# CARACO PHARMACEUTICAL LABORATORIES LTD

Form SB-2/A June 17, 2003

AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON JUNE 17, 2003

REGISTRATION NO. 333-91968

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SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

PRE-EFFECTIVE AMENDMENT NO. 5 TO FORM SB-2 REGISTRATION STATEMENT UNDER

THE SECURITIES ACT OF 1933

CARACO PHARMACEUTICAL LABORATORIES LTD. (EXACT NAME OF SMALL BUSINESS ISSUER IN ITS CHARTER)

MICHIGAN 2834 38-2505723

(State or other jurisdiction of (Primary Standard Industrial (I.R.S. Employer incorporation or organization) Classification Code Number) Identification No.)

1150 ELIJAH MCCOY DRIVE, DETROIT, MICHIGAN 48202 (313) 871-8400 (Address and telephone number of principal executive offices)

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MR. NARENDRA N. BORKAR CHIEF EXECUTIVE OFFICER 1150 ELIJAH MCCOY DRIVE, DETROIT, MICHIGAN 48202 (313) 871-8400 (Name, address and telephone number of agent for service)

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COPIES OF ALL COMMUNICATIONS TO:

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APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO PUBLIC: from time to time after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box: [ X ]

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. []

If this Form is a post-effective amendment filed pursuant to Rule  $462\,(c)$  under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule  $462\,(d)$  under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering. [ ]

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.  $\lceil$ 

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8 (A) OF THE SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SECTION 8 (A), MAY DETERMINE.

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PROSPECTUS

5,000,000 SHARES

COMMON STOCK

CARACO PHARMACEUTICAL LABORATORIES LTD.

Of the 5,000,000 shares of common stock, no par value offered hereby, 4,365,000 shares are being sold by Caraco Pharmaceutical Laboratories Ltd. and 635,000 shares are being sold by certain of our shareholders (the "Selling Shareholders"). We will not receive any of the proceeds from the sale of shares of common stock by the Selling Shareholders.

Our common stock is listed on the OTC Bulletin Board under the symbol "CARA." On June 16, 2003, the last reported closing price of our common stock on the OTC Bulletin Board was \$5.35.

SEE "RISK FACTORS" ON PAGES 5 TO 13 FOR A DISCUSSION OF CERTAIN MATERIAL FACTORS THAT SHOULD BE CONSIDERED IN CONNECTION WITH AN INVESTMENT IN THE COMMON STOCK OFFERED HEREBY.

THESE SECURITIES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION NOR HAS THE SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

	Price to Public(i)	Proceeds to Caraco
Per Share	\$ 5.35	\$ 5.35
Total Minimum	\$ 535,000	\$ 535,000
Total Maximum	\$23,352,750	\$23,352,750

- (i) This is the price offered by Caraco. Selling Shareholders will sell their shares at the then market prices or negotiated prices.
- (ii) Before deducting offering expenses payable by Caraco estimated to be approximately \$156,000.

This is a best-efforts, minimum-maximum offering by us. There is no minimum number of shares that must be sold by the Selling Shareholders. Our officers and selected brokers and dealers, if any, must sell a minimum offering of 100,000 shares (the "Minimum Offering"). Funds received from subscribers from the sale of our common stock will be held in escrow by Bank One, Michigan. Unless collected funds sufficient to purchase at least the Minimum Offering of our shares are received by the escrow agent from accepted subscribers within 180 days from the date of commencement of the offering, all purchase payments for such shares will be returned in full to subscribers, without interest or deduction. We may, however, extend the offering, in our sole discretion, for an additional 90 days. If the Minimum Offering is sold within the foregoing period, our offering may continue until the remaining shares are sold or May 31, 2004, whichever occurs first. However, we may terminate our offering at any earlier time if we choose to do so.

PROSPECTUS DATED June 25, 2003

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#### PROSPECTUS SUMMARY

THIS SUMMARY HIGHLIGHTS WHAT WE BELIEVE IS THE MOST MATERIAL INFORMATION CONTAINED ELSEWHERE IN THIS PROSPECTUS. YOU SHOULD READ THIS ENTIRE PROSPECTUS CAREFULLY, HOWEVER, INCLUDING "RISK FACTORS" AND THE FINANCIAL STATEMENTS AND THE RELATED NOTES.

#### THE COMPANY

We are a Michigan corporation, incorporated in 1984, engaged in the business of developing, manufacturing and marketing generic drugs for prescription and non-prescription markets. Operations are conducted in an approximately 72,000 square foot facility, which was designed and constructed to our specifications and completed in 1992. The facility contains our production, packaging, research and corporate offices, all located on a 4-acre site.

Our present product portfolio includes 14 prescription products in 24 strengths in 50 package sizes. The products and their use for the indications are set forth in the table below:

GENERIC NAME

PURPOSE

Analgesic

Schizophrenia

Guaifenesin LA\*
Metroprolol Tartrate
Miraphen PSE
Paromomycin Sulfate
Salsalate
CMT
Guai/DM
Clonazepam
Flurbiprofen
Carbamazepine
Oxaprozin
Metformin Hydrochloride
Tramadol Hydrochloride
Clozapine

Decongestant
Hyper-Tension
Decongestant
Antibacterial
Decongestant
Arthritis/NSAID
Decongestant
Seizure, Panic Disorders
Arthritis/NSAID
Epilepsy
Rheumatoid Disease
Diabetes

The FDA has directed the manufacturers and distributors of Guaifenesin LA which, including us, consists of 66 companies, to cease manufacturing Guaifenesin LA by May 23, 2003 and to cease all sales after November 2003. The FDA has determined that Guaifenesin LA is a new drug which requires a new drug application and approval before it may be manufactured and sold. We intend to comply with the FDA's directive. We do not intend to file a new drug application with the FDA with respect to Guaifenesin LA. However, we are seeking clarification from the FDA as to whether application to manufacture and sell Guaifenesin LA may be made other than through a new drug application. Net sales of Guaifenesin LA during the year ended December 31, 2002 and during the quarter ended March 31, 2003 were \$1.65 million and \$0.36 million, respectively.

A significant source of our funding has been from private placement offerings and loans. In 1991, we received a \$9.1 million loan from the Economic Development Corporation of the City of Detroit ("EDC"). Sun Pharmaceutical Industries Limited, a specialty pharmaceutical corporation organized under the laws of India ("Sun Pharmaceutical") which beneficially owns approximately 49% of our outstanding shares, has contributed in 1997 and 1998 a total of \$7.5 million to us for the purchase of 5.3 million shares of common stock, has current loans outstanding to us of approximately \$9.85 million and has assisted us in obtaining line of credit loans, by acting as guarantor, in the amount of \$17.5 million.

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We market our products through wholesale buying groups, distributors and mail order companies. As a result, our product line is now represented in major drug wholesalers, such as the McKesson Corporation, Amerisource Bergen and Cardinal Health.

#### RECENT DEVELOPMENTS

During the last two quarters of 2001, the Food and Drug Administration, (the "FDA") approved 3 of our Abbreviated New Drug Applications ("ANDA" or "ANDAs"). During 2002, the FDA approved 6 additional ANDAs. In February 2003, the FDA approved an additional ANDA.

Three of the ANDAs have not yet been marketed and are not included in the above disclosure of our product portfolio. The products and their use for the indications are set forth in the table below:

GENERIC NAME PURPOSE

Ticlopidine Hydrochloride Cardiology
Meperidine Hydrochloride Analgesic
Digoxin Cardiology

These products, when launched, will increase our product portfolio to 17 prescription products in 29 strengths in 61 package sizes.

During 2002, we filed a total of 3 ANDAs with the FDA. We have 3 currently pending ANDAs with the FDA, most of which, we believe, may be approved by 2003 year-end.

During the first quarter of 2002, we received an increase of \$2.5 million in our term loan from the Bank of Nova Scotia, bringing the total term loan to \$12.5 million.

In addition, during the first six months of 2002, we completed a private placement of 635,000 shares of common stock resulting in aggregate proceeds to us of \$1,692,000.

We recently restructured our mortgage loan of approximately \$7.6 million from the Economic Development Corporation of the City of Detroit (the "EDC"). The loan, effective as of January 1, 2003, is for a term of six years with interest rates starting at 2.75% and increasing to 5.16%. Under the terms of the restructured loan, the EDC retains a first mortgage on our property and a first lien on our furniture, fixtures and equipment and intellectual property. The EDC has removed its first lien on our accounts receivable and inventory.

On November 21, 2002, we entered into a products agreement with Sun Pharma Global, Inc. ("Sun Global"), a wholly-owned subsidiary of Sun Pharmaceutical. The previous products agreement with Sun Pharmaceutical had expired. Under the agreement, which was approved by our independent directors, Sun Global has agreed to provide us with 25 new generic drugs over a five year period. In return, Sun Global will

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receive 544,000 shares of a newly created preferred stock for each generic drug transferred. The preferred shares are convertible into common shares after three

years on a one-to-one basis.

We underwent FDA inspection in November 2002 and we were found to be in substantial compliance with current good manufacturing practices ("cGMPs"). Although we did receive an FDA 483, a written list of observations, we do not believe the observations are material and we have taken appropriate remedial actions.

Our net sales for the three months ended March 31, 2003 and 2002 were \$8.7 million and \$3.3 million, respectively, reflecting an increase of almost 164%. We earned a net income of \$2.2 million for the three months ended March 31, 2003 as compared to a net loss of \$0.5 million for the same period of 2002, reflecting an improvement of almost 525%.

Our net sales for the twelve months ended December 31, 2002 and 2001 were \$22,380,964 and \$5,922,431, respectively, reflecting an increase of almost 278%. Our net losses for the twelve months ended December 31, 2002 and 2001 were \$2,256,004 and \$5,757,463, respectively, reflecting a reduction of almost 61%. The net losses for the twelve month period ended December 31, 2002 included a non-cash research and development expense (technology transfer cost) of \$3,887,423 for the 1,632,000 shares of common stock issued to Sun Global for three product transfers made to us during 2002. There was no similar expense for the corresponding period of 2001.

THE OFFERING

Common Sto	ck Offered	by Caraco	4,365,000	Shares
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> "Minimum Offering"), all proceeds will be deposited into escrow. If the Minimum Offering is not sold within 180 days from the commencement of the offering, all purchase payments for such shares will be returned in full to subscribers, without interest or deduction. We may, however, extend the offering, in our sole discretion, for an additional 90 days. If the Minimum Offering is sold within the foregoing period, our offering may continue

whichever occurs first.

on a best efforts basis by our officers who will not receive any commissions or remuneration for selling shares. In addition, shares may also be offered through

The shares will be offered

until the remaining shares are sold or May 31, 2004,

Type of Offering by Caraco.....

brokers or dealers who may receive compensation in the form of commissions and fees not to exceed 8% of the selling price of the shares.

