CARACO PHARMACEUTICAL LABORATORIES LTD
Form 10-K
March 15, 2005

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

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2004

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

For the period from _____ to _____.

Commission File No. 0-24676

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

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

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

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

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

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

Securities Registered Pursuant to Section 12(g) of the Exchange Act: None.

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

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2) Yes No

The aggregate market value of the voting common stock held by non-affiliates, based on the last sale price of the common stock on June 30, 2004, as reported on the American Stock Exchange, was $90,511,898.

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 4, 2005, there were 26,360,294 shares of common stock outstanding

Documents Incorporated By Reference:

Portions of registrant s definitive 2005 Proxy Statement in connection with the Annual Meeting of Stockholders to be held in June 2005 (2005 Proxy Statement) to be filed on or before April 30, 2005 are incorporated by reference into Part III.

CARACO PHARMACEUTICAL LABORATORIES, LTD.
FORM 10-K

PART I

Item 1. Business

Introduction

Caraco Pharmaceutical Laboratories, Ltd. (Caraco which is also referred to as the Company, the Corporation, we, us or our) is a corporation organized under Michigan law in 1984, 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 and our principal Internet address at www.caraco.com. We believe that these reports are made available as soon as reasonably practicable after we electronically file with or furnish them to the SEC.

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). Since August 1997, capital infusions and loans have primarily come from Sun Pharmaceutical Industries Limited, a specialty pharmaceutical corporation organized under the laws of India (Sun Pharma). Among other things, Sun Pharma has acted as a guarantor on loans to Caraco, has supplied 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 4, 2005, Sun Pharma beneficially owns approximately 64% (69% including its convertible Series B Preferred Stock) of the outstanding common shares of Caraco. See Current Status and Sun Pharmaceutical Industries Limited.

Current Status

We posted record net sales during 2004. Net sales for 2004 were $60.3 million as compared to $45.5 million for 2003. We earned operating income of $0.2 million for 2004 as compared to $12.4 million for 2003. After interest costs, we incurred a net loss of $0.2 million for 2004 as compared to net income of $11.2 million for 2003. We incurred non-cash R&D expenses of $24.4 million during 2004 compared to $3.1 million during 2003. Net cash generated from operating activities was $22.0 million for 2004 as compared to of $15.5 million for 2003. At December 31, 2004, we had a stockholders equity of $25.8 million as compared to a stockholders deficit of $5.0 million at December 31, 2003. In

addition, for the first time since inception, in 2004 we have assets in excess of liabilities. See Part II Item 6. Management s Discussion and Analysis of Financial Condition and Results of Operations.

We received two Abbreviated New Drug Application (ANDA) approvals in 2004. Additionally, 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.

Pursuant to our products agreement with Sun Pharma Global, Inc. (Sun Global), a wholly-owned subsidiary of Sun Pharma, we have selected, through December 31, 2004, 18 products out of the 25 products to be transferred to us by Sun Global. Of these, eight products passed their bio-equivalency studies as of December 31, 2004, and two products passed since then. Sun Global has thereby earned 544,000 shares of Series B Preferred Stock for each product. Under the products agreement, Sun Global earns 544,000 preferred shares for each product. See Sun Pharmaceutical Industries Limited and Part II Item 6. Future Outlook.

We filed six ANDAs with the FDA during 2004, and one since then. This brings our total number of ANDAs pending approval by the FDA to seven.

One of the filed ANDAs is for a generic version of Ortho-McNeil Pharmaceutical Inc. s Ultracet®, challenging its patent under a procedure commonly known as a Paragraph IV Certification . We believe that we were the third company to file a Paragraph IV Certification for the drug product and we do not expect to get 180 days exclusivity. Ortho-McNeil Pharmaceutical Inc. has instituted patent litigation against Caraco. (See Item 3. Legal Proceedings below.)

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

During 2004, we repaid the entire balance of $4.4 million due to ICICI Bank Limited and the $6.4 million mortgage loan due to the Economic Development Corporation of the City of Detroit (the EDC), and repaid $12.5 million due to the Bank of Nova Scotia. We have also repaid the entire borrowing of $10.0 million from Citibank during 2004. These repayments leave us debt-free (other than normal accounts payables and accruals) at December 31, 2004, and our entire property, plant, equipment and intellectual property free of any mortgages, liens or similar restrictions.

During the first quarter of 2004, Sun Pharma acquired 3,452,291 additional shares of common stock and 1,679,066 stock options from two former directors and a significant shareholder. Sun Pharma exercised these stock options during the fourth quarter of 2004, thereby increasing its beneficial ownership to 64% (69% including its convertible Series B Preferred Stock).

On January 27, 2005, the Board of Directors of the Company resolved to change the Company s fiscal year from December 31 to March 31 commencing in 2005. This change is being effectuated in order to make the Company s fiscal year conform to the March 31 fiscal year of its parent company, Sun Pharma. The Company intends to file a transition report for the period January 1, 2005 through March 31, 2005 on Form 10-K no later than June 14, 2005. Subsequent to this, the Company s Form 10-Ks will cover the fiscal year April 1 to March 31, the same as Sun Pharma s fiscal year.

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) increased number of formerly patented drugs which have become available to generic competition.

Although generic pharmaceuticals must meet the same quality standards as branded pharmaceuticals, they are sold at prices that are typically up to 90% (in some cases even more) below those of their branded counterparts. This discount tends to increase, and margins consequently decrease, as the number of generic competitors rises for a given branded product.

Companies aspiring to earn higher margins for generic drugs have a strategy of patent challenge and first to file and obtain 180 days exclusivity. The developer of a generic product that is the first to have its ANDA accepted for filing by the FDA and whose filing includes a Paragraph IV Certification that the patent on the brand-name drug is invalid, unenforceable and/or not infringed may be eligible to receive a 180-day period of generic market exclusivity. During that 180-day period, the exclusive generic product would tend to earn higher margins on a higher volume of sales than in a situation in which other generic competition was also present.

Products that are difficult to develop requiring difficult-to-source raw materials or representing smaller therapeutic niche markets, are generally marketed by fewer companies and may also offer margins that are higher than those where barriers to entry do not exist.

Caraco s Products and Product Strategy

Our present product portfolio includes 19 prescription products in 34 strengths in 82 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
Guaifenesin/DM	Decongestant
Clonazepam	Seizure, Panic Disorders
Flurbiprofen	Arthritis/NSAID
Carbamazepine	Epilepsy
Oxaprozin	Rheumatoid Disease
Metformin Hydrochloride	Diabetes
Tramadol Hydrochloride	Analgesic
Miraphen PE	Decongestant
Meperidine Hydrochloride*	Analgesic
Ticlopidine	Reduction of incidence of Strokes
Tizanidine	Management of Muscle Tone associated with spasticity
Digoxin	Heart Failure
Mirtazapine	Anti-depressant
Citalopram Hbr	Anti-depressant

* Expected to be marketed sometime in 2005.

We have submitted 22 ANDAs to the FDA for approval since August 1997, including six filed during 2004 and one filed subsequent to year-end. Of these 22 ANDAs, the FDA has approved 15 through December 31, 2004. Accordingly, we have seven pending ANDAs.

Our strategy has been to analyze the marketplace and try to determine opportunities for products having good market potential, that are difficult to develop, that require difficult-to-source raw materials and/or products representing smaller therapeutic niche markets. Recently, we have started looking at products which have potential patent litigation, and/or first to file opportunities.

