

CARACO PHARMACEUTICAL LABORATORIES LTD  
Form 10-K  
June 14, 2006

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

FORM 10-K

(Mark one)

- Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the Fiscal Year ended March 31, 2006
- Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Commission File No. 0-24676

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**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)

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

Title of Each Class to be so Registered	Name of Each Exchange On which Each Class is to be Registered
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Common Stock, No Par Value      American Stock Exchange  
**Securities Registered Pursuant to Section 12(g) of the Exchange Act: None.**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports),

and (2) has been subject to such filing requirements for the

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past 90 days. Yes  No

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

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

Large Accelerated Filer  Accelerated Filer  Non-Accelerated Filer

The aggregate market value of the voting common stock held by non-affiliates, based on the last sale price of the common stock as of September 30, 2005, the last day of the Registrant's most recently completed second quarter, as reported on the American Stock Exchange, was \$82,145,710.

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 7, 2006, there were 26,421,994 shares of common stock outstanding.

**Documents Incorporated By Reference:**

Portions of registrant's definitive 2006 Proxy Statement in connection with its Annual Meeting to be held in September 2006 to be filed on or before July 31, 2006.

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

**Forward Looking Statements**

This report, other than the historical financial and business information, may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act. Without limitation, the words believes, plans, expects, and similar expressions are intended to identify forward-looking statements. Those statements include statements regarding our intent, belief, and current expectation. These statements are not guarantees of future performance and are subject to risks and uncertainties that cannot be predicted or quantified. Consequently, actual results could differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to those referenced in Part I, Item 1A below. These forward-looking statements represent our judgment as of the date of this report. We disclaim, however, any intent or obligation to update our forward-looking statements.

**PART I**

**Item 1. Business**

**Introduction**

Caraco Pharmaceutical Laboratories, Ltd. ( Caraco which is also referred to as the Company, the Corporation, we, us or our corporation organized under Michigan law in 1984, engaged in the business of developing, manufacturing, marketing and distributing generic and private-label pharmaceuticals to the nation's largest wholesalers, distributors, warehousing and non- warehousing chain drugstores and managed care providers, throughout the U.S.

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 the 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 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 was made in order to make the Company's fiscal year conform to the March 31 fiscal year of its parent company, Sun Pharmaceutical Industries Limited ( Sun Pharma ). This Form 10-K covers the audited fiscal year, April 1, 2005 to March 31, 2006 ( Fiscal 2006 ). Comparative financial information to Fiscal 2006 is provided in this Form 10-K with respect to the twelve month period, April 1, 2004 to March 31, 2005, which is unaudited ( Fiscal 2005 ). Additional information is provided with respect to the transition period (January 1, 2005 through March 31, 2005) which is audited (the Transition Period ). See Item 6 and Item 7 below.

**Overview**

Our manufacturing facility 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 7,

2006, Sun Pharma beneficially owns approximately 64% (75% including its convertible Series B Preferred Stock) of the outstanding shares of Caraco. See [Current Status](#) and [Sun Pharmaceutical Industries Limited](#).

### **Current Status**

During Fiscal 2006 we recorded net sales of \$82.8 million compared to \$64.1 million Fiscal 2005. We have generated cash from operations of \$8.9 million as compared to \$20.6 million during the relevant periods. Cash was used primarily to augment working capital. We incurred a net loss of \$10.4 million compared to net loss of \$2.3 million during the relevant periods. The higher loss was primarily due to higher non-cash research and development expense (R&D) of \$35.1 million as compared to \$26.8 million during the relevant period. This non-cash R&D expense relates to nine products passing their bio-equivalency studies during Fiscal 2006 and the related value of the preferred stock issued to Sun Pharma Global, Inc., a wholly-owned subsidiary of Sun Pharma, ( [Sun Global](#) ) pursuant to the Products Agreement as defined below, as compared to eight products during Fiscal 2005. At March 31, 2006, we had stockholders' equity of \$56.4 million as compared to stockholders' equity of \$31.7 million at March 31, 2005 and a stockholders' equity of \$25.8 million at December 31, 2004. See [Part II Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations](#).

Pursuant to our products agreement with Sun Global., we have selected, through March 31, 2005, all products out of the 25 products to be transferred to us by Sun Global. Of these, twenty products passed their bio-equivalency studies as of March 31, 2006, and one since then. Sun Global has thereby earned 544,000 preferred shares for each such product. See [Sun Pharmaceutical Industries Limited](#) and [Part II Item 7. Future Outlook](#).

We filed ten ANDAs with the FDA during Fiscal 2006. This brings our total number of ANDAs pending approval by the FDA to 14.

### **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 potentially be sold at prices that reflect a discount up to 90% (in some cases even more) than the price of their branded counterparts. The discount is relevant to the amount of competitors on any 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 product to a generic manufacturer or has chosen to produce another label and provide 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 21 prescription products in 44 strengths in 99 package sizes. The products and their use for the indications are set forth in the table below:

<b>Generic Name</b>	<b>Purpose</b>
Metroprolol Tartrate	Hyper-Tension
Paromomycin Sulfate	Antibacterial
Salsalate	Decongestant
Choline Magnesium Trisalicylate	Arthritis/NSAID
Clonazepam	Seizure, Panic Disorders
Flurbiprofen	Arthritis/NSAID
Carbamazepine Chewable	Anti-convulsant
Carbamazepine IR	Anti-convulsant
Oxaprozin	Rheumatoid Disease
Metformin Hydrochloride	Diabetes
Tramadol Hydrochloride	Opiate Agonist/Analgesic
Tramadol Hydrochloride with Acetaminophen	Opiate Agonist/Analgesic
Meperidine Hydrochloride*	Analgesic
Ticlopidine	Reduction of incidence of strokes
Tizanidine	Management of muscle tone associated with spasticity
Digoxin	Heart failure
Mirtazapine	Anti-depressant
Citalopram Hbr	Anti-depressant
Clozapine	Anti-psychotic
Midrin**	Vascular & Migraine Headache suppressant
Fluvoxamine	Anti-depressant

\* Expected to be marketed sometime in Fiscal 2007.