Common Stock Offered by the Selling	
Shareholders	635,000 Shares
Common Stock to be Outstanding after the Offering	28,127,532 Shares. This amount is based upon shares outstanding as of March 31, 2003 and excludes 2,916,199 shares issuable upon the exercise of outstanding options.
Use of Proceeds by Caraco	Caraco will not receive any of the proceeds from the sale of shares by the Selling Shareholders. The net proceeds from our sale of common stock will be used for capital improvements, research
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	and development, for working capital and debt repayment. See "Use of Proceeds."
OTC Bulletin Board Quotation	
Symbol	CARA
Risk Factors	You should read the "Risk Factors" section as well as the other cautionary statements throughout the entire prospectus, so that you understand the risks associated with an investment in our securities.

### OFFICES AND WEBSITES

Our principal executive offices are located at 1150 Elijah McCoy Drive, Detroit, Michigan 48202, and our telephone number is (313) 871-8400. Our main website is located at www.caraco.com. The information on our website is not a part of this prospectus.

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#### RISK FACTORS

This offering involves a high degree of risk. You should carefully consider the risks and uncertainties described below in addition to the other information contained in this prospectus, including the section entitled "Cautionary Statement Concerning Forward-looking Statements" before deciding whether to invest in shares of our common stock. If any of the following risks actually occur, our business, financial condition or operating results could be harmed. In that case, the trading price of our common stock could decline and you may lose part or all of your investment. These risks and uncertainties described below are not the only ones facing Caraco. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations and adversely affect the market price of our common stock.

RISKS RELATING TO OUR COMPANY

WE HAVE A HISTORY OF OPERATING LOSSES.

We commenced manufacturing and sales operations in 1992. Since that time, we have sustained substantial operating losses. However, for the first time since inception, during the first quarter of 2003 and the second, third and fourth quarters of 2002, we have achieved sales necessary to support operations. Our net sales for the three months ended March 31, 2003 and 2002 were \$8.7 million and \$3.3 million, respectively. We earned net income of \$2.2 million for the three months ended March 31, 2003 as compared to a net loss of \$0.5 million for the same period of 2002. For the year ended December 31, 2002, our net sales were \$22,380,964 and our net losses were \$2,256,004 compared to \$5,922,431 and \$5,767,464, respectively, for 2001. As of December 31, 2002, we had a shareholders' deficit of \$19,623,290. There is no assurance that our recent history of having sufficient sales to support operations will continue. This will be dependent on a number of factors including market acceptance of our products, stability of active raw materials prices, obtaining regulatory approvals for our products and competition.

WE ARE HIGHLY LEVERAGED AND WE WILL NEED TO RAISE CAPITAL FROM THIS OFFERING AND/OR SEEK FINANCING TO PAY OFF LOANS THAT ARE COMING DUE.

As of March 31, 2003, we had total liabilities of \$42,377,352 and a negative working capital of \$2,211,655. The negative working capital position as of March 31, 2003 was mainly due to the classification of certain portions of the loans payable to Bank of Nova Scotia and ICICI Bank coming due within the next twelve months and \$5.5 million of the loans payable to Sun Pharmaceutical and Sun Global coming due in October 2003. While we believe sales will be sufficient to support our operations, we will need to raise capital from this offering and/or seek financing to pay off the \$5.5 million in loans to Sun Pharmaceutical and Sun Global. If we are unable to raise the capital and/or obtain the financing we will attempt to negotiate an extension of the Sun Pharmaceutical and Sun Global loans, of which there is no assurance.

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WHILE SUN PHARMACEUTICAL HAS PROVIDED SIGNIFICANT SUPPORT TO US, IT IS UNDER NO LEGAL OBLIGATION TO CONTINUE TO DO SO.

Since its acquisition of a major portion of our common stock in August 1997, Sun Pharmaceutical has made a significant investment in Caraco through \$7.5 million in capital contributions, \$9.85 million in currently outstanding loans and \$17.5 million in guarantees of loans. As of March 31, 2003, Sun Pharmaceutical beneficially owns approximately 49% of our outstanding shares. While management believes that because of Sun Pharmaceutical's substantial investment in Caraco, Sun Pharmaceutical has sufficient economic incentive to continue to assist and support us in developing our business and while Sun Pharmaceutical has generally expressed an intent to continue to support our operations in 2003, as it has done in the past, there can be no assurance that such support will, in fact continue for a period of time sufficient to ensure our ultimate business success. Sun Pharmaceutical has stated in writing to our auditors that should Caraco experience a cash shortage situation during 2003, it would, as it has in the past, do its best to bridge the financial gap. During the first quarter ended March 31, 2003, Sun Pharmaceutical assisted Caraco with a \$500,000 demand loan. Sun Pharmaceutical, however, is not legally obligated to fund our operations. Sun Pharmaceutical is also subject to the prevailing regulatory process in India and may be constrained from fully pursuing its business interests outside of India. We believe that our financial reliance on Sun Pharmaceutical to support our existing operations has significantly decreased as a result of our increased revenues and cash flow. If we are unable to successfully raise capital and Sun Pharmaceutical does not or is not able to continue to fund our growth, it may have a material adverse effect on our expansion of our product portfolio, including the suspension of Sun Global's obligations to deliver products to us under its agreement with us.

In addition to its financial assistance, Sun Pharmaceutical has assisted us by acting as an alternative source for active raw materials: approximately \$2.4 million sold to us in 2002; sold equipment to us: approximately \$310,000 in 2002; established a research and development center in Mumbai with a staff of 30 persons to perform formulation and analytical development for us; lease of production machinery: \$33,960 in 2002; and provided us with technical professional employees. This is in addition to the transfer of technology formula for 13 products to us under the now expired products agreement. Sun Pharmaceutical's affiliate, Sun Global, has entered into a new products agreement with us for the transfer of technology formula for 25 products during the next five years.

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WE ARE MAKING THE CURRENT OFFERING TO FUND AN EXPANSION OF OUR OPERATIONS BUT WE MAY BE UNABLE TO RAISE SUCH FUNDS.

This offering is being made in order to provide us with sufficient funds to grow our business. The funds are intended to be used for capital improvements, research and development expenses, working capital needs and debt

repayment. We cannot be certain, however, that this offering will be successful or that any other financing will be available when needed. As disclosed under "Use of Proceeds" below, if the Minimum Offering is subscribed, it is anticipated that the net proceeds will be used for the research and development expenses of one bioequivalency study for one new product. If we fail to raise any additional financing or only achieve the Minimum Offering, it will have the effect of delaying, suspending or terminating part of our product development programs and inhibiting our flexibility to make debt repayments. There is no certainty that Sun Pharmaceutical will be able to support us at such time. See immediately preceding risk factor. We believe that we will have sufficient cash flow, however, to continue current operations.

OUR FAILURE TO OBTAIN FDA APPROVALS OF OUR PRODUCTS AND/OR OUR FAILURE TO COMPLY WITH APPLICABLE FDA REGULATIONS COULD HINDER OUR DEVELOPMENT ACTIVITIES AND OPERATIONS.

We must obtain regulatory approval from the FDA for each product that we intend to commercialize. The granting of approvals by the FDA for generic pharmaceuticals has been subject to substantial delays and rigorous scrutiny. Moreover, we are subject to periodic inspection of our facilities and operations and testing of our products by the FDA. In November 2002 and in April 2001, we completed FDA inspections and were found to be substantially compliant in good manufacturing practices. For the period March 1999 to April 2001, however, we were not substantially compliant. Until we corrected the situation by, among other things, hiring an FDA consulting firm and new personnel to head the areas of quality control, quality assurance and regulation, the FDA did not grant approval of any then pending ANDAs, our research and development activities and development of new products were significantly reduced, our revenues were significantly reduced and we had to borrow funds to meet our cash flow requirements. The FDA has extensive enforcement powers over pharmaceutical manufacturers, including the power to seize products, to prohibit product sales and to halt operations. Any manufacturer failing to comply with FDA requirements would be unable to obtain approvals for the introduction of new products. We cannot predict the extent to which we may be affected by legislative and regulatory developments concerning our products or the healthcare field generally. Should regulatory compliance issues arise or regulatory changes occur, our business could be adversely affected.

SUN PHARMACEUTICAL AND ITS AFFILIATES MAY HAVE CONFLICTS OF INTEREST WITH CARACO WITH RESPECT TO TRANSFER OF PRODUCTS, SALE OF ACTIVE RAW MATERIALS, SALE OF EQUIPMENT, TIMING OF DEBT REPAYMENT, FUNDING AND SHAREHOLDER MATTERS SUCH AS MERGERS.

Sun Pharmaceutical beneficially owns approximately 49% of the currently outstanding shares of Caraco. Four of the eight members of the Board of Directors of Caraco are affiliated with Sun Pharmaceutical. The Chief Executive Officer of Caraco is affiliated with Sun Pharmaceutical and the Chief Financial and Chief Operating Officer of Caraco was formerly employed by Sun Pharmaceutical. As a result, Sun Pharmaceutical is subject to a number of conflicts of interests. As noted, Sun Global entered into a products agreement with us pursuant to which Sun Global will receive shares of a newly created Series B preferred stock. Among other things, pursuant to the terms of the Series B preferred stock, Sun Global has a liquidation preference ahead of

the holders of our common stock to our assets and surplus funds, if any, after the payment of all outstanding debt. Accordingly, upon a liquidation, there may not be available assets to distribute to holders of common stock after payment of all debt and the Series B preferred stock liquidation preference. The preferred stock also prohibits us from issuing any securities having a preference ahead of the Series B preferred stock without the consent of a majority of the outstanding shares of the Series B preferred stock.

Sun Pharmaceutical is engaged in the same business as Caraco and there may be conflicts in determining which products will be transferred to Caraco by Sun Pharmaceutical's wholly-owned subsidiary, Sun Global, pursuant to its products agreement and which to keep, and how much to charge for active raw materials, equipment and/or production machinery it sells or leases to Caraco. At this time, we are substantially dependent on Sun Pharmaceutical and its affiliates for the development of new products. We only have a small in-house development center. We are not prohibited, however, from expanding our in-house development center or from contracting with third parties for technology transfers. We are also considering manufacturing on a contract basis certain products of which the technology and ownership would belong to Sun Pharmaceutical. There may also be conflicts in determining when and how its loans to Caraco shall be repaid, whether to continue to perform its formulation and analytical research at its Mumbai facility on behalf of Caraco, and whether and how much it shall fund Caraco's operations and which Sun Pharmaceutical employees, if any, it determines to transfer to Caraco. Although Caraco and Sun Pharmaceutical attempt, to the extent possible, to avoid conflicts by causing Caraco directors who are affiliated with Sun Pharmaceutical to abstain from voting on matters in which Sun Pharmaceutical is an interested party, and requiring all business relationships to be on terms no less favorable than with unaffiliated parties, such requirements will not necessarily deter Sun Pharmaceutical from taking actions it believes are in Sun Pharmaceutical's best interests but which may be detrimental to Caraco. This could include keeping products with a greater potential for itself. It could also include situations in which, although other shareholders believe it would be advantageous for Caraco to take certain actions, for example, a merger or sale of significant assets, Sun Pharmaceutical would not agree and would block it. Caraco believes, that with respect to most matters, Sun Pharmaceutical's substantial investment in Caraco will provide it with an economic incentive to assist Caraco and to favor arrangements which are beneficial to both Sun Pharmaceutical and Caraco.

