# [QUESTCOR LETTERHEAD]

June 15, 2005

## **VIA FACSIMILE AND EDGAR**

U.S. Securities and Exchange Commission 450 Fifth Street, N.W. Washington, D.C. 20549

Attention: Jim B. Rosenberg, Senior Assistant Chief Accountant

RE: Questcor Pharmaceuticals, Inc.

Form 10-K for the fiscal year ended December 31, 2004

File No. 1-14758

## Dear Mr. Rosenberg:

Questcor Pharmaceuticals, Inc. (the "Company") is in receipt of your letter dated May 3, 2005 with respect to the Company's Form 10-K for the fiscal year ended December 31, 2004 ("Form 10-K"). We have responded to your comments as set forth below. For ease of reference, we have set forth the Staff's comments and the Company's response for each item below. Capitalized terms used but not otherwise defined herein have the meanings assigned to such terms in Form 10-K.

## Management's Discussion and Analysis of Financial Condition and Results of Operations

## **Critical Accounting Policies**

## Sales Reserves, Product Returns, and Rebates, pages 28-30

- 1. Staff Comment No. 1: We believe your disclosure related to estimates of items that reduce gross revenue such as product returns and rebates could be improved as follows:
- a. Staff Comment No. 1a: Disclose the nature and amount of each accrual at the balance sheet date and the effect that could result from using other reasonably likely assumptions than what you used to arrive at each accrual such as a range of reasonably likely amounts or other type of sensitivity analysis.

Company Response: The Company describes and discloses in Item 7, Management's Discussion and Analysis, Critical Accounting Policies, on page 28 of Form 10-K, the nature of the accruals for which the related expenses reduce gross revenue, namely expenses resulting from reserves for product returns, government chargebacks, Medicaid rebates, and cash discounts. In the Company's opinion, no other accruals are or should be recorded the expense related to which would reduce gross revenue under generally accepted accounting principles.

With the exception of the reserve for product returns under the credit memoranda policy, the amounts of the sales accruals or reserves are not individually material in relation to total current liabilities or total liabilities and shareholders' equity as of December 31, 2004. The sum of the reserves for government chargebacks, Medicaid rebates, and replacements under the product exchange policy constitutes less than 8% of total current liabilities and less than 3% of total liabilities and shareholders' equity. The allowance for cash discounts constitutes less than 2% of accounts receivable before allowances for doubtful accounts and cash discounts. The reserve for product returns under the credit memoranda policy, which is material and is disclosed separately, constitutes approximately 12% and approximately 4% of total current liabilities and total liabilities and shareholders' equity, respectively. The amount of the reserve for product returns under the credit memoranda policy is disclosed individually in Management's Discussion and Analysis, Critical Accounting Policies, on page 29 of Form 10-K, and in Note 1 to the Consolidated Financial Statements, on page 64 of Form 10-K.

The expenses related to the sales reserves are not individually material in relation to gross sales for either 2003 or 2004. For 2003, none of the expenses related to the sales reserves individually constituted more than 4% of product sales before deduction of such expenses, and in total were less than 9% of product sales before deduction of such expenses. For 2004, none of the expenses related to the sales reserves, other than the reserve for product returns under the credit memoranda policy, individually constituted more than 4% of product sales before deduction of such expenses, and in total were less than 8% of product sales before deduction of such expenses. The 2004 expense related to the reserve for product returns under the credit memoranda policy is individually disclosed in Form 10-K, as described in the preceding paragraph.

The Company believes that the assumptions used to estimate the sales reserves are the most reasonably likely assumptions and that the range of other substantially less likely assumptions would not produce results materially different from those which were recorded.

b. Staff Comment No. 1b: Disclose the factors that you consider in estimating each accrual such as historical return of products, levels of inventory in the distribution channel, estimated remaining shelf life, price changes from competitors and introductions of generics and/or new products.

The Company has disclosed all factors considered in estimating each sales reserve accrual in Item 7, Management's Discussion and Analysis, Critical Accounting Policies, and in Note 1 to the Financial Statements of Form 10-K.

The Company considers the following factors in estimating product returns from wholesalers, hospitals and pharmacies: i) historical returns and sales patterns; ii) current inventory on hand at wholesalers and the remaining shelf life of that inventory; iii) changes in demand measured by prescriptions or other data as provided by an independent third party source and the Company's internal estimates; iv) analysis of return merchandise authorizations; and v) returns received. These factors are disclosed in Item 7, Management's Discussion and Analysis, Critical Accounting Policies, on page 29 of Form 10-K, and in Note 1 to the Consolidated Financial Statements on page 63 of Form 10-K.

The Company considers the following factors in estimating government chargebacks for goods purchased by certain Federal government organizations including the Veterans Administration: i) actual chargeback amounts by product; and ii) sales to which chargebacks apply. These factors are disclosed in Item 7, Management's Discussion and Analysis, Critical Accounting Policies, on page 30 of Form 10-K.

The Company considers the following factors in estimating Medicaid rebates: i) historical percentage of actual rebates to quantity of product sold by pharmacies; ii) sales to which rebates apply; and iii) Medicaid allowable prices. These factors are disclosed in Item 7, Management's Discussion and Analysis, Critical Accounting Policies, on page 30 of Form 10-K.

c. Staff Comment No. 1c: To the extent that information you consider in b) is quantifiable, disclose both quantitative and qualitative information and discuss to what extent information is from external sources, such as end-customer prescription demand, third-party market research data comparing wholesaler inventory levels to end-customer demand. For example, in discussing your estimate of product that may be returned, consider disclosing and discussing, preferably by product and in tabular format, the total amount of product in sales dollars that could be potentially be returned as of the balance sheet date and disaggregated by expiration period.