\*\* Product marketed on behalf of Sun Pharmaceutical Industries Inc., a wholly owned subsidiary of Sun Pharma, in one strength and one pack size.

We have submitted 34 ANDAs to the FDA for approval as of March 31, 2006, including 10 filed during Fiscal 2006. Of these 34 ANDAs filed, the FDA has approved 20 through March 31, 2006. Accordingly, we have 14 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 to develop 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 2003, we had repaid all of such loans. Sun Pharma also assisted us, by acting as guarantor, in obtaining line of credit loans from ICICI Bank Limited, The Bank of Nova Scotia and Citibank FSB in the amounts of \$5.0 million, \$12.5 million and \$10.0 million, respectively, all of which have been terminated as of December 31, 2004.

In August 1997, we entered into an agreement, whereby Sun Pharma was required to transfer to us the technology formula for 25 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 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 receives 544,000 shares of 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, twenty of which passed bio-equivalency studies as of March 31, 2006, and one since then. See Part II Item 7. 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, 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 Fiscal 2006, we purchased approximately \$28.1 million in raw materials and formulations from Sun Pharma and its subsidiaries, as compared to \$5.3 million during the Transition Period and \$16.7 million during calendar 2004. We acquired \$0.2 million worth of machinery and equipment from Sun Pharma as compared to \$0.1 million during the Transition Period and \$0.6 million during calendar 2004. 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, of which only one is being marketed..

During the Transition Period, SPARC Bioresearch Private Limited ( SPARC ), an affiliate of Sun Pharma,

performed certain analytical studies required as part of the bio-equivalency process for two products. The Corporation incurred approximately \$172,000 of costs during the period for the studies performed by SPARC. No similar studies were performed by SPARC during Fiscal 2006 or during the years ended December 31, 2004 and 2003.

During the first quarter of 2004, Sun Pharma acquired 3,452,291 additional shares of common stock and 1,679,066 stock options from two former directors and a significant shareholder. Sun exercised these stock options during the fourth quarter of 2004. Sun Pharma's current beneficial ownership is 64% (75% including its convertible Series B Preferred Stock).

## Marketing

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

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

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

Our marketing objective is to compete effectively, encourage long-term relationships, and supply contracts, increase our market share on products that have not matured, gain market share on new products that are to be launched, and continue to expand our customer base.

## Sales and Customers

Our sales team effectively addressed the challenges in Fiscal 2006 of price erosion, increase market share on certain products that had room for improvement, improved the balance of sales to the trade classes we service, increased sales with a limited number of approvals, executed our plan well and improved on our capacity constraints, improved inventory levels and geared up to meet the challenges inherent in the generic industry in fiscal 2007. Every functional area has been fortified to meet the demand of our 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 as discussed below, has selected McKesson as its designated wholesaler. Accordingly, shipments to three large wholesale customers, namely McKesson Corporation (51% and 55%), Amerisource-Bergen Corporation (9% and 11%) and Cardinal Health (17% and 12%), accounted for approximately 77% and 78% of gross sales for Fiscal 2006 and the Fiscal 2005, respectively. Balances due from these customers represented approximately 72% and 75% of gross accounts receivable at March 31, 2006 and 2005, respectively. No other single customer represented more than 10% of our gross sales during Fiscal 2006 and Fiscal 2005.

We have entered into a sales contract on June 21, 2002 with the Veterans Administration, an agency of the U.S. government. Our agreement with this customer commenced on August 5, 2002 for a one-year period, with four 1-year option periods thereafter, and is for the purchase of one product, Metformin Hydrochloride. The first three 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. The Company's research and development consists principally in conducting market research and patent research on brand name pharmaceuticals and generic pharmaceuticals in order to determine which products we may want to develop. A majority of our research and development is provided by Sun Global as a result of our technology transfer agreement and a portion is being done by Caraco. Our development list consists of both near term launches and launches that we intend to market several years in the future.

We incurred total R&D Expense for Fiscal 2006, Fiscal 2005 and calendar 2004 as set forth below:

Fiscal 2006	\$43.5 million
Fiscal 2005 (Unaudited)	\$33.4 million
Calendar 2004	\$30.5 million

The non-cash R&D Expense for the Fiscal 2006, Fiscal 2005 and calendar 2004 are set forth below:

Fiscal 2006	\$35.1 million
Fiscal 2005 (Unaudited)	\$26.8 million
Calendar 2004	\$24.4 million

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

## Regulation

The research and development, 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, 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 routinely performs inspection of pharmaceutical companies facilities. On May 1, 2006 the FDA initiated an inspection of our facility for cGMP compliance. This inspection will be completed over the next few weeks. While there is no

assurance that the FDA will not issue observations, we believe that we are cGMP compliant.

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 have not submitted an NDA to date.

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.

Competition continues to be intense which could result in further erosion of prices and profit margins. The number of generic manufacturers both domestic and from overseas is increasing resulting in increased pricing pressure. The most significant means of competition are price, innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, customer service and reputation. Other principal competitive factors in the generic pharmaceutical market are the ability to be the first company, or among the first companies, to introduce a generic product after the related patent expires, methods of distribution, maintenance of inventories for timely delivery, and breadth of product line. Approvals for new products may have a synergistic effect on a company's entire product line since orders for new products are frequently accompanied by, or bring about, orders for other products available from the same source. We believe that price is the most significant competitive factor in the generic industry, particularly as the number of generic entrants with respect to a particular product increases. As competition from other manufacturers intensifies, selling prices typically decline. We compete by keeping our prices competitive, selecting appropriate products, based on therapeutic segments, market sizes and number of competitors manufacturing the products, by providing reliability in the timely delivery, and in the continued quality, of our products.

