Amendment to Employment Agreement of Robert Kurkiewicz dated as of April 1, 1997. (6)
10.16	Employment Agreement dated September 22, 1998 with Narendra N. Borkar. (7)
10.17	1999 Equity Participation Plan. (8)
10.18	Agreement between ICICI Bank and the Corporation for the term loan of $5 million. (9)
10.19	Term Sheet between Bank of Nova Scotia and the Corporation for the term loan of $12.5 million. (10)
10.20	Renewal to Employment Agreement of Robert Kurkiewicz dated as of January 1, 1999. (11)
10.21	Third Amendment to Employment Agreement of Robert Kurkiewicz dated August 30, 2002. (11)
10.22	Employment Agreement of Jitendra N. Doshi. (11)
10.23	Agreement between Caraco and Sun Pharma Global, Inc. dated November 21, 2002. (13)
10.24	Sales contract with government vendor. (12)
10.25	Third Note Modification Agreement (13)
10.26	Third Mortgage Modification Agreement (13)
10.27	Agreement of Narendra N. Borkar (+)

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

\+ Filed herewith

(1) Incorporated by reference from Exhibits to Registrant's Registration Statement on Form SB-2, as amended, filed on November 5, 1993 as Commission File No. 33-71398C.

(2) Incorporated by reference from Exhibits to Registrant's Form 10-KSB filed on or about March 30, 1995 as Commission File no. 0-24676.

(3) Incorporated by reference from Exhibits to Registrant's Form

10-KSB filed on or about March 30, 1996 as Commission File no. 0-24676.

(4) Incorporated by reference from Exhibits to Registrant's Form 10-KSB filed on or about March 31, 1997, as Commission File No. 0-24676.

(5) Incorporated by reference from Exhibits to Registrant's Form 10-QSB filed on November 14, 1997 as Commission File No. 0-24676.

(6) Incorporated by reference from Exhibits to Registrant's Form 10-KSB filed on or about March 31, 1998, as Commission File No. 0-24676.

(7) Incorporated by reference from Exhibits to Registrant's Form 10-QSB dated as of November 13, 1998 as Commission File No. 0-24676.

(8) Incorporated by reference from Exhibit A to Registrant's Proxy Statement dated April 28, 1999 as Commission File No. 0-24676.

(9) Incorporated by reference from Exhibits to Registrant's Form 10-QSB filed on August 14, 2000 as Commission File No. 0-24676.

(10) Incorporated by reference from Exhibits to Form SB-2 filed on July 3, 2002 as Commission File No. 333-91968.

(11) 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.

(12) Incorporated by reference from Exhibits to Registrant's Form 10-KSB filed on or about March 31, 2003, Commission File No. 0-24676.

(13) Incorporated by reference from Exhibit to Registrant's Form 10-QSB filed on or about May 15, 2003, Commission File No. 0-24676.

(b) Reports on Form 8-K

On November 21, 2003, the Corporation filed a Form 8-K disclosing in Item 5 thereof the resignation of two directors.

On October 22, 2003, the Corporation filed a Form 8-K disclosing in Item 12 thereof its expected earnings from operations for the third quarter of 2003.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information with respect to principal accountant fees and services is included in the Corporation's definitive 2004 Proxy Statement under the heading "Relationship With Principal Auditors," which is incorporated herein by reference.

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 30th day of March, 2004

CARACO PHARMACEUTICAL LABORATORIES LTD.

/s/ Jitendra N. Doshi

Chief Executive Officer and Chief Financial Officer

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POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jitendra N. Doshi, this 30th day of March, 2004, 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 Act of 1934, this report has been signed below by the following persons in the capacities and on the date indicated above.

/s/ Dilip S. Shanghvi --- Dilip S. Shanghvi	Chairman of the Board
/s/ Jitendra N. Doshi --- Jitendra N. Doshi	Director, CEO and CFO (and Principal Accounting Officer)
/s/ William C. Brooks --- William C. Brooks	Director
/s/ Sailesh T. Desai --- Sailesh T. Desai	Director
/s/ Timothy Manney --- Timothy Manney	Director
/s/ Georges Ugeux --- Georges Ugeux	Director
/s/ Sudhir V. Valia --- Sudhir V. Valia	Director

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CARACO PHARMACEUTICAL LABORATORIES, LTD.

FINANCIAL STATEMENTS

AND

INDEPENDENT AUDITORS' REPORT

FOR THE YEARS ENDED DECEMBER 31, 2003 AND 2002

CARACO PHARMACEUTICAL LABORATORIES, LTD.

INDEX TO FINANCIAL STATEMENTS

2003

INDEPENDENT AUDITORS' REPORT

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) as of December 31, 2003 and 2002, and the related statements of operations, stockholders' deficit and cash flows for the years then ended. 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 auditing standards generally accepted in the United States of America. 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 December 31, 2003 and 2002 and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

REHMANN ROBSON

Troy, Michigan
February 23, 2004

CARACO PHARMACEUTICAL LABORATORIES, LTD.

