

CARACO PHARMACEUTICAL LABORATORIES LTD  
Form 10-KT  
June 13, 2005

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

---

**FORM 10-K/T**

(Mark one)

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

For the period from January 1, 2005 to March 31, 2005.

**Commission File No. 0-24676**

---

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

Michigan  
(State of Incorporation)

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

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

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

---

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

Title of Each Class to be so Registered	Name of Each Exchange On which Each Class is to be Registered
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/T or any amendments to this Form 10-K/T.

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 June 9, 2005, there were 26,360,694 shares of common stock outstanding.

**Documents Incorporated By Reference:**

None

---

**CARACO PHARMACEUTICAL LABORATORIES, LTD.  
FORM 10-K/T**

**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 pharmaceuticals.

A generic pharmaceutical 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 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 5<sup>th</sup> 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 at our principal Internet address at [www.caraco.com](http://www.caraco.com). We believe that these reports are made available as soon as reasonably practicable after we electronically file with or furnish them to the SEC.

On January 27, 2005, the Board of Directors of the Company resolved to change the Company's fiscal year 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 ( Sun Pharma ). This Form 10-K/T is intended to cover the transition report for the period January 1, 2005 through March 31, 2005 (the Transition Period ). Subsequent to this, the Company's Form 10-K will cover the fiscal year April 1 to March 31.

**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 June 9, 2005, Sun Pharma beneficially owns approximately 64% (71% including its convertible Series B Preferred Stock) of the outstanding shares of Caraco. See Current Status and Sun Pharmaceutical Industries Limited.

**Current Status**

The Transition Period has been a milestone quarter. We recorded net sales of \$17.3 million during the Transition Period compared to \$13.6 million during the corresponding period of 2004. We have generated cash from operations of \$4.8 million as compared to \$6.2 million during the relevant periods. This cash was used primarily to augment working capital. We incurred a net loss of \$4.3 million compared to net loss of \$2.2 million during the relevant periods. The higher loss was primarily due to higher non-cash research and development expense (R&D) of

\$10.2 million as compared to \$7.8 million during the relevant period. This non-cash R&D expense relates to three products passing their bio-equivalency studies during the Transition Period as compared to two during the corresponding period. At March 31, 2005, we had a stockholders' equity of \$31.6 million as compared to a stockholders' deficit of \$3.7 million at March 31, 2004 and a stockholders' equity of \$25.8 million at December 31, 2004. See Part II Item 6. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Pursuant to our products agreement with Sun Pharma Global, Inc. (Sun Global), a wholly-owned subsidiary of Sun Pharma, we have selected, through March 31, 2005, seven products for development. With this, all products out of the 25 products to be transferred to us by Sun Global have been selected. Of these 25 products, eleven products passed their bio-equivalency studies as of March 31, 2005, and one product since then. Sun Global has thereby earned 544,000 preferred shares for each product. See Sun Pharmaceutical Industries Limited and Part II Item 6. Future Outlook.

We filed three ANDAs with the FDA during the Transition Period. This brings our total number of ANDAs pending approval by the FDA to nine.

The FDA commenced an inspection of the Company's facility during the Transition Period. The FDA completed its inspection in May 2005 and issued observations on Form 483. Though we cannot be certain, we believe that the observations are not material and we are in the process of remedying them. See Regulation.

### **Overview of the Generic Drug Industry**

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

The generic pharmaceutical business is highly competitive. Although generic pharmaceuticals must meet the same quality standards as branded pharmaceuticals, they could be sold at prices that are up to 90% (in some cases even more) below those of their branded counterparts. The discount is relevant to the amount of competition on a given product.

Companies aspiring to earn higher margins for generic drugs may have a strategy of manufacturing niche products or hard to replicate products or could include a litigious strategy of patent challenges and first to file. 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. Recently this strategy has also seen reduced margins as authorized generics have become more prevalent. Authorized generics occur when the brand innovator has licensed its brand products to a generic manufacturer or has chosen to produce another label and provided the brand drug generically at typical generic discounts.

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 17 prescription products in 36 strengths in 89 package sizes. The products and their use for the indications are set forth in the table below:

<b>Generic Name</b>	<b>Purpose</b>
Metoprolol Tartrate	Hyper-Tension
Paromomycin Sulfate	Antibacterial
Salsalate	Decongestant
CMT	Arthritis/NSAID
Clonazepam	Seizure, Panic Disorders
Flurbiprofen	Arthritis/NSAID
Carbamazepine	Epilepsy
Oxaprozin	Rheumatoid Disease
Metformin Hydrochloride	Diabetes
Tramadol Hydrochloride	Analgesic
Meperidine Hydrochloride*	Analgesic
Ticlopidine	Reduction of incidence of strokes
Tizanidine	Management of muscle tone associated with spasticity
Digoxin	Heart failure
Mirtazapine	Anti-depressant
Citalopram Hbr	Anti-depressant
Clozapine	Anti-psychotic

\* Expected to be marketed sometime in calendar 2005.

We have submitted 24 ANDAs to the FDA for approval since August 1997, including three filed during the Transition Period. Of these 24 ANDAs, the FDA has approved 15 through March 31, 2005. Accordingly, we have nine 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. We anticipate also seeking opportunities to in-license authorized generics and other generic pharmaceuticals.

**Sun Pharmaceutical Industries Limited**

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

Sun Pharma and its affiliates had loaned us approximately \$10 million since August 1997. As of December 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 all the 25 products, eleven of which passed bio-equivalency studies as of March 31, 2005, and one product since then. 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 the Transition Period, we purchased approximately \$5.3 million in raw materials and formulations from Sun Pharma and its subsidiaries, as compared to \$4.5 million during the corresponding period of 2004. We acquired \$0.1 million worth of machinery and equipment from Sun Pharma as compared to \$0.2 during the same relevant periods. 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 are using Caraco as a contract manufacturer and/or distributor for two of their products pursuant to agreements entered into in December 2004 and in January 2005.

During the Transition Period, SPARC Bioresearch Private Limited ( SPARC ), an affiliate of Sun Pharma, performed certain analytical studies required as part of the bio-equivalency process for two products transferred to us by Sun Pharma pursuant to the products agreement. We incurred approximately \$172,000 of costs during this period for the studies performed by SPARC. No similar studies were performed by SPARC during the three months ended March 31, 2004 or during the years ended December 31, 2004, 2003 and 2002.

During the first quarter of 2004, Sun Pharma acquired 3,452,291 additional shares of common stock and 1,679,066 stock options from two former directors and a significant shareholder. Sun exercised these stock options during the fourth quarter of 2004, thereby increasing its beneficial ownership to 64% (currently 71% 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, increased competition, 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 continue to expand our customer base.

### **Sales and Customers**

Our sales team effectively addressed the challenges in 2004 and during the Transition Period and is geared up to meet the objectives set up for fiscal 2006. The sales team is being strengthened to meet the demand of continued growth..

Certain of our end-use customers purchase our products through designated wholesalers, such as Amerisource-Bergen Corporation , McKesson Corporation and/or Cardinal Health, 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. Accordingly, shipments to three large wholesale customers, namely McKesson Corporation (54% and 0%), Amerisource-Bergen Corporation (7% and 64%) and Cardinal Health (13% and 10%), accounted for approximately 74% of gross sales during both the Transition Period and the corresponding period of 2004. Balances due from these customers represented approximately 77% and 76% of gross accounts receivable at March 31, 2005 and 2004, respectively. No other single customer represented more than 10% of our gross sales during the past two years.

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, 2006, 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 March 31, 2005 and 2004 and the fiscal years ended December 31, 2004, 2003 and 2002 are as follows, (\$000 s):

	March 31,		
	2005	2004 (unaudited)	
Salaries	\$ 446	\$	473
Raw Materials/Supplies	170		67
Bio-equivalency Studies	737		370
Laboratory	289		224
Technology Transfer, non-cash	10,200		7,828
Other	77		
<b>TOTAL</b>	<b>11,919</b>		<b>8,961</b>

  

	December 31,		
	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
<b>TOTAL</b>	<b>\$ 30,450</b>	<b>\$ 6,216</b>	<b>\$ 7,236</b>

The non-cash technology transfer charges are based on the fair value of the preferred shares on the date the respective product formula passes the bio-equivalency studies. The fair value of such shares is based upon an independent valuation, which includes a discount for marketability.

### Regulation

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

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.

The FDA commenced its inspection of the Company's facility during the Transition Period, completed its inspection in May 2005, and issued observations on Form 483. Though we cannot be certain, we believe that the observations are not material and we are in the process of remedying them.

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 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 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 March 31, 2005, we had a total of 193 full-time equivalent as compared to a total of 191 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 during December 31, 2004. 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.

### **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.**

### **The Facilities**

Our entire property, plant, equipment and intellectual property are free of any mortgages, liens or similar restrictions. 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 \$0.6 million in upgrades to our facility during the Transition Period as compared to \$1.3 million during the corresponding period of 2004. We invested \$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 submitted the matter 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. Since this action, Ortho-McNeil has entered into a license agreement with another manufacturer and has launched its product generically while another manufacturer has launched its approved generic at risk.

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

<b>2005</b>	<b>High</b>	<b>Low</b>
Transition Period	\$ 9.32	\$ 7.44
<b>2004</b>		
	<b>High</b>	<b>Low</b>
First Quarter	\$ 13.74	\$ 7.31
Second Quarter	\$ 11.94	\$ 9.40
Third Quarter	\$ 10.24	\$ 6.80
Fourth Quarter	\$ 10.00	\$ 6.82
<b>2003</b>		
	<b>High</b>	<b>Low</b>
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 June 9, 2005 there were 101 registered holders of our Common Stock.

During the Transition Period, we issued to Sun Global 1,632,000,000 preferred shares in exchange for the transfer of three products. During 2004, we issued to Sun Global 4,352,000 preferred shares in exchange for the transfer of 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 periods ended March 31, 2005 and 2004 respectively. The data are derived from our financial statements. The Transition Period financial statements have been audited by Rehmann Robson, our registered independent public accountants. The corresponding period data are unaudited. 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.