## Line of Credit

On November 17, 2005, the Company entered into a one-year, \$10 million Credit Agreement with JP Morgan Chase Bank, N.A. Under the Credit Agreement, the lender may make loans and issue letters of credit to the Company for the Company's working capital needs and general corporate purposes. Letters of credit, if issued, expire one year from their date of issuance, but no later than November 17, 2007. During Fiscal 2006, we utilized \$1.5 million of the available line and have repaid the

same. Borrowings are secured by the Company's receivables, inventory and all proceeds therefrom. Borrowings may be prepaid at any time by the Company. Interest is payable based on LIBOR or an alternate base rate (determined by reference to the prime rate or the federal funds effective rate), as selected by the Company. The rate of interest is LIBOR plus 75 basis points or Prime rate minus 100 basis points (effective rates of 6.0% and 6.75%, respectively at March 31, 2006.) The Credit Agreement requires that certain financial covenants be met on a quarterly basis. The Corporation is in compliance with these financial covenants at March 31, 2006. There are no borrowings under this Credit Agreement at March 31, 2006.

### **Employees**

We had a total of 272 and 205 full-time equivalent and contract employees at March 31, 2006 and 2005, respectively, engaged in research and development, quality assurance, quality control, administration, sales and marketing, materials management, facility management and manufacturing and packaging. Most of our scientific and engineering employees have had prior experience with pharmaceutical or medical products companies, including Sun Pharma. See Sun Pharmaceutical Industries Limited.

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

### **Product Liability and Insurance**

We currently maintain general and product liability insurance, with coverage limits of \$10 million per incident and in the aggregate. Our insurance policies provide coverage on a claims made basis and are subject to annual renewal. Such insurance may not be available in the future on acceptable terms or at all. There can be no assurance that the coverage limits of such policies will be adequate to cover our liabilities, should they occur. See Item 3. Legal Proceedings.

### **Item 1A. Risk Factors:**

#### **Risks Related to Our Business**

The following discussion highlights some of the risks related to our business and others are discussed elsewhere in this report. These and other risks could materially and adversely affect our business, financial condition, operating results or cash flows and the market value of our common stock.

#### **If we are unable to successfully develop or commercialize new products, our operating results will suffer.**

Our future results of operations depend to a significant extent upon our ability to successfully commercialize new products in a timely manner. There are numerous difficulties in developing and commercializing new products, including:

developing, testing and manufacturing products in compliance with regulatory standards in a timely fashion;

receiving the requisite regulatory approvals for such products in a timely manner;

the availability of raw materials at a competitive cost, including active pharmaceutical ingredients and other key ingredients;

development and commercializing a new products is time consuming, costly and subject to various factors, including litigation brought by our competitors, that may delay or prevent the development and commercialization of new products expected to market;

**Our gross profit may fluctuate from period to period depending upon our product sales mix including new launches, our product pricing, customer class of trade, and our costs for active ingredients.**

Some specific issues that could result in a fluctuation could include any or all of the following:

the amount of new product introductions;

the level of competition and associated pricing pressure in the marketplace for certain products;

the availability of raw materials;

The profitability of our product sales is also dependent upon the prices we are able to charge for all our products, the costs of excipients purchased from third parties, and our ability to manufacture our products in a cost effective manner.

**An unaffiliated third party may make a claim for royalties which could have a material adverse effect on our results of operations.**

In 1993, we entered into a products agreement with an unaffiliated generic drug company (the Non-Affiliate). Under the agreement, two products were to be delivered to us in exchange for royalties and options. Pursuant to the agreement, we received a formulation for one product (the Product) from the Non-Affiliate. However, we have determined that the formula provided to us by the Non-Affiliate with respect to the Product is different than the formula approved by the FDA and manufactured and introduced by us. Accordingly, since April 2003, we have discontinued to accrue royalties. The Product has been one of our top selling products. There is no assurance that the Non-Affiliate will not challenge our determination and make a claim that royalties and/or options are owed. If successful, such a claim could have a material adverse effect on our results of operations.

**If brand pharmaceutical companies are successful in limiting the use of generics through litigation, legislature and regulatory efforts, our sales of generic products may suffer.**

Many brand pharmaceutical companies increasingly have used state and federal legislative and regulatory and other litigation as means to delay generic competition. These efforts have included:

pursuing new patents for existing products which may be granted just before the expiration of one patent, which could extend patent protection for additional years or otherwise delay the launch of our generic product;

submitting for changes in U. S. Pharmacopoeia which is an organization that publishes industry wide compendia of drug standards;

using the Citizen's Petition process to request amendments to FDA standards;

attaching patent extension amendments to non-related federal legislation;

engage in state-by-state initiative to enact legislation that restricts substitution of certain generic drugs which could possibly impact products that we are developing.

**Third parties may claim that we infringe their proprietary rights and may prevent us from manufacturing and selling some of our products.**

The manufacture, use and sale of new products that are the subject of conflicting patent rights have been the subject of substantial litigation in the pharmaceutical industry. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. We may have to defend against charges that we violated patents or proprietary rights of third parties. Litigation may be costly and time-consuming, and could divert the attention of our management and technical personnel. If it is found that we infringe on the rights of others, we could lose our right to develop or manufacture products or could be required to pay monetary damages or royalties to license proprietary rights from third parties. As a result, an adverse determination in a judicial or administrative proceeding could prevent us from manufacturing and selling a product(s), which could negatively affect our financial condition and results of operations.