BALANCE SHEETS

ASSETS	DE
	2 0 0 3
CURRENT ASSETS	
Cash and cash equivalents	$ 4,206,28
Accounts receivable, net	4,538,47
Inventories	9,610,81
Prepaid expenses and deposits	562,03
TOTAL CURRENT ASSETS	18,917,59
PROPERTY, PLANT AND EQUIPMENT	
Land	197,30
Buildings and improvements	7,917,98
Equipment	6,991,02
Furniture and fixtures	364,14
Total	15,470,45
Less accumulated depreciation	5,963,78
NET PROPERTY, PLANT AND EQUIPMENT	9,506,67
TOTAL ASSETS	$28,424,26

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

LIABILITIES AND STOCKHOLDERS' DEFICIT	DE
	2 0 0 3
CURRENT LIABILITIES	
Accounts payable	$ 1,386,16
Accounts payable, Sun Pharma	3,839,81
Accrued expenses	4,917,21
Current portion of subordinated notes payable to stockholder	
Current portion of loans payable to financial institutions	8,750,00
Current portion of EDC loan payable	1,115,21
Preferred stock dividends payable	
Accrued interest	
TOTAL CURRENT LIABILITIES	20,008,40
Loans payable to financial institutions, net of current portion	8,125,00
EDC loan payable, net of current portion	5,270,27
Subordinated notes payable to stockholder, net of current portion	
TOTAL LIABILITIES	33,403,68
COMMITMENTS AND CONTINGENCIES (NOTES 5, 9 AND 12)	
STOCKHOLDERS' DEFICIT	
Series A preferred stock, no par value; no shares issued or outstanding	
Series B convertible preferred stock, no par value; 544,000 shares to be issued as of December 31, 2003	
Common stock, no par value; authorized 30,000,000 shares, issued and outstanding 24,577,828 shares (23,767,532 shares in 2002)	41,442,311
Additional paid-in capital	2,718,73
Preferred stock dividends payable	
Accumulated deficit	(49,140,45
TOTAL STOCKHOLDERS' DEFICIT	(4,979,41
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 28,424,26

CARACO PHARMACEUTICAL LABORATORIES, LTD.

STATEMENTS OF OPERATIONS

YEAR END

	2003
Net sales	$ 45,498,40
Cost of goods sold	19,507,40
GROSS PROFIT	25,990,99
Selling, general and administrative expenses	7,363,34
Research and development costs - affiliate (Note 7)	3,103,37
Research and development costs - other	3,112,29
OPERATING INCOME (LOSS)	12,411,98
OTHER INCOME (EXPENSE)	
Interest expense	(1,233,53
Interest income	9,10
Gain on sale of property, plant and equipment	25,53
Other income	9,62
OTHER EXPENSE - NET	(1,189,27
NET INCOME (LOSS)	$ 11,222,71
NET INCOME (LOSS) PER SHARE:	
Basic	$ 0.4
Diluted	$ 0.4

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

CARACO PHARMACEUTICAL LABORATORIES, LTD.

STATEMENTS OF STOCKHOLDERS' DEFICIT

	PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN	PREFE STO
	SHARES	AMOUNT	SHARES	AMOUNT	CAPITAL	DIVID
Balances at January 1, 2002	285,714	$ 1,000,000	21,173,818	$34,111,543	$ -	$(300
Preferred stock dividends	-	-	-	-	-	(50
Issuance of common stock to directors in lieu of cash compensation	-	-	36,000	41,400	-	

Issuance of common stock under private placement	-	-	635,000	1,692,000	-	
Issuance of common stock to affiliate in exchange for product technology transfers	-	-	1,632,000	3,887,423	-	
Common stock subscribed	-	-	-	7,520	-	
Preferred stock converted to common stock	(285,714)	(1,000,000)	285,714	717,142	282,858	
Net loss	-	-	-	-	-	
BALANCES AT DECEMBER 31, 2002	-	-	23,762,532	40,457,028	282,858	(350
Payment of preferred stock dividends	-	-	-	-	-	350
Issuance of common stock to directors in lieu of cash compensation	-	-	31,000	112,310	-	
Common stock options exercised	-	-	784,296	872,973	2,435,877	
Net income	-	-	-	-	-	
BALANCES AT DECEMBER 31, 2003	-	$ -	24,577,828	$41,442,311	$2,718,735	

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

CARACO PHARMACEUTICAL LABORATORIES, LTD.