Company Response: The Company discloses which factors used in estimating sales reserves are based on external information sources and which are based on internally-generated data in its descriptions of the factors which it uses. As described in the Company's response to Staff Comment 1b, the following are factors based on external information sources: i) current inventory on hand at wholesalers; ii) changes in demand measured by prescriptions or other data as provided by an independent third party source; iii) quantity of product sold by pharmacies; and v) Medicaid allowable prices.

The factors which the Company considers in estimating each sales reserve accrual are not individually quantitatively significant to the estimation. The Company uses a combination of individual factors in estimating each sales reserve accrual, as described in the Company's response to Staff Comment 1b, so that disclosure of each individual factor would not provide information meaningful to an evaluation of the Company's financial position or results of operations.

The Company discloses the total amount of product in sales dollars that could potentially be returned under the Company's credit memoranda policy as of the balance sheet date in Item 7, Management's Discussion and Analysis, Critical Accounting Policies, on page 29 of Form 10-K in the statement, "A reserve for the sales value of estimated returns on shipments of Acthar and Nascobal product lots released and shipped after May 31, 2004 has been recorded as a liability in the amount of \$1,054,000 as of December 31, 2004." The Company proposes to provide additional disclosure regarding the gross sales value of product which customers have requested to be replaced, which has not yet been replaced as of December 31, 2004. Exhibit A attached herewith presents the Company's proposed revision to Form 10-K, Item 7, Management's Discussion and Analysis, Results of Operations, for the fiscal year ended December 31, 2004. The Company does not accept product returns for Glofil and VSL#3.

As product returns are accepted for a six-month period after expiration of the product lot, and the Company is unable to predict with certainty when within that six-month period the product returns may occur, the Company believes that presentation of potential product returns in sales dollars disaggregated by expiration period would not provide information meaningful to an evaluation of the Company's financial position or results of operations.

d. Staff Comment No. 1d: If applicable, discuss any shipments made as a result of incentives and/or in excess of your customer's ordinary course of business inventory level. Discuss your revenue recognition policy for such shipments.

Company Response: The Company does not give any incentives to its customers to encourage product sales, and therefore discussion of a revenue recognition policy relating to such incentives is not applicable. Volume discounts were given for purchases of VSL#3, but such discounts were offered in the normal course of business to all customers throughout the year, were not restricted as to customer or time period, and are reflected in net product sales. Net product sales for VSL#3 in fiscal year 2004 represented approximately 8% of total net product sales. Volume discounts for VSL#3 represented approximately 12% of VSL#3 gross product sales, and less than 1% of total gross product sales. Therefore, the Company believes that disclosure of volume discounts given for purchases of VSL#3 is not meaningful nor is it material to the financial results. In January 2005, the VSL#3 promotion agreement expired in accordance with its terms, and the product will be sold in the future by Sigma-Tau Pharmaceuticals.

The business inventory levels of the Company's wholesaler customers vary continuously based upon prescription demand and its customers' individual and unique internal business operating policies and requirements. The Company is not privy to its customers' business operating policies and requirements regarding inventory levels, and therefore has no knowledge as to what its customers' "ordinary course of business inventory level" is. Therefore, the Company believes that a discussion of a revenue recognition policy relating to such shipments, if any, is not applicable.

# e. Staff Comment No. 1e: You should consider disclosing a roll forward of the accrual for each estimate for each period presented showing the following:

- Beginning balance,
- Current provision related to sales made in current period,
- Current provision related to sales made in prior periods
- Actual returns or credits in current period related to sales made in current period,
- Actual returns or credits in current period related to sales made in prior periods, and
- Ending balance.

Company Response: The Company believes the roll forward disclosure contained in Schedule II Valuation and Qualifying Accounts in Form 10-K provides adequate disclosure of transactions relating to sales reserves, considering the relative dollar amount of the liabilities recorded and the nature of the Company's business operations. In addition, it is not practical or possible for the Company to provide information on actual returns or credits by period in which related sales were made.

With the exception of the reserve for product returns under the credit memoranda policy, the amounts of the sales accruals or reserves are not individually material in relation to total current liabilities or total liabilities and shareholders' equity as of December 31, 2004. The sum of the reserves for government chargebacks, Medicaid rebates, and replacements under the product exchange policy constitutes less than 8% of total current liabilities and less than 3% of total liabilities and shareholders' equity. The allowance for cash discounts constitutes less than 2% of accounts receivable before allowances for doubtful accounts and cash discounts. The reserve for product returns under the credit memoranda policy, which is material and is disclosed separately, constitutes approximately 12% and approximately 4% of total current liabilities and total liabilities and shareholders' equity, respectively. The amount of the reserve for product returns under the credit memoranda policy is disclosed individually in Management's Discussion and Analysis, Critical Accounting Policies, on page 29 of Form 10-K, and in Note 1 to the Consolidated Financial Statements, on page 64 of Form 10-K.

The expenses related to the sales reserves are not individually material in relation to gross sales for either 2003 or 2004. For 2003, none of the expenses related to the sales reserves individually constituted more than 4% of product sales before deduction of such expenses, and in total were less than 9% of product sales before deduction of such expenses. For 2004, none of the expenses related to the sales reserves, other than the reserve for product returns under the credit memoranda policy, individually constituted more than 4% of product sales before deduction of such expenses, and in total were less than 8% of product sales before deduction of such expenses. The 2004 expense related to the reserve for product returns under the credit memoranda policy is individually disclosed in Form 10-K, as described in the preceding paragraph.

The current period expense recorded for each sales reserve relates primarily to sales made in the current period. The Company believes