THE PAYMENT OF SHARES OF PREFERRED STOCK TO SUN GLOBAL IN EXCHANGE FOR THE PRODUCTS IT TRANSFERS TO CARACO MAY SIGNIFICANTLY INCREASE RESEARCH AND DEVELOPMENT EXPENSES AND THEREBY REDUCE EARNINGS OR CREATE A LOSS.

Pursuant to its products agreement with Caraco, Sun Global transfers technology to Caraco. Sun Global earns 544,000 shares of preferred stock (convertible into common stock after three years) for each ANDA product transferred at the time such product passes its bioequivalency study. The value of the shares issued to Sun Global for the transfer of the products shall be included in research and development expenses. Depending on the number of products transferred and the price attributable thereto, the issuance of preferred stock to Sun Global could cause Caraco's research and development expenses to increase to an amount which would significantly decrease profit or create a loss. Preferred shares can be earned by Sun Global even if the product is not successfully produced and marketed. To date, no shares of preferred stock have been earned by or issued to Sun Global.

CLAIMS BY OTHERS THAT OUR PRODUCTS INFRINGE THEIR PATENTS OR OTHER INTELLECTUAL

PROPERTY RIGHTS COULD ADVERSELY AFFECT OUR FINANCIAL CONDITION.

The pharmaceutical industry has been characterized by frequent litigation by patent and other intellectual property rights. Any claims of patent infringement would be time-consuming and could likely result in costly litigation, divert the time and attention of our technical personnel and management and cause product development delays. An adverse determination in a judicial or administrative proceeding could prevent us from developing, manufacturing and selling some of our products, which could harm our business, financial condition and operating results. There is no such litigation currently pending against us.

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PRODUCT LIABILITY CLAIMS COULD ADVERSELY AFFECT OUR FINANCIAL CONDITION.

The design, development and manufacture of pharmaceutical products involve an inherent risk of product liability claims and associated adverse publicity. Subsequent to the introduction of a product or with respect to new products under development, there may occur adverse drug reactions which were not identified prior thereto which could have a material adverse effect on our sales of such products. Insurance coverage is expensive, difficult to obtain and may not be available in the future on acceptable terms. Although we currently maintain liability insurance for all of our products, in the amount of up to \$10 million per incident and in the aggregate, there can be no assurance that the coverage limits of our insurance policies will be adequate. Claims brought against us, whether fully covered by insurance or not, could have a material adverse affect upon us. See rule factor below and "Business - Litigation."

WE ARE INVOLVED IN TWO PRODUCT LIABILITY SUITS IN WHICH DAMAGES IN EXCESS OF \$20 MILLION ARE CLAIMED AND FOR WHICH WE ARE NOT INSURED.

Two product litigation cases have recently been filed against us involving Miraphen LA which contains phenylptopanolamine ("PPA"). In one suit we are one of two defendants and in the other we are one of numerous defendants. At this time, discovery is only in its initial stages. Our product liability insurer has recently informed us that we are not covered with respect to product liability claims involving PPA. Damages sought in the two lawsuits against all of the defendants exceed \$20 million. The ultimate outcome of these cases and the potential effect on us cannot be determined at this time. However, we believe we have substantial defenses to the claims and we intend to vigorously defend the lawsuits.

### RISKS RELATING TO OUR INDUSTRY

BECAUSE OUR INDUSTRY IS VERY COMPETITIVE AND MANY OF OUR COMPETITORS HAVE SUBSTANTIALLY GREATER CAPITAL RESOURCES AND MORE EXPERIENCE IN RESEARCH AND DEVELOPMENT, MANUFACTURING AND MARKETING THAN US, WE MAY NOT SUCCEED IN DEVELOPING OUR PROPOSED PRODUCTS AND BRINGING THEM TO MARKET.

Competition in the pharmaceutical industry is intense. Potential competitors in the United States are numerous and most have substantially

greater capital resources and more experience in research and development, manufacturing and marketing than us. We believe that our primary competitors are EON Labs, Inc., Ivax Pharmaceuticals, Inc., Mylan Laboratories, Inc. and Taro Pharmaceutical Industries, Ltd. Because selling prices of generic drug products typically decline as competition intensifies, the achievement of profitable operations will be dependent, in part, on our ability to maintain efficient production capabilities and to develop and introduce, or to obtain access through strategic alliances with others, new products in a timely manner. New drugs or future developments in alternative drug development technologies may provide therapeutic or cost advantages to competing products. There can be no assurance that developments by others will not render our products or technologies non-competitive or obsolete.

WE ARE DEPENDENT UPON KEY PERSONNEL, MANY OF WHOM WOULD BE DIFFICULT TO REPLACE.

Our success will be largely dependent upon the efforts of Narendra N. Borkar, our Chief Executive Officer and Jitendra N. Doshi, our Chief Operating Officer and Chief Financial Officer. Mr. Borkar's current employment agreement expires on September 22, 2003. We do not have key person life insurance on any of our key personnel. Our future success also will depend in large part on our ability to identify, attract and retain other highly qualified managerial, technical and sales and marketing personnel. Competition for these individuals is intense. The loss of the services of any of our key personnel, the inability to identify, attract or retain qualified personnel in the future or delays in hiring qualified personnel, could make it more difficult for us to manage our business and meet key objectives, such as the timely introduction of our proposed products, which would harm our business, financial condition and operating results.

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RISKS RELATING TO THIS OFFERING AND OUR COMMON STOCK

BECAUSE OUR COMMON STOCK IS QUOTED ON THE OTC BULLETIN BOARD, YOUR ABILITY TO SELL YOUR SHARES IN THE SECONDARY TRADING MARKET MAY BE LIMITED.

Our common stock currently is quoted on the over-the-counter market on the OTC Bulletin Board. Consequently, the liquidity of our common stock is impaired, not only in the number of shares that are bought and sold, but also through delays in the timing of transactions, and coverage by security analysts and the news media, if any, of our company. As a result, prices for shares of our common stock may be lower than might otherwise prevail if our common stock was quoted on the Nasdaq Stock Market or traded a national securities exchange, like the New York Stock Exchange or American Stock Exchange.

BECAUSE OUR SHARES ARE "PENNY STOCKS," YOU MAY HAVE DIFFICULTY SELLING THEM IN THE SECONDARY TRADING MARKET.

Federal regulations under the Securities Exchange Act of 1934 regulate the trading of so-called "penny stocks," which are generally defined as any security not listed on a national securities exchange or Nasdaq, priced at less than \$5.00 per share and offered by an issuer with limited net tangible assets and revenues. Since our common stock currently is quoted on the OTC Bulletin Board at less than \$5.00 per share, our common stock is a "penny stock" and may not be traded unless a disclosure schedule explaining the penny stock market and the risks associated therewith is delivered to a potential purchaser prior to any trade.

In addition, because our common stock is not listed on Nasdaq or any national securities exchange and currently trades at less than \$5.00 per share, trading in our common stock is subject to Rule 15g-9 under the Exchange Act. Under this rule, broker-dealers must take certain steps prior to selling a "penny stock," which steps include:

- obtaining financial and investment information from the investor;
- obtaining a written suitability questionnaire and purchase agreement signed by the investor; and
- providing the investor a written identification of the shares being offered and the quantity of the shares.

If these penny stock rules are not followed by the broker-dealer, the investor has no obligation to purchase the shares. The application of these comprehensive rules will make it more difficult for the broker-dealers to sell our common stock and our stockholders, therefore, may have difficulty in selling their shares in the secondary trading market.

SALES OF A SUBSTANTIAL NUMBER OF SHARES OF OUR COMMON STOCK IN THE PUBLIC MARKET, INCLUDING THE SHARES OFFERED UNDER THIS PROSPECTUS AND UNDER OTHER REGISTRATION STATEMENTS, COULD LOWER OUR STOCK PRICE AND IMPAIR OUR ABILITY TO RAISE FUNDS IN NEW STOCK OFFERINGS.

Future sales of a substantial number of shares of our common stock in the public market, including the shares offered under this prospectus and under other registration statements, or the perception that such sales could occur, could aversely affect the prevailing market price of our common stock and could make it more difficult for us to raise additional capital through the sale of equity securities.

OUR STOCK PRICE MAY BE VOLATILE AND YOUR INVESTMENT IN OUR COMMON STOCK COULD SUFFER A DECLINE IN VALUE.

Our common stock is quoted on the OTC Bulletin Board. The market price of our common stock may fluctuate significantly in response to a number of factors, some of which are beyond our control. These factors include:

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- progress of our products through the regulatory process;
- announcements of technological innovations or new products by us or our competitors;
- government regulatory action affecting our products or our competitors' products;
- developments or disputes concerning patent or proprietary rights;
- actual or anticipated fluctuations in our operating results;
- changes in our financial estimates by securities analysts;
- general market conditions for emerging growth and pharmaceutical companies;

- broad market fluctuations; and
- economic conditions in the United States.

From July 1, 2000 through March 31, 2003, the closing sales price of our stock has ranged from \$0.20\$ to \$4.65.

PROVISIONS IN OUR CHARTER DOCUMENTS AND MICHIGAN LAW MAY PREVENT OR FRUSTRATE ANY ATTEMPT TO REPLACE OR REMOVE CURRENT MANAGEMENT BY SHAREHOLDERS.

Provisions of our articles of incorporation and bylaws, as well as provisions of Michigan law, could make it more difficult for shareholders to replace or remove current management. These provisions include:

- our Board of Directors has the authority to issue common stock and preferred stock and to determine the price, rights and preferences of any new series of preferred stock without further shareholder approval;
- our Board of Directors is divided into three classes, with each class serving staggered three-year terms;
- super majority voting is required to amend key provisions of our articles of incorporation and bylaws;
- there are limitations on who can call special meetings of shareholders; and
- in order to nominate a director or make a proposal at a shareholders' meeting, a shareholder must give us advance notice.

We refer you to "Business - 1999 Equity Participation Plan" for disclosure of provisions which provide that all outstanding options shall vest upon a change in control. This may discourage a third party from attempting a change in control of our Company.

We also refer you to "Description of Securities - Anti-Takeover Provisions of Michigan Law and our Articles of Incorporation" for more information on the specific provisions of our articles of incorporation, our bylaws and Michigan law that could discourage, delay or prevent a change of control of our company.