STATEMENTS OF CASH FLOWS

	YEAR ENDED DECEMBER 31	
	2003	2002
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income (loss)	$ 11,222,718	$(2,256,004)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities		
Depreciation	683,339	539,374
Capital stock issued or to be issued to affiliate in exchange for product formula	3,103,370	3,887,423
Common shares issued in lieu of compensation	112,310	41,400
Gain on sale of property, plant and equipment	(25,531)	-
Variable compensation expense for stock options extended to director and officer	2,435,877	262,265
Changes in operating assets and liabilities which provided (used) cash:		
Accounts receivable	945,662	(3,997,627)
Inventories	(3,994,848)	(2,706,907)
Prepaid expenses and deposits	(90,716)	(292,112)
Accounts payable	1,243,139	3,019,936

Accrued expenses and interest	(126,829)	663,652
NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES	15,508,491	(838,600)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(2,493,173)	(1,592,802)
Proceeds from sale of property, plant and equipment	76,200	-
NET CASH USED IN INVESTING ACTIVITIES	(2,416,973)	(1,592,802)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from loans payable to financial institutions	1,600,000	900,000
Repayments of loans payable to financial institutions	(625,000)	-
Payment of preferred stock dividends	(350,380)	-
Repayments of short-term borrowings	-	(75,000)
Net (repayments of) borrowings on subordinated stockholder notes	(9,700,000)	1,400,000
Repayments of EDC loan	(1,217,057)	(1,200,000)
Proceeds from issuance of common stock	872,973	1,699,520
NET CASH (USED IN) PROVIDED BY FINANCING ACTIVITIES	(9,419,464)	2,724,520
NET INCREASE IN CASH AND CASH EQUIVALENTS	3,672,054	293,118
Cash and cash equivalents, beginning of year	534,228	241,110
CASH AND CASH EQUIVALENTS, END OF YEAR	$ 4,206,282	$ 534,228

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

CARACO PHARMACEUTICAL LABORATORIES, LTD.

NOTES TO FINANCIAL STATEMENTS

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 a limited number of products in certain 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.

Over the years, significant sources of funding for the Corporation have been received from private placement offerings, stockholder and financial institution loans and debt financing from the Economic Development Corporation of the City of Detroit (the "EDC"), which loaned approximately $9.1 million to the Corporation in accordance with a Development and Loan Agreement dated August 10, 1990 (see Note 5). During 2002 and 2001, the Corporation also obtained total

credit facilities of $17.5 million from two foreign banks in the form of term loans.

The Corporation and a Mumbai, India based specialty pharmaceutical manufacturing company, Sun Pharmaceutical Industries, Ltd. ("Sun Pharma") completed an agreement, in 1997, whereby Sun Pharma invested $7.5 million into the common stock of the Corporation, and was required to transfer to the Corporation the technology formula for 25 generic pharmaceutical products over a period of five years through August 2002 in exchange for 544,000 shares of Caraco common stock to be issued for each ANDA product and 181,333 shares for each DESI (Drug Efficacy Study Implementation) product. As of December 31, 2003, Sun Pharma had delivered to Caraco the formula for 13 products under this agreement and beneficially owns approximately 48% of the outstanding common stock of the Corporation (see Note 12 for subsequent stock acquisition). With the expiration of the 1997 agreement, a new agreement was reached in November 2002 with Sun Pharma Global (Sun Global) a wholly-owned subsidiary of Sun Pharma. Sun Global agreed to transfer to the Corporation the technology formulations for 25 generic pharmaceutical products over a period of five years through November 2007 in exchange for 544,000 shares of a new convertible preferred stock for each generic drug transferred when such drug passes its bio-equivalency study (Note 7).

In addition to Sun Pharma's equity holdings, the product and technology transfers (which include various research and development activities conducted on an ongoing basis by Sun Pharma), loans made directly to the Corporation and loans guaranteed on behalf of Caraco (see Note 5), Sun Pharma has also supplied Caraco with certain raw materials and equipment (see Note 4) and transferred to the Corporation a number of qualified technical and management professionals having pharmaceutical experience. Furthermore, four of the seven Caraco directors are or were affiliated with Sun Pharma. Caraco is substantially dependent on the active involvement and continued support of Sun Pharma.

In addition to its substantial dependence on Sun Pharma, 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 achieving profitable operations, the future 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.

OPERATIONS

During the last three quarters of 2002 and throughout 2003, the Corporation, for the first time since inception, achieved sales necessary to support operations. Operating results for 2003 improved such that the Corporation generated its first annual net profit of approximately $11. 2 million, an improvement of approximately $13.4 million over the 2002 net loss of $2.2 million. During 2003 and 2002, results of operations include approximately $3.1 million and $3.9 million, respectively, of research and development costs related to technology transfers from Sun Pharma and its subsidiaries in exchange for capital stock of Caraco as explained above. While management views these results as positive developments, the Corporation must still overcome its stockholders' deficit, which is $5.0 million as of December 31, 2003. Caraco's ability to realize a major portion of its assets is thus dependent upon its

ability to meet future financing requirements and the success of future operations. Management believes that continued improvement in profitability and cash flows, along with sustained financial and operating support from Sun Pharma, are key factors in the Corporation's ability to continue to operate in the normal course of business. 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 for a period of time sufficient to ensure Caraco's ultimate business success. For example, Sun Pharma, which is subject to the prevailing regulatory process in India, may be constrained from fully pursuing its business interests outside of India.