Sun Pharmaceutical Industries Limited

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

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

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 2003. We exchanged 544,000 shares of our common stock for each technology transfer of an ANDA product (when bio-equivalency studies were successfully completed) and 181,333 shares for each technology transfer of a DESI 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. The products are selected by mutual agreement. 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 Series B 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, comprised of the three independent directors, in the first quarter of 2004 to eliminate the provision requiring that the Independent Committee concur in the selection of each product, and provides instead, that each product satisfy certain objective criteria developed by management and approved by the Independent Committee. Pursuant to such objective criteria, we have selected 18 products, eight of which passed bio-equivalency studies as of December 2004 and two products since then. Sun Global has thereby earned 544,00 shares of Series B Preferred Stock 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 and its subsidiaries supply us with certain raw materials and formulations. In addition, Sun Pharma assists us in acquiring machinery and equipment to enhance our production capacities. During 2004, we purchased approximately $16,710,000 in raw materials and formulations from Sun Pharma, as compared to $10,270,000 during 2003. We acquired $611,000 worth of machinery and equipment from Sun Pharma during 2004 as compared to $510,000 during 2003. Such machinery and equipment are sold to us at their cost.

Sun Pharma also assists us by sending qualified technical professionals who work as Caraco employees.

Sun Pharma and its affiliates may use Caraco as a contract manufacturer and/or distributor of their products. In December 2004, Caraco entered into such agreements for one product.

During the first quarter of 2004, Sun Pharma acquired 3,452,291 additional shares of common stock and 1,679,066 stock options from two former directors and a significant shareholder. Sun Pharma exercised these stock options during the fourth quarter of 2004, thereby increasing its beneficial ownership to 64% (69% including its convertible Series B Preferred Stock).

Prior Products Agreement With Non-Affiliate

In 1993, we entered into a products agreement with an unaffiliated large generic drug company (the Non-Affiliate). Under the agreement, two products were to be delivered to us in exchange for royalties and options exercisable at $3.50 per share which could only be paid for out of royalties. Pursuant to the agreement, we received a formulation for one product, Metoprolol Tartrate (the Product), from the Non-Affiliate in March 1995. However, we have determined that the formula provided to us by the Non-Affiliate with respect to the Product is different than the formula submitted 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. The Product has been one of our top selling products. There is no assurance that the Non-Affiliate will not challenge our determination and make a claim that royalties and/or options are owed.

Marketing

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

Caraco competes effectively with respect to each of these factors; however, price is a key competitive factor in the generic pharmaceutical business. To compete effectively on the basis of price and remain profitable, a generic drug manufacturer must manufacture its products in a cost-effective manner. In addition, we maintain an adequate level of inventories to meet customer demands in a timely manner.

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

Our marketing objective is to compete effectively, encourage long-term relationships and supply contracts and also expand our customer base.

Sales and Customers

Our sales team effectively addressed the challenges in 2004 and is geared up to meet the objectives set up for 2005. The sales team is being strengthened to meet the growth needs.

Shipments to three large wholesale customers, namely McKesson Corporation (44% and 10%), Amerisource-Bergen Corporation (24% and 61%) and Cardinal Health (11% and 9%), accounted for approximately 79% and 80% of gross sales in 2004 and 2003, respectively. Balances due from these customers represented approximately 82% and 84% of gross accounts receivable at December 31, 2004 and 2003, respectively. No other single customer represented more than 10% of our gross sales during the past two years.

Certain of our customers purchase our products through designated wholesalers, such as Amerisource Bergen Corporation and/or McKesson Corporation, who act as intermediary distribution channels for our products. For example, the Veterans Administration, which has entered into the sales contract discussed below, has selected Mckesson 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 two option periods were 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.

Seasonality

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

Research and Development

The development of new prescription ANDA products, including formulation, stability testing and the FDA approval process, averages from two to five years. A drug is bioequivalent to a brand-name drug if the rate and extent of absorption of the drug are not significantly different from those of the brand-name drug. Although we perform our own stability testing, bioequivalence is done through independent testing laboratories.

An outline of research and development expenses incurred directly by Caraco for 2004, 2003 and 2002 are as follows ($000 s):

	2004	2003	2002
Salaries	$ 917	$ 719	$ 678
Raw Materials/Supplies	677	439	165
Bio-equivalency Studies	2,068	179	594
Laboratory	826	559	505
Technology Transfer, non-cash	24,397	3,103	3,887
Other	1,565	1,217	1,407
TOTAL	**$ 30,450**	**$ 6,216**	**$ 7,236**

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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.

Following such inspections, the FDA may issue notices on Form 483 and Warning Letters that could cause a company to modify certain activities identified during the inspection. A Form 483 notice may be issued at the conclusion of an FDA inspection and lists conditions the FDA inspectors believe may violate cGMP or other FDA regulations. FDA guidelines specify that a Warning Letter is issued only for violations of regulatory significance for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action.

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.

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 Hatch-Waxman Act established a statutory procedure for submission of ANDAs to the FDA covering generic equivalents of previously approved brand-name drugs. Under the ANDA procedure, an applicant is not required to submit complete reports of preclinical and clinical studies of safety and efficacy, but instead is required to provide

bioavailability data illustrating that the generic drug formulation is bioequivalent to a previously approved drug. Bioavailability measures the rate and extent of absorption of a drug s active ingredient and its availability at the site of drug action, typically measured through blood levels. A generic drug is bioequivalent to the previously approved drug if the rate and extent of absorption of the generic drug are not significantly different from that of the previously approved brand-name drug.

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

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

FDA policy and its stringent requirements have increased the time and expense involved in obtaining ANDA approvals and in complying with FDA s cGMP standards. The ANDA filing and approval process takes approximately 12 to 18 months. The timing of final FDA approval of ANDA applications depends on a variety of factors, including whether or not the maker of the applicable branded drug is entitled to the protection of one or more statutory exclusivity periods, during which the FDA is prohibited from approving generic products. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on the patent expiration date. For example, the FDA may now extend the exclusivity of a product by six months past the date of a patent expiration if the manufacturer undertakes studies on the effect of their product in children (a so-called pediatric extension). FDA approval is required before each dosage form of any new drug can be marketed. Applications for FDA approval must contain information relating to bio-equivalency, product formulation, raw material suppliers, stability, manufacturing processes, packaging, labeling and quality control. FDA procedures require full-scale manufacturing equipment to be used to produce test batches for FDA approval. Validation of manufacturing processes by the FDA also is required before a company can market new products. The FDA conducts pre-approval and post-approval reviews and plant inspections to enforce these rules. Supplemental filings are required for approval to transfer products from one manufacturing site to another and may be under review for a year or more. In addition, certain products may only be approved for transfer once new bio-equivalency studies are conducted.

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

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

If a suit is commenced by the patent holder, the Hatch-Waxman Act provides for an automatic stay on the FDA s ability to grant final approval of the ANDA for the generic product. The period during which the FDA may not approve the ANDA and the patent challenger therefore may not market the generic product is 30 months, or such shorter or longer period as may be ordered by the court. The 30-month period may or may not, and often does not, coincide with the timing of the resolution of the lawsuit or the expiration of a patent, but if the patent challenge is successful or the challenged patent expires during the 30-month period, the FDA may approve the generic drug for marketing, assuming there are no other obstacles to approval such as exclusivities given to the NDA holder.

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

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

Each domestic drug product-manufacturing establishment must be registered with the FDA. Establishments, like ours, handling controlled substances, must be licensed by the DEA. We are licensed by both the FDA and DEA.

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

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

Environment

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

The Company believes that its operations comply in all material respects with applicable laws and regulations concerning the environment. While it is impossible to accurately predict the future costs associated with environmental compliance and potential compliance with environmental laws, any compliance is not expected to require significant

capital expenditures and has not had, and is not presently expected to have, a material adverse effect on the Company s earnings or competitive position.

Suppliers and Materials

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

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

Competition

The generic pharmaceutical industry is undergoing rapid and significant changes due to increasing number of generic manufacturers, introduction of authorized generics, technological advancement and consolidation among the customers. Many of our competitors have greater financial, production, and research and development resources and greater name recognition.