	Three Months Ended March 31,	
	2005	2004
	(unaudited)	
Statement of operations data	(in thousands, except per share data)	
Net sales	\$ 17,337	\$ 13,561
Cost of goods sold	7,879	5,391
Gross profit	9,457	8,170
Selling, general and administrative expenses	1,879	1,282
Research and development costs - affiliate non cash	10,200	7,828
Research and development costs - other	1,720	1,133
Operating loss	(4,342)	(2,073)
Other income (expenses)	21	(169)
Net Loss	(4,322)	(2,243)
Net Loss per share		
Basic	(0.16)	(0.09)
Diluted	(0.16)	(0.09)
Weighted Average Shares Outstanding:		
Basic	26,348	24,578
Diluted	26,348	24,578

	As of March 31,	
	2005	2004
(in thousands)		
<b>Balance Sheet Data</b>		
Current assets	\$ 32,938	\$ 20,245
Property, plant and equipment, net	12,897	10,594
Total assets	45,835	30,839
Current liabilities	14,149	19,252
Long term debt		7,878
Total liabilities	14,149	27,130
Stockholders' Equity	31,685	3,709
Working Capital	18,788	993

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 registered independent public accountants. 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.

	Year Ended December 31,				
	2004	2003	2002	2001	2000
(in thousands, except per share data)					
<b>Statement of operations data</b>					
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)
<b>Net (Loss) Income per share</b>					
Basic	(0.01)	0.46	(0.10)	(0.29)	(0.39)
Diluted	(0.01)	0.44	(0.10)	(0.29)	(0.39)
<b>Weighted Average Shares Outstanding:</b>					
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)					
<b>Balance Sheet Data</b>					
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		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.

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 made in order to make the Company's fiscal year conform to the March 31 fiscal year of its parent company, Sun Pharma. The three-month results being reported below by the Company relate to the transitional three month fiscal period ended March 31, 2005.

**Overview of Transition Period**

The Transition Period has been a milestone quarter. We recorded net sales of \$17.3 million during the Transition Period compared to \$13.6 million during the corresponding period of 2004. We have generated cash from operations of \$4.8 million as compared to \$6.2 million during the relevant periods. This cash was used primarily to augment working capital. We incurred a net loss of \$4.3 million compared to net loss of \$2.2 million during the relevant periods. The higher loss was primarily due to higher non-cash research and development expense (R&D) of \$10.2 million as compared to \$7.8 million during the relevant period. This non-cash R&D expense relates to three products passing their bio-equivalency studies during the Transition Period as compared to two during the corresponding period. At March 31, 2005, we had a stockholders' equity of \$31.6 million as compared to a stockholders' deficit of \$3.7 million at March 31, 2004 and a stockholders' equity of \$25.8 million at December 31, 2004.

**FDA Compliance**

The FDA commenced an inspection of the Company's facility during the Transition Period. The FDA completed its inspection in May 2005 and issued observations on Form 483. Though we cannot be certain, we believe that the observations are not material and we are in the process of remediating them.

**Transition Period Ended March 31, 2005 (Audited) Compared with Period ended March 31, 2004 (Unaudited)**

**Net Sales.** Net sales for the relevant periods of 2005 and 2004 were \$17.3 and \$13.6 million, reflecting an increase of almost 27%. 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 three and two products accounted for approximately 77% and 74% of net sales for the relevant periods, respectively. See Note 1 to Financial Statements - Revenue Recognition

for explanation of the determination of Net Sales.

**Gross Profit.** We earned a gross profit of \$9.5 million as compared to a gross profit of \$8.2 million during the relevant periods, reflecting an increase of 16%. The improvement was primarily due to higher sales volumes during the Transition Period as compared to the corresponding period of 2004.

The gross profit margin declined to 55% as compared to 60% during the relevant periods. The decrease was primarily the result of increased competition, both domestic and foreign, resulting in erosion of prices and profit margins.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses during the relevant periods were \$1.9 million and \$1.3 million, representing an increase of 46%. The selling, general and administrative expenses have increased to 10.8% of net sales as compared to 9.5% of net sales during the relevant periods.

The increase in SG&A of approximately \$0.6 million has been due to the increase in regulatory costs for compliance with SEC regulations (\$0.2 million), higher insurance costs for product liability (\$0.1 million) and increased SG&A expenses due to higher volumes of sales.

**Research and Development Expenses.** Total R&D expenses for the relevant periods were \$11.9 million and \$9.0 million. Cash research and development expenses were \$1.7 million and \$1.1 million during the relevant periods. We incurred non-cash research and development expenses (technology transfer cost) of \$10.2 million for the 1,632,000 shares of preferred stock for three product transfers as compared to \$7.8 million for the 1,088,000 shares of preferred stock for two product transfers. The substantially higher R&D expenses, both cash and non-cash, represent increased R&D activities.

**Interest Expense.** We did not incur any interest cost during the Transition Period. Interest expense on loans from the EDC, ICICI Bank, the Bank of Nova Scotia and Citibank was \$0.2 million during the relevant period of 2004. 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.

**Results of Operations.** We incurred a net loss of \$4.3 million and \$2.2 million during the relevant periods. The significantly lower results of operation are primarily due to higher non-cash R&D expenses.

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

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

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

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

Change in the product mix of sales.

Reduction in manufacturing costs due to increased batch sizes.

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

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

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

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

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

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

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

#### **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 tables present a summary of our audited quarterly results for the Transition Period and 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.

Transition Period (audited)

(In thousands, except per share data)

	<u>Quarter 1</u>
Net Sales	\$ 17,337
Net Profit (Loss)	(4,418)
Earnings Per Share	
Basic	(0.17)
Diluted	(0.17)

2004 (unaudited)

	(in thousands, except per share data)			
	<u>Quarter 1</u>	<u>Quarter 2</u>	<u>Quarter 3</u>	<u>Quarter 4</u>
Net Sales	13,561	14,800	15,299	16,680
Net Profit (Loss)	(2,243)	1,527	1,062	(545)
<b>Earnings Per Share</b>				
Basic	(0.09)	0.06	0.04	(0.02)
Diluted	(0.09)	0.05	0.04	(0.02)

2003 (unaudited)

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

**Liquidity and Capital Resources**Transition Period and period ended March 31, 2004

We generated cash of \$4.8 million from operations as compared to cash of \$6.2 million during the relevant periods. The lower net cash generated from operations was a result of higher working capital requirements. In addition to augmenting working capital, the cash generated from operations was used to finance our capital expenditures of \$0.6 million and \$1.3 million during the relevant periods.

During the first quarter of 2004, we repaid the entire balance of \$4.4 million due to ICICI Bank Limited. These payoffs were funded from internal cash flow and by utilizing a \$10.0 million credit line arranged with Citibank, FSB.

At March 31, 2005, we had working capital of \$18.8 million compared to a working capital of \$1.0 million at March 31, 2004. The lower working capital as on March 31, 2004 was primarily due to classification of loans as current of \$9.3 million due to the Bank of Nova Scotia and \$1.2 million due to the EDC.

Years ended December 31, 2004 and 2003

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

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

During 2004, we repaid the entire balance of \$4.4 million due to ICICI Bank Limited and the \$6.4 million mortgage loan due to the Economic Development Corporation of the City of Detroit (the EDC), and repaid \$12.5



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

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

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

	<b>(In thousands) Payment Due</b>
Contractual Obligations	1-3 years
Operating Leases	398

There are no other contractual obligations requiring disclosure.

##### Off Balance Sheet Transactions

None

#### Future Outlook

Management is optimistic about our future outlook. 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 fiscal 2006.

Pricing pressures, however, due to increased competition, have continued during 2004 and the Transition Period and are expected to continue in fiscal 2006, 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 all 25 products for development and twelve of these products have passed their respective bio-equivalency studies (one in December 2003, seven in 2004, three during the Transition Period and one since then). If some or all of the remaining products pass their bio-equivalency studies in fiscal 2006, 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%, 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 fiscal 2006 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.
- (j) Research alternate product development sources and product licenses such as in licensing authorized generics from brand innovator companies and acquisitions of ANDAs from competitor manufacturers.

#### **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**

**INDEX TO FINANCIAL STATEMENTS**

	<u>Page</u>
1. Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting	F-3 & F-4
2. Report of Independent Registered Public Accounting Firm	F-5
3. Financial Statements:	
Balance Sheets as of March 31, 2005, December 31, 2004 and 2003	F-6 & F-7
Statements of Operations for the Transition Period and for the years ended December 31, 2004, 2003 and 2002	F-8
Statements of Stockholders' Equity (Deficit) for the Transition Period and for the years ended December 31, 2004, 2003 and 2002	F-9
Statements of Cash Flows for the Transition Period and for the years ended December 31, 2004, 2003 and 2002	F-10
Notes to Financial Statements	F-11

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

None.

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

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

b. There has been no change in the Company s internal control over financial reporting that occurred during the Transition Period that materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

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

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

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

Based on our evaluation, management concluded that our internal control over financial reporting was effective as of March 31, 2005. Our management s assessment of the effectiveness of our internal control over financial reporting as of March 31, 2005 has been audited by Rehmann Robson, an independent registered public accounting firm, as stated in its Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting which appears on pages F-3 and F-4 below.

**Item 9B. Other Information.**

None.

**PART III**

**Item 10. Directors and Executive Officers of the Registrant.**

Caraco s Board of Directors is divided into three classes with each class of directors elected to a three-year term of office. At each annual meeting of shareholders, shareholders elect one class of directors for a three-year term to succeed the class of directors whose term of office expires at that meeting. Set forth below is a list of the directors of Caraco as of June 9, 2005. As previously disclosed, on April 15, 2005, the Board appointed Daniel H. Movens as a director of the 2005 class effective May 2, 2005, and nominated him, together with Sailesh T. Desai

and Georges Ugeux, for election as directors at the 2005 Annual Meeting to serve until 2008, and the election and qualification of their successors.