**Our policies regarding returns and chargebacks by wholesalers may reduce our revenues in future fiscal periods.**

Based on industry practice, generic product manufacturers including Caraco have liberal return policies and make decisions whether or not to provide shelf stock allowances (or credits) for inventories on hand on product that has already been sold to the customer. If a new competitor enters the marketplace and significantly lowers the price of any of its competing products, it is possible that we would make a decision to reduce the price of our product. As a result, we would be obligated to provide significant credits to our customers who are then holding inventories of such products, which could reduce sales revenue and gross margin for the period the credit is provided. Like our competitors, we also give credits for chargebacks to wholesale customers that have contracts with us for their sales to chain drug retail, group purchasing organizations, or other retail customers. A chargeback represents an amount payable in the future to a wholesaler for the

difference between the invoice price paid to us by our wholesale customer for a particular product and the negotiated contract price that the wholesaler's customer pays for that product. Although we establish reserves based on our historical experience and our best estimates of the potential impact that these policies may have, we cannot ensure that our reserves are adequate or that actual product returns, allowances and chargebacks will not exceed our estimates, which could adversely affect our financial condition, cash flows and market price of our stock.

**The loss of our key personnel could cause our business to suffer.**

The success of our present and future operations will depend, to a significant extent, upon the experience, abilities and continued services of key personnel. We cannot assure you that we will be able to attract and retain key personnel.

**Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities.**

All pharmaceutical companies, are subject to complex, costly regulations that continue to evolve as set forth by the federal government, principally the FDA and to a lesser extent by the DEA and state government agencies. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other federal statutes and regulations govern the testing, manufacturing, storage, packing, labeling, record keeping, safety, sales and marketing, promotion, and distribution of our products.

Under these regulations, we are subject to periodic routine inspection of our facilities, procedures, operations and the testing of our products by the FDA, the DEA and other authorities that regulate our business. These inspections are designed to confirm that we are in compliance with all applicable regulations. Following an inspection, the FDA may issue notices on Form 483 and /or warning letters that could cause us to modify certain activities identified during the inspection. A Form 483 notice is generally issued at the conclusion of a FDA inspection and lists conditions the FDA inspectors believe may violate cGMP or other FDA regulations. FDA guidelines specify that a warning letter is issued only for violations of regulatory significance for which the failure to promptly and adequately achieve correction may be expected to result in an enforcement action. Possible sanctions could include among others, FDA issuance of adverse publicity, fines, product recalls, total or partial suspension of production and/or distribution, suspension of the FDA's review of product applications, enforcement actions, injunctions, and civil or criminal prosecution. These sanctions, if imposed, could materially harm our operating results and financial condition. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Although we have internal compliance programs in place these programs may not meet regulatory agency standards or if compliance is deemed deficient in any significant way, it could materially harm our business. Certain of our vendors that sell to us are also subject to similar regulation and periodic inspections.

**Sales of our products may continue to be adversely affected by the continuing consolidation of the distribution network and the concentration of customers.**

Our principal customers are wholesale drug distributors, major retail drug store chains and managed care. These customers comprise a significant part of the distribution network for pharmaceutical products in the U.S. This distribution network is continuing to undergo significant consolidation marked by mergers and acquisitions among wholesale distributors and the growth of large retail drug store chains and managed care companies. As a result, a small number of large wholesale distributors and large chain drug stores and managed care providers control a significant share of the market. We expect that consolidation of drug wholesalers, retailers and managed care providers will increase pricing and other competitive pressures on drug manufacturers, including Caraco.

**Even if we are able to obtain regulatory approvals for our new pharmaceutical products, the success of those products is dependent upon market acceptance. Levels of market acceptance for our new products could be impacted by several factors, including:**

- availability of alternate product from our competitors;
- the timing of our market entry;
- acceptance of our product on government and private formularies;

and the prices that we sell our products at versus our competitors' prices. These factors amongst others are beyond our control and could materially have a negative effect on operations and the market value of our common stock.

**From time to time a relatively small group of products could represent a significant portion of our sales and if the products sales of these product decline unexpectedly it could have a negative material effect on our business and could cause our market value of our common stock to decline.**

Sales of a limited number of our products often represent a significant portion of our net revenues and net earnings. If the volume or pricing of our largest selling products declines in the future, our business, financial position and results of operations could be materially adversely affected, and the market value of our common stock could decline.

**Our competitors may be able to develop products and processes competitive with or superior to our own for many reasons, including that they may have:**

- proprietary processes or product delivery systems;
- larger research and development and marketing staffs;
- larger production capacity in general or for a given product;
- more financial resources than Caraco;
- more experience in developing new drugs;

**Our reporting and payment obligations under Medicaid and other governmental programs are complex and may change periodically based upon new guidelines provided those agencies.**

Although the regulations regarding reporting and payment obligations are complex, we believe we are properly and accurately calculating and reporting the amounts owed in respect of Medicaid and other governmental pricing programs. Our calculations are subject to review and challenge by the applicable governmental agencies, and it is possible that any such review could result in material changes. Any governmental agencies may initiate an investigation of the Company and could impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs (including Medicaid and Medicare).

**Sun Global could determine not to assist us in our research and development and Sun Pharma could cease supplying support and raw materials**

Collectively Sun Global and Sun Pharma could determine that its own research and development takes precedent over the research and development it provides to Caraco. This could cause a gap in our research and development timelines until Caraco could increase its own capabilities. This gap could possibly cause future growth concerns until resolved. Sun Pharma which supplies us raw material could face supply issues or not be capable of supplying the raw material for certain products we manufacture. This could cause lower sales or possibly lower margins until we negotiate new suppliers and gain the requisite approvals to manufacture our product with a new raw material source.