The competition is becoming intense which is resulting in rapid erosion of prices and profit margins. The number of generic manufacturers both domestic and from overseas is increasing resulting in increased pricing pressure. The most significant means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, customer service, reputation and price.

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, 2004 and 2003, we had a total of 191 and 200 full-time equivalent 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 substantially all of our permanent, full-time hourly employees. In September 2004, we successfully negotiated a four-year collective bargaining agreement with the union. This agreement sets forth the wage increases which the union employees will receive in each of the next four years, and thereby giving us and the union employees, we believe, a measure of certainty and stability.]

We believe that we have a cordial relationship with our employees.

Product Liability and Insurance

We currently maintain general and product liability insurance, with coverage limits of $10 million per incident and in the aggregate. We also maintain special product liability insurance coverage for one of our products, Citalopram Hbr, considered as a SSRI product, with coverage limits of $1 million per incident and in the aggregate. Our insurance policies provide coverage on 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. Properties.

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 Part I, Item 1, Business 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.

During 2004, we completely repaid the loan of $6.4 million. Accordingly, as of December 31, 2004, our entire property, plant, equipment and intellectual property are free of any mortgages, liens or similar restrictions.

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 $4.0 million in 2004, $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 and anticipated growth in the near future. We also believe that our facility is adequately covered by insurance.

Item 3. Legal Proceedings.

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. Dr. 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 each filed a motion for summary disposition. Both parties motions were denied, and the parties have agreed that the matter will be submitted to binding arbitration. We intend to vigorously defend ourselves against these claims, which we believe have no merit.

On September 22, 2004, Ortho-McNeil Pharmaceutical, Inc. (Ortho-McNeil) filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Company s filing of an ANDA seeking approval to market its generic version of Ortho-McNeil s Ultracet® drug product infringed Ortho-McNeil s patent, which expires on September 6, 2011. Ortho-McNeil seeks an order from the Court which, among other things, directs the FDA not to approve Caraco s ANDA any earlier than the claimed expiration date. As noted above under Part I, Item 1, Business Current Status , the ANDA filed by Caraco contained a Paragraph IV Certification challenging the Ortho-McNeil patent. We believe that the Ortho-McNeil patent is invalid and/or will not be infringed by Caraco s manufacture, use or sale of the product, and we intend to vigorously defend this action.

From time to time, we are also involved in other legal proceedings incidental to our normal business activities, and while the outcome of any such proceedings cannot be accurately predicted, we do not believe the ultimate resolution of any existing matters would have a material adverse effect on our financial position or results of operations.

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

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

PART II

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

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 2004, the high and low sales prices for each of the calendar quarters, and for 2003 and 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.

2004	**High**	**Low**
First Quarter	$ 13.74	$ 7.31
Second Quarter	$ 11.94	$ 9.40
Third Quarter	$ 10.24	$ 6.80
Fourth Quarter	$ 10.00	$ 6.82

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 4, 2005 there were 105 registered holders of our Common Stock.

During 2004, we issued to Sun Global 4,352,000 preferred shares in exchange for the transfer of seven products (of which 544,000 preferred shares were earned during 2003 for one product transfer) pursuant to our current products agreement. During 2002, we issued to Sun Global 1,632,000 shares of common stock in exchange for the transfer of three products under the then existing products agreement.

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

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

During 2003 and 2002, certain of our then non-employee directors were issued 31,000 and 36,000 shares, respectively, of common stock for attending board and committee meetings.

During 2003, one of our then non-employee directors was issued 224,158 shares of common stock upon exercise of stock options.

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 shares of preferred stock and 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, and other factors deemed relevant by our Board of Directors.

Item 6. Selected Financial Data

The following table sets forth selected historical financial data as of and for the years ended December 31, 2004, 2003, 2002, 2001 and 2000. The data are derived from our financial statements, which have been audited by Rehmann Robson, our independent auditors. The selected financial data should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations, the Financial Statements and the Notes to Financial Statements included elsewhere in this report.

	YEARS ENDED DECEMBER 31,				
	2004	2003	2002	2001	2000
Statement of operations data	(In thousands, except per share data)				
Net sales	$ 60,340	$ 45,498	$ 22,381	$ 5,922	$ 2,378
Cost of goods sold	24,441	19,507	12.047	4,186	2,679
Gross profit (loss)	35,899	25,991	10,334	1,736	(301)
Selling, general and administrative expenses	5,277	7,363	3,828	2,680	2,509
Research and development costs affiliate non cash	24,397	3,103	3,887	0	230
Research and development costs - other	6,053	3,112	3,348	3,080	3,065
Operating income (loss)	172	12,412	(730)	(4,024)	(6,106)
Other expenses	(371)	(1,189)	(1,526)	(1,734)	(1,517)
Net (Loss) Income	(199)	11,223	(2,256)	(5,757)	(7,623)
Net (Loss) Income per share					
Basic	(0.01)	0.46	(0.10)	(0.29)	(0.39)
Diluted	(0.01)	0.44	(0.10)	(0.29)	(0.39)
Weighted Average Shares Outstanding:					
Basic	24,734	24,137	22,031	21,173	19,755
Diluted	24,734	25,482	22,031	21,173	19,755

	AS OF DECEMBER 31,				
	2004	2003	2002	2001	2000
	(In thousands)				
Balance Sheet Data					
Current assets	$ 24,857	$ 18,918	$ 12,106	$ 4,816	$ 2,129
Property, plant and equipment, net	12,546	9,506	7,747	6,694	7,094
Total assets	37,403	28,424	19,853	11,510	9,223
Current liabilities	11,627	20,008	13,753	10,855	11,311
Long term debt	0	13,395	25,724	23,600	15,040
Total liabilities	11,627	33,404	39,476	34,455	26,351
Stockholders Equity (Deficit)	25,776	(4,980)	(19,623)	(22,945)	(17,128)
Working Capital (Deficit)	13,230	(1,090)	(1,647)	(6,039)	(9,182)

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

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

Overview

2004 was a milestone year. We recorded net sales of $60.3 million during 2004 compared to $45.5 million during 2003. During 2004, we have generated cash from operations of $22.0 million as compared to $15.5 million for 2003. This cash was used primarily to pay off Company debt, fund our capital expenditures and augment working capital. We incurred a net loss of $0.2 million during 2004 compared to net income of $11.2 million during 2003. The lower net income was primarily due to non-cash research and development expense (R&D) of $24.4 million for 2004 compared to $3.1 million for 2003. This non-cash R&D expense relates to seven products passing their bio-equivalency studies during 2004 as compared to one during 2003.

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 22 ANDAs to the FDA for approval since August 1997, including six filed in 2004 and one since then. Of these, 15 have been approved and seven are pending approval.

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

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

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

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

Change in the product mix of sales.

Reduction in manufacturing costs due to increased batch sizes.

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

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

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

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

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

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

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

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.

The following table presents a summary of our unaudited quarterly results of operations for each of the four quarters in 2004 and 2003. The unaudited interim financial statements include all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of such information when read in conjunction with our audited consolidated financial statements and related notes. Our quarterly operating results have varied in the past, may continue to do so and are not necessarily indicative of results for any future period.

2004

(In thousands, except per share data)

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Net Sales	13,561	14,800	15,299	16,680
Net Profit (Loss)	(2,243)	1,527	1,062	(545)
Earnings Per Share				
Basic	(0.09)	0.06	0.04	(0.02)
Diluted	(0.09)	0.05	0.04	(0.02)

2003

	(In thousands, except per share data)			
	Quarter 1	**Quarter 2**	**Quarter 3**	**Quarter 4**
Net Sales	8,722	11,890	12,294	12,593
Net Profit (Loss)	2,205	4,326	4,538	154
Earnings Per Share				
Basic	0.09	0.18	0.19	(0.01)
Diluted	0.09	0.17	0.18	(0.01)

Liquidity and Capital Resources

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

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

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

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

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

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

Contractual Obligations and Off Balance Sheet Transactions

Contractual Obligations

	(In thousands) Payment Due
Contractual Obligations	1-3 years
Operating Leases	453

There are no other contractual obligations requiring disclosure.