**INCUMBENT DIRECTORS TERMS EXPIRING 2005**

<b>Nominees</b>	<b>Age</b>	<b>Principal Occupation and Business Experience During Past 5 Years and other Directorships</b>	<b>Director Since</b>
Sailesh T. Desai	50	Mr. Desai has served as a full time director of Sun Pharmaceutical Industries Limited ( Sun Pharma ), since 1999, responsible for domestic marketing of pharmaceutical formulations. From 1994 to 1998, Mr. Desai was the principal shareholder and Managing Director of Milmet Laboratories, Pvt. Ltd., a manufacturer and marketer of ophthalmic solutions which was organized under the laws of the Commonwealth of India and merged into Sun Pharma in 1998.	2000
Daniel H. Movens	47	Mr. Movens became the CEO of Caraco effective May 2, 2005. Prior to this, Mr. Movens was President of Anda, Inc., a wholly owned subsidiary of Andrx, Inc., a position he held since February 2004. Since 1995 Mr. Movens held a number of positions of increasing responsibility, including Executive Vice President of Operations. Mr. Movens was also an Operating Committee member for Andrx Corporation. For fifteen (15) years before joining Anda, Inc., Mr. Movens worked in the retail pharmacy industry, working for independent pharmacies and pharmacy chains.	2005
Georges Ugeux	60	In October 2003, Mr. Ugeux founded Galileo Global Advisors LLC (a company offering strategic advice on international business development). From September 1996 to October 2003, Mr. Ugeux was a Group Executive Vice President, International and Research and a member of the Office of the Chief Executive of NYSE. From 1995 until September 1996, Mr. Ugeux served as President of the European Investment Fund. From 1992 until 1995, Mr. Ugeux was President of Kidder, Peabody Europe as well as Managing Director while serving as a member of the Managing Committee of the Board of Directors of Kidder, Peabody Inc. From 1988 until 1992, Mr. Ugeux was Group Finance Director at Societe Generale de Belgique, a Belgian diversified industrial and financial conglomerate.	2004

**DIRECTORS TERMS EXPIRING 2006**

<b>Nominees</b>	<b>Age</b>	<b>Principal Occupation and Business Experience During Past 5 Years and other Directorships</b>	<b>Director Since</b>
Dilip S. Shanghvi	49	Mr. Shanghvi has served as Chairman of the Board of Directors of Caraco since 1997. Mr. Shanghvi is the founder of Sun Pharma, its Managing Director since its inception in 1993, responsible for marketing, research and development and human resource development, and its Chairman since 1999. Mr. Valia is Mr. Shanghvi's brother-in-law.	1997
Jitendra N. Doshi	54	Mr. Doshi was the Chief Executive Officer of Caraco from September 2003 to May 2005, and has been the Chief Financial Officer since November 2002 and its Chief Operating Officer since August 30, 2002. Mr. Doshi commenced employment with Caraco as its Senior Vice President - Commercial in April 2001. From September 1999 to April 2001, Mr. Doshi was employed by Sun Pharma as General Manager - Operations. From 1991 to 1999, Mr. Doshi was Managing Director of Aqua Bearing Ltd., an auto parts manufacturer organized under the laws of the Commonwealth of India.	2001

**DIRECTORS TERMS EXPIRING 2007**

<b>Nominees</b>	<b>Age</b>	<b>Principal Occupation and Business Experience During Past 5 Years and other Directorships</b>	<b>Director Since</b>
Timothy S. Manney	46	Since May 2002, Mr. Manney has been President and Director of Synova, Inc. (a privately-held information technology staffing and creative services consulting firm). From 1990 to May 2002, Mr. Manney served as the Chief Financial Officer of Covansys Corporation (a publicly-held information technology solutions company).	2004
Sudhir Valia	48	Mr. Valia has worked for Sun Pharma as a full time director responsible for finance, commercial, operations, projects and quality control since December 1993. Prior to then, Mr. Valia was a chartered accountant in private practice. Mr. Valia is a qualified chartered accountant in India. Mr. Shanghvi is Mr. Valia's brother-in-law.	1997

**Audit Committee**

The Board maintains an Audit Committee. The Audit Committee is responsible for selecting, evaluating, retaining and, where appropriate, replacing Caraco's independent auditors. Generally, the Audit Committee monitors the integrity of Caraco's financial statements and the independence and qualifications of the independent auditors. The Audit Committee is governed by a written charter. The Audit Committee has been established in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934, as amended. The current members of the Audit Committee are Mr. Manney and Mr. Ugeux. Mr. Manney is the committee's Chairman. Each of these members is independent under Section 121(A) of Amex listing standards currently in effect. The Board of Directors has determined that Mr. Manney is an audit committee financial expert. The Board of Directors is currently actively searching for a third independent director to serve on its Board of Directors to replace Mr. William C. Brooks (who resigned as a director on April 14, 2005), in order to bring it into compliance with the Amex requirements which require three independent directors on its Audit Committee. There have been no material changes to the procedures by which shareholders may recommend nominees to Caraco's Board of Directors as previously disclosed in Caraco's 2005 Proxy Statement.



**EXECUTIVE OFFICERS**

The following table provides information about Caraco's executive officers who are not a directors as of June 9, 2005.

<b>Name</b>	<b>Age</b>	<b>Five-Year Business Experience</b>	<b>Executive Officer Since</b>
Robert Kurkiewicz	54	Commenced employment with Caraco as its Vice President Quality Assurance in November 1993 and was promoted to Sr. Vice President - Technical, October 1998.	1993
Gurpartap Singh Sachdeva	36	Vice President - Sales and Marketing since September 2003 and National Sales and Marketing Manager since September 2000. From May 1998 to September 2000, Mr. Singh was the Manager of Bulk Drugs for Sun Pharma.	2005

**Code of Business Conduct and Ethics**

The Company has adopted a Code of Business Conduct and Ethics (the "Code") applicable to its directors, officers and employees. A copy of the Code is available at no charge by contacting the Human Resources Manager, Michael Perry, at 1150 Elijah McCoy Drive, Detroit, MI 48202, or by telephone: (313) 871-8400 or by email: mperry@caraco.com.

**Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Securities Exchange Act of 1934 requires that Caraco's directors, executive officers and persons who own more than ten percent of a registered class of Caraco's equity securities file reports of stock ownership and any subsequent changes in stock ownership with the SEC not later than specified deadlines. To Caraco's knowledge, based solely on a review of the copies of such reports furnished to Caraco, all directors, executive officers and persons who own more than ten percent of Caraco's equity securities complied with applicable Section 16(a) filing requirements, except as follows: Sun Pharma and Sun Pharma Global are currently preparing reports to be filed to report the transfer by Sun Pharma to Sun Pharma Global of 5,137,357 shares of common stock as represented by a stock certificate issued in January 2005 and to report Sun Pharma Global's direct acquisition of 6,528,000 shares of Series B Preferred Stock pursuant to its products agreement with Caraco (with respect to the transfer of 12 products) and Sun Pharma's indirect acquisition of such shares as the parent of Sun Pharma Global. See "Security Ownership of Certain Beneficial Owners" below.



**Item 11. Executive Compensation.****COMPENSATION OF EXECUTIVE OFFICERS**

The following table shows, as to the Chief Executive Officer and as to the other executive officers whose salary and bonus exceeded \$100,000 during the last fiscal year, information concerning all compensation paid for services to Caraco during the Transition Period and for the last three fiscal years:

Name and Principal Position	Year	Annual Compensation			Long Term Compensation				
		Salary (\$)	Bonus (\$)	Other Annual Compensation (\$)	Awards		Payouts		All Other Compensation (\$)
					Restricted Stock Awards (\$)	Securities Underlying Options (#)	LTP Payments (\$)		
Jitendra N. Doshi CFO and COO (1)	Transition Period	38,077	0	0	0	0	0	1,140(2)	
	2004	159,854	0	0	0	0	0	4,560(2)	
	2003	134,758	0	0	0	0	0	4,560(2)	
	2002	109,769	0	0	0	0	0	4,560(2)	
Robert Kurkiewicz Sr. Vice President Technical	Transition Period	33,462	0	0	0	0	0	1,140(2)	
	2004	142,604	0	0	0	0	0	4,560(2)	
	2003	134,208	0	0	0	0	0	4,560(2)	
	2002	127,492	0	0	0	0	0	4,560(2)	
Gurpartap Singh Sachdeva Vice President Sales & Marketing	Transition Period	31,154	0	0	0	0	0	760(2)(3)	
	2004	114,818	0	0	0	0	0	0	
	2003	83,105	0	0	0	0	0	0	
	2002	68,856	0	0	0	0	0	0	

(1) Formerly CEO from September 2003 to May 2005.

(2) \$380.00 per month was given for car allowance.

(3) Appointed as an executive officer in January 2005.

**Option Grants in Transition Period**

No stock options were granted during the Transition Period to the named executive officers.

**Aggregated Option Exercises in Transition Period and Transition Period-End Option Values**

The following table sets forth information for the named executive officers with regard to the aggregate stock options exercised during the Transition Period ended March 31, 2005, and the stock options held as of March 31, 2005.

Name	Shares Acquired on Exercise	Value Realized (\$)(1)	Number of Securities Underlying Unexercised Options at Transition Period End (#) Exercisable/Unexercisable	Value of Unexercised In-the-Money Options at Transition Period End (\$) (2) Exercisable/Unexercisable
Jitendra N. Doshi	25,000	\$ 187,500	0/50,000	\$ 0/ 346,500
Robert Kurkiewicz	0	\$ 0	6,000/ 4,000	\$ 44,280/ 29,520
Gurpartap Singh Sachdeva	0	\$ 0	2,000/ 2,000	\$ 14,760/ 14,760

- (1) The value is based on the difference between the exercise prices and the closing sales prices on the dates of exercise.
- (2) The value is based on the difference between the exercise prices and the closing sale price of Caraco's common stock on March 31, 2005.

### Employment Agreements

Mr. Movens, the Chief Executive Officer of Caraco, entered into an employment agreement, effective May 2, 2005, pursuant to which he agreed to serve as Chief Executive Officer of the Company for period of thirty-six (36) calendar months which will automatically renew at the end of thirty-six (36) months. However, after the initial thirty-six (36) month period, each party may terminate the agreement upon ninety (90) days written notice to the other party. Mr. Movens shall receive a base salary of \$390,000, may receive a bonus of up to fifty (50%) percent of the base compensation (with twenty-five (25%) percent of the base compensation guaranteed only for the first year), and shall receive stock options for 40,000 shares upon the effective date at the fair market value of the common stock on the day immediately preceding the effective date and stock options for 40,000 shares of the Company annually thereafter (all such options to vest over a period of three years from the date of their respective grants), a stock grant on the effective date of 45,000 shares of the Company's common stock (which will vest over a period of three (3) years), and a stock grant of an additional 10,000 shares if the employment agreement is renewed. In addition, the Company will reimburse Mr. Movens for his reasonable relocation expenses; any such expense over and above \$50,000 will require prior approval of the Company.