**A significant portion of our net sales are from the sales of a limited number of customers. Should we lose a particular contract with a customer or the customer is acquired by a non-customer, our sales and operational results could face a significant decline.**

A significant portion of our net revenues are derived from sales to a limited number of customers. As such, a reduction in or loss of business with one customer, or if one customer were to experience difficulty in paying us on a timely basis, our business, financial position and results of operations could be materially adversely affected.

**Our product liability insurance may not be enough to mitigate risk associated with our products**

Though we believe we carry adequate product liability insurance it is possible that a lawsuit or lawsuits could exceed our insurance levels and have a negative impact on our financial results

**We manufacture our product line predominately from one FDA approved facility. There is a possibility that our production could be negatively impacted by a closure of this facility**

Should our facility located in Detroit incur a closure of any type it would have a negative impact on our results. We carry a limited amount of finished goods on hand and much of our inventory is either work in progress or is in bulk amounts. Should we experience an act of God that closes our facility, or production is stopped or a power outage continues for an inordinate period of time, it could have a significant negative effect on our results.

Any of these factors and others could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

#### **Item 1B. Unresolved Staff Comments**

None

#### **Item 2. Properties.**

##### **The Facilities**

Our entire property, plant, equipment and intellectual property are free of any mortgages, liens or similar restrictions. Our primary facility located in Detroit, Michigan, which was designed and constructed to our specifications and completed in 1994, contains our production, research and development and corporate office. During Fiscal 2006, we added approximately 10,000 square feet of manufacturing space, giving us a total of 80,000 square feet of usable space. The manufacturing portion of the facility has a special building and systems design, with each processing area equipped with independent zone and air handling units to provide temperature and humidity control to each room. These air handling units are designed to prevent product cross contamination through the use of pre-filter and final HEPA filter banks. All processing air quarters are maintained in a negative pressure mode using laminar airflow design. This system of airflow provides a measurable control of air borne particulate entrapment in each room. Environmental segregation of individual rooms within a particular zone is accomplished by the use of duct HEPA filter booster fan units that facilitate the isolation and confinement of room activities. These special dynamics provide an added dimension and flexibility in product selection and processing techniques.

We have leased an approximately 55,000 square foot facility located near our primary facility for finished goods distribution, storage of inventory and office space. The lease expires in 2009 and includes an option to renew until 2011.

We also have leased an approximately 7,000 square foot office space for our administrative, sales and marketing and accounting offices. The lease expires in 2009.

We have invested approximately \$3.6 million during Fiscal 2006 as compared to \$3.3 million during twelve months ending March 31,2005 to upgrade our facilities. We have invested approximately \$0.6 million during the Transition Period as compared to \$1.3 million during the corresponding period of 2004. We invested \$4.0 million in 2004 and \$2.4 million in 2003

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

#### **Item 3. Legal Proceedings.**

As previously disclosed, on June 9, 2005, Novo Nordisk A/S and Novo Nordisk, Inc. ( Novo Nordisk ) filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Company s filing of an ANDA seeking approval to market its generic version of Novo Nordisk s Prandin® drug product infringed Novo Nordisk s patent, which expires June 12, 2018. Novo Nordisk 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 Caraco contains a Paragraph IV certification challenging the Novo Nordisk patent. We believe that the Novo Nordisk 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 in order to



capitalize on potential 180 days of marketing exclusivity available for this product.

As previously disclosed, on September 22, 2004, Ortho-McNeil Pharmaceutical, Inc. ( Ortho-McNeil ) filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Company's filing of an ANDA seeking approval to market its generic version of Ortho-McNeil's Ultracet® 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 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. On October 8, 2005, arguments were heard in the US District Court in the Eastern District of Michigan, on our motion for summary judgment on the issue of non-infringement. On October 19, 2005 our motion for summary judgment was granted in our favor. On December 19, 2005, the FDA approved the manufacture, use and sale of the product. Ortho-McNeil has filed an appeal of the finding of non-infringement by the Eastern District of Michigan. Additionally, the United States Patent and Trademark Office has allowed Ortho-McNeil's request for a reissue patent that, when issued, Ortho-McNeil contends will be infringed by Caraco's now-marketed product. We believe that, like its original patent, Ortho-McNeil's reissue patent will be invalid and unenforceable.

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 sought 175,000 shares of our common stock (35,000 shares for each of the first five ANDAs approved by the FDA). We and the plaintiff each filed a motion for summary disposition. Both parties' motions were denied, and the parties submitted the matter to binding arbitration. In connection with the submission to arbitration, the parties agreed that Mr. Curry would receive a minimum of 15,000 shares of common stock. On April 20, 2006, the arbitrator entered a determination of no cause of action against Mr. Curry and in favor of the Company.

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 Fiscal 2006 through the solicitation of proxies or otherwise.

**PART II**

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

Our common stock is listed on the American Stock Exchange under the symbol CPD. The following table sets forth for Fiscal 2006, the Transition Period and the year ended December 31, 2004, the high and low sales prices for each of the applicable quarters.

<b>Fiscal 2006</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 8.97	\$ 7.06
Second Quarter	\$ 9.29	\$ 8.10
Third Quarter	\$ 9.81	\$ 7.50
Fourth Quarter	\$ 13.42	\$ 8.76
<b>2005</b>	<b>High</b>	<b>Low</b>
Transition Period	\$ 9.32	\$ 7.44

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

As of June 7, 2006 there were 93 registered holders of our Common Stock.