Management's plans for the remainder of 2004 include:

- Continued focus on FDA compliance.

- Continued research and development activities.

- Continued expenditures for capital investment, including equipment and expansion of capacity.

- Increased market share for certain existing products and recently introduced new products and enhanced customer reach and satisfaction.

- Prompt introduction of newly 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 that, in turn, will improve manufacturing capacity utilization.

- Considering alternative ways of increasing cash flow including developing, manufacturing and marketing ANDAs owned by Sun Pharma.

- Locating and utilizing facilities of contract-manufacturers to enhance production and therefore sales.

- Raising of additional lines of credit to support increasing working capital requirements.

- Further reducing debt, if adequately supported by positive cash flows.

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 date of the financial statements and the reported amounts of revenues and expenses

NOTES TO FINANCIAL STATEMENTS

during the reporting period. Actual results could differ from those estimates. Significant estimates include, but are not limited to, valuation allowances for accounts receivable and the recoverability of the Corporation's property, plant and equipment.

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 Company invests its excess cash primarily in deposits with major banks within the State of Michigan and in other high quality short-term liquid money market investments. During the normal course of business, the Company may maintain cash on deposit in excess of federally insured limits with financial institutions. The Company maintains a policy of making investments only with institutions with at least an investment grade credit rating.

REVENUE RECOGNITION

The Corporation recognizes revenue at the time its products are shipped to its customers as, at that time, the risk of loss or physical damage to the product passes to the customer, and the obligations of customers to pay for the products are not dependent on the resale of the product or the Corporation's assistance in such resale. Customers are permitted to return unused product, in certain instances, after approval from the Corporation upon the expiration date of the product's lot.

Provisions for estimated customer returns, discounts, rebates and other price adjustments, including customer "chargebacks", can be reasonably determined in the normal course of business based on historical results and contractual arrangements. "Chargebacks" are price adjustments given to wholesale customers for product such customers resell to parties with whom the Corporation has established contractual pricing. The chargeback represents the difference between the sales price to the wholesaler and the contracted price. Approximately 92% of the current allowance for trade receivables has been established to provide for estimated charge backs.

Amounts billed by the Corporation, if any, in advance of performance for contracts to render certain manufacturing or research and development services are deferred and then recognized upon performance of those services.

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 principally of raw materials, as well as work-in-process and finished goods, are stated at the lower of cost, determined by the first-in, first-out method, or market.

CARACO PHARMACEUTICAL LABORATORIES, LTD.

NOTES TO FINANCIAL STATEMENTS

INCOME (LOSS) PER SHARE

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

At December 31, 2002, options to purchase 310,000 shares, were excluded from the computation of loss per share because the options' exercise prices were greater than the average market price of the common shares.

The following table sets forth the computation of basic and diluted income (loss) per common share for the years ended December 31:

	2003	2002
Numerator:		
Income (loss) from continuing operations	$ 11,222,718	$ (2,256,004)
Preferred stock dividends	-	50,380
Income (loss) available for common stockholders	$ 11,222,718	$ (2,306,384)
Denominator:		
Weighted average shares outstanding, basic	24,137,108	22,031,425
Incremental shares from assumed conversion of common stock options	1,344,851	-
Weighted average shares outstanding, diluted	25,481,959	22,031,425
Income (loss) per common share		
Basic	$ .46	$ (.10)
Diluted	$ .44	$ (.10)

PROPERTY, PLANT AND EQUIPMENT AND DEPRECIATION

Depreciation is computed using the straight line method over the estimated useful lives of the related assets, which range from 3 to 40 years. Management annually reviews these assets for impairment and reasonably believes the carrying value of these assets will be recovered through cash flow from operations, assuming the Corporation is successful in continuing to operate in the normal course of business.

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 enacted tax rates that will be in effect when these differences reverse. The principal difference between assets and liabilities for financial statement and federal income tax return purposes is attributable to accounts receivable allowances and the anticipated utilization of net operating losses.

RESEARCH AND DEVELOPMENT COSTS

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

Series B convertible preferred stock (Note 7) may be issued from time to time to Sun Pharma Global and its affiliates in exchange for the formulations of technology products delivered by Sun Pharma Global to the Corporation. The amount of research and development costs associated with the issued stock and charged to operations is determined based on the fair value of the preferred shares on the date the respective product formula has passed the bio-equivalency studies.

COMMON STOCK ISSUED TO DIRECTORS

Common stock is issued from time to time in lieu of cash for director's fees, and is recorded as compensation expense at the fair values of such shares on the dates they were earned.