If Mr. Movens is terminated without cause and for a reason other than for nonperformance, if Mr. Movens terminates for good reason, or if there is a change in control (as defined in the employment agreement) of the Company or Sun Pharmaceutical Industries Limited and Mr. Movens terminates within six months thereof because he reasonably determines that there has been a significant change in the nature and scope of his duties and powers, he is entitled to a lump sum severance payment in an amount equal to 1 ½ times the highest annual base and last earned bonus(es), together with certain benefits for a period of at least twelve (12) months, and all stock options and stock grants shall be deemed vested in full. With respect to any such amounts which are considered to be parachute payments under Internal Revenue Code §280G, the Company shall pay an additional amount representing a gross-up of any federal, state and local income tax liability arising from such payments. After one year of employment with the Company, the amount of this severance could be reviewed to be increased to two (2) times the highest annual base and last earned bonus(es).

If Mr. Movens becomes disabled (as defined in the employment agreement), or dies, the Company shall be obligated to pay accrued unpaid salary and benefits for a one (1) year period following such date of disability or death. If Mr. Movens quits before the first anniversary of the employment agreement, he will receive no severance compensation. If Mr. Movens quits after one (1) year of service, the Company shall pay him his base salary for a maximum period of one (1) year following such termination, or until he finds another position, whichever comes

first. In addition, if Mr. Movens is terminated for nonachievement of performance objectives, to be agreed upon, during his first year of employment, the Company will pay him his base salary for a maximum period of one (1) year, or until he finds another position, whichever comes first, and one-third (1/3) of the stock options and stock grants awarded to him will vest. If Mr. Movens is terminated for nonachievement of performance objectives, to be agreed upon, following his first year of employment, the Company will pay him 1 ½ times his base salary for a maximum period of one (1) year or until he finds another position, whichever comes first, and all of his stock options and stock grants awarded to him will vest. Mr. Movens is under no duty to seek other employment or to attempt in any way to reduce any amounts payable to him by means of mitigation or set off.

The Company and Mr. Movens have also entered into a Confidentiality And Non-Competition agreement, pursuant to which Mr. Movens agrees not to solicit any customer of the Company for business in competition with the Company, or solicit for employment any other employee of the Company, for a period of two (2) years following his termination. In addition, for a period of twelve (12) months following the termination of his employment, Mr. Movens agrees not to engage in any activity within North America which is competitive in any material respect with the business of the Company, including generic pharmaceutical manufacturing and marketing, but excluding wholesale distribution. In addition, for a period of twelve (12) months following termination of his employment, Mr. Movens agrees that he will not perform services for any business or organization, whether as an employee, consultant, advisor, independent contractor, or otherwise, which engages in any activity within North America that is competitive in any material respect with the business conducted by the Company, including any business engaged in generic pharmaceutical manufacturing and marketing and any other business in which the Company generates more than ten (10%) percent of its gross revenues.

Jitendra N. Doshi, the former Chief Executive Officer of Caraco, and currently Chief Financial Officer and Chief Operating Officer, entered into an employment agreement with Caraco dated August 30, 2002 in his capacity as Chief Operating Officer. The employment agreement provides Mr. Doshi with a salary at the rate of \$130,000 annually, which may be reviewed and adjusted, and a car allowance of \$380.00 per month. The employment agreement is for a term of five (5) years, commencing on January 1, 2002 and ending on December 31, 2006. The agreement automatically renews for successive one-year periods unless terminated by Caraco or Mr. Doshi upon ninety (90) days notice. In the event of the death or Disability (as such term is defined in the employment agreement) or if Caraco terminates Mr. Doshi for just cause (as such term is defined in the employment agreement), Mr. Doshi shall be entitled to his base salary and to benefits earned by him prior to the date of death, Disability or termination for just cause. In the event Caraco terminates Mr. Doshi without cause or if Mr. Doshi terminates for cause (as such term is defined in the employment agreement), he will receive base salary payments and his premium payments for health insurance benefits for six (6) months from the date of termination. In addition, any stock options that would become available for exercise at the end of the year during which such termination occurred shall immediately vest. In October 2003, Mr. Doshi became the interim Chief Executive Officer of Caraco. In October, 2004, the Compensation Committee increased his salary to \$165,000 annually.

Robert Kurkiewicz, the Senior Vice President - Technical, entered into a five-year employment agreement on November 22, 1993 which was amended on January 1, 1999 to extend the term until January 1, 2003 and which was further amended on August 30, 2002 to extend the term until December 31, 2007. The agreement, as amended, provides Mr. Kurkiewicz with a salary of \$129,800 per year, which may be reviewed and adjusted, and a car allowance of \$380.00 per month. The agreement provides that at the end of the term, it is renewable for successive one-year terms. In the event that Caraco terminates the agreement without cause, Mr. Kurkiewicz is entitled to receive monthly base salary payments and his premium payments for health insurance benefits for six (6) months from the date of termination. In addition, any stock options that would become available for exercise at the end of the year during which such termination occurred shall immediately vest. In October 2004, the Compensation Committee increased his salary to \$145,000 annually.

Gurpartap Singh Sachdeva, the Vice President of Sales and Marketing, entered into an employment agreement with Caraco dated February 1, 2005. The employment agreement provides Mr. Sachdeva with a salary at the rate of \$135,000 annually, which may be reviewed and adjusted, and a car allowance of \$380.00 per month. The employment agreement is for a term of five (5) years, commencing on February 1, 2005. The agreement automatically renews for successive one-year periods unless terminated by Caraco or Mr. Sachdeva upon ninety (90) days notice. In the event of the death or Disability (as such term is defined in the employment agreement) or if

Caraco terminates Mr. Sachdeva for just cause (as such term is defined in the employment agreement), Mr. Sachdeva shall be entitled to his base salary and to benefits earned by him prior to the date of death, Disability or termination for just cause. In the event Caraco terminates Mr. Sachdeva without cause or if Mr. Sachdeva terminates for cause (as such term is defined in the employment agreement), he will receive base salary payments and his premium payments for health insurance benefits for six (6) months from the date of termination. In addition, any stock options that would become available for exercise at the end of the year during which such termination occurred shall immediately vest.

#### **Change in Control Arrangements**

Under our 1999 Equity Participation Plan, options granted under that plan will become fully exercisable following certain changes in control of our company, such as:

A person, other than Sun Pharma, becomes the owner of a majority of the outstanding shares of our company;

A public announcement is made of a tender or exchange offer by any person, other than Sun Pharma, for 50% or more of the outstanding shares of our company;

The shareholders of our company approve a merger or consolidation with any other corporation or entity, unless, following the merger, the shares outstanding immediately before the merger continue to represent a majority of the outstanding shares of the surviving entity immediately following the merger;

Where shareholders approve a plan of complete liquidation of our company or an agreement for the sale of disposition by the company of all or substantially all of the assets of our company; or

Certain changes in the composition of our Board of Directors.

#### **Compensation Committee Interlocks and Insider Participation**

As noted, Mr. Dilip S. Shanghvi is the Chairman of our Compensation Committee and the Chairman of the Board of Caraco, a non-executive position. Mr. Shanghvi is also the Managing Director of Sun Pharma. As disclosed above, Sun Pharma engages in a number of transactions with Caraco. See Item 13. Certain Relationships and Related Transactions.

#### **Compensation of Directors**

Directors who are employees of Caraco or who are directors and/or employees of Sun Pharma and its affiliates do not receive additional compensation for their service on the Board of Directors and its Committees. Each non-employee director receives an annual retainer of \$12,000, a fee of \$1,500 if in person (\$500 if by telephone) for each attended Board and Committee meeting (with \$500 extra for the chairman of the Committee), a one time grant of 3,000 stock options upon initial election and an annual grant of 1,500 stock options on each anniversary date of election. No additional Committee fees are paid if the Committee meets on the same day as the Board meets. Non-employee directors are also reimbursed for out-of-pocket expenses incurred in connection with attending Board and Committee meetings.

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

##### **SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS**

The SEC requires that Caraco provide information about any shareholder who beneficially owns more than

5% of Caraco's common stock. The following table provides the required information, as of June 9, 2005, about the shareholders (who are not officers or directors) known to Caraco to be the beneficial owner of more than 5% of Caraco's common stock. Caraco relied solely on information furnished by its transfer agent and Schedule 13Ds.

**Amount and Nature of Beneficial Ownership as of June 9, 2005**

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percentage of Class
Sun Pharma Corp Comm Dept, Acme Plaza Andheri Kurla Road, Andheri (East) Mumbai 400 059 India	16,868,680(1)	64%

- (1) Sun Pharma directly owns 8,382,666 shares of common stock of Caraco and beneficially owns 8,486,014 shares registered in the name of Sun Global, whose address is Akara Building, 24 DeCastro Street, Wickhams Clay 1 Road, Town Tartola, British Virgin Islands. In addition, Sun Pharma and its affiliates own 6,528,000 shares of Series B preferred stock which are convertible into shares of common stock three years from the date of their respective issuance or upon a change in control. The earliest any shares of such series B preferred stock becomes convertible is December 2006.

**SECURITY OWNERSHIP OF MANAGEMENT AND DIRECTORS**

The following table contains information, as of June 9, 2005, about the number of shares of Caraco's common stock beneficially owned by incumbent directors, the executive officers and by all current directors, nominees and executive officers as a group. The number of shares of common stock beneficially owned by each individual includes shares of common stock which the individual can acquire by August 9, 2005 through the exercise of any stock option or other right. Unless indicated otherwise, each individual has sole investment and voting power (or shares those powers with his or her spouse) with respect to the shares of common stock listed in the table.