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

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

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

All shares of preferred stock and common stock specified above that were issued by the Company were issued pursuant to exemptions from registration under Section 4(2) of the Securities Act of 1933.

#### 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 selected financial data of the Company is qualified by reference to and should be read in conjunction with the financial statements and notes thereto and other financial information included elsewhere herein. The summary balance sheet data as of March 31, 2006 and 2005 and summary statements of operations data for the years ended December 31, 2003 and 2004, the three month period ended March 31, 2005 and the year ended March 31, 2006 are derived from and qualified by reference to the audited financial statements of the Company which are included elsewhere herein. The summary balance sheet data as of December 31, 2004, 2003 and 2002 and the summary of the statements of operations for the years ended December 31, 2004, 2003, 2002 and 2001 are derived from the audited financial statements of the Company which are not included herein and have been previously filed with the SEC.

In January 2005, the Company changed its fiscal year from December 31st to March 31st. The results from the twelve month period March 31, 2005 were derived from the Company's published quarterly results and are unaudited. Accordingly, this twelve month period is not disclosed in the accompanying financial statements. It is included in the selected financial data for comparative purposes only as defined below.

**Financial Data**

(In thousands, except per share data)

Statements of operations data	Year ended March 31,	
	2006 (Audited)	2005 (Unaudited)
Net sales	\$ 82,789	\$ 64,116
Cost of goods sold	41,873	26,930
Gross profit	40,916	37,185
Selling, general and administrative expenses	8,183	5,874
Research and development costs affiliate non cash	35,055	26,769
Research and development costs other	8,437	6,640
Operating loss	(10,759)	(2,097)
Other income / (expenses)	336	(181)
Net Loss	(10,423)	(2,278)
Net Loss per share		
Basic	(0.39)	(0.09)
Diluted	(0.39)	(0.09)
Weighted Average Shares Outstanding:		
Basic	26,392	26,348
Diluted	26,392	26,348

**Financial Data (continued)**

(In thousands, except per share data)

Statements of operations data	Transition Period Ended March 31,	Year ended December 31,			
		2005	2004	2003	2002
Net sales	\$ 17,337	\$ 60,340	\$ 45,498	\$ 22,381	\$ 5,922
Cost of goods sold	7,879	24,441	19,507	12,047	4,186
Gross profit	9,457	35,899	25,991	10,334	1,736
Selling, general and administrative expenses	1,879	5,277	7,363	3,828	2,680
Research and development costs affiliate non cash	10,200	24,397	3,103	3,887	0
Research and development costs other	1,720	6,053	3,112	3,348	3,080
Operating (loss) / income	(4,342)	172	12,412	(730)	(4,024)
Other income / (expense)	21	(371)	(1,189)	(1,526)	(1,734)
Net (Loss) / Income	(4,322)	(199)	11,223	(2,256)	(5,757)
Net (Loss) / Income per share					

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Basic	(0.16)	(0.01)	0.46	(0.10)	(0.29)
Diluted	(0.16)	(0.01)	0.44	(0.10)	(0.29)

Weighted Average Shares Outstanding:

Basic	26,348	24,734	24,137	22,031	21,173
Diluted	26,348	24,734	25,482	22,031	21,173

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## Financial Data (continued)

(In thousands)

Balance Sheet Data	As at March 31,		As at December 31,		
	2006	2005	2004	2003	2002
Current assets	\$ 62,282	\$ 32,938	\$ 24,857	\$ 18,918	\$ 12,106
Property, plant and equipment, net	14,960	12,897	12,546	9,506	7,747
Total assets	77,242	45,835	37,403	28,424	19,853
Current liabilities	20,864	14,149	11,627	20,008	13,753
Long term debt				13,395	25,724
Total liabilities	20,864	14,149	11,627	33,404	39,476
Stockholders' Equity (Deficit)	56,378	31,686	25,776	(4,980)	(19,623)
Working Capital (Deficiency)	41,418	18,789	13,230	(1,090)	(1,647)

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

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

**Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. Certain of our accounting policies are particularly important to the portrayal of our financial position and results of operations and require management's subjective judgments. As a result, these judgments are subject to an inherent degree of uncertainty. In applying these policies, management makes estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates. Our significant estimates include our provisions for price adjustments (primarily chargebacks), valuation allowances for deferred tax assets, and valuation of overhead components in inventory.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements. There have neither been material changes to our critical accounting policies for the periods presented nor any material quantitative revisions to our critical accounting estimates for the periods presented.

## Revenue Recognition

Revenue from product sales, net of estimated provisions, is recognized when there is persuasive evidence that an arrangement exists, shipment of the goods has occurred, the selling price is fixed or determinable, and collectibility is reasonably probable. Our customers consist primarily of large pharmaceutical wholesalers who sell directly into the retail channel. Provisions for sales discounts, and estimates for chargebacks, rebates, and product returns are established as a reduction of product sales revenue at the time revenues are recognized, based on historical experience and current market trends adjusted to reflect known changes in the factors that impact these reserves. These revenue reductions are reflected as a direct reduction to accounts receivable through an allowance.

### *Chargebacks*

Chargebacks represent our most significant provision against gross accounts receivable and related reduction to gross revenue. Chargebacks are credits given to our wholesale customers for the price difference on our product they sell (at a contractual price) to retail, chain stores, and managed care organizations at prices lower than we sell to our wholesale customer. We record an estimate at the end of the reporting period to the wholesaler of the amount to be charged back to us, over and above those already received by us. Such estimated amounts, in addition to certain other deductions, are deducted from our gross sales to determine our net revenues. We have recorded provisions for chargebacks based upon various factors, including current contract prices, historical trends, and our future expectations. The amount of actual chargebacks claimed could be either higher or lower than the amounts we accrued. Changes in our estimates, if any, would be recorded in the income statement in the period of the change. If we over or under estimate the amount that will ultimately be charged back to us by our wholesaler customers, there could be a material impact on our financial statements.