SUN PHARMACEUTICAL AND ITS AFFILIATES AND OUR DIRECTORS AND EXECUTIVE OFFICERS OWN A SUFFICIENT NUMBER OF SHARES OF OUR CAPITAL STOCK TO CONTROL OUR COMPANY, WHICH COULD DISCOURAGE OR PREVENT A TAKEOVER, EVEN IF AN ACQUISITION WOULD BE BENEFICIAL TO OUR SHAREHOLDERS.

Sun Pharmaceutical and its affiliates and our directors and executive officers currently own or control approximately 65% of our outstanding voting power. This percentage excludes the effect of shares issuable upon the exercise of outstanding options and the issuance of any additional shares to Sun Global

for product technology transfers. Accordingly, these shareholders, individually and as a group, may be able to influence the

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outcome of shareholder votes, involving votes concerning the election of directors, the adoption or amendment of provisions in our articles of incorporation and bylaws and the approval of certain mergers or other similar transactions, such as a sale of substantially all of our assets. Such control by existing shareholders could have the effect of delaying, deferring or preventing a change in control of our company.

PURCHASERS IN THIS OFFERING WILL EXPERIENCE IMMEDIATE AND SUBSTANTIAL DILUTION OF THEIR INVESTMENT.

We expect that the public offering price per share will significantly exceed the net tangible book value per share of the outstanding common stock. Accordingly, purchasers of common stock in this offering will:

- pay a price per share that substantially exceeds the value of our assets after subtracting our liabilities; and
- assuming a purchase price of U.S. \$5.35 per share, contribute approximately 36.6% of the total amount to fund us to date, but will only own approximately 15.5% of the shares outstanding. The shares outstanding exclude shares issuable upon the exercise of outstanding options and the conversion of preferred stock and the issuance of any additional shares to Sun Global for product technology transfers.

EXERCISE OF OUTSTANDING OPTIONS WILL DILUTE EXISTING SHAREHOLDERS AND COULD DECREASE THE MARKET PRICE OF OUR COMMON STOCK.

As of March 31, 2003, we had issued and outstanding 23,762,532 shares of common stock and outstanding options of 2,916,199 additional shares of common stock at an average exercise price of approximately \$1.78 per share. To the extent these outstanding options are ultimately exercised, there will be further dilution to investors in this offering. The existence of the outstanding options and convertible preferred stock may adversely affect the market price of our common stock and the terms under which we could obtain additional equity capital.

WE LIKELY WILL ISSUE ADDITIONAL EQUITY SECURITIES WHICH WILL DILUTE YOUR SHARE OWNERSHIP.

We likely will issue additional equity securities through the exercise of options that are outstanding or may be outstanding, through the conversion of preferred stock that may become outstanding pursuant to the terms of the products agreement between Sun Global and us, and possibly to raise capital. These additional issuances will dilute your share ownership.

WE DO NOT INTEND TO PAY ANY CASH DIVIDENDS ON COMMON STOCK IN THE FORESEEABLE FUTURE AND, THEREFORE, ANY RETURN ON YOUR INVESTMENT IN OUR COMMON STOCK MUST

COME FROM INCREASES IN THE FAIR MARKET VALUE AND TRADING PRICE OF OUR COMMON STOCK.

We have never paid a cash dividend on our common stock. We do not intend to pay cash dividends on our common stock in the foreseeable future and, therefore, any return on your investment in our common stock must come from increases in the fair market value and trading price of our common stock. Further, the EDC loan restricts the payment of dividends without its consent.

MANAGEMENT HAS BROAD DISCRETION AS TO THE USE OF PROCEEDS OF THIS OFFERING AND COULD SPEND OR INVEST THE NET PROCEEDS IN WAYS IN WHICH THE SHAREHOLDERS MAY NOT AGREE.

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We expect to use most of the net proceeds from this offering for expenses related to capital improvements, research and development and working capital purposes and debt repayment. As noted, we could decide to pay off all or part of the Sun Pharmaceutical debt or the EDC debt. Our management has broad discretion as to the use of proceeds of this offering and could spend or invest the net proceeds from this offering in ways in which the shareholders may not agree.

#### CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements concerning our financial condition, results of operations and business, the anticipated financial and other benefits of this offering and the plans and objectives of our management following this offering, including, without limitation, statements pertaining to:

- our anticipated future profitability;
- our need to raise additional capital through future equity financings;
- our spending capital on research and development of new products;
- our expectations of future FDA approvals of pending ANDAs;
- our expectations of introducing new products into the marketplace;
- our existing cash and any net proceeds from this offering and whether and how long these funds will be sufficient to fund our growth; and
- restructuring of the EDC loan.

These and other forward-looking statements are primarily in the sections entitled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." Generally, you

can identify these statements because they use phrases like "anticipates," "believes," "expects," "future," "intends," "plans," and similar terms. These statements are only predictions. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy, and actual results may differ materially from those we anticipated due to a number of uncertainties, many of which are unforeseen. You should not place undue reliance on these forward-looking statements which apply only as of the date of this prospectus. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including, among others, the risks we face as described in the section entitled "Risk Factors" and elsewhere in this prospectus.

Among the important factors that could cause actual results to differ materially from those indicated by such forward-looking statements are: (i) that the information is of a preliminary nature and may be subject to further adjustment; (ii) variations in quantity results; (iii) lack of success in obtaining additional financing; (iv) inability to renegotiate and extend our loan with the EDC; (v) governmental restrictions on the sale of certain products; (vi) not obtaining FDA approvals for new products or delays in receiving FDA approvals; (vii) lack of successful manufacturing and marketing of commercially viable products on a timely basis; (viii) dependence on key personnel; (ix) development by competitors of new or superior products or cheaper products or new technology for the production of products or the entry into the market of new competitors; (x) market and customer acceptance and demand for new pharmaceutical products; (xi) availability of active raw materials; (xii) timing and success of product development and launch; (xiii) integrity and reliability of our data; (xiv) lack of success in attaining full compliance with regard to regulatory and cGMP compliance; and (xv) other risks

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identified from time to time in our reports and registration statements filed with the Securities and Exchange Commission.

We are not obligated to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as otherwise required by law. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this prospectus and other statements made from time to time from us or our representatives, might not occur. For these statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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#### PLAN OF DISTRIBUTION

SALES BY CARACO

We are offering the shares on a "best efforts minimum-maximum" basis directly through our officers, who will not receive any commissions or other remuneration of any kind for selling shares in this offering, other than reimbursement of offering expenses incurred by them. This offering is a self

underwritten offering, which means that it does not involve the participation of an underwriter to market, distribute or sell the shares offered under this prospectus. We may sell shares directly by us and/or we may offer the shares through brokers or dealers, who may receive compensation in the form of commissions. We do not currently have any understandings or arrangements with any person to act as a broker or dealer in this offering. Any broker or dealer that participates in the distribution of shares may be deemed to be an underwriter, and any profits on the sale of the shares by any such broker or dealer and any commissions received by any such broker or dealer may be deemed to be underwriting compensation under the Securities Act of 1933, as amended (the "Securities Act"). If one or more brokers or dealers are engaged, the total commission and fees paid to such brokers and dealers in connection with the sale of the shares offered under this prospectus will not exceed 8% of the selling price of the shares.

The shares may not be offered or sold in certain jurisdictions unless they are registered or otherwise comply with the applicable securities laws of such jurisdictions by exemption, qualification or otherwise. We intend to sell the shares only in the states in which this offering has been qualified or an exemption from the registration requirements is available, and purchases of shares may be made only in those states. To comply with the securities laws of certain jurisdictions, as applicable, the shares may be required to be offered and sold only through registered or licensed brokers or dealers. If such brokers or dealers are engaged, the total commission and fees paid to such brokers and dealers in connection with the sale of shares will not exceed 8% of the selling price of the shares.

Until 100,000 shares (the "Minimum Offering") have been sold, all funds received from subscribers for our common stock will be held in escrow by Bank One, Michigan, as escrow agent, pursuant to an agreement with the escrow agent. Pending disbursement, subscription proceeds will be deposited in a non-interest bearing account. All funds received after the Minimum Offering has been obtained, will be deposited directly with us for immediate use.

Unless collected funds sufficient to purchase at least the Minimum Offering are received by the escrow agent from accepted subscribers within 180 days from the date of commencement of the offering, the offering will terminate and all funds received from subscribers will be promptly returned in full by the escrow agent directly to subscribers, without interest or deduction, as provided in the escrow agreement. We may, however, extend the offering, in our sole discretion, for an additional 90 days. Provided that at least 100,000 shares of common stock are sold within the foregoing period, we may continue to offer our common stock for sale until 4,365,000 shares are sold or May 31, 2004, whichever occurs first. However, we may terminate our offering at any earlier time if we choose to do so. For services performed by it pursuant to the escrow agreement, we have paid the escrow agent fees in the amount of \$1,500.

To purchase common stock in this offering, a prospective investor must (1) complete and sign a subscription agreement and any other documents that we may require and (2) deliver such documents, together with payment in an amount equal to the full purchase price of the shares of common stock being purchased, to

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the officer or broker or dealer, as applicable. Until the Minimum Offering is sold, checks should be made payable to "Bank One, Michigan, Escrow Agent." After the Minimum Offering, checks should be made payable directly to "Caraco." WE WILL DETERMINE, IN OUR SOLE DISCRETION, TO ACCEPT OR REJECT SUBSCRIPTIONS WITHIN

FIVE DAYS FOLLOWING THEIR RECEIPT. FUNDS OF AN INVESTOR WHOSE SUBSCRIPTION IS REJECTED WILL BE PROMPTLY RETURNED DIRECTLY TO SUCH PERSON, WITHOUT INTEREST OR DEDUCTION, PURSUANT TO THE TERMS OF THE ESCROW AGREEMENT. NO SUBSCRIPTION MAY BE WITHDRAWN, REVOKED OR TERMINATED BY THE PURCHASER. WE RESERVE THE RIGHT TO REFUSE TO SELL OUR COMMON STOCK TO ANY PERSON AT ANY TIME.

We anticipate that we will indemnify brokers or dealers against any costs or liabilities incurred by them by reasons of misstatements or omissions to state material facts in connection with statements made in the registration statement or the prospectus. We also anticipate that brokers or dealers will, in turn agree to indemnify us against any liabilities by reason of misstatements or omissions to state material facts in connection with the statements made in the prospectus, based on information relating to the brokers or dealers and furnished in writing. To the extent that this indemnification may purport to provide exculpation from possible liabilities arising from the federal securities laws, in the opinion of the Securities and Exchange Commission, such indemnification is contrary to public policy and therefore unenforceable.

#### SALES BY SELLING SHAREHOLDERS

The Selling Shareholders acquired their shares of Caraco common stock directly from us in private transactions in March, April and May 2002. To our knowledge, none of the Selling Shareholders has entered into any agreement, arrangement or understanding with any particular broker or market maker with respect to the shares offered under this prospectus, nor do we know the identity of any broker or market maker that will participate in the offering. The shares of common stock may be offered and sold from time to time by the Selling Shareholders or by their respective pledgees, donees, transferees and other successors in interest.