Name of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percentage of Class
Daniel H. Movens (1)	45,000(2)	*
Jitendra N. Doshi(1)	60,000(3)	*
Dilip S. Shanghvi(4)	0(5)	*
Robert Kurkiewicz(1)	10,013(6)	*
Gurpartap Singh Sachdeva (1)	9,800(7)	*
Sailesh T. Desai (4)	0(5)	*
Timothy S. Manney (8)	1,000(9)	*
Georges Ugeux (10)	1,000(11)	*
Sudhir Valia (4)	0(5)	*
All current executive officers and directors as a group (8 persons)	141,813(12)*	*

\* Less than 1.0% of the outstanding shares

- (1) The mailing address of each of these holders is 1150 Elijah McCoy Drive, Detroit, Michigan 48202.
- (2) Represents the grant of restricted stocks, one-third of which vests on each of May 2, 2006, May 2, 2007 and May 2, 2008.



- (3) Includes no stock options that are currently exercisable.
- (4) The mailing address of S. Desai, D. Shanghvi and S. Valia is Sun Pharmaceutical Industries Limited, Corp Comm Dept, Acme Plaza, Andheri Kurla Road, Andheri (East), Mumbai 400 059 India.
- (5) Excludes 16,868,680 shares of common stock and 6,528,000 shares of Series B preferred stock beneficially owned by Sun Pharma and its affiliates. (See footnote 1 under Security Ownership of Certain Beneficial Owners and Transactions of Directors, Executive Officers and Certain Beneficial Holders of Caraco. ) Messrs. Desai, Shanghvi and Valia are directors of, and Mr. Shanghvi, together with his associate companies, is also the majority shareholder of, Sun Pharma, and, therefore, may be deemed to share investment control over the shares of common stock held by Sun Pharma and its affiliates. Each of Messrs. Desai, Shanghvi and Valia disclaims beneficial ownership of the shares of common stock beneficially owned by Sun Pharma and its affiliates.
- (6) Includes stock options that are currently exercisable to purchase 8,000 shares of common stock.
- (7) Includes stock options that are currently exercisable to purchase 2,000 shares of common stock and 1,800 shares held in the name of his wife.
- (8) Mr. Manney's mailing address is c/o Synova, Inc., 1000 Town Center, Suite 700, Southfield, MI 48075.
- (9) Includes stock options that are currently exercisable to purchase 1,000 shares of common stock.
- (10) Mr. Ugeux's mailing address is c/o Galileo Global Advisors, One Rockefeller Center, New York, New York, 10020.
- (11) Includes stock options that are currently exercisable to purchase 1,000 shares of common stock.

**Equity Compensation Plan Information**  
**3-31-05**

<i>Plan category</i>	<i>Number of securities to be issued upon exercise of outstanding options, warrants and rights.</i>	<i>Weighted-average exercise price of outstanding options, warrants and rights.</i>	<i>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</i>
	(a)	(b)	(c)
<i>Equity compensation plans approved by security holders</i>	157,000	\$ 1.39	2,681,000
<i>Equity compensation plans not approved by security holders</i>	200,000	\$ 3.50	
<b>Total</b>	<b>357,000</b>	<b>\$ 2.03</b>	<b>2,681,000</b>

The equity compensation plan approved by security holders consists of the 1999 Equity Participation Plan. Options under the 1999 Plan were generally granted as incentive stock options to employees (279,000) and as non-qualified stock options to former directors and consultants (37,000).

**Item 13. Certain Relationships and Related Transactions.**

The following discloses transactions during the Transition Period, 2004, 2003 and 2002 and proposed

transactions between Caraco and several of the incumbent directors, executive officers and security holders who beneficially hold in excess of five percent of our outstanding shares:

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 5-year period. In exchange for each new generic drug transferred to us by Sun Global which passes a bioequivalency test, we issue Sun Global 544,000 shares of Series B preferred stock

During the Transition Period, 2004 and 2003, Sun Global earned 1,632,000, 3,808,000 and 544,000 shares of Series B preferred stock for three products, seven products and one product transfer, respectively, as provided under the November 2002 products agreement. During 2002, we issued to Sun Pharma 1,632,000 shares of our common stock for three product transfers under the former 1997 products agreement with Sun Pharma.

During 2003 and 2002, we borrowed approximately \$0.6 million and \$1.4 million, respectively, from Sun Pharma, and in 2003 we repaid the entire balance of all of our outstanding loans from Sun Pharma in the amount of approximately \$10 million. Prior to April 1, 2001, the interest rate was 10%; thereafter it was 8%.

During the Transition Period, 2004, 2003 and 2002, we purchased approximately \$5.3, \$16.7 million, \$10.3 million and \$2.4 million, respectively, of our materials from Sun Pharma. We intend to continue to purchase raw materials from Sun Pharma in fiscal 2006.

During the Transition Period, 2004, 2003 and 2002, Caraco purchased at Sun Pharma's cost, approximately \$0.1 million, \$0.61 million, \$0.51 million, and \$0.31 million, respectively, of equipment from Sun Pharma. We intend to continue to purchase equipment from Sun Pharma in fiscal 2006.

We entered into two non-cancelable operating leases during 2000 with Sun Pharma to lease production machinery. The leases each require rental payments of \$4,245 and expire during fiscal 2006.

Caraco entered into a manufacturing and supply agreement and a distribution and sale agreement with respect to one product in December 2004 with an affiliate of Sun Pharma. In January of 2005, Caraco entered into a distribution and sale agreement for another product with the same affiliate. Caraco earned \$0.1 million on sales of such products during the Transition Period. No similar sale for the products were present in the sales of 2004, 2003 and 2002.

During the Transition Period, SPARC, an affiliate of Sun Pharma, performed certain analytical studies required as part of the bio-equivalency process for two products transferred to us by Sun Pharma pursuant to the products agreement. We incurred approximately \$172,000 of costs during this period for the studies performed by SPARC. No similar studies were performed by SPARC during the three months ended March 31, 2004 or during the years ended December 31, 2004, 2003 and 2002.

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

Rehmann Robson audited the financial statements of Caraco for the Transition Period ended March 31, 2005.

##### **Audit and Non-Audit Fees**

Aggregate fees for professional services rendered for Caraco by Rehmann Robson as of the Transition Period and December 31, 2004 and 2003 are set forth below. The aggregate fees included in the Audit category are fees billed *for* the Transition Period fiscal years for the audit of Caraco's annual financial statements and review of quarterly financial statements and statutory and regulatory filings or engagements, as applicable. The aggregate fees included in each of the other categories are fees billed *in* the fiscal years.



	<u>Transition Period</u>	<u>2004</u>	<u>2003</u>
<b>Audit Fees</b>	\$ 112,000	\$ 123,000	\$ 95,500
<b>Audit-Related Fees</b>	\$ 4,700	\$ 7,280	\$ 13,875
<b>Tax Fees</b>	\$ 2,100	\$ 10,245	\$ 15,450
<b>All Other Fees</b>	\$ 0	\$ 0	\$ 0
<b>Total</b>	\$ 118,800	\$ 140,525	\$ 124,825

*Audit Fees* for the Transition Period and December 31, 2004 and 2003 were for professional services rendered for the audits of the financial statements of Caraco, quarterly review of the financial statements included in Caraco's Quarterly Reports on Form 10-Q, or services that are normally provided by Rehmann Robson in connection with statutory and regulatory filings or engagements for such years, including Rehmann's Robson's audit of management's assessment of internal control over financial reporting as of March 31, 2005 and December 31, 2004.

*Audit-Related Fees* for the Transition Period and December 31, 2004 and 2003 were for assurance and related services by Rehmann Robson that are reasonably related to the performance of the audit or review of Caraco's financial statements.

*Tax Fees* for the Transition Period and December 31, 2004 and 2003 were for professional services rendered by Rehmann Robson for services related to tax compliance, tax advice and tax planning.

None of the services described above was approved by the Audit Committee under the *de minimus* exception provided by Rule 2-01(c)(7)(i)(C) under Regulation S-X.

#### **Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditors**

Pursuant to its charter, the Audit Committee pre-approves all audit and non-audit services provided by the independent auditors prior to the engagement of the independent auditors with respect to such services.

### **Part IV**

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

- (a) 1 Financial Statements

	<u>Page</u>
1. Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting	F-3 & F-4
2. Report of Independent Registered Public Accounting Firm	F-5
3. Financial Statements:	
Balance Sheets as of March 31, 2005, December 31, 2004 and 2003	F-6 & F-7
Statements of Operations for the Transition Period and for the years ended December 31, 2004, 2003 and 2002	F-8
	F-9

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

Statements of Stockholders' Equity (Deficit) for the Transition Period and for the years ended December 31, 2004, 2003 and 2002

Statements of Cash Flows for the Transition Period and for the years ended December 31, 2004, 2003 and 2002

F-10

Notes to Financial Statements

F-11

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 10th day of June, 2005.

CARACO PHARMACEUTICAL LABORATORIES, LTD.

/s/ Daniel H. Movens

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

**POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Daniel H. Movens and / or Jitendra N. Doshi, this 8th day of June, 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 Exchange Act of 1934, this report has been signed below by the following persons in the capacities and on the date indicated above.