We consider the following factors in the determination of the estimates of chargebacks.

1. We consider the historical data of chargebacks as a percentage of sales, as well as the various chargeback reports that we receive from the customers.
2. Volume of product sold to wholesalers and the average chargeback rates, on a quarterly and annualized basis are applied to current period and annual product sales to make a realistic accrual.
3. The sales trends for future estimated prices, wholesale acquisition cost (WAC), the contract prices with the retailers, chain stores and managed care organizations (end-users). Our prices with the wholesalers and end users are contracted prices.

### *Shelf Stock Adjustments*

Shelf stock adjustments are credits issued to our customers to reflect decreases in the selling prices of our product. These credits are customary in the industry and are intended to reduce the customers' inventory cost to better reflect current market prices. The determination to grant a shelf stock adjustment to a customer following a price decrease is at our discretion.

Factors considered when recording a reserve for a shelf stock adjustments include estimated launch dates of competing products based on market intelligence, estimated decline in market price of our product based on historical experience and input from customers and levels of inventory held by customers at the date of the adjustments as provided by them.

### *Product returns and other allowances*

In the pharmaceutical industry, customers are normally granted the right to return product for credit if the product has not been used prior to its expiration date. Our return policy typically allows product returns for products within a 12-month window from six months prior to the expiration date and up to six months after the expiration date. We estimate the level of sale, which will ultimately be returned pursuant to our return policy, and record a related reserve at the time of sale. These amounts are deducted from our gross sales to determine our net revenues. Our estimates take into consideration historical returns of our products and our future expectations. We periodically review the reserves established for returns and adjust them based on actual experience, if necessary. The primary factors we consider in estimating our potential product returns include shelf life of expiration date of each product and historical levels of expired product returns. In case we become aware

of any returns due to product related issues, such information from the customers, is used to estimate an additional reserve. The amount of actual product return could be either higher or lower than the amounts we accrued. Changes in our estimates, if any, would be recorded in the income statement in the period of the change. If we over or under estimate the quantity of product which will ultimately be returned, there may be a material impact to our financial statements.

Discounts (trade and prompt payment discounts) are accrued at the end of every reporting period based on the gross sales made to the customers during the period and based on their terms of trade. We review the contracts between the customer and us as well as the historical data and percentages to estimate the discount accrual.

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

*Doubtful Accounts*

Doubtful accounts are estimated based on the data available from external sources, including information on financial condition of customers. Also, a regular review of past due receivables is done on a quarterly basis to identify and make provision for such receivables not expected to be recovered.

Our gross sales for Fiscal 2006 were \$200.4 million, as compared to \$141.9 million for Fiscal 2005. Chargebacks, returns, discounts and other customary customer deductions and other sales costs constituted approximately 59% for Fiscal 2006 compared to 54% for Fiscal 2005. Net sales for Fiscal 2006 were \$82.8 million, as compared to \$64.1 million for Fiscal 2005. The primary cause of increase in the sales diluters by almost 4% between the periods is the impact of price erosions for the products we sell and the corresponding impact of such price erosions on chargebacks

The following is a roll forward of the provisions for chargebacks, shelf stock adjustments, returns and allowances and estimated doubtful account allowances during Fiscal 2005 and Fiscal 2006.

(\$ in Millions)

	<u>Balances at begining of period</u>	<u>Allowances charged to Gross Sales</u>		<u>Credits taken by customers</u>	<u>Balance at the end of period</u>
		<u>Current Period</u>	<u>Prior Period</u>		
<b>For Fiscal 2005</b>					
Chargebacks & shelf stock adjustments	16,051	72,505	-0-	68,746	\$ 19,810
Returns and other allowances	878	4,258	-0-	4,016	1,120
Doubtful Accounts	500	-0-	-0-	400	100
<b>For Fiscal 2006</b>					
Chargebacks & shelf stock adjustments	\$ 19,810	\$ 111,525	-0-	\$ 119,868	\$ 11,467
Returns and other allowances	1,120	7,471	-0-	7,091	1,500
Doubtful Accounts	100	-0-	-0-	-0-	100

### **Income Taxes**

As part of the process of preparing our financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. We account for income taxes by the liability method. Under this method, deferred income taxes are recognized for tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end, based on enacted laws and statutory tax rates applicable for the differences that are expected to affect taxable income. Valuation allowances are provided if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. We have not recorded any federal tax provision or benefit for the Fiscal 2006, the Transition Period or for the years ended December 31, 2004 and 2003. We have provided a valuation allowance for the full amount of our net deferred tax assets since realization of any future benefit from deductible temporary differences and net operating loss carry forwards cannot be sufficiently assured at March 31, 2006, March 31, 2005, December 31, 2004 and 2003. At March 31, 2006, we had federal net operating loss carryforwards of approximately \$58.8 million available to reduce future taxable income, which will expire between 2007 and 2017. Under the provisions of the Internal Revenue Code, certain substantial changes in our ownership may result in a limitation on the amount of net operating loss carry forwards which can be used in future years. We believe that ownership changes to date will not limit future utilization of net operating loss carryforwards.

### **Inventory**

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

### **FDA Compliance**

The FDA commenced an inspection of the Company's facility on May 1, 2006. This is a routine inspection which will continue over the next few weeks. While there is no assurance that the FDA will not issue observations, we believe that we are cGMP compliant.