Off Balance Sheet Transactions

None

Future Outlook

Management feels that our future outlook looks bright, as we have been substantially compliant with cGMPs since 2001, and received approvals of 13 ANDAs, expanded and upgraded our facilities and expanded our customer base during the last four years. Our efforts in developing new products has also picked up momentum and this should permit us to grow at a reasonable level. We are optimistic that we will achieve our previously stated guidance of 15% to 20% revenue growth during 2005.

Pricing pressures, however, due to increased competition, have continued during 2004 and are expected to continue in 2005, which may result in lower growth rates and gross margins. Management has and will continue to work diligently to counter the pricing pressures through increased sales volumes, better-cost absorption of operational overheads, and cost reductions.

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, the Company has selected 18 products for development and nine of these products have passed their respective bio-equivalency studies (one in December 2003, seven in 2004 and one in January 2005). If some or all of the remaining products pass their bio-equivalency studies in 2005, 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 both our cash and non-cash R&D expense and will impact EPS, we expect that cash will be available, among other things, to meet increased working capital requirements, fund potential Paragraph IV Certification litigation and finance further capital investments.

The Company will continue to aggressively move forward with the development of new products. We believe that receiving products from Sun 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 64% (69% including its convertible Series B Preferred Stock), should, we believe, provide it with the incentive to continue to help us succeed. Sun Pharma has previously provided us with capital, loans, guarantees of loans, personnel, raw materials and equipment, which have significantly helped us to date.

Management s plans for the remainder of 2005 include:

(a) Continued focus and improvement on FDA compliance.

(b) Increased pace of research and development activities, with a view to maximize ANDA filings.

(c) Continue to invest in equipment and facility to expand capacity to meet requirements of projected growth in near term.

(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.

Forward Looking Statements

This report, other than the historical financial and business information, may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act. Without limitation, the words believes, plans, expects, and similar expressions are intended to identify forward-looking statements. Those statements include statements regarding our intent, belief, and current expectation. These statements are not guarantees of future performance and are subject to risks and uncertainties that cannot be predicted or quantified. Consequently, actual results could differ materially from those expressed or implied by such forward-looking statements.

Such risks and uncertainties include, but are not limited to: (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; (xvii) subjectivity in judgment of

management in applying certain significant accounting policies derived based on historical experience, terms of contracts, our observations of trends of industry, information received from our customers and other sources, to estimate revenues, accounts receivable allowances including chargebacks, rebates, income taxes, values of assets and inventories; (xviii) litigation involving claims of patent infringement; (xix) litigation involving claims for royalties relating to a prior contract for one product and (xx) 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.

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

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

Item 8. Financial Statements and Supplementary Data

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

None.

Item 9A. Controls and Procedures.

a. The term disclosure controls and procedures is defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the Exchange Act). These rules refer to the controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is recorded, processed, summarized and reported within required time periods. Our Chief Executive Officer, 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, 2004 that materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

As permitted under Securities Exchange Act of 1934 Release No. 50754, registrant has omitted *Management s annual report on internal control over financial reporting* and the related *Attestation report of our registered public accounting firm*. Such reports will be included in an amendment to this Form 10-K to be filed on or before April 30, 2005.

Item 9B. Other Information.

None.

PART III

Item 10. Directors and Executive Officers 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 included under the sections Nominees For Directors Terms Expiring in 2008, Incumbent Directors Terms Expiring in 2006, Incumbent Directors Terms Expiring in 2007, Committees and Meetings of Directors, Nomination of Directors, Executive Officers, Code of Business Conduct and Ethics, and Section 16(a) Beneficial Ownership Reporting Compliance in our 2005 Proxy Statement to be filed with the Securities and Exchange Commission on or before April 30, 2005, is incorporated herein by reference.

Item 11. Executive Compensation.

The information regarding executive compensation included under the section Compensation of Executive Officers and Compensation of Directors in our 2005 Proxy Statement to be filed with the Securities and Exchange Commission on or before April 30, 2005, is incorporated herein by reference.

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

The information with respect to the security ownership of certain beneficial owners and management and with respect to equity compensation plans included under the sections Security Ownership of Certain Beneficial Owners, Security Ownership of Management and Directors and Equity Compensation Plan Information in our 2005 Proxy Statement to be filed with the Securities and Exchange Commission on or before April 30, 2005, is incorporated herein by reference. In addition, the information contained under the Equity Compensation Plan Information subheading under Item 5 of this report is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions.

The information with respect to certain relationships and related transactions included under the section Transactions of Directors, Executive Officers and Certain Beneficial Owners of Caraco in our 2005 Proxy Statement to be filed with the Securities and Exchange Commission on or before April 30, 2005, is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information under the caption Relationship with Independent Auditors Audit and Non-Audit Fees in our 2005 Proxy Statement to be filed with the Securities and Exchange Commission on or before April 30, 2005, is incorporated herein by reference.

Part IV

Item 15. Exhibits Financial Statement Schedules.

(a) 1 Financial Statements

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2 Financial Statement Schedules

None

3 Exhibits

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

(b) Exhibits

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

(c) Other Schedules

None

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on the 11th day of March, 2005.

CARACO PHARMACEUTICAL LABORATORIES, LTD.

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

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jitendra N. Doshi, this 11th day of March, 2005, 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

CARACO PHARMACEUTICAL LABORATORIES, LTD.

(a subsidiary of Sun Pharmaceutical Industries Limited)

FINANCIAL STATEMENTS

AND

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

FOR THE YEARS ENDED DECEMBER 31, 2004, 2003 AND 2002

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

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of Caraco Pharmaceutical Laboratories, Ltd. (a subsidiary of Sun Pharmaceutical Industries Limited) (a Michigan corporation) as of December 31, 2004 and 2003, and the related statements of operations, stockholders equity (deficit) and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Corporation s management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Caraco Pharmaceutical Laboratories, Ltd. as of December 31, 2004 and 2003 and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America.

Troy, Michigan
March 4, 2005

5750 New King Street Suite 100 Troy, MI 48098 248.952.2676 Fax 248.952.5464 www.rehmann.com

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

BALANCE SHEETS

ASSETS	December 31	
	2004	2003
Current assets		
Cash and cash equivalents	$ 2,456,469	$ 4,206,282
Accounts receivable, net	4,602,866	4,538,472
Inventories	17,133,811	9,610,810
Prepaid expenses and deposits	663,811	562,030
Total current assets	**24,856,957**	**18,917,594**
Property, plant and equipment		
Land	197,305	197,305
Buildings and improvements	9,302,317	7,917,986
Equipment	9,351,502	6,991,024
Furniture and fixtures	585,705	364,140
Total	19,436,829	15,470,455
Less accumulated depreciation	6,890,796	5,963,780
Net property, plant and equipment	**12,546,033**	**9,506,675**
Total assets	**$ 37,402,990**	**$ 28,424,269**