The Selling Shareholders will act independently of us in making decisions with respect to the timing, manner, size and price of each sale. Sales may be made over the OTC Bulletin Board, in the over-the-counter market, in privately negotiated transactions or otherwise, at then prevailing market prices, at prices relating to prevailing market prices or at negotiated prices. Sales may be made directly or through agents designated from time to time or through dealers or underwriters to be designated or in negotiated transactions. The shares may be sold by one or more of, or a combination of, the following methods:

- a block trade in which the broker or dealer engaged by a Selling Shareholder will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by the broker or dealer as principal and resale by the broker or dealer for its account pursuant to this prospectus;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers; and
- privately negotiated transactions.

Caraco has been advised by the Selling Shareholders they have not, as of May 27, 2003, entered into any arrangement with a broker or dealer for the sale of shares through a block trade, special offering, or secondary distribution of a purchase by a broker or dealer. In effecting sales, brokers or dealers engaged by the Selling Shareholders may arrange for other brokers or dealers to participate.

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In connection with distributions of the shares or otherwise, the Selling Shareholders may, if permitted by law, also enter into hedging transactions. For example, the Selling Shareholder may:

- enter into transactions involving short sales of the shares of common stock by brokers or dealers;
- sell shares of common stock short and redeliver these shares to close out the short position;
- enter into option or other types of transactions that require the Selling Shareholders to deliver shares of common stock to a broker or dealer, who will then resell or transfer the shares of common stock under this prospectus; or
- loan or pledge shares of common stock to a broker or dealer, who
  may sell the loaned shares, or in the event of default, sell the
  pledged shares.

Brokers or dealers or agents may receive compensation in the form of commissions, discounts or concessions from the Selling Shareholders or the purchasers of the common stock in amounts to be negotiated in connection with the sale. Brokers or dealers and any other participating brokers or dealers may be deemed to be underwriters within the meaning of the Securities Act in connection with the sales, and any commission, discount or concession may be deemed to be underwriting discounts or commissions under the Securities Act. In addition, any securities covered by this prospectus which qualify for sale under Rule 144 of the Securities Act may be sold under Rule 144 rather than under this prospectus. No period of time has been fixed within which the shares covered by this prospectus may be offered and sold.

We have informed the Selling Shareholders that the anti-manipulation rules under the Securities Exchange Act of 1934, including Regulation M thereunder, may apply to their sales of shares in the market and have furnished each of the Selling Shareholders with a copy of these rules. We have also informed the Selling Shareholders of the need for delivery of copies of this prospectus in connection with any sale of shares of common stock hereunder.

This offering will terminate on the earlier to occur of:

- the date on which all shares offered have been sold by the Selling Shareholders; or
- the date on which all shares held by a Selling Shareholder may be sold by such Selling Shareholder in compliance with Rule 144 under the Securities Act within any three-month period.

We will pay the expenses of registering the shares under the Securities Act, including registration and filing fees, printing expenses, fees and disbursements of our counsel and accountants, all of our internal expenses, and all legal fees and disbursements and other expenses of complying with state securities or blue sky laws of any jurisdictions in which the securities to be offered are to be registered or qualified. The Selling Shareholders will bear all discounts, commissions or other amounts payable to underwriters, brokers, dealers or agents.

SELLING SHAREHOLDERS

All of the Selling Shareholders named below acquired shares of our common stock being offered under this prospectus directly from us in private transactions in March, April and May 2002. Mr. LeRoy Carter, Berlin Capital Growth, LP and J. George Investments, LLC purchased the securities referenced in the table below in the ordinary course of business, and at the time of purchase of the securities to be resold, had no agreements or understandings, directly or indirectly, with any persons to distribute the securities. The following table sets

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forth information known to us with respect to the beneficial ownership of Caraco common stock as of March 31, 2003, by the Selling Shareholders.

The percentage of beneficial ownership for the following table is based on 23,762,532 shares of common stock outstanding as of March 31, 2003. To our knowledge, each person named in the table has sole voting and investment power with respect to all shares of common stock shown in the table to be beneficially owned by such person.

None of the Selling Shareholders has had any position, office or other material relationship with us within the past three years. The table assumes that the Selling Shareholders will sell all of the shares offered by them in this offering, however, the Selling Shareholders may offer all or part of the shares for resale from time to time. We are unable to determine the exact number of shares that will actually be sold or when or if these sales will occur. We will not receive any of the proceeds from the sales of the shares offered under this prospectus.

Selling Shareholder	Shares of Common Stock Beneficially Owned Prior to the Offering		Number of Shares Being Offered
	Total Shares Beneficially Owned	Percentage	
Daniel Bauer	30,000	*	30,000
Berlin Capital Growth, LP	200,000	0.8%	200,000
LeRoy Carter	30,000	*	30,000
Verle Carter	25,000	*	25,000
J. George Investments, LLC	350,000	1.5%	350,000

<sup>\*</sup>less than 1.0%

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USE OF PROCEEDS

Caraco will not receive any of the proceeds from the sale of shares by the Selling Shareholders. If all 4,365,000 shares of common stock offered by Caraco are sold pursuant to this offering, we will receive gross proceeds of approximately \$23,352,750. The gross proceeds will be reduced by legal, accounting and other miscellaneous expenses of approximately \$156,000. If we utilize the services of registered brokers and dealers, the gross proceeds will be further reduced by the commissions payable to such brokers and dealers. Set

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forth below is an estimate of how we intend to use the net proceeds of the offering, assuming the gross proceeds of \$23,352,750: \$2 million towards capital improvements, \$6 million towards research and development, \$6-8 million towards working capital requirements and the balance for debt elimination. If the net proceeds are less than fully subscribed, we shall determine the proper allocation among the foregoing proposed uses. We may also determine to pay off all or a portion of the \$5.5 million in loans from Sun Pharmaceutical and Sun Global which are due October 2003. This may reduce the amounts available for the other proposed uses. If only the Minimum Offering of 100,000 shares (\$535,000) is subscribed, it is anticipated that the net proceeds will be used for the research and development expenses of one bioequivalency study; in such case, we would need to seek additional financing to grow our business. See "Risk Factors."

#### DIVIDEND POLICY

We never have declared or paid any cash dividends on our common stock. We currently intend to retain all future earnings for the operation and expansion of our business. We do not anticipate declaring or paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends on the common stock will be at the discretion of the Board of Directors and will depend upon our results of operations, earnings, capital requirements, contractual restrictions and other factors deemed relevant by our Board of Directors. No dividend may be declared without the consent of the EDC.

### PRICE RANGE OF COMMON STOCK

Our common stock trades in the over-the-counter market on the OTC Bulletin Board, under the symbol "CARA." The following table sets forth, in U.S. dollars and in dollars and cents (in lieu of fractions), the high and low bid prices for each of the calendar quarters indicated. These bid prices were obtained from the Nasdaq OTCBB. These quotations reflect inter-dealer prices, without retail mark up, mark down or commissions and may not represent actual transactions.

2003	HIGH	LOW
First Quarter	\$3.95	\$2.60
2002	HIGH	LOW
First Quarter	\$4.96	\$1.10

Second Quarter Third Quarter Fourth Quarter	\$3.73 \$3.07 \$2.77	\$2.25 \$1.73 \$1.72
2001	HIGH	LOW
First Quarter Second Quarter Third Quarter Fourth Quarter	\$0.60 \$0.85 \$0.70 \$1.11	\$0.20 \$0.32 \$0.55 \$0.58

As of March 31, 2003, there were approximately 155 holders of record of our common stock.

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#### SELECTED FINANCIAL DATA

The selected statements of operations data shown below for the years ended December 31, 2002, 2001 and 2000 and the balance sheet data as of December 31, 2002 and 2001 are derived from our audited financial statements included elsewhere in this prospectus. The selected statement of operations data shown below for the three months ended March 31, 2003 and 2002 and the balance sheet dated as of March 31, 2003 have been derived from the unaudited financial statements included elsewhere in this prospectus. In the opinion of management, all adjustments necessary for a fair presentation of such financial statements have been included. Such adjustments consisted only of normal recurring items. Interim results are not necessarily indicative of results for the full year. When you read this selected consolidated financial data, it is important that you also read the historical financial statements and related notes included in this prospectus, as well as "Management's Discussion and Analysis of Financial Condition and Results of Operations." Historical results are not necessarily indicative of future results.

	STATEMENT OF OPERATIONS	THREE MONTHS ENDED  MARCH 31  (unaudited)				
		2003		2002		2002
Net sales		\$ 8,721,600	\$	3,301,959	\$	22,380,96
Cost of goods so	ld	 4,225,949		1,847,547	_	12,047,41

Gross profit (loss)	4,495,651	1,454,412	10,333,55
Selling, general and administrative expenses	949,784	754 <b>,</b> 655	3 <b>,</b> 827 <b>,</b> 70
Research and development costs (affiliate) Research and development costs	899 <b>,</b> 931	- 850,873	3,887,42 3,348,78
nobodien and development costs	033,301	000,070	3,313,73
Operating income/(loss)	2,645,936	(151,116)	(730 <b>,</b> 36
Interest cost - net of interest income	(441,187)	(368,127)	(1,525,63
Net income/(loss)	\$ 2,204,749	\$ (519,243)	\$ (2,256,00
	========		
Net income/(loss) per basic and diluted common shar		\$ (0.03)	\$ (0.1
Weighted average common shares outstanding	23, 162, 532	21,242,874	22,031,42

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	MARCH 31			
BALANCE SHEETS	(unaudited)			
	2003	2002		
Cash and cash equivalents	\$ 337,415	\$ 534,228		
Other current assets	16,767,706	11,571,411		
Property, plant & equipment (net)	7,853,688	7,747,510		
Current liabilities	19,316,777	13,752,892		
Long term liabilities	23,060,575	25,723,547		
Accumulated deficit	(57,808,047)	(60,012,796)		
Stockholders deficit	(17,418,541)	(19,623,290)		

\*Caraco recorded a prior period adjustment to restate common stock and the accumulated deficit as of January 1, 2000 in connection with the valuation of its common shares issued to Sun Pharmaceutical in exchange for product technology transfers received through that date. The restatement served to increase the accumulated deficit and capital previously reported at that date by \$983,660. The 2000 operating results have been restated by increasing the net loss by \$171,832 in connection with the valuation of common shares issued to Sun Pharmaceutical in exchange for the product technology transfer during 2000.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

DECEMBER

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and related notes included elsewhere in this registration statement and the cautionary statements concerning forward-looking statements presented in the sections entitled "Risk Factors" and "Cautionary Statement Concerning Forward-looking Statements."