/s/ Dilip S. Shanghvi Chairman of the Board

Dilip S. Shanghvi

/s/ Daniel H. Movens Director, Chief Executive Officer

Daniel H. Movens

/s/ Jitendra N. Doshi Director, CFO and COO (and Principal Accounting Officer)

Jitendra N. Doshi

/s/ Sailesh T. Desai Director

Sailesh T. Desai

/s/ Timothy Manney Director

Timothy Manney

/s/ Georges Ugeux Director

Georges Ugeux

/s/ Sudhir V. Valia Director

Sudhir V. Valia

**CARACO PHARMACEUTICAL LABORATORIES, LTD.**

(a subsidiary of Sun Pharmaceutical Industries Limited)

**FINANCIAL STATEMENTS**

**AND**

**REPORTS OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

**FOR THE THREE MONTHS ENDED MARCH 31, 2005 AND**  
**THE YEARS ENDED DECEMBER 31, 2004, 2003 AND 2002**

F-1

---

**CARACO PHARMACEUTICAL LABORATORIES, LTD.**

(a subsidiary of Sun Pharmaceutical Industries Limited)

**INDEX TO FINANCIAL STATEMENTS**

---

<b><u>Report of Independent Registered Public Accounting Firm</u></b> <b><u>on Internal Control Over Financial Reporting</u></b>	F-3 & F-4
<b><u>Report of Independent Registered Public Accounting Firm</u></b>	F-5
<b>Financial Statements as of March 31, 2005, December 31, 2004, December 31, 2003 and for the Three Months Ended March 31, 2005 and 2004 (unaudited) and for the Years Ended December 31, 2004, 2003 and 2002</b>	
<u>Balance Sheets</u>	F-6 & F-7
<u>Statements of Operations</u>	F-8
<u>Statements of Stockholders' Equity (Deficit)</u>	F-9
<u>Statements of Cash Flows</u>	F-10
<u>Notes to Financial Statements</u>	F-11 & F-27

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

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

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting that the Corporation maintained effective internal control over financial reporting as of March 31, 2005, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Corporation's internal control over financial reporting based on our audit.

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

A corporation's internal control over financial reporting is a process designed by, or under the supervision of, the corporation's principal executive and principal financial officers, or persons performing similar functions, and effected by the corporation's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. A corporation's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the corporation; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America and that receipts and expenditures of the corporation are being made only in accordance with authorizations of management and directors of the corporation; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the corporation's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may

become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that the Corporation maintained effective internal control over financial reporting as of March 31, 2005, is fairly stated, in all material respects, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, the Corporation maintained, in all material respects, effective internal control over financial reporting as of March 31, 2005, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the *Public Company Accounting Oversight Board (United States)*, the financial statements as of and for the three months ended March 31, 2005 of the Corporation and our report dated June 7, 2005 expressed an unqualified opinion on those financial statements.

Troy, Michigan

June 7, 2005



**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited the accompanying balance sheets of Caraco Pharmaceutical Laboratories, Ltd. (a Michigan corporation) (a subsidiary of Sun Pharmaceutical Industries Limited) as of March 31, 2005, December 31, 2004 and 2003, and the related statements of operations, stockholders' equity (deficit) and cash flows for the three months ended March 31, 2005 and 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 March 31, 2005, December 31, 2004 and 2003 and the results of its operations and its cash flows for the three months ended March 31, 2005 and for each of the three years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the *Public Company Accounting Oversight Board (United States)*, the effectiveness of the Corporation's internal control over financial reporting as of March 31, 2005, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated June 7, 2005 expressed an unqualified opinion on management's assessment of the effectiveness of the Corporation's internal control over financial reporting and an unqualified opinion on the effectiveness of the Corporation's internal control over financial reporting.

Troy, Michigan  
June 7, 2005

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

**BALANCE SHEETS**

ASSETS	March 31		December 31	
	2005	2004	2004	2003
<b>Current assets</b>				
Cash and cash equivalents	\$ 6,627,425	\$ 2,456,469	\$ 4,206,282	
Accounts receivable, net	6,736,778	4,602,866	4,538,472	
Inventories	18,467,693	17,133,811	9,610,810	
Prepaid expenses and deposits	1,105,618	663,811	562,030	
<b>Total current assets</b>	<b>32,937,514</b>	<b>24,856,957</b>	<b>18,917,594</b>	
<b>Property, plant and equipment</b>				
Land	197,305	197,305	197,305	
Buildings and improvements	9,605,888	9,302,317	7,917,986	
Equipment	9,701,979	9,351,502	6,991,024	
Furniture and fixtures	589,329	585,705	364,140	
Total	20,094,501	19,436,829	15,470,455	
Less accumulated depreciation	7,197,422	6,890,796	5,963,780	
<b>Net property, plant and equipment</b>	<b>12,897,079</b>	<b>12,546,033</b>	<b>9,506,675</b>	
<b>Total assets</b>	<b>\$ 45,834,593</b>	<b>\$ 37,402,990</b>	<b>\$ 28,424,269</b>	

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

LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)	December 31		
	March 31	December 31	
	2005	2004	2003
<b>Current liabilities</b>			
Accounts payable, trade	\$ 2,577,668	\$ 2,557,078	\$ 1,386,160
Accounts payable, Sun Pharma	9,639,890	7,359,687	3,839,815
Accrued expenses	1,931,442	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
<b>Total current liabilities</b>	<b>14,149,000</b>	<b>11,627,414</b>	<b>20,008,404</b>
Loans payable to financial institutions, net of current portion			8,125,000
EDC loan payable, net of current portion			5,270,277
<b>Total liabilities</b>	<b>14,149,000</b>	<b>11,627,414</b>	<b>33,403,681</b>
<b>Commitments and contingencies (Notes 9, 11 and 12)</b>			
<b>Stockholders equity (deficit) (Note 7)</b>			
Series B convertible preferred stock, no par value; issued and outstanding 5,984,000 shares (March 31, 2005) 4,352,000 shares (December 31, 2004) (Note 12)	37,700,410	27,500,410	
Common stock, no par value; authorized 30,000,000 shares, issued and outstanding 26,360,294 shares (March 31, 2005) 26,334,694 shares (December 31, 2004) 24,577,828 shares (December 31, 2003)	44,927,987	44,896,257	41,442,311
Additional paid-in capital	2,718,735	2,718,735	2,718,735
Accumulated deficit	(53,661,539)	(49,339,826)	(49,140,458)
<b>Total stockholders equity (deficit)</b>	<b>31,685,593</b>	<b>25,775,576</b>	<b>(4,979,412)</b>
<b>Total liabilities and stockholders equity (deficit)</b>	<b>\$ 45,834,593</b>	<b>\$ 37,402,990</b>	<b>\$ 28,424,269</b>

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

**STATEMENTS OF OPERATIONS**

	Three Months Ended March 31, 2005	Three Months Ended March 31, 2004 (Unaudited)	Year Ended December 31		
			2004	2003	2002
Net sales	\$ 17,336,500	\$ 13,561,088	\$ 60,340,309	\$ 45,498,400	\$ 22,380,964
Cost of goods sold (Notes 1 and 4)	7,879,425	5,390,702	24,441,569	19,507,406	12,047,410
<b>Gross profit</b>	<b>9,457,075</b>	<b>8,170,386</b>	<b>35,898,740</b>	<b>25,990,994</b>	<b>10,333,554</b>
Selling, general and administrative expenses	1,879,480	1,282,355	5,276,755	7,363,341	3,827,707
Research and development costs - affiliate (Note 7)	10,200,000	7,828,160	24,397,040	3,103,370	3,887,423
Research and development costs - other	1,719,865	1,133,331	6,053,334	3,112,294	3,348,789
<b>Operating (loss) income</b>	<b>(4,342,270)</b>	<b>(2,073,460)</b>	<b>171,611</b>	<b>12,411,989</b>	<b>(730,365)</b>
<b>Other income (expense)</b>					
Interest expense		(181,542)	(407,330)	(1,233,531)	(1,539,075)
Interest income	16,385	2,015	40,316	9,102	13,436
(Loss) gain on sale of equipment			(10,636)	25,531	
Other income	4,172	10,067	6,671	9,627	
<b>Other income (expense) - net</b>	<b>20,557</b>	<b>(169,460)</b>	<b>(370,979)</b>	<b>(1,189,271)</b>	<b>(1,525,639)</b>
<b>Net (loss) income</b>	<b>\$ (4,321,713)</b>	<b>\$ (2,242,920)</b>	<b>\$ (199,368)</b>	<b>\$ 11,222,718</b>	<b>\$ (2,256,004)</b>
<b>Net (loss) income per share:</b>					
Basic	\$ (0.16)	\$ (0.09)	\$ (0.01)	\$ 0.46	\$ (0.10)
Diluted	\$ (0.16)	\$ (0.09)	\$ (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)**

	Common		Stock		Additional Paid-in Capital	Preferred Stock Dividends	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
<b>Balances at January 1, 2002</b>	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)
<b>Balances at December 31, 2002</b>			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
<b>Balances at December 31, 2003</b>			24,577,828	41,442,311	2,718,735		(49,140,458)	(4,979,412)
Issuance of preferred stock to affiliate in exchange for product technology transfers	4,352,000	27,500,410						27,500,410
Common stock options exercised			1,756,866	3,453,946				3,453,946
Net loss							(199,368)	(199,368)
<b>Balances at December 31, 2004</b>	4,352,000	27,500,410	26,334,694	44,896,257	2,718,735		(49,339,826)	25,775,576
Issuance of preferred stock to affiliate in exchange for product technology transfers	1,632,000	10,200,000						10,200,000
Common stock options exercised			25,600	31,730				31,730
Net loss							(4,321,713)	(4,321,713)
<b>Balances at March 31, 2005</b>	<b>5,984,000</b>	<b>\$ 37,700,410</b>	<b>26,360,294</b>	<b>\$ 44,927,987</b>	<b>\$ 2,718,735</b>	<b>\$</b>	<b>\$ (53,661,539)</b>	<b>\$ 31,685,593</b>