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

LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)	December 31	
	2004	2003
Current liabilities		
Accounts payable, trade	$ 2,557,078	$ 1,386,160
Accounts payable, Sun Pharma	7,359,687	3,839,815
Accrued expenses	1,710,649	4,917,216
Current portion of loans payable to financial institutions		8,750,000
Current portion of EDC loan payable		1,115,213
Total current liabilities	**11,627,414**	**20,008,404**
Loans payable to financial institutions, net of current portion		8,125,000
EDC loan payable, net of current portion		5,270,277
Total liabilities	**11,627,414**	**33,403,681**
Commitments and contingencies (Notes 9, 11 and 12)		
Stockholders equity (deficit) (Note 7)		
Series B convertible preferred stock, no par value; issued and outstanding 4,352,000 shares	27,500,410	
Common stock, no par value; authorized 30,000,000 shares, issued and outstanding 26,334,694 shares (24,577,828 shares in 2003)	44,896,257	41,442,311
Additional paid-in capital	2,718,735	2,718,735
Accumulated deficit	(49,339,826)	(49,140,458)
Total stockholders equity (deficit)	**25,775,576**	**(4,979,412)**
Total liabilities and stockholders equity (deficit)	**$ 37,402,990**	**$ 28,424,269**

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

STATEMENTS OF OPERATIONS

	Year Ended December 31		
	2004	**2003**	**2002**
Net sales	$ 60,340,309	$ 45,498,400	$ 22,380,964
Cost of goods sold (Notes 1 and 4)	24,441,569	19,507,406	12,047,410
Gross profit	**35,898,740**	**25,990,994**	**10,333,554**
Selling, general and administrative expenses	5,276,755	7,363,341	3,827,707
Research and development costs - affiliate (Note 7)	24,397,040	3,103,370	3,887,423
Research and development costs - other	6,053,334	3,112,294	3,348,789
Operating income (loss)	**171,611**	**12,411,989**	**(730,365)**
Other income (expense)			
Interest expense	(407,330)	(1,233,531)	(1,539,075)
Interest income	40,316	9,102	13,436
(Loss) gain on sale of equipment	(10,636)	25,531	
Other income	6,671	9,627	
Other expense - net	**(370,979)**	**(1,189,271)**	**(1,525,639)**
Net (loss) income	**$ (199,368)**	**$ 11,222,718**	**$ (2,256,004)**
Net (loss) income per share:			
Basic	$ (0.01)	$ 0.46	$ (0.10)
Diluted	$ (0.01)	$ 0.44	$ (0.10)

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

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

STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Preferred Stock Dividends	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balances at January 1, 2002	285,714	$ 1,000,000	21,173,818	$34,111,543	$	$ (300,000)	$ (57,756,792)	$(22,945,249)
Preferred stock dividends						(50,380)		(50,380)
Issuance of common stock to directors in lieu of cash compensation			36,000	41,400				41,400
Issuance of common stock under private placement			635,000	1,692,000				1,692,000
Issuance of common stock to affiliate in exchange for product technology transfers			1,632,000	3,887,423				3,887,423
Common stock subscribed				7,520				7,520
Preferred stock converted to common stock	(285,714)	(1,000,000)	285,714	717,142	282,858			
Net loss							(2,256,004)	(2,256,004)
Balances at December 31, 2002			23,762,532	40,457,028	282,858	(350,380)	(60,012,796)	(19,623,290)
Payment of preferred stock dividends						350,380	(350,380)	
Issuance of common stock to directors in lieu of cash compensation			31,000	112,310				112,310
Common stock options exercised			784,296	872,973	2,435,877			3,308,850
Net income							11,222,718	11,222,718
Balances at December 31, 2003			24,577,828	41,442,311	2,718,735		(49,140,458)	(4,979,412)
Issuance of preferred stock to affiliate in exchange for product technology transfers	4,352,000	27,500,410						27,500,410
Common stock options exercised			1,756,866	3,453,946				3,453,946
Net loss							(199,368)	(199,368)

Balances at December 31, 2004	**4,352,000**	**$ 27,500,410**	**26,334,694**	**$ 44,896,257**	**$ 2,718,735**	**$**	**$ (49,339,826)**	**$ 25,775,576**

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

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

STATEMENTS OF CASH FLOWS

	Year Ended December 31		
	2004	**2003**	**2002**
Cash flows from operating activities			
Net (loss) income	$ (199,368)	$ 11,222,718	$ (2,256,004)
Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities			
Depreciation	932,419	683,339	539,374
Capital stock issued or to be issued to affiliate in exchange for product formula	24,397,040	3,103,370	3,887,423
Common shares issued in lieu of compensation		112,310	41,400
Loss (gain) on sale of property, plant and equipment	10,636	(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	(64,393)	945,662	(3,997,627)
Inventories	(7,523,001)	(3,994,848)	(2,706,907)
Prepaid expenses and deposits	(140,430)	(90,716)	(292,112)
Accounts payable	4,690,789	1,243,139	3,019,936
Accrued expenses	(64,548)	(126,829)	663,652
Net cash provided by (used in) operating activities	**22,039,144**	**15,508,491**	**(838,600)**
Cash flows from investing activities			
Purchases of property, plant and equipment	(3,982,413)	(2,493,173)	(1,592,802)
Proceeds from sale of property, plant and equipment		76,200	
Net cash used in investing activities	**(3,982,413)**	**(2,416,973)**	**(1,592,802)**
Cash flows from financing activities			
Proceeds from loans payable to financial institutions	10,000,000	1,600,000	900,000
Repayments of loans payable to financial institutions	(26,875,000)	(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	(6,385,490)	(1,217,057)	(1,200,000)
Proceeds from issuance of common stock	3,453,946	872,973	1,699,520
Net cash (used in) provided by financing activities	**(19,806,544)**	**(9,419,464)**	**2,724,520**
Net (decrease) increase in cash and cash equivalents	**(1,749,813)**	**3,672,054**	**293,118**
Cash and cash equivalents, beginning of year	4,206,282	534,228	241,110
Cash and cash equivalents, end of year	**$ 2,456,469**	**$ 4,206,282**	**$ 534,228**

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

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

NOTES TO FINANCIAL STATEMENTS

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 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.

The Corporation s manufacturing facility and executive offices were constructed in 1991, pursuant to a $9.1 million loan from the Economic Development Corporation of the City of Detroit (the EDC). Since August 1997, capital infusions and loans have primarily come from Sun Pharmaceutical Industries Limited, a specialty pharmaceutical corporation organized under the laws of India (Sun Pharma). Among other things, Sun Pharma has acted as a guarantor on loans to Caraco, has supplied the Corporation with raw materials for certain products, assisted in obtaining machinery and equipment to enhance production capacities at competitive prices, and has transferred certain generic products. 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 4, 2005, Sun Pharma beneficially owns approximately 64% (69% including its convertible Series B Preferred Stock) of the outstanding common shares of Caraco.

Sun Pharmaceutical Industries Limited

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

Sun Pharma and its affiliates loaned the Corporation approximately $10 million since August 1997. As of December 31, 2003, all such loans had been repaid. Sun Pharma has also assisted the Corporation, by acting as guarantor, in obtaining line of credit loans from ICICI Bank Limited, The Bank of Nova Scotia and Citibank FSB in the amounts of $5.0 million, $12.5 million and $10.0 million, respectively (see Note 5). The loans for which Sun Pharma had provided guarantees have all been repaid as of December 31, 2004.

In August 1997, Caraco entered into an agreement, whereby Sun Pharma was required to transfer the technology formula for 25 generic pharmaceutical products over a five-year period through August 2003 in exchange for 544,000 shares of Caraco common stock for each technology transfer of an ANDA product (when bio-equivalency studies were successfully completed) and 181,333 shares for each technology transfer of a DESI (Drug Efficacy Study Implementation) product. The products provided to the Corporation from Sun Pharma were selected by mutual agreement. Under such agreement, Caraco conducted, at its own expense, all tests including bio-equivalency studies. Pursuant

CARACO PHARMACEUTICAL LABORATORIES, LTD.
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NOTES TO FINANCIAL STATEMENTS

to such agreement through 2002, Sun Pharma delivered the technology formula for 13 products. This agreement expired on November 21, 2002, and the Corporation entered into a new technology transfer agreement with Sun Global, Inc. (Sun Global), an affiliate of Sun Pharma.