#### OVERVIEW

The first quarter of 2003 was a quarter of record revenues and net income. 2002 was a year of record revenues, significantly lower net losses and significantly improved cash flow. In comparison we have historically experienced limited sales, operating losses and cash-flow difficulties.

During 2001 and 2000, Sun Pharmaceutical assisted Caraco in obtaining loans from ICICI Bank Limited and The Bank of Nova Scotia of \$5.0 million and \$12.5 million. We have utilized the \$5.0 million from ICICI Bank Limited during 2000 and \$10.9 million from The Bank of Nova Scotia during 2002, 2001 and 2000. Also, Sun Pharmaceutical provided loans of an additional \$0.5 million, \$1.4 million and \$2.45 million to us during the first quarter of 2003, and the years ended December 31, 2002 and 2001, respectively. The \$0.5 million is a demand loan used for working capital needs. The loans in 2002 and 2001 were primarily utilized by us to fund the operations, research and development of new products and finance the increased working capital needs resulting from the increase in our product portfolio following FDA approvals of 3 products during the last two quarters of 2001 and 6 products in 2002. In February 2003, the FDA approved an additional ANDA. We also filed 3 ANDA applications to the FDA

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during 2002, bringing the total pending approvals to 3. We successfully restructured our EDC loan in April 2003. See "Business Property" and "Business - EDC Financing."

#### FDA COMPLIANCE AND PRODUCT APPROVALS

Towards the end of the first and beginning of the second quarters of 2001, and in November 2002, the FDA conducted inspections of our facility. During these inspections, we were found to be substantially in compliance with the cGMP regulations. While the FDA did issue us an FDA 483 list of observations after each inspection, we do not believe they are material and we have taken appropriate remedial actions. During 2002, the FDA approved 6 ANDAs. In February 2003, the FDA approved an additional ANDA. 3 ANDAs are currently pending approval.

THREE MONTHS ENDED MARCH 31, 2003 COMPARED WITH THREE MONTHS ENDED MARCH 31, 2002

NET SALES. Net sales for the three months ended March 31, 2003 and 2002 were

\$8,721,600 and \$3,301,959, respectively, reflecting an increase of almost 164%. The increase is due to the higher production and marketing of most of our products following the achievement of substantial compliance with cGMPs. Sales of Metformin Hydrochloride, Tramadol Hydrochloride and Metoprolol Tartrate accounted for 85% of our net sales for the quarter. Sales of Metformin Hydrochloride increased because of our contract with the Veterans Administration, however, the sales of Metformin Hydrochloride to such agency have been made at lower sales prices. (See "Gross Profit" below).

GROSS PROFIT. We earned a gross profit of \$4,495,651 during the three months ended March 31, 2003 as compared to a gross profit of \$1,454,412 during the corresponding period in 2002. The improvement was primarily due to higher sales volumes with improved margins due to change in sales mix to more profitable products such as Metroprolol Tartrate, Metformin Hydrochloride; Tramadol Hydrochloride and Oxaprozin; acquiring active raw materials at more competitive prices; reduction in manufacturing costs due to increased batch sizes; improved efficiency in the overall manufacturing process associated with higher utilization of plant capacity; and utilization of equipment installed during the twelve months ended December 31, 2002 of \$1.6 million, and ability to absorb operational overheads due to higher sales.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES. Selling, general and administrative expenses for the three months ended March 31, 2003 and March 31, 2002 were \$949,784 and \$754,655 respectively, representing an increase of 25%. Selling, general and administrative expenses have effectively decreased down to 10.8% of net sales during the three months ended March 31, 2003 from almost 22% of net sales during the same period in 2002.

The actual increase of approximately \$195,000 was due to additional professional costs (\$25,000) primarily in connection with the ongoing litigation against the Company, costs of introducing new products into the market (\$25,000), additional sales personnel (\$15,000), increases in the salaries of sales and administrative staff (\$25,000), recording of variable compensation expense on stock options granted and extended to a director (\$35,000) and costs associated with development of improved services and quality measures to customers.

RESEARCH AND DEVELOPMENT EXPENSES. Cash research and development expenses of \$899,931 for the three months ended March 31, 2003 were higher by 5% when compared with \$850,873 incurred during the corresponding period of 2002. The major reason for the additional cash research and development expenses was the costs for raw material of approximately \$80,000 for one of the projects currently undergoing efficacy studies and other filing costs.

DEPRECIATION EXPENSE. We incurred depreciation expense of \$138,770 for the first three months of March 2003 as compared to \$108,208 incurred in the corresponding period of 2002. Depreciation has increased due to additional investment into capital assets during 2002 of \$1.6 million.

INTEREST EXPENSE. Interest expense, which was incurred in connection with our mortgage obligation to the EDC, interest on notes payable to Sun Pharmaceutical

and Sun Global as well as on term loans granted to us by ICICI Bank and the Bank of Nova Scotia, and guaranteed by Sun Pharmaceutical, was \$441,187 and \$368,127, for the three months ended March 31, 2003 and 2002, respectively. The increase in the amount of interest is due to the increase in borrowing levels. We have utilized the \$1.6 million of the remaining draws from Bank of Nova Scotia as well as having borrowed \$500,000 from Sun Pharma (a demand loan) to finance increased working capital.

RESULTS OF OPERATIONS. We earned net income of \$2,204,749 for the three months ended March 31, 2003 as compared to a net loss of \$519,243 for the same period of 2002, respectively, reflecting an improvement of almost 525%. The significantly improved results of operations in the current three-month period as compared to the previous respective period are primarily due to significantly higher sales volumes, improved cost absorption due to increased sales, improved product mix and obtaining more competitive prices for active raw materials.

A number of uncertainties exist that may influence our future operating results, including general economic conditions, changes in conditions affecting the pharmaceutical industry primarily related to generic drug competition, obtaining additional financing, government restrictions on sale of certain products, obtaining new FDA approvals, development by competitors of new or superior products or new technology for production of products or the entry into the market of new competitors.

TWELVE MONTHS ENDED DECEMBER 31, 2002 COMPARED WITH TWELVE MONTHS ENDED DECEMBER 31, 2001

NET SALES. Net sales for the twelve months ended December 31, 2002 and 2001 were \$22,380,964 and \$5,922,431, respectively, reflecting an increase of almost 278%. The increase is due to the higher production and marketing of our existing and newly approved products following the achievement of substantial compliance with cGMPs. Currently, we manufacture and market six of the nine ANDAs which were approved by the FDA during 2001 and 2002. Net sales of these newly approved products were almost 45% of total net sales for the twelve months ended December 31, 2002. The majority of the net sales increase from sales of new products were from net sales of Metformin Hydrochloride and Tramadol Hydrochloride, 55% and 5% of net sales for the twelve months ended December 31, 2002, respectively.

Net sales have also improved for the following reasons:

- Net sales of Metoprolol Tartrate have increased significantly to \$6.60 million during the twelve months of 2002 as compared to \$1.85 during the same period of 2001.
- We have been successful in obtaining larger sales contracts in 2002 with an agency of the U.S. government, the Veterans Administration, and with one large mail order company, however, the sales of Metformin Hydrochloride to such agency have been made at lower profit margins. (See discussion on "Gross Profit" below)
- With our larger base of products, we have been able to attract both new customers as noted above, and larger orders.

GROSS PROFIT. We earned a gross profit of \$10,333,554 during the twelve

months ended December 31, 2002 as compared to a gross profit of \$1,736,372 during the corresponding period in 2001. 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 2001 and ability to absorb operational overheads due to higher sales.

As a result of increased sales, the gross profit margin has also improved when comparing the gross profit margins for the twelve month periods ending December 31, 2002 and 2001. Gross profit margin for the twelve months ended December 31, 2002 was 46% as compared to almost 29% for the twelve months ended December 31, 2002. The increases were the result of:

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- Change in sales mix to higher profit margin products such as Metoprolol Tartrate, Tramadol Hydrochloride and Oxaprozin.
- Reduction in manufacturing costs due to increased batch sizes. For example, Metoprolol Tartrate batch sizes have increased by approximately four fold.
- Improved efficiency in the overall manufacturing process associated with higher utilization of plant capacity.
- Utilization of newly installed larger and faster equipment to achieve economics of scale.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES. Selling, general and administrative expenses for the twelve months ended December 31, 2002 and 2001, respectively were \$3,827,727 and \$2,680,494 respectively, representing an increase of 43%. Selling, general and administrative expenses have effectively decreased to 14.8% of net sales during the twelve months ended December 31, 2002 from almost 37% of net sales during the same period in 2001.

The actual increase of approximately \$1,147,213 between the selling, general and administrative expenses incurred during 2002 in comparison to 2001 was due to additional legal and professional costs (\$250,000) primarily in connection with the negotiations of a new product agreement with Sun Global, litigation defense, SEC and blue sky registration, and negotiations with the EDC, costs of introducing new products into the market (\$150,000), additional sales personnel (\$40,000), increases in the salaries of sales and administrative staff (\$80,000), recording of variable compensation expense on the extension of the term of a director's stock options (\$262,000), and the balance for royalties and costs associated with development of improved services and quality measures to customers.

RESEARCH AND DEVELOPMENT EXPENSES. Cash research and development expenses of \$3,348,789 for the twelve months ended December 31, 2002 were higher by 9% when compared with \$3,079,804 incurred during the corresponding period of 2001. We incurred non-cash research and development expenses (technology transfer cost) of \$3,887,424 for the 1,632,000 shares of common stock issued to Sun Global for three product transfers made to us during 2002. There was no similar expense for the corresponding period of 2001. The major reason for the additional cash research and development expenses were the costs for three bio-study projects, for which we recorded expenditures of approximately \$593,000 during 2002.

INTEREST EXPENSE. Interest expense, which was incurred in connection with our mortgage obligation to the EDC, interest on notes payable to Sun Pharmaceutical and Sun Global as well as on term loans granted to us by ICICI Bank and the Bank of Nova Scotia, and guaranteed by Sun Pharmaceutical, was

\$1,539,075 and \$1,748,922, for the twelve months ended December 31, 2002 and 2001, respectively. The decrease in the amount of interest is due to a lower LIBOR rate on the loans from ICICI Bank of India and Bank of Nova Scotia, despite an increase in borrowing levels. Also, effective April 1, 2001, Sun Pharmaceutical and Sun Global reduced the rate of interest payable to them from 10% to 8%.

RESULTS OF OPERATIONS. The net losses for the twelve months ended December 31, 2002 and 2001 were \$2,256,004 and \$5,757,464, respectively, reflecting a reduction of almost 61%. The net losses for the twelve month periods are directly related to net sales, which were inadequate to absorb our interest costs and the impact of our non-cash technology transfer cost of \$3,887,424 recorded during the twelve months ended December 31, 2002. The significantly lower net losses in the current twelve-month period as compared to the previous period are primarily due to significantly higher sales volumes and better-cost absorption due to

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increased sales and an improved product mix. Also, the utilization in the third and fourth quarters of 2002 of \$1.59 million of new equipment installed during the twelve months ended December 31, 2002 helped to improve productivity.