FAIR VALUES OF FINANCIAL INSTRUMENTS

The carrying values of cash equivalents, accounts receivable, and accounts payable approximate their values due to the short-term maturities of these financial instruments. The carrying amounts of short-term borrowings, notes payable to stockholders, and loans payable approximate their fair values because the interest rates are representative of, or change with, market rates.

RECENT ACCOUNTING PRONOUNCEMENTS

In January 2003, the Financial Accounting Standards Board (FASB) issued Financial Interpretation No. (FIN) 46 "Consolidation of Variable Interest Entities". This standard clarifies the application of Accounting Research Bulletin No. 51, "Consolidated Financial Statements" and addresses consolidation by business enterprises of variable interest entitles, more commonly known as "Special Purpose Entities" or "SPE's". FIN 46 requires existing unconsolidated variable interest entities' interests to be consolidated by their primary beneficiaries if the entities do not effectively disperse risk among the parties involved. FIN 46 also enhances the disclosure requirements related to variable interest entities. The interpretation is effective with respect to interests in variable interest entities created after January 31, 2003. For interests in variable interest entities created before February 1, 2003, the interpretation applies to the first interim or annual reporting period beginning after June 15, 2003. The subject matter of FIN 46 is not currently applicable to the Corporation; accordingly, it is not expected that the provisions of FIN 46 will have a material impact on financial position, results of operations or cash flows of the Corporation.

In April 2003 the FASB issued Statement of Financial Accounting Standards (SFAS) No. 149, which amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments imbedded in other contracts and for hedging activities under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities". SFAS No. 149 clarifies under what circumstances a contract with an initial net investment meets the characteristic of a derivative discussed in paragraph 6 (b) of SFAS No. 133, clarifies when a derivative contains a financing component, amends a definition to conform to language used in FASB interpretation No. 45, and amends certain other existing pronouncements. SFAS No. 149 is effective for contracts entered into or modified after June 30, 2003. The subject matter of SFAS No. 149 is not currently applicable to the Corporation; accordingly, it is not expected that the provisions of SFAS No. 149 will have a material impact on the financial position, results of operations or cash flows of the Corporation.

In May 2003 the FASB issued SAFS No. 150, which establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both debt and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise was effective for the beginning of the first interim period beginning after June 15, 2003. It is to be implemented by cumulative effect of a change in accounting principle for financial instruments created before the issuance date of SFAS No. 150 and still existing at the beginning of the interim period of adoption. It is not expected that the provisions of Statement No. 150 will have a material impact on the financial position, results of operations or cash flows of the Corporation.

2. SUPPLEMENTAL CASH FLOWS INFORMATION

OTHER CASH FLOWS INFORMATION

Cash paid for interest during 2003 and 2002 was approximately $1,783,000 and $1,820,000, respectively.

3. ALLOWANCES FOR SALES ADJUSTMENTS AND DOUBTFUL ACCOUNTS RECEIVABLE

Accounts receivable and related allowances are summarized as follows as of December 31:

	2003	2002
Accounts receivable	$ 20,328,472	$ 14,774,382
Allowances:		
Chargebacks (Note 1)	14,783,000	8,972,247
Sales returns and allowances	650,000	223,000
Doubtful accounts	610,000	95,000
Total allowances	15,790,000	9,290,247
Accounts receivable, net of allowances	$ 4,538,472	$ 5,484,135

4. INVENTORIES

Inventories consist of the following amounts at December 31:

	2003	2002
Raw materials	$ 4,226,363	$ 3,117,293
Goods in transit	1,874,625	801,043
Work in process	1,633,963	1,153,913
Finished goods	1,875,859	543,713
Total	$ 9,610,810	$ 5,615,962

The principal components used in the Corporation's 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. 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 2003 and 2002, the Corporation purchased inventory components of approximately $1.3 million and $2.4 million, respectively, from Sun Pharma.

5. LONG-TERM DEBT (INCLUDING RELATED PARTY DEBT)

EDC LOAN

The EDC loan was restructured on April 23, 2003, with the revised terms effective as of January 1, 2003. The agreement provided for a six year extension of the loan of approximately $7.8 million, with interest rates starting at 2.75% per annum and increasing to 5.16% per annum over the term of the extension. The EDC retains a first mortgage on the property, and a first lien on furniture, fixtures, equipment, ANDA's and intellectual property. The EDC removed its first lien on accounts receivable and inventory. In addition to other covenants, the Corporation may not redeem any of its outstanding shares, pay any dividends with respect to its outstanding common or preferred shares or merge or consolidate with any other corporation or entity without the prior written approval of the EDC. In addition, the EDC eliminated the prior restriction on capital investment in excess of $2 million by permitting the Corporation, so long as it is not in default of any of its obligations, to purchase new capital assets and sell its existing capital assets so long as a result of such transactions the book value of its assets is not reduced below the balance as of December 31, 2002 and the Corporation retains the proceeds of any such sales.