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

The products agreement was amended by the Independent Committee, comprised of the three independent directors, in the first quarter of 2004 to eliminate the provision requiring that the Independent Committee concur in the selection of each product, and provides instead, that each product satisfy certain objective criteria developed by management and approved by the Independent Committee. Pursuant to such objective criteria, 18 products have been selected, eight of which passed bio-equivalency studies through December 31, 2004 and two additional products since then (Note 12).

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

Sun Pharma and its subsidiaries supply the Corporation with certain raw materials (Note 4) and formulations, assist in acquiring machinery and equipment to enhance production capacities, and provide qualified technical professionals who work as Caraco employees. Also, four of the seven Caraco directors are, or were, affiliated with Sun Pharma. Further, Sun Pharma and its affiliates may use Caraco as a contract manufacturer and/or distributor of their products. In December 2004, Caraco entered into an agreement for one such product.

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

During the first quarter of 2004, Sun Pharma acquired 3,452,291 additional shares of common stock and 1,679,066 stock options from two former directors and a significant shareholder. Sun Pharma exercised these stock options during the fourth quarter of 2004, thereby increasing its beneficial ownership to 64%.

In addition to its substantial relationship with and dependence on Sun Pharma as described above, the Corporation is subject to certain risks associated with companies in the generic pharmaceutical

CARACO PHARMACEUTICAL LABORATORIES, LTD.
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NOTES TO FINANCIAL STATEMENTS

industry. Profitable operations are dependent on the Corporation s ability to market its products at reasonable profit margins. In addition to maintaining profitable operations, the ongoing success of the Corporation will depend, in part, on its continuing ability to attract and retain key employees, obtain timely approvals of its ANDAs, and develop new products (see Operations , below).

Operations

The Corporation posted record net sales during 2004. Net sales for 2004 were $60.3 million as compared to $45.5 million for 2003. The Corporation earned operating income of $0.2 million for 2004 as compared to $12.4 million for 2003. After interest costs, the Corporation incurred a net loss of $0.2 million for 2004 as compared to net income of $11.2 million for 2003. The Corporation incurred non-cash R&D expenses of $24.4 million during 2004 compared to $3.1 million during 2003. Net cash generated from operating activities was $22.0 million for 2004 as compared to $15.5 million for 2003. At December 31, 2004, the Corporation had a stockholders equity of $25.8 million as compared to a stockholders deficit of $5.0 million at December 31, 2003. In addition, for the first time since its inception, in 2004, the Corporation had assets in excess of liabilities.

Management s plans for 2005 include:

Continued focus on FDA compliance.

Increased pace of research and development activities, with a view to maximize ANDA filings.

Continuing to invest in equipment and facilities to expand capacity to meet requirements of projected growth in the near term.

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.

CARACO PHARMACEUTICAL LABORATORIES, LTD.
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NOTES TO FINANCIAL STATEMENTS

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 during the reporting period. Actual results could differ from those estimates. Significant estimates include, but are not limited to, provisions for estimated customer returns, discounts, rebates and other price adjustments, including customer chargebacks (see Revenue Recognition , below), valuation allowances for deferred tax assets, and valuation of overhead components in inventory.

Cash and Cash Equivalents

Cash and cash equivalents consist of demand deposits in banks, cash on hand and all highly liquid investments purchased with an original maturity of three months or less. The Company invests its excess cash primarily in deposits with major banks and in other high quality short-term liquid money market investments. During the normal course of business, the 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 products 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 93% of the allowance for trade receivables at December 31, 2004 has been established to provide for estimated chargebacks (see Note 3).

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

CARACO PHARMACEUTICAL LABORATORIES, LTD.
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NOTES TO FINANCIAL STATEMENTS

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, goods in transit and finished goods, as well as work-in-process, are stated at the lower of cost, determined using the specific identification method, or market.

Net (Loss) Income Per Share

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

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

	2004	2003	2002
Numerator:			
Net (loss) income from continuing operations	$ (199,368)	$ 11,222,718	$ (2,256,004)
Preferred stock dividends			(50,380)
Net (loss) income available for common stockholders	$ (199,368)	$ 11,222,718	$ (2,306,384)
Denominator:			
Weighted average shares outstanding, basic	24,734,282	24,137,108	22,031,425
Incremental shares from assumed conversion of common stock options		1,344,851	
Weighted average shares outstanding, diluted	24,734,282	25,481,959	22,031,425
Net (loss) income per common share			
Basic	$ (0.01)	$ .46	$ (0.10)
Diluted	$ (0.01)	$ .44	$ (0.10)

Property, Plant and Equipment and Depreciation

CARACO PHARMACEUTICAL LABORATORIES, LTD.
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NOTES TO FINANCIAL STATEMENTS

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.

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 tax net operating losses.

Research and Development Costs

Series B convertible preferred stock (Note 7) is issued on an ongoing basis to Sun Pharma and its affiliates under the Products Agreement between the Corporation and Sun Global in exchange for the formulations of technology products delivered by Sun Pharma Global to the Corporation. The resulting amount of research and development expense is charged to operations and is determined based on the fair value of the preferred shares on the date the respective product formula passes its bio-equivalency studies. The fair value of such shares is based upon an independent valuation and includes a discount for marketability.

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

Common Stock Issued to Directors

Common stock was issued from time to time in lieu of cash for directors fees, and was recorded as compensation expense at the fair values of such shares on the dates they were earned. Subsequent to December 31, 2003, directors fees are paid in cash. Also, since December 31, 2003, independent directors are granted stock options upon completion of their anniversary of serving on the board.

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 November 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 151 *Inventory Costs, an Amendment of ARB No. 43, Chapter 4*. SFAS 151 amends ARB 43, Chapter 4, to clarify that abnormal amounts of idle facility expense,

freight, handling costs and wasted materials (spoilage) be recognized as current period charges. It also requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. SFAS 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company does not believe that the adoption of SFAS 151 will have a material impact on its results of operations or financial position.

In December 2004, the FASB issued SFAS 123R (revised 2004), *Share-Based* Payment, (SFAS 123R). SFAS 123R addresses the accounting for share-based payments to employees, including grants of employee stock options. Under the new standard, Caraco will no longer be able to account for share-based compensation transactions using the intrinsic method in accordance with APB Opinion No. 25, *Accounting for Stock Issued to* Employees. Instead, Caraco will be required to account for such transactions using a fair-value method and recognize the expense in the statement of operations. SFAS 123R will be effective for periods beginning after June 15, 2005 and allows, but does not require, companies to restate the full fiscal year of 2005 to reflect the impact of expensing share-based payments under SFAS 123R. The Company has not yet determined which fair-value method and transitional provision it will follow. However, the Company expects that the adoption of SFAS 123R will not have a significant impact on its results of operations, nor does it expect that the adoption of SFAS 123R will impact its overall financial position. See Note 8 for the proforma impact on operating results from calculating stock-based compensation costs under the fair value alternative of SFAS 123. However, the calculation of compensation cost for share-based payment transactions after the effective date of SFAS 123R may be different from the calculation of compensation cost under SFAS 123, but such differences have not yet been quantified.

In December 2004, the FASB issued SFAS 153 *Exchanges of Nonmonetary Assets, and Amendment of APB Opinion No.* 29. The guidance in APB Opinion No. 29, *Accounting for Nonmonetary Transactions*, is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in APB Opinion No. 29, however, included certain exceptions to the principle. SFAS 153 amends APB Opinion No. 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS 153 is effective for nonmonetary asset exchanges in fiscal periods beginning after June 15, 2005. The Company does not believe that the adoption of SFAS 153 will have a material impact on its results of operations or financial position.