YEAR ENDED DECEMBER 31, 2001 COMPARED WITH YEAR ENDED DECEMBER 31, 2000

NET SALES. Net sales for the years ended December 31, 2001 and 2000 were \$5,922,431 and \$2,377,546, respectively. While this represents a 150% increase over the previous year due to increased production and marketing of our existing products, it was still at a low level. During the third quarter, we began the manufacture and marketing of 2 of the 3 FDA approved products. The sales of these products were only a small part of the gross sales during the last six months of 2001. Sales of Metroprolol Tartrate, Guaifenesin and Paramomycin Sulfate started to see substantial increases due to the facility being cGMP approved. Gross sales from these products increased \$2.5 million, \$965,000 and \$703,000, respectively in 2001 from 2000 levels. This represented \$3.25 million of additional net sales in 2001 or 92% of the \$3.5 million increase.

GROSS PROFIT/ LOSS. We earned a gross profit of \$1,736,372 for the year ended December 31, 2001, compared to a gross loss of \$301,354 during the same period of 2000. The improvement was primarily due to higher sales volumes in the current period as compared to those during the corresponding period of 2000 and ability to absorb operational overheads due to higher sales.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES. Selling, general and administrative expenses for 2001 were \$2,680,494 compared to \$2,508,738 in 2000 for a slight increase of 7%. The increase was mainly a result of higher selling expenses of approximately \$50,000 due to increased sales and increased expenditures of \$90,000 incurred for maintaining FDA compliance.

RESEARCH AND DEVELOPMENT EXPENSES. Research and development expenses of \$3,079,804 for the year ended December 31, 2001 were approximately the same, when compared with \$3,467,267, as restated, incurred during the corresponding period of 2000. However, during 2001, we did not incur any non-cash expense in relation to shares of common stock issued in exchange for the product technology transfer by Sun Pharmaceutical. During 2000, such non-cash expenses totaled

\$401,472 as restated. The 2000 research and development expenses, and the non-cash expenses, as restated were increased in connection with the valuation of the common stock issued to Sun Pharmaceutical in exchange for the product technology transfer.

INTEREST EXPENSE. Interest expense, which was incurred in connection with our mortgage obligation to the EDC, interest on notes payable to Sun Pharmaceutical and Sun Pharma Global as well as on term loans granted to us by ICICI Bank and the Bank of Nova Scotia, and guaranteed by Sun Pharmaceutical, was \$1,748,922 and \$1,555,192, for the years ended December 31, 2001 and 2000, respectively. The increase is primarily the result of higher borrowing levels. Effective April 1, 2001, Sun Pharmaceutical and its affiliates reduced the rate of interest payable to them from 10% to 8% per annum. Interest income for 2001 and 2000 was \$15,385 and \$38,010, respectively.

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RESULTS OF OPERATIONS. Net losses for the years ended December 31, 2001 and 2000 were \$5,757,463 and \$7,794,540 as restated, respectively. This represents a reduction of 35.4% over the previous year. The operating losses were directly related to (1) net sales, which were inadequate to absorb our fixed costs of the operational expenses and (2) the impact of research and development spending. The losses were lower in 2001 compared to 2000 primarily due to higher sales volumes and better-cost absorption due to increased sales, despite higher interest expense. The 2000 operating results were restated by increasing the net loss by \$171,832 in connection with the valuation of common shares issued to Sun Pharmaceutical in exchange for the product technology transfer during 2000.

LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2003, we had negative working capital of \$2,211,655 compared with a negative working capital of \$4,693,663 at the corresponding period of 2002. The negative working capital positions as of March 31, 2003 and 2002, respectively, were mainly due to the classification of certain portions of the loans payable to Bank of Nova Scotia and ICICI Bank coming due within the next twelve months and \$5.5 million of the loans payable to Sun Pharmaceutical and Sun Global coming due in October 2003. In the first quarter of 2002, \$3,208,769 of the EDC debt was reclassified from accrued interest to principal.

To enable us to fund our research and development activities, repay certain term loans and fund working capital needs, Sun Pharmaceutical has become a security guarantor for a credit line of \$5 million from ICICI Bank of India and \$12.5 million from Bank of Nova Scotia. As of March 31, 2003, we have received \$5,000,000 from ICICI Bank of India and \$12,500,000 from Bank of Nova Scotia through these credit facilities. Further, we have received an additional short-term loan of \$500,000 during the first quarter of 2003 from Sun Pharmaceutical to help us finance our increased working capital requirements. The cash generated out of the operations has generally been sufficient to run our operations as well as repay a portion of the EDC debt.

FUTURE OUTLOOK

We have experienced difficult times in the past. With our having been

found to be in substantial compliance by the FDA with respect to cGMPs during the second quarter of 2001 and the fourth quarter of 2002, and also with the approvals of 11 ANDAs during 2001, 2002 and 2003, management feels that our future outlook is brighter. Revenues have been improving and consequently, so have operational profits, net income and cash flows. Also, management is focused on cost controls and consumption controls. Management's future plans for improving profitability, cash flow positions and operations include increased sales of existing and new approved products (see below) and infusion of additional funding through the issuance of equity. See "Business" - Caraco's Products and Product Strategy for disclosure relating to the cessation of sales of Guaifenesin LA.

Management believes that the new products agreement ("Products Agreement") with Sun Global, pursuant to which products are paid for in a newly created preferred stock and not in cash should benefit Caraco. As noted below, in "Business-Sun Pharmaceutical Industries Ltd," under the Products Agreement, we conduct, at our expense, all tests, including bioequivalency studies. The new Products Agreement, which was approved by an independent committee of directors of Caraco, provides that Sun Global, an affiliate of Sun Pharmaceutical, will provide us with 25 ANDAs in exchange for convertible preferred stock (544,000 shares of preferred stock for each ANDA). The preferred stock has a number of restrictive features. It is non-voting, does not pay dividends and, unless there is a change in control, may not be converted for a period of 3 years from the date it is earned. We believe that the new Products Agreement benefits us by, among other things, preserving our cash resources. By acquiring products for stock instead of cash or instead of for cash and for royalties, we should thereby have

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such cash available to support our operations. While the payment for products in stock would have the effect of reducing earnings or causing a loss because the stock will be valued on the respective dates on which it is earned and constitute a non-cash research and development expense, we believe that the advantages to us of preserving our cash for operations outweighs the non-cash effect on earnings. We also believe that receiving products from Sun Global, which products, it is believed, will be originated by Sun Pharmaceutical, provides us with a partner with a proven track record; one that already has provided us with quality products. In addition, the products to be selected must receive the concurrence of the independent committee. This will help provide independent input into the process of selecting products which appear likely to be economically sound. Moreover, the new Products Agreement, which will have the effect of increasing Sun Pharmaceutical's beneficial ownership in us, should, we believe, provide it with the incentive to continue to help us succeed. Sun Pharmaceutical has already provided us with millions of dollars in capital, loans, and quarantees of loans, and with personnel, active raw materials and equipment which have significantly helped us to date.

During the first quarter of 2003, we have generated substantial revenues as compared to the past. Capacity utilizations are improving and costs are being controlled. We expect revenues to improve during the rest of 2003.

Management's plans for the remainder of 2003 include:

- o Continued focus on FDA compliance.
- o Continued research and development activities.
- o Increased market share for certain existing products and recently introduced new products and enhanced customer reach and satisfaction.
- o Prompt introduction of new approved products to the market.
- o Striving to capture larger market share for existing products.
- o Achieving operational efficiencies by attaining economies of scale, cost reduction per unit, and obtaining additional cost reductions for active substances acquired from competitors and/or Sun Pharmaceutical.
- o Increase the width and depth of product portfolio to serve customers effectively.
- o Increase the number of products, as well as anticipated volume increases for existing products, which, in turn, will improve manufacturing capacity utilization.
- O Considering alternative ways of increasing cash flow including developing, manufacturing and marketing ANDAs owned by Sun Pharmaceutical.
- o Locating and utilizing facilities of contract-manufacturers to enhance production and therefore sales.

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### BUSINESS

General. We were organized under Michigan law in 1984, to engage in the business of developing, manufacturing and marketing generic drugs for the ethical or prescription and over-the-counter or non-prescription or "OTC" markets.

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

A significant source of our funding has been from private placement offerings and loans. Sun Pharmaceutical a specialty pharmaceutical corporation organized under the laws of India which currently beneficially owns approximately 49% of our outstanding shares, has contributed equity capital and has advanced us loans. Also, pursuant to a products agreement with us, Sun Pharmaceutical has transferred certain products to us. See "Current Status" and "Sun Pharmaceutical Industries Limited" below. Our manufacturing facility and

executive offices were constructed pursuant to a \$9.1 million loan in 1990 from the EDC. See "Current Status" and "Property and - EDC Financing" below.

Current Status. For the first time since inception, during the first quarter of 2003 and the second, third and fourth quarters of 2002, we achieved sales necessary to support our operations. Our net sales for the three months ended March 31, 2003 and 2002 were \$8.7 million and \$3.3 million, respectively. We earned net income of \$2.2 million for the three months ended March 31, 2003 as compared to a net loss of \$0.5 million for the same period of 2002. Net sales for the twelve months ended December 31, 2002 were \$22.4 million as compared to \$5.9 million for the twelve months ended December 31, 2001. We have incurred a nominal operating loss of \$730,365 for the twelve months ended December 31, 2002 as compared to an operating loss of \$4,023,926 for the twelve months ended December 31, 2001. After interest costs, we have incurred a net loss of \$2,256,004 for the twelve months ended December 31, 2002 as compared to a net loss of \$5,757,463 for the twelve months ended December 31, 2001. At March 31, 2003, we had a stockholders' deficit of \$17,418,541 as compared to a deficit of \$22,945,249 at December 31, 2002. We have continued to be dependent on the support of Sun Pharmaceutical, but the financial support is reduced due to the increased revenues and improved cash flows from internal operations. See "Sun Pharmaceutical Industries, Ltd." and Management's Discussion and Analysis of Financial Condition and Results of Operations" below.

We received 6 Abbreviated New Drug Application ("ANDA") approvals during the twelve months ended December 31, 2002 and 1 ANDA approval during the first quarter of 2003. See "Caraco's Products and Product Strategy" below. We also filed 3 ANDAs with the FDA during the twelve months of 2002, bringing the total pending approvals to 3.

Our debt includes term loans totaling \$17.5 million, of which \$17.3 million has been drawn down from two foreign banks and our note payable to the EDC, stands at approximately \$7.6 million as at March 31, 2003. See "Property and EDC Financing" below for a discussion of the restructuring of the EDC loan.