LOANS PAYABLE TO FINANCIAL INSTITUTIONS

Loans payable to financial institutions consist of the following obligations as of December 31:

	2003	2002
Term loan payable to ICICI Bank of India, with quarterly principal payments of $625,000 commencing on December 31, 2003 and ending on September 30, 2005. Interest is adjusted semi-annually and is charged at the LIBOR rate plus 140 basis points (effective rate of 2.6% per annum at December 31, 2003), and is due in quarterly installments. (see below)	$ 4,375,000	$ 5,000,000
$12.5 million term loan payable to Bank of Nova Scotia, with semi-annual principal payments of $3,125,000 commencing in February 2004 and ending in August 2005. Interest is charged at the LIBOR rate plus basis points that range from 155 to 180 depending on the outstanding balance (effective rate of 2.9% per annum at December 31, 2003), and is due in quarterly installments. An additional annual fee of $15,000 is charged.	12,500,000	10,900,000
Total loans payable to financial institutions	16,875,000	15,900,000
Less current portion	8,750,000	625,000
Loans payable to financial institutions, net of current portion	$ 8,125,000	$15,275,000

The term loan to ICICI Bank of India was paid in full on February 23, 2004. The repayment of the Bank of Nova Scotia term loans is guaranteed by Sun Pharma.

The Corporation had at December 31, 2002 $9.8 million of subordinated notes payable to Sun Pharma which were repaid in full during 2003. Interest incurred on these notes amounted to $0.5 million and $0.8 million in 2003 and 2002, respectively. Accrued expenses on the accompanying balance sheets at December 31, 2002 include approximately $0.4 million of accrued interest payable on these Sun Pharma notes.

Scheduled future minimum principal payments on long-term debt for each of the five years succeeding December 31, 2003 are summarized as follows:

Year ending December 31	Amount

2004	$ 9,870,000
2005	7,750,000
2006	1,260,000
2007	1,310,000
2008	1,370,000

NEW LINE OF CREDIT

The Corporation began negotiations to secure a $10 million line of credit with a financial institution. Management expects the line of credit to be approved sometime in 2004.

6 INCOME TAXES

The Corporation's deferred income taxes result principally from its net operating loss (NOL) carryforwards and allowances recorded against accounts receivable. At December 31, 2003 a deferred income tax asset of approximately $14.0 million (computed using a 34% tax rate) relating to these temporary differences exists. Based on the Corporation's prior operating results and operating characteristics, utilization of these deferred tax assets to offset future taxable income is not reasonably assured. Accordingly, Caraco has recorded a valuation allowance to fully offset the deferred tax asset, resulting in no net deferred tax asset or liability in the accompanying balance sheets. The valuation allowance decreased by approximately $4.1 million in 2003 and increased by approximately $0.8 million in 2002, respectively.

At December 31, 2003, net operating loss carryforwards of approximately $23.0 million, which expire between 2012 and 2017, are available to offset future federal taxable income, if any. As discussed in Note 12, Sun Pharma acquired a majority of the Corporation's common stock subsequent to year end. Under rules established by the Internal Revenue Code, such change in ownership may effect the Corporation's ability to utilize these net operating loss carry forwards in future years.

7 STOCKHOLDERS' DEFICIT

COMMON STOCK

During 2003, the Corporation's shareholders approved the authorization of an additional 20,000,000 shares of common stock. The Corporation has not yet filed an amendment to its articles of incorporation to effect this change.

PREFERRED STOCK

During 2003, the Corporation's shareholders approved the authorization of an additional 10,000,000 shares of preferred stock bringing to 15,000,000 the number of total preferred shares authorized. The Corporation has not yet filed

an amendment to its articles of incorporation to effect this change. The shares are issuable in series with the terms and amounts set at the Board of Director's discretion.

The Corporation has designated two series of preferred stock: Series A and Series B. Each share of Series A Preferred Stock is nonvoting and is

convertible, at the option of the holder, into one share of common stock. The Series A preferred shares require annual dividends of $0.21 per share on a cumulative basis. Accrued dividends of $0.4 million on Series A preferred shares were paid during 2003, and the holder, then a company director, converted all such outstanding shares into an equivalent number of common shares.

In November 2002, in connection with the new technology transfer agreement established with Sun Pharma Global (Note 1), the Corporation designated a new series of preferred stock, the Series B Convertible Preferred Stock. The Series B preferred shares are non-redeemable and have no par value. In addition, the Series B 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 3 years from the issuance date into one share of common stock, subject to a conversion adjustment (Note 1).