**Overview of Fiscal 2006**

We recorded net sales of \$82.8 million during Fiscal 2006 compared to \$64.1 million during Fiscal 2005. We have generated cash from operations of \$8.9 million during Fiscal 2006 as compared to \$20.6 million during Fiscal 2005. This cash was generated after funding our working capital requirements of \$17.5 million and \$4.9 million during the relevant periods. We incurred a net loss of \$10.4 million during Fiscal 2006 compared to net loss of \$2.3 million during Fiscal 2005. The higher loss was primarily due to higher non-cash research and development expense (R&D) of \$35.1 million during Fiscal 2006 as compared to \$26.8 million during Fiscal 2005. This non-cash R&D expense relates to nine products passing their bio-equivalency studies and related value of the preferred stock issued to Sun Global during Fiscal 2006 as compared to eight products during Fiscal 2005. At March 31, 2006, we had stockholders' equity of \$56.4 million as compared to stockholders' equity of \$31.7 million at March 31, 2005.

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

**Fiscal 2006 Compared to Fiscal 2005**

	Year ended March 31,	
	2006 (Audited)	2005 (Unaudited)
Statement of operations data	(in thousands, except per share data)	
	\$	\$
Net sales	82,789	64,116
Cost of goods sold	41,873	26,930
Gross profit	40,916	37,186
Selling, general and administrative expense	8,183	5,874
Research and development costs - affiliate non cash	35,055	26,769
Research and development costs - other	8,437	6,640
Operating loss	(10,759)	(2,097)
Other income (expense)	336	(181)
Net Loss	(10,423)	(2,278)
Net Loss per share		
Basic	(0.39)	(0.08)
Diluted	(0.39)	(0.08)
Weighted Average Shares Outstanding:		
Basic	26,392	26,348
Diluted	26,392	26,348



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Change in the product mix of sales.

Reduction in manufacturing costs due to increased batch sizes.

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

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

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

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

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

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

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

**Liquidity and Capital Resources**

**Fiscal 2006 and Fiscal 2005**

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



finance capital expenditure of \$3.3 million.

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

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

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

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

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

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

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

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

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

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

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

The following tables present a summary of each of the four quarters of Fiscal 2006. The unaudited interim financial statements include all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of such information when read in conjunction with our audited financial statements and related notes. Our quarterly operating results have varied in the past, may continue to do so and are not necessarily indicative of results for any future period.

Fiscal 2006 April 1, 2005 to March 31, 2006 (unaudited)



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 2007 include:

Continued focus and improvement on FDA compliance.

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

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

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

Prompt introduction of new approved products to the market.

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

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

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

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

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

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

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

#### **Line of Credit**

On November 17, 2005, the Company entered into a one-year, \$10 million Credit Agreement with JP Morgan Chase Bank, N.A. Under the Credit Agreement, the lender may make loans and issue letters of credit to the Company for the Company's working capital needs and general corporate purposes. Letters of credit, if issued, expire one year from their date of issuance, but no later than November 17, 2007. As of March 31, 2006, we utilized \$1.5 million of the available line and have repaid the same. Borrowings are secured by the Company's receivables, inventory and all proceeds therefrom. Borrowings may be prepaid at any time by the Company. Interest is payable based on LIBOR or an alternate base rate (determined by reference to the prime rate or the federal funds effective rate), as selected by the Company. The rate of interest is LIBOR plus 75 basis points or Prime rate minus 100 basis points. The Credit Agreement requires that certain financial covenants be met on a quarterly basis. The Company is in compliance with these financial covenants at March 31, 2006.

#### **Item 8. Financial Statements and Supplementary Data**

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

None.

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

a. The term "disclosure controls and procedures" is defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the Exchange Act). These rules refer to the controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is recorded, processed, summarized and reported within required time periods. Our Chief Executive Officer 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, 2006. Our management's assessment of the effectiveness of our internal control over financial reporting as of March 31, 2006 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 Report 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.**

The information with respect to directors and executive officers of the Corporation, the Corporation's Code of Ethics, and compliance with Section 16(a) of the Exchange Act included under the sections Nominees For Directors Terms Expiring in 2008, Incumbent Directors Terms Expiring in 2006, Incumbent Directors Terms Expiring in 2007, Committees and Meetings of Directors, Nomination of Directors, Executive Officers, Code of Business Conduct and Ethics, and Section 16(a) Beneficial Ownership Reporting Compliance in our 2005 Proxy Statement to be filed with the Securities and Exchange Commission on or before July 31, 2006, is incorporated herein by reference.

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

The information regarding executive compensation included under the section Compensation of Executive Officers and Compensation of Directors in our 2005 Proxy Statement to be filed with the Securities and Exchange Commission on or before July 31, 2006, is incorporated herein by reference.

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

The information with respect to the security ownership of certain beneficial owners and management and with respect to equity compensation plans included under the sections Security Ownership of Certain Beneficial Owners, Security Ownership of Management and Directors and Equity Compensation Plan Information in our 2005 Proxy Statement to be filed with the Securities and Exchange Commission on or before July 31, 2006, is incorporated herein by reference. In addition, the information contained under the Equity Compensation Plan Information subheading under Item 5 of this report is incorporated herein by reference.

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

The information with respect to certain relationships and related transactions included under the section Transactions of Directors, Executive Officers and Certain Beneficial Owners of Caraco in our 2005 Proxy Statement to be filed with the Securities and Exchange Commission on or before July 31, 2006, is incorporated herein by reference.

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

The information under the caption Relationship with Independent Auditors Audit and Non-Audit Fees in our 2005 Proxy Statement to be filed with the Securities and Exchange Commission on or before July 31, 2006, is incorporated herein by reference.

### **Part IV**

#### **Item 15. Exhibits Financi**