CARACO PHARMACEUTICAL LABORATORIES, LTD.
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NOTES TO FINANCIAL STATEMENTS

2. SUPPLEMENTAL CASH FLOWS INFORMATION

Non-cash Investing and Financing Activities

As described in Notes 1 and 7, pursuant to the technology transfer agreement with an affiliate of the Corporation s parent, Caraco, on an ongoing basis, finances the acquisition of research and development costs in exchange for the issuance of capital stock to its parent. Capital stock earned or issued to affiliates had fair values of $24,397,040, $3,103,370 and $3,887,423 in 2004, 2003 and 2002, respectively.

Other Cash Flows Information

Cash paid for interest during 2004, 2003 and 2002 was approximately $407,330, $1,783,000 and $1,820,000, respectively.

3. ALLOWANCES FOR SALES ADJUSTMENTS AND DOUBTFUL ACCOUNTS RECEIVABLE (NOTE 1)

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

	2004	2003
Accounts receivable - Gross	$ 22,737,866	$ 20,328,472
Allowances:		
Chargebacks	16,835,000	14,783,000
Sales returns and allowances	800,000	650,000
Doubtful accounts	500,000	610,000
Total allowances	18,135,000	16,043,000
Accounts receivable, net of allowances	$ 4,602,866	$ 4,285,472

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

	Total Allowances
Balance at January 1, 2002	$ 400,000
Additions charged to net sales	28,911,000
Deductions allowed to customers	(20,006,000)
Balance at December 31, 2002	9,305,000
Additions charged to net sales	56,515,000
Deductions allowed to customers	(49,777,000)
Balance at December 31, 2003	16,043,000
Additions charged to net sales	67,670,000

	Total Allowances
Deductions allowed to customers	(65,578,000)
Balance at December 31, 2004	$ 18,135,000

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4. INVENTORIES

Inventories consist of the following amounts at December 31:

	2004	2003
Raw materials	$ 5,030,430	$ 4,226,363
Goods in transit	2,901,626	1,874,625
Work in process	2,993,587	1,633,963
Finished goods	6,208,168	1,875,859
Total	$ 17,133,811	$ 9,610,810

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

During 2004 and 2003, the Corporation purchased inventory components of approximately $16.7 million and $10.3 million, respectively, from Sun Pharma.

5. DEBT

EDC Loan

During 2004, the Company repaid the entire amount due to the EDC under the Development and Loan Agreement dated August 10, 1990.

Loans Payable to Financial Institutions

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

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NOTES TO FINANCIAL STATEMENTS

	2004	2003
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, and is due in quarterly installments. This term loan was paid in full during 2004.	$	$ 4,375,000
$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, and is due in quarterly installments. This term loan was paid in full during 2004.		12,500,000
Total loans payable to financial institutions		16,875,000
Less current portion		8,750,000
Loans payable to financial institutions, net of current portion	$	$ 8,125,000

During 2004, the Corporation obtained a $10,000,000 line-of-credit with Citibank, N.A., that incurred interest at the London Interbank Offered Rate (LIBOR) plus 125 basis points. Borrowings on the line-of-credit are available to Caraco only when secured by an irrevocable standby letter-of-credit from Sun Pharma. Such a letter was provided by Sun Pharma during 2004. The letter has expired as of December 31, 2004, and has not subsequently been reissued. There were no borrowings on the line-of-credit at December 31, 2004.

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 in 2003 and $0.8 million in 2002.

6. INCOME TAXES

The Corporation s deferred income taxes result principally from its net operating loss carryforwards. At December 31, 2004 a net deferred income tax asset of approximately $14.4 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 net deferred tax asset, resulting in no net deferred tax asset or liability in the accompanying balance sheets. The valuation allowance increased by approximately $0.4 million in 2004, decreased by approximately $4.1 million in 2003 and increased by approximately $0.8 million in 2002.

At December 31, 2004, net operating loss carryforwards of approximately $41.6 million, which expire between 2007 and 2016, are available to offset future federal taxable income, if any. Sun Pharma has, over time, increased its ownership of the Corporation s capital stock. Under rules established by the Internal Revenue Code, this change in ownership may adversely affect how the Corporation is able to utilize these net operating loss carryforwards in future years.

7. STOCKHOLDERS EQUITY (DEFICIT)

Common Stock

During 2003, the Corporation s shareholders approved the authorization of an additional 20,000,000 shares of common stock. The Corporation 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. Out of the authorized preferred shares, two separate series had been designated, Series A and Series B.

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. Accordingly, at December 31, 2003 and 2004, no Series A shares remain designated.

In November 2002, in connection with the new technology transfer agreement established with Sun Pharma Global (Note 1), the Corporation designated the Series B Convertible Preferred Stock. The Series B preferred shares are non-redeemable and have no par value. In addition, the Series B Convertible Preferred Stock has no voting or dividend rights or liquidation preference other than priority liquidation based on their values on the dates they were earned, and can be converted after three years from the issuance date (or immediately upon a change in control) into one share of common stock, subject to a conversion adjustment (Note 1). While such preferred shares are outstanding, Caraco cannot, without the consent of the holders of a majority of the outstanding shares of the preferred stock, amend or repeal its articles of incorporation or bylaws if such action would adversely affect the rights of the preferred stock. In addition, without such consent, capital stock having any preference or priority superior to the preferred stock may not be issued. As of December 31, 2004, the Corporation has issued 4,352,000 shares of

the Series B Convertible Preferred stock to Sun Pharma in exchange for eight product transfers. Such shares have been valued at $27.5 million as of December 31, 2004 (Note 12).

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 Global 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 studies 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 were 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. No shares were earned by non-employee directors during 2004 and accordingly no similar expense was recorded during the year.

8. COMMON STOCK OPTIONS

Common Stock Option Plans

As of December 31, 2004, the Corporation maintains one stock option plan, the 1999 Equity Participation 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 for the year ended December 31:

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	2004		2003		2002	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding, beginning of year	277,000	$ 1.00	687,138	$ 1.04	701,138	$ 1.03
Granted	9,000	9.60				
Exercised	(80,400)	1.08	(410,138)	0.97		
Terminated	(24,000)	0.80			(14,000)	1.74
Outstanding, end of year	181,600	$ 1.41	277,000	$ 1.00	687,138	$ 1.01
Options exercisable, end of year	49,800	$ 1.02	102,500	$ 1.07	288,075	$ 1.04

Options at December 31, 2004:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Shares	Remaining Contractual Life *	Exercise Price *	Shares	Exercise Price *
$0.68 to $1.00	97,600	2.4	0.79	24,800	0.78
$1.01 to $2.00	75,000	3.0	1.25	25,000	1.25
$9.01 to $10.00	9,000	2.7	9.60		
Total	181,600	2.7	1.35	49,800	1.02

*Weighted average

Other Common Stock Option Agreements

The Corporation has issued other stock options outside of the 1999 Plan. These stock options have been issued with various vesting schedules and expire at various dates through October 2006. Activity with respect to these options is summarized as follows for the year ended December 31:

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	2004		2003		2002	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding, beginning of year	1,876,666	$ 2.01	2,250,824	$ 2.00	2,250,824	$ 2.00
Exercised	(1,676,666)	2.01	(374,158)	1.16		
Outstanding, end of year	200,000	$ 3.5	1,876,666	$ 2.01	2,250,824	$ 2.00
Options exercisable, end of year	200,000	$ 3.5	1,876,666	$ 2.01	2,250,824	$ 2.00

Options at December 31, 2004:

	Options Outstanding and Exercisable		
Range of Exercise Prices	Shares	Remaining Contractual Life	Exercise Price
$3.01 to $4.00	200,000	3.3	3.5

The Corporation follows only the disclosure aspects of Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation* . Management believes that the fair value and pro-forma disclosures required by SFAS No. 123 are not material to the financial statements, and, as a result, these specific disclosures have not been made. 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. Options to purchase 9,000 shares of common stock were granted in 2004 to the independent directors of the Corporation. 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 Options Agreement

Pursuant to an agreement between the Corporation and an unaffiliated generic pharmaceutical company, dated October 1, 1993, the Corporation was to receive the formulations, technology, manufacturing processes and know-how, and other relevant information, and to pay for the bio-equivalency studies required for the preparation of ANDAs for two products. Pursuant to the agreement, the Corporation was required to pay (i) a Sign-Up Option to purchase 100,000 shares of Common Stock at $3.50 per share; and (ii) a Product Option to purchase shares 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 (Note 12).