#### OVERVIEW OF THE GENERIC DRUG INDUSTRY

Sales of generic drugs have increased in recent years because of a number of factors including (i) modification of state laws to permit or require substitution of generic drugs by pharmacists; (ii) enactment of ANDAs procedures for obtaining FDA approval to manufacture generic prescription drugs; (iii) changes in governmental and third-party payor health care reimbursement policies to encourage cost containment; (iv) increased acceptance of generic drugs by physicians, pharmacists and consumers; and (v) the increasing number

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of formerly patented drugs which have become available to generic competition. Moreover, every year branded drugs with significant sales volumes come off-patent.

CARACO'S PRODUCTS AND PRODUCT STRATEGY

Our present product portfolio includes 14 prescription products in 24 strengths in 50 package sizes. The products and their use for the indications

are set forth in the table below:

GENERIC NAME

Miraphen PE

Clozapine

PURPOSE

Guaifenesin LA\* Metroprolol Tartrate Hyper-Tension Miraphen PSE Paromomycin Sulfate Antibacterial Salsalate CMT Guai/DM Clonazepam Flurbiprofen Carbamazepine Oxaprozin Metformin Hydrochloride Tramadol Hydrochloride

Decongestant Decongestant Decongestant Arthritis/NSAID Decongestant Seizure, Panic Disorders

Arthritis/NSAID

Epilepsy

Rheumatoid Disease

Diabetes Analgesic Decongestant Schizophrenia

The FDA has directed the manufacturers and distributors of Guaifenesin LA which, including us, consists of 66 companies, to cease manufacturing Guaifenesin LA by May 23, 2003 and to cease all sales after November 2003. The FDA has determined that Guaifenesin LA is a new drug which requires a new drug application and approval before it may be manufactured and sold. We intend to comply with the FDA's directive. We do not intend to file a new drug application with the FDA with respect to Guaifenesin LA however, we are seeking clarification from the FDA as to whether application to manufacture and sell Guaifenesin LA may be made other than through a new drug application. Net sales of Guaifenesin LA during the year ended December 31, 2002 and during the quarter ended March 31, 2003 were \$1.65 million and \$0.36 million, respectively.

We have submitted 13 ANDAs to the FDA for approval since August 1997, including 3 filed during 2002. Of these 13 ANDAs, the FDA approved 3 during 2001, 6 during 2002 and one during the first quarter of 2003. Accordingly, we have 3 pending ANDAs, most of which, we believe, may be approved by 2003 year-end. Of the 13 ANDAs, Sun Pharmaceutical has transferred the technology for 11 of them to us pursuant to its now expired products agreement. See "Sun Pharmaceutical Industries Limited" below.

Three of the ANDAs have not yet been marketed and are not included in the above disclosure of our product portfolio. The products and their use for the indications are set forth in the table below:

GENERIC NAME

PURPOSE

Meperidine Hydrochloride Digoxin

Cardiology Analgesic Cardiology

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These products, when launched, will increase our product portfolio to 17 prescription products in 29 strengths in 61 package sizes.

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

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#### HEXAL-PHARMA GMBH & CO., KG

Pursuant to an agreement between us and Hexal-Pharma GmbH & Co., KG, a German pharmaceutical company and its United States affiliate (together, "Hexal") dated as of October 1, 1993, Hexal agreed to convey to us the formulations, technology, manufacturing processes and know-how, and other relevant information, and to pay for the bioequivalency studies required for the preparation of ANDAs for each of two specified generic drugs (the "Products"). We agreed to pay Hexal royalties on the yearly sales of each Product. We filed an ANDA in March 1995 with respect to Metoprolol Tartrate, received approval from the FDA in December 1996 and introduced it in 1997. Metoprolol Tartrate is one of our 14 current products. See "Caraco's Products and Product Strategy." Hexal has decided not to proceed with the development of the second Product.

Pursuant to the agreement, with respect to the Products Hexal was granted, (i) a Sign-Up Option, effective on the date the agreement was signed, to purchase 100,000 shares of our common stock at \$3.50 per share; and (ii) a Product Option, effective on the date the ANDA relating to the Product was filed with the FDA, to purchase an indeterminate number of our shares at an exercise price of \$3.50 per share. These options may be exercised and payment for shares may be made only out of royalties, and any interest earned on the royalties while held by us, payable to Hexal for sales of the product. No options have yet been exercised. Royalties payable to Hexal, which are included in accrued expenses, amount to \$801,144 at December 31, 2002.

We have recently learned that the formula provided to us by Hexal with respect to Metoprolol Tartrate may be different than the formula currently used for manufacturing, and we are investigating further whether or not we should continue to accrue royalties based on the formula differences. If we find that the formula as provided by Hexal is indeed different from ours, we would cease to accrue any royalties.

#### SUN PHARMACEUTICAL INDUSTRIES LIMITED

Pursuant to a stock purchase agreement, Sun Pharmaceutical had, as of December 31, 1998, remitted a total of \$7.5 million to us for the purchase of 5.3 million common shares.

On October 15, 1998 Sun Pharmaceutical also made a loan to us of \$5.3 million at an annual interest rate of 10%. This loan was amended to provide Sun Pharmaceutical with a security interest subordinated to the loan of the EDC. The loan is payable in full in October 2003. The rate of interest on the loan from Sun Pharmaceutical has been reduced from 10% to 8% effective April 1, 2001. In 2001, Sun Pharmaceutical loaned us an additional \$2.45 million at an interest rate of 8%. During the first quarter of 2002, Sun Pharmaceutical loaned us an additional \$1.4 million at an interest rate of 8%. The \$2.45 million and \$1.4 million loans mature and are due and payable on August 31, 2006. During the first quarter of 2003, Sun Pharmaceutical loaned us \$500,000 at an interest rate of 8.0% payable on demand. Prior to this, Sun Global, made a loan to us of \$650,000 at an annual interest rate of 10%. We have repaid \$100,000 of this loan during 2001 and \$350,000 during the first quarter of 2003. The interest rate on this loan has also been reduced by Sun Global from 10% to 8% effective April 1, 2001. The loan is payable in full in October 2003.

Sun Pharmaceutical has assisted us in obtaining line of credit loans from ICICI Bank Limited and The Bank of Nova Scotia in the amount of \$5.0 million and \$12.5 million, respectively. We have utilized, \$5 million from ICICI Bank Limited and \$12.3 million from The Bank of Nova Scotia. The amounts borrowed under the ICICI Bank Limited credit facility must be repaid in eight equal quarterly installments beginning

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December 31, 2003 and ending September 30, 2005. The amounts borrowed under The Bank of Nova Scotia credit facility must be repaid in four semi-annual installments on February 4, 2004, August 24, 2004, February 24, 2005 and August 25, 2005. The loan may not be prepaid until August 24, 2003. Interest is at LIBOR plus 140 basis points on the loan from ICICI Bank Limited and LIBOR plus 155 basis points on the loan from The Bank of Nova Scotia, and is payable at one, two, three or six months periods at our option.

In August 1997, we entered into an agreement (the "Products Agreement"), whereby Sun Pharmaceutical was required to transfer to us the technology formula for 25 generic pharmaceutical products over a period of five years through August 2002. We exchanged 544,000 shares of our common stock for each ANDA product, generally when a bio-equivalency study is successfully

completed and 181,333 shares for each DESI ("Drug Efficacy Study Implementation") product. The products provided to us from Sun Pharmaceutical were selected by mutual agreement. Under such agreement, which has expired, we conducted, at our expense, all tests including bioequivalency studies. Also, under such agreement, Sun Pharmaceutical delivered to us the formula for 13 products and Sun Pharmaceutical and its affiliates were issued 5,802,666 shares of our common stock in exchange therefor. Sun Pharmaceutical currently beneficially owns approximately 49% of our outstanding common stock.

On November 21, 2002, we entered into a products agreement with Sun Global. Under the agreement, which was approved by our independent directors, Sun Global has agreed to provide us with 25 new generic drugs over a five year period. Our rights to the products are limited to the United States and its territories or possessions, including Puerto Rico. Sun Global retains rights to the products in all other territories. Under such agreement, we conduct, at our expense, all tests including bioequivalency studies. We are also obligated to market the products consistent with our customary practices. and to provide marketing personnel. In return for the technology transfer, Sun Global will receive 544,000 shares of a newly created preferred stock for each generic drug transferred when such drug has passed its bioequivalency study. To date, no shares of preferred stock have been earned by or issued to Sun Global. 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. See "Management's Discussion and Analysis of Financial Condition and Results of Operations - Future Outlook."

Sun Pharmaceutical has established a Research and Development Center in Mumbai with a staff of 30 persons, including PhDs, pharmacy graduates, analytical chemists and regulatory professionals. Sun Pharmaceutical primarily performs formulation and analytical development work for us at this laboratory.

Sun Pharmaceutical also supplies us with certain active raw materials and machinery and equipment to enhance our production capacities. In the year ended December 31, 2002, we purchased approximately \$2,422,000 in active raw materials, and purchased and leased \$310,000 and \$33,960, respectively, in machinery and equipment from Sun Pharmaceutical. Sun Pharmaceutical has also provided us with qualified technical professionals. Twenty-one of our technical professional employees were former Sun Pharmaceutical employees.

### MARKETING

Our marketing objective has been to create a distribution system by which to obtain access to a wide range of purchasers of generic pharmaceutical products. Internally, this requires at least a minimum sales force. See "Sales and Customers" below. Externally, it requires forging relationships with wholesaler buying groups, distributors and mail order companies, among others. Management is aware that, despite any success in creating these distribution links, sales volume will remain low until we can offer a broader range of

products needed by drug purchasers in significant amounts.

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

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

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

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

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

#### SALES AND CUSTOMERS

Presently, we have only a small in-house sales organization comprised of 4 persons. In time as new products are added to the existing product line, we plan to expand our customer sales effort through adding additional sales personnel and/or contracting with an independent sales and marketing firm.

Shipments to one wholesale customer, Amerisource Bergen, accounted for approximately 65% and 35% of sales in 2002 and 2001, respectively. Balances due from this customer represented approximately 80% and 40% of accounts receivable at December 31, 2002 and 2001, respectively. As disclosed above under "Marketing," certain of our customers purchase our products through designated wholesale customers, such as Amerisource Bergen who act as an intermediary distribution channel for our products. For example, the Veterans Administration, which has entered into the sales contract discussed below, has selected Amerisource Bergen as its designated wholesaler.

We have entered into a sales contract with the Veterans Administration, an agency of the U.S. government. Our agreement with this customer is for the period of June 21, 2002 through June 20, 2003 ("base contract period"), with four 1-year option periods and is for the purchase of one product, Metformin

Hydrochloride. 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 approximately \$13.0 million of product should be shipped to the customer over the base contract period, and further provides that certain penalties would be incurred if we are unable to meet our sales commitment.

#### RESEARCH AND DEVELOPMENT

The development of new prescription ANDA products, including formulation, stability testing and the FDA approval process, averages from two to five years. A drug is "bioequivalent" to a brand-name drug if the rate and e