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

F-9

---

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

**STATEMENTS OF CASH FLOWS**

	Three Months Ended March 31, 2005	Three Months Ended March 31, 2004 (Unaudited)	Year Ended December 31		
			2004	2003	2002
<b>Cash flows from operating activities</b>					
Net (loss) income	\$ (4,321,713)	\$ (2,242,920)	\$ (199,368)	\$ 11,222,718	\$ (2,256,004)
Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities					
Depreciation	306,626	189,074	932,419	683,339	539,374
Capital stock issued or to be issued to affiliate in exchange for product formula	10,200,000	7,828,160	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	(2,133,911)	1,778,135	(64,393)	945,662	(3,997,627)
Inventories	(1,333,882)	(3,035,765)	(7,523,001)	(3,994,848)	(2,706,907)
Prepaid expenses and deposits	(441,807)	(31,178)	(140,430)	(90,716)	(292,112)
Accounts payable	2,300,793	1,587,310	4,690,789	1,243,139	3,019,936
Accrued expenses	220,793	159,863	(64,548)	(126,829)	663,652
<b>Net cash provided by (used in) operating activities</b>	<b>4,796,899</b>	<b>6,232,679</b>	<b>22,039,144</b>	<b>15,508,491</b>	<b>(838,600)</b>
<b>Cash flows from investing activities</b>					
Purchases of property, plant and equipment	(657,673)	(1,276,372)	(3,982,413)	(2,493,173)	(1,592,802)
Proceeds from sale of property, plant and equipment				76,200	
<b>Net cash used in investing activities</b>	<b>(657,673)</b>	<b>(1,276,372)</b>	<b>(3,982,413)</b>	<b>(2,416,973)</b>	<b>(1,592,802)</b>
<b>Cash flows from financing activities</b>					
Proceeds from loans payable to financial institutions			10,000,000	1,600,000	900,000
Repayments of loans payable to financial institutions		(4,500,000)	(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		(417,774)	(6,385,490)	(1,217,057)	(1,200,000)
Proceeds from issuance of common stock	31,730		3,453,946	872,973	1,699,520
<b>Net cash provided by (used in) financing activities</b>	<b>31,730</b>	<b>(4,917,774)</b>	<b>(19,806,544)</b>	<b>(9,419,464)</b>	<b>2,724,520</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>4,170,956</b>	<b>38,533</b>	<b>(1,749,813)</b>	<b>3,672,054</b>	<b>293,118</b>
Cash and cash equivalents, beginning of year	2,456,469	4,206,282	4,206,282	534,228	241,110
<b>Cash and cash equivalents, end of year</b>	<b>\$ 6,627,425</b>	<b>\$ 4,244,815</b>	<b>\$ 2,456,469</b>	<b>\$ 4,206,282</b>	<b>\$ 534,228</b>

The accompanying notes are an integral part of these 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 generic pharmaceuticals and markets them throughout 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 various strengths and package sizes. The Corporation's drugs relate to a variety of therapeutic segments including the central nervous system, cardiology, pain management and diabetes.

The Corporation's manufacturing facility and executive offices were constructed in 1991, pursuant to a \$9.1 million loan from the Economic Development Corporation of the City of Detroit (the EDC ). Since August 1997, capital infusions and loans have primarily come from Sun Pharmaceutical Industries Limited, a specialty pharmaceutical corporation organized under the laws of India ( Sun Pharma ). Among other things, Sun Pharma has acted as a guarantor on loans to Caraco, has supplied the Corporation with raw materials for certain products, assisted in obtaining machinery and equipment to enhance production capacities at competitive prices, and has transferred certain generic products. 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 June 7, 2005, Sun Pharma beneficially owns approximately 64% (71% including its convertible Series B Preferred stock) of the outstanding common shares of Caraco.

Change in Fiscal Year

On January 27, 2005, the Corporation's Board of Directors resolved to change the Corporation's fiscal year from December 31 to March 31, commencing in 2005. This change was made in order to conform the Corporation's fiscal year to the March 31 fiscal year of its parent company, Sun Pharmaceutical Industries Limited ( Sun Pharma ) (see below). The resulting three month period ended March 31, 2005 may be referred to herein as The Transition Period .

Sun Pharmaceutical Industries Limited

Pursuant to a stock purchase agreement, Sun Pharma a Mumbai, India based specialty pharmaceutical manufacturing company, 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 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, eleven of which passed bio-equivalency studies through March 31, 2005 and one additional product 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, provide qualified technical professionals who work as Caraco employees and perform certain analytical studies for the Corporation. 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 and during the transition period, Caraco entered into agreements for two 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%.

During the Transition Period, SPARC Bioresearch Private Limited ( SPARC ) performed certain analytical studies required as part of the bioequivalency process for two products transferred to the Corporation by Sun Pharma pursuant to the products agreement. The Corporation incurred approximately \$172,000 of costs during this period for the studies performed by SPARC. No similar studies were performed by SPARC during the three months ended March 31, 2004 or during the years ended December 31, 2004, 2003 and 2002.

The Corporation entered into a manufacturing and supply agreement and a distribution and sale agreements for one product in December 2004 and an additional product in January of 2005 with an affiliate of Sun Pharma. Caraco earned approximately \$100,000 on sales related to these agreements during the Transition Period. No similar amounts were earned during the three months ended March 31, 2004 or during the years ended December 31, 2004, 2003, and 2002.

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

### Operations

The Corporation posted record net sales during 2004 and continued to post record net sales for the three month period ended March 31, 2005. Net sales for the Transition Period were \$17.3 million as compared to \$13.6 million for the comparable period of 2004. The Corporation incurred a net loss of \$4.3 million for the Transition Period as compared to a net loss of \$2.2 million for the corresponding period of 2004. The Corporation incurred non-cash R&D expenses of \$10.2 million during this period during 2005 compared to \$7.8 million during 2004. Net cash generated from operating activities was \$4.8 million for the three months ended March 31, 2005 as compared to \$6.2 million for the same period in 2004.

Management's plans for fiscal 2006 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.

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

#### Use of Estimates

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

#### Cash and Cash Equivalents

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

#### Revenue Recognition

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 94% of the allowance for trade receivables at March 31, 2005 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 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 period and considers a dual presentation and reconciliation of basic and diluted per share amounts. Diluted reflects the potential dilution of all common stock equivalents.

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

	<u>Three Months Ended March 31</u>		<u>Year Ended December 31</u>		
	<u>2005</u>	<u>2004</u>	<u>2004</u>	<u>2003</u>	<u>2002</u>
	(unaudited)				
Numerator:					
Net (loss) income from continuing operations	\$ (4,321,713)	\$ (2,247,920)	\$ (199,368)	\$ 11,222,718	\$ (2,256,004)
Preferred stock dividends					(50,380)
Net (loss) income available for common stockholders	<u>\$ (4,321,713)</u>	<u>\$ (2,242,920)</u>	<u>\$ (199,368)</u>	<u>\$ 11,222,718</u>	<u>\$ (2,306,384)</u>

	Three Months Ended March 31		Year Ended December 31		
	2005	2004	2004	2003	2002
	(unaudited)				
Denominator:					
Weighted average shares outstanding, basic	26,348,347	24,577,828	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	26,348,347	24,577,828	24,734,282	25,481,959	22,031,425
Net (loss) income per common share					
Basic	\$ (0.16)	\$ (0.09)	\$ (0.01)	\$ .46	\$ (0.10)
Diluted	\$ (0.16)	\$ (0.09)	\$ (0.01)	\$ .44	\$ (0.10)

#### Property, Plant and Equipment and Depreciation

Depreciation is computed using the straight-line method over the estimated useful lives of the related assets, which range from 3 to 40 years. Major improvements and renewals are capitalized while ordinary maintenance and repairs are expensed. 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, certain accruals, depreciation 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 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 Corporation 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. On April 14, 2005, the Securities and Exchange Commission announced the adoption of a new rule that amends the compliance dates for SFAS 123 (R). The new rule allows companies to implement SFAS 123 (R) at the beginning of their next fiscal year, instead of their next reporting period beginning after June 15, 2005. The Corporation plans to adopt the new statement beginning in the first quarter of fiscal 2007. The Corporation 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. 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. These differences have been quantified by management which believes the impact will not be material to the financial statements.

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 Corporation does not believe that the adoption of SFAS 153 will have a material impact on its results of operations or financial position.

**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 \$10,200,000 and \$7,828,160 for the three month periods ended March 31, 2005 and March 31, 2004 and \$24,397,040, \$3,103,370 and \$3,887,423 for the years ended December 31, 2004, 2003 and 2002, respectively.

Other Cash Flows Information

Cash paid for interest for the three month period ended March 31, 2004 and was \$212,433 and was approximately \$407,000, \$1,783,000 and \$1,820,000 for the years ended December 31, 2004, 2003 and 2002, respectively. No cash was paid for interest for the period ended March 31, 2005.

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

Accounts receivable and related allowances are summarized as follows:

	March 31	December 31	
	2005	2004	2003
Accounts receivable - gross	\$ 27,766,778	\$ 22,737,866	\$ 20,328,472
Allowances:			
Chargebacks	19,810,000	16,835,000	14,530,000
Sales returns and allowances	1,120,000	800,000	650,000
Doubtful accounts	100,000	500,000	610,000
Total allowances	21,030,000	18,135,000	15,790,000
Accounts receivable, net of allowances	\$ 6,736,778	\$ 4,602,866	\$ 4,538,472

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

	<b>Total Allowances</b>
<b>Balance at January 1, 2002</b>	<b>\$ 400,000</b>
Additions charged to net sales	28,911,000
Deductions allowed to customers	(20,006,000)
<b>Balance at December 31, 2002</b>	<b>9,305,000</b>
Additions charged to net sales	56,262,000
Deductions allowed to customers	(49,777,000)
<b>Balance at December 31, 2003</b>	<b>15,790,000</b>
Additions charged to net sales	67,670,000
Deductions allowed to customers	(65,325,000)
<b>Balance at December 31, 2004</b>	<b>18,135,000</b>
Additions charged to net sales	21,712,000
Deductions allowed to customers	(18,817,000)
<b>Balance at March 31, 2005</b>	<b>\$ 21,030,000</b>

#### 4. INVENTORIES

Inventories consist of the following components:

	<b>March 31</b>	<b>December 31</b>	
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Raw materials	\$ 5,504,006	\$ 5,030,430	\$ 4,226,363
Goods in transit	3,700,651	2,901,626	1,874,625
Work in process	2,607,903	2,993,587	1,633,963
Finished goods	6,655,133	6,208,168	1,875,859
<b>Total inventories</b>	<b>\$ 18,467,693</b>	<b>\$ 17,133,811</b>	<b>\$ 9,610,810</b>

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

During the three months ended March 31, 2005 and 2004 and during the years ended December 31, 2004 and 2003, the Corporation purchased inventory components of approximately \$5.3 and \$4.5, and \$16.7 million and \$10.3 million, respectively, from Sun Pharma.

#### 5. DEBT

##### EDC Loan

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

F-19

---

Loans Payable to Financial Institutions

Loans payable to financial institutions consisted of the following obligations:

	<u>March 31</u>	<u>December 31</u>	
	<u>2005</u>	<u>2004</u>	<u>2003</u>
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
<b>Total loans payable to financial institutions</b>			<b>16,875,000</b>
Less current portion			8,750,000
<b>Loans payable to financial institutions, net of current portion</b>	<b>\$</b>	<b>\$</b>	<b>\$ 8,125,000</b>

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 had expired as of December 31, 2004, and was terminated on March 15, 2005.