OTHER COMMON STOCK ISSUANCES (ALSO SEE NOTE 2)

During 2002, the Corporation issued 1,632,000 shares of common stock to an affiliate of Sun Pharma in exchange for the formula for three ANDA products delivered to Caraco. Research and development expense charged to operations related to the issued shares, which was based on the fair value of the respective shares on the dates bio-equivalency passed, totaled $3.9 million in 2002. These shares are also included in the calculation of the weighted average number of common shares outstanding in the year the respective formula was delivered.

During 2002, 285,714 shares of Series A preferred stock was converted into 285,714 shares of common stock. The Corporation recorded additional paid-in capital of $0.3 million for the difference between the fair value of the common stock on the conversion date and the stated value of the Series A preferred stock.

During 2002, the Corporation issued 635,000 shares of common stock in connection with a private placement offering resulting in net proceeds of $1,692,000 or approximately $2.66 per share.

During 2003 and 2002, the Corporation issued 31,000 and 36,000 shares, respectively, of common stock to non-employee directors in exchange for services rendered. The Corporation recorded compensation expense of $112,310 and $41,400, respectively, based on the fair values of such shares on the dates they were earned.

8 COMMON STOCK OPTIONS

COMMON STOCK OPTION PLANS

As of December 31, 2003, the Corporation maintains one stock option plan, the 1999 Plan (all options under the 1993 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 five year period, and expire within six years from the date of the grant. Activity with respect to these options is summarized as follows:

NOTES TO FINANCIAL STATEMENTS

	2003		2002	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding, beginning of year	687,138	$ 1.04	701,138	$ 1.03
Exercised	410,138	0.97	-	-
Terminated	-	-	(14,000)	1.74
Outstanding, end of year	227,000	$ 1.00	687,138	$ 1.01
Options exercisable, end of year	102,500	$ 1.07	288,075	$ 1.04

Options at December 31, 2003

	Options Outstanding			Options Exercisab	
Range of Exercise Prices	Shares	Remaining Contractual Life *	Exercise Price *	Shares	Exerci Price
$0.68 to $1.00	152,000	2.4 years	0.79	76,000	0.79
$1.01 to $2.00	125,000	3 years	1.25	62,500	1.25
Total	277,000	2.7 years	1.00	178,500	1.07

* Weighted average

CARACO PHARMACEUTICAL LABORATORIES, LTD.

NOTES TO FINANCIAL STATEMENTS

OTHER COMMON STOCK OPTION AGREEMENTS

The Corporation has issued other stock options outside of the 1999 and 1993 Plans. These stock options have been issued with various vesting schedules and expire at various dates through October 2006. Activity with respect to these options is summarized as follows:

	2003		2002	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price

Outstanding, beginning of year	2,250,824	$ 2.00	2,250,824	$ 2.00
Exercised	374,158	1.16	-	-
Outstanding, end of year	1,876,666	$ 2.01	2,250,824	$ 2.00
Options exercisable, end of year	1,876,666	$ 2.01	2,250,824	$ 2.00

Options at December 31, 2003:

	Options Outstanding and Exercised		
Range of Exercise Prices	Shares	Remaining Contractual Life *	Exercise Price *
$0.66 to $1.00	100,000	1.0 year	$ 0.88
$1.01 to $2.00	800,000	1.8 years	1.06
$2.01 to $3.00	666,666	2.3 years	2.63
$3.01 to $4.00	310,000	0.4 years	3.50
Total	1,876,666	1.7 years	$ 2.01

* Weighted average

As mentioned in Note 12, Sun Pharma acquired a majority of these options subsequent to year-end.

The Corporation follows only the disclosure aspects of Statement of Financial Accounting Standards (SFAS) No. 123, "Accounting for Stock-Based Compensation". The Corporation continues to apply Accounting Principles Board (APB) Opinion No. 25 in accounting for its plans and, accordingly, no compensation cost has generally been recognized in the financial statements for its outstanding stock options. No options were granted during 2003 or 2002.

In December 2001, the Board of Directors extended the exercise date to December 31, 2005 with respect to options for 224,158 shares of Caraco common stock previously granted to a then independent director. Variable compensation expense of $2.1 million and $0.3 million triggered by the extension was recorded during 2003 and 2002 in recognition of this modification.

On October 2, 2003, the Corporation entered into a severance agreement with its former Chief Executive Officer. The agreement allowed vesting of options for the purchase of 40,000 common shares held by the former officer to be accelerated. The modification resulted in the options being treated as variable rather than fixed in accordance with Financial Accounting Standards Board Interpretation 44 (FIN 44). As a result variable compensation expense of $0.3

million was charged to operations during 2003 for the difference between the fair value of the underlying common stock and the exercise price of the respective options.

The options modified for the independent director and for the former officer were exercised during 2003 resulting in an increase to additional paid in capital of $2.4 million during 2003.