9. LEASES (INCLUDING RELATED PARTY)

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

The Corporation entered into a non-cancelable operating lease with an unrelated party during 2002 to lease additional warehouse space. This lease was subsequently canceled during 2003 in lieu of a new non-cancelable 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 with an option to renew for an additional year.

Net rental expense on these operating leases was $181,129, $176,065 and $51,460 in 2004, 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 non-cancelable lease terms in excess of one year as of December 31, 2004:

Year	Amount
2005	$ 205,000
2006	198,000
2007	50,000
Total minimum payments due	$ 453,000

The Corporation also paid approximately $0.6 million and $0.5 million to Sun Pharma during 2004 and 2003, respectively, for the purchase of various parts and machinery needed for operations.

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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 2004, 2003 or 2002.

11. CONCENTRATIONS AND COMMITMENTS

Major Customers

Shipments to three wholesalers accounted for approximately 79%, 80% and 86% of sales in 2004, 2003 and 2002, respectively. Two of these customers accounted for 44% and 24%, respectively, of 2004 sales. Balances due from these customers represented approximately 82% and 84% of gross accounts receivable at December 31, 2004 and 2003, respectively.

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

Major Products

Shipments of two products accounted for approximately 80%, 87% and 78% of gross sales in 2004, 2003 and 2002, respectively.

Approximately 75%, 73% and 20% of Caraco s raw material purchases in 2004, 2003 and 2002, respectively, were made from Sun Pharma.

Product Sales Commitment

Certain of the Corporation s customers purchase its products through designated wholesalers, who act as an intermediary distribution channel for the Corporation s products. One such customer, the Veterans Administration, an agency of the United States Government, entered into a sales contract with the Corporation effective August 5, 2002 to 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 two of which were 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.

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Labor Contract

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

12. OTHER MATTERS

Employment Contracts

The Corporation has employment agreements with three of its executive officers (one of which was entered into subsequent to December 31, 2004) 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. Dr. Curry is seeking 175,000 shares of Caraco common stock (35,000 shares for each of the first five ANDAs approved by the FDA). The Corporation and plaintiff each filed a motion for summary disposition. Both parties motions were denied, and have agreed that the matter will be submitted to binding arbitration. The Corporation intends to vigorously defend itself against these claims, which management believes have no merit.

On September 22, 2004, Ortho-McNeil Pharmaceutical, Inc. (Ortho-McNeil) filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Company s filing of an ANDA seeking approval to market its generic version of Ortho-McNeil s Ultracet® drug product infringed Ortho-McNeil s patent, which expires on September 6, 2011. Ortho-McNeil seeks an order from the Court which, among other things, directs the FDA not to approve Caraco s ANDA any earlier than the claimed expiration date. The ANDA filed by the Corporation challenged Ortho-McNeil s patent and the Corporation believes that the Ortho-McNeil patent is invalid and/or will not be infringed by Caraco s manufacture, use or sale of the product. The Corporation intends to vigorously defend this action.

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

Product Liability and Insurance

The Corporation currently maintains general and product liability insurance, with coverage limits of $10 million per incident and in the aggregate. The Corporation also maintains special product liability insurance coverage for one of its products with coverage limits of $1 million per incident and in the aggregate. The Corporation s insurance policies provide coverage on a claim made basis and are

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subject to annual renewal. Such insurance may not be available in the future on acceptable terms or at all. There can be no assurance that the coverage limits of such policies will be adequate to cover the Corporation s liabilities, should they occur.

Royalty Accrual

Pursuant to the Strategic Alliance Stock Options Agreement (Note 8), Caraco received the formulation for one product, Metoprolol Tartrate, in March 1995. However, Caraco has determined that the formula provided to it with respect to Metoprolol Tartrate is different than the formula submitted in an ANDA to the FDA in 1995, approved by the FDA in 1996 and manufactured and introduced by Caraco since 1997. The Corporation has accrued royalties of approximately $1 million, which is included with accrued expenses in the accompanying balance sheets at December 31, 2004 and 2003, and since April 2003 has discontinued to accrue royalties related to this agreement.

Subsequent Transactions With And Relating To Sun Pharma

Sun Global earned 1,088,000 shares of Series B preferred stock pursuant to the products transfer agreement subsequent to December 31, 2004 (Note 1).

Change in Fiscal Year

On January 27, 2005, the Board of Directors of the Corporation resolved to change the Corporation s fiscal year from December 31 to March 31 commencing in 2005. This change is being made in order to make the Company s fiscal year conform to the March 31 fiscal year of its parent company, Sun Pharmaceutical Industries Limited.

* * * * *

EXHIBIT INDEX

3.01	Registrant s Amended and Restated Articles of Incorporation, as amended. (1)
3.02	Certificate of Amendment to the Articles of Incorporation filed February 13, 1997. (2)
3.03	Certificate of Amendment to the Articles of Incorporation filed February 10, 2000. (3)
3.04	Certificate of Determination of Rights, Privileges and Preferences Series B Preferred Stock. (4)
3.05	Registrant s Amended and Restated Bylaws. (+)
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. (5)
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. (5)
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. (5)
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. (5)
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. (5)
10.06	Agreement, dated as of October 1, 1993, among Registrant and Non-Affilate (5)
10.07	Employment Agreement, dated October 22, 1993, of Robert Kurkiewicz. (5)
10.08	Stock Purchase Agreement by and between Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries, Ltd. dated as of April 23, 1997. (6)
10.09	Products Agreement by and between Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries, Ltd. dated as of April 23, 1997. (6)
10.10	Registration Rights Agreement dated as April 1997. (6)
10.11	Second Note and Mortgage Modification Agreement (7)
10.12	Amendment to Employment Agreement of Robert Kurkiewicz dated as of April 1, 1997. (7)
10.13	1999 Equity Participation Plan. (8)
10.14	Agreement between ICICI Bank and the Corporation for the term loan of $5 million. (9)

10.15	Term Sheet between Bank of Nova Scotia and the Corporation for the term loan of $12.5 million. (10)
10.16	Renewal to Employment Agreement of Robert Kurkiewicz dated as of January 1, 1999. (3)
10.17	Third Amendment to Employment Agreement of Robert Kurkiewicz dated August 30, 2002. (3)
10.18	Employment Agreement of Jitendra N. Doshi. (3)
10.19	Agreement between Caraco and Sun Pharma Global, Inc. dated November 21, 2002. (4)
10.20	Sales contract with government vendor. (4)
10.21	Third Note Modification Agreement (11)
10.22	Third Mortgage Modification Agreement (11)
10.23	Employment Agreement of Mr. Singh (+)
21	Subsidiaries of the Registrant (+)
23.01	Consent of Independent Registered Public Accounting Firm (+)
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 Form 10-KSB filed on or about March 30, 1995 as Commission File no. 0-24676.

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

(3) Incorporated by reference from Exhibits to Pre-Effective Amendment No. 1 to Form SB-2 filed on September 4, 2002 as Commission File No. 333-91968.

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

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

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

(7) Incorporated by reference from Exhibits to Registrant s Form 10-KSB filed on or about March 31, 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 Exhibit to Registrant s Form 10-QSB filed on or about May 15, 2003, Commission File No. 0-24676.