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 March 31, 2005 a net deferred income tax asset of approximately \$16.4 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 \$2.0 million for the three month period ended March 31, 2005, \$0.4 million in 2004, decreased by approximately \$4.1 million in 2003, and increased by approximately \$0.8 million in 2002.

At March 31, 2005, net operating loss carryforwards of approximately \$48.0 million, which expire between 2007 and 2017, 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

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 March 31, 2005 and at December 31, 2004 and 2003, no Series A shares remain designated.

In November 2002, in connection with the new technology transfer agreement established with Sun Global (Note 1), the Corporation designated the Series B Convertible Preferred Stock. The Series B preferred shares are non-redeemable and have no par value. In addition, the Series B Convertible Preferred Stock has no voting or dividend rights or liquidation preference other than priority liquidation based on their values on the dates they were earned, and can be converted after three years from the issuance date (or immediately upon a change in control) into one share of common stock, subject to a conversion adjustment (Note 1). While such preferred shares are outstanding, Caraco cannot, without the consent of the holders of a majority of the outstanding shares of the preferred stock, amend or repeal its articles of incorporation or bylaws if such action would adversely affect the rights of the preferred stock. In addition, without such consent, capital stock having any preference or priority superior to the preferred stock may not be issued. As of March 31, 2005, the Corporation has issued 5,984,000 shares of the Series B Convertible Preferred stock to Sun Pharma in exchange for eleven product transfers. Such shares have been valued at \$37.7 million as of March 31, 2005 (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 or 2005 and accordingly no similar expense was recorded during the year.

## 8. COMMON STOCK OPTIONS

### Common Stock Option Plans

As of March 31, 2005, 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:

	Three Months Ended March 31,		Year Ended December 31,					
	2005		2004		2003		2002	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding, beginning of period	181,600	1.41	277,000	\$ 1.00	687,138	\$ 1.04	701,138	\$ 1.03
Granted	3,000	9.60	9,000	9.60				
Exercised	(25,600)	1.24	(80,400)	1.08	(410,138)	0.97		
Terminated	(2,000)		(24,000)	0.80			(14,000)	1.74
Outstanding, end of period	157,000	1.49	181,600	1.41	277,000	1.00	687,138	1.01
Options exercisable, end of period	52,800	1.50	49,800	1.02	102,500	1.07	288,075	1.04

Options at March 31, 2005:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Shares	Remaining Contractual Life *	Exercise Price *	Shares	Exercise Price *
\$0.68 to \$ 1.00	97,000	2.3	0.79	24,800	0.78

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

\$1.01 to \$ 2.00	50,000	2.7	1.25	25,000	1.25
\$9.01 to \$10.00	10,000	2.1	9.59	3,000	9.59
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Total	157,000	2.4	1.49	52,800	1.50
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>

\*Weighted average

F-22

---

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:

	Three Months Ended March 31,		Year Ended December 31,					
	2005		2004		2003		2002	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding, beginning of period	200,000	3.50	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 period	200,000	3.50	200,000	3.50	1,876,666	2.01	2,250,824	2.00
Options exercisable, end of period	200,000	3.50	200,000	3.50	1,876,666	2.01	2,250,824	2.00

Options at March 31, 2005:

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

The Corporation 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. 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 4,500 and 9,000 shares of common stock were granted for the three month period ended March 31, 2005 and the year ended December 31, 2004, respectively, 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 large 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 fiscal 2006.

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 fiscal 2007 with an option to renew for an additional year.

Net rental expense on these operating leases was \$64,896 and \$38,438 for the three months ended March 31, 2005 and 2004, respectively and \$181,129, \$176,065 and \$51,460 for the years ended December 31, 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 March 31, 2005:

<u>Year</u>	<u>Amount</u>
2006	\$ 198,177
2007	199,752
	<u>                    </u>
Total minimum payments due	\$ 397,929
	<u>                    </u>

The Corporation also paid approximately \$0.1 million and \$0.2 million for the three month periods ended March 31, 2005 and 2004, respectively, and \$0.6 million and \$0.5 million to Sun Pharma during the years ended December 31, 2004 and 2003, respectively, for the purchase of various parts and machinery needed for operations.

**10. RETIREMENT PLAN**

The Corporation maintains a deferred compensation plan qualified under Section 401(k) of the Internal Revenue Code. Under this plan, eligible employees are permitted to contribute up to the maximum allowable amount determined by the Internal Revenue Code. The Corporation may make discretionary matching and profit sharing contributions under the provisions of the Plan. The Corporation made no discretionary contributions during the three months ended March 31, 2005 and 2004 or for the years ended December 31, 2004, 2003 and 2002.

**11. CONCENTRATIONS AND COMMITMENTS**

Major Customers

Shipments to three wholesalers accounted for approximately 74% for both the three months ended March 31, 2005 and 2004 and 79%, 80% and 86% of sales for the years ended December 31, 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 77%, 82% and 84% of gross accounts receivable at March 31, 2005 and December 31, 2004 and 2003, respectively. These wholesaler customers traditionally facilitate and support distribution to certain end user customers that the Corporation has contracted with on an indirect basis.

Major Products

Shipments of two products accounted for approximately 74% and 81% of gross sales for the three months ended March 31, 2005 and 2004, respectively and 80%, 87% and 78% of gross sales for the years ended December 31, 2004, 2003 and 2002, respectively.

Approximately 84% and 83% for the three months ended March 31, 2005 and 2004, respectively and 75%, 73% and 20% of Caraco's raw material purchases for the years ended December 31, 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 purchase approximately \$13,000,000 of product per year over a one year base contract period that ended June 30, 2003. The contract has four one-year option periods, the 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.

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 that provide for fixed annual salaries and a six-month continuance including insurance benefits and immediate vesting of stock options upon termination without cause. In addition, subsequent to March 31, 2005, the Corporation executed an employment agreement with a new Chief Executive Officer. Under certain circumstances, including termination without cause and a change in control (as defined in the employment agreement), severance pay of as much as 1½ times the highest annual base pay and last earned bonus(es), together with certain benefits and full vesting of all stock options and stock grants, would accrue to the CEO. After one year of employment, this severance could be increased to 2 times the highest annual base pay and last earned bonus(es).

### 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 the parties have submitted the matter 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 Corporation'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. Since this action Ortho-McNeil has entered into a license agreement with another manufacturer and has launched their product generically while another manufacturer has launched their approved generic at risk.

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 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 March 31, 2005, December 31, 2004 and December 31, 2003, and since April 2003, has discontinued to accrue royalties related to this agreement.

Subsequent Transactions With And Relating To Sun Pharma

Between April 1 and June 7, 2005, Sun Global earned 544,000 shares of Series B preferred stock pursuant to the products transfer agreement for one product transfer (Note 1).

Other Subsequent Event

Effective April 25, 2005, the Articles of Incorporation of the Corporation were amended to increase the authorized number of preferred shares from 5,000,000 to 15,000,000.

\* \* \* \* \*

**EXHIBIT INDEX**

- 3.01 Registrant s Amended and Restated Articles of Incorporation, as amended. (1)
- 3.02 Certificate of Amendment to the Articles of Incorporation filed February 13, 1997. (2)
- 3.03 Certificate of Amendment to the Articles of Incorporation filed February 10, 2000. (3)
- 3.04 Certificate of Determination of Rights, Privileges and Preferences Series B Preferred Stock. (4)
- 3.05 Registrant s Amended and Restated Bylaws. (5)
- 10.01 Agreement, dated as of October 1, 1993, among Registrant and Non-Affiliate (6)
- 10.02 Employment Agreement, dated October 22, 1993, of Robert Kurkiewicz. (6)
- 10.03 Stock Purchase Agreement by and between Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries, Ltd. dated as of April 23, 1997. (7)
- 10.04 Products Agreement by and between Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries, Ltd. dated as of April 23, 1997. (7)
- 10.05 Registration Rights Agreement dated as April 1997. (7)
- 10.06 Amendment to Employment Agreement of Robert Kurkiewicz dated as of April 1, 1997. (8)
- 10.07 1999 Equity Participation Plan. (9)
- 10.08 Renewal to Employment Agreement of Robert Kurkiewicz dated as of January 1, 1999. (3)
- 10.09 Third Amendment to Employment Agreement of Robert Kurkiewicz dated August 30, 2002. (3)
- 10.10 Employment Agreement of Jitendra N. Doshi. (3)
- 10.11 Agreement between Caraco and Sun Pharma Global, Inc. dated November 21, 2002. (4)
- 10.12 Sales contract with government vendor. (4)
- 10.13 Employment Agreement of Mr. Singh (5)
- 10.14 Employment Agreement of Mr. Movens (10)
- 10.15 Confidentiality and Non-Competition Agreement of Dan Movens (10)
- 21 Subsidiaries of the Registrant (+)
- 23.01 Consent of Registered Independent Public Accountants (+)
- 24.1 Power of Attorney (included on signature page) (+)
- 31.1 Certificate of Chief Executive Officer (+)
- 31.2 Certificate of Chief Financial Officer(+)

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

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 Exhibit to Registrant's Form 10-K filed on or about March 15, 2005, Commission File No. 0-24676.
  - (6) Incorporated by reference from Exhibits to Registrant's Registration Statement on Form SB-2, as amended, filed on November 5, 1993 as Commission File No. 33-71398C.
  - (7) Incorporated by reference from Exhibits to Registrant's Form 10-QSB filed on November 14, 1997 as Commission File No. 0-24676.
  - (8) Incorporated by reference from Exhibits to Registrant's Form 10-KSB filed on or about March 31, 1998, as Commission File No. 0-24676.
  - (9) Incorporated by reference from Appendix A to Registrant's Proxy Statement dated April 28, 1999 as Commission File No. 0-24676.
  - (10) Incorporated by reference for Exhibits to Registrant's Form 10-K/A filed on or about May 2, 2005, Commission File No. 0-24676.
-