STRATEGIC ALLIANCE STOCK OPTION ARRANGEMENT

Pursuant to an agreement between the Corporation and Hexal-Pharma GmbH & Co., KD, a German pharmaceutical company and its United States affiliate (together, "Hexal") dated as of October 1, 1993, Hexal agreed to convey to the Corporation 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 Hexal (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 to 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.

Pursuant to the agreement, Caraco received a formulation for one product, Metoprolol Tartrate, from Hexal in March 1995. However, Caraco has determined that the formula provided to it by Hexal 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. Accordingly, since April 2003, Caraco has discontinued to accrue royalties.

9. LEASES (INCLUDING RELATED PARTY)

The Corporation entered into two noncancelable operating leases during 2000 with Sun Pharma to lease production machinery. The leases each require quarterly rental payments of $4,245 and expire during 2005.

The Corporation entered into a noncancelable operating lease with an unrelated party during 2002 to lease additional warehouse space. This lease was subsequently canceled during 2003 in lieu of a new noncancelable operating lease for additional space at this warehouse. The new lease requires monthly payments that increase from $15,458 to $16,892 over the term of the lease that expires in 2007.

Net rental expense on these operating leases was $176,065 and $51,460 in 2003 and 2002, respectively.

The following is a schedule of annual future minimum lease payments required under the operating leases (including the leases with Sun Pharma) with remaining noncancelable lease terms in excess of one year as of December 31, 2003:

Year	Amount
2004	$ 237,828
2005	205,223
2006	198,276
2007	50,676

Total minimum payments due	$ 692,003

CARACO PHARMACEUTICAL LABORATORIES, LTD.

NOTES TO FINANCIAL STATEMENTS

The Corporation also paid approximately $0.5 million and $0.3 million to Sun Pharma during 2003 and 2002, respectively, 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 no discretionary contributions during either 2003 or 2002.

11. CONCENTRATIONS AND COMMITMENT

MAJOR CUSTOMER

Shipments to one wholesale customer accounted for approximately 61% and 65% of sales in 2003 and 2002, respectively. Balances due from this customer represented approximately 57% and 80% of gross accounts receivable at December 31, 2003 and 2002, respectively.

The loss of this customer could have a materially adverse effect on short-term operating results.

MAJOR PRODUCTS

Sales of two products accounted for approximately 87% of sales in 2003 and 78% of sales in 2002.

MAJOR SUPPLIER

Approximately 73% and 20% of Caraco's raw material purchases in 2003 and 2002, respectively, were made from Sun Pharma.

LABOR CONTRACT

The majority of the Corporations hourly work force is covered by a collective bargaining agreement that expires in May 2004.

PRODUCT SALES COMMITMENT

Certain of the Corporation's customers purchase its products through designated wholesale customers, 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 ship 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 first of which was exercised. 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.

12. OTHER MATTERS

EMPLOYMENT CONTRACTS

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

LITIGATION

On February 12, 2003, C. Arnold Curry filed a complaint in the Wayne County Circuit Court alleging breach of a written employment agreement. Mr. Curry is seeking 175,000 shares of the Corporations' common stock (35,000 shares for each of the first five ANDAs approved by the FDA). The Corporation and the plaintiff, have each filed a motion for summary judgment. The Corporation intends to vigorously defend itself against these claims, which it believes will have no merit.

The Corporation had been named as one of two defendants and as one of several defendants in two separate product liability suits, involving Miraphen, which contains phenylpropanalomine (PPA), one in federal court in Pennsylvania and another in state court in New Jersey, respectively. These lawsuits seek damages generally for personal injury as well as punitive damages under a variety of liability theories including strict products liability, breach of warranty and negligence. The Federal lawsuit does not set forth a specific dollar amount of damages requested; the state lawsuit seeks damages of $20 million. The plaintiff in the federal lawsuit stipulated to a dismissal of the lawsuit and the federal court formally dismissed the case in December 2003. The Corporation believes that the state lawsuit has not been appropriately served on the Corporation and the Corporation is treating the matter as if it is not an active party..

PRODUCT LIABILITY AND INSURANCE

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

SUBSEQUENT TRANSACTIONS WITH AND RELATING TO SUN PHARMA

During the first quarter of 2004, Sun Pharma acquired 3,452,291 additional shares of common stock and 1,329,066 stock options directly from two former directors and a significant shareholder, thereby increasing its beneficial ownership of the Corporation from approximately 48% to 63%.

In February of 2004, Sun Global earned 544,000 shares of Series B preferred stock pursuant to the products transfer agreement (Note 1).

* * * * *

EXHIBIT INDEX

3.08	Amendment to Amended and Restated Bylaws dated November 2003
10.27	Agreement of Narendra N. Borkar.
21	Subsidiaries of the registrant.
23.01	Consent of Independent Auditors.
31.1	Certification of Chief Executive Officer and Chief Financial Officer.
32.1	Certification Pursuant to 18 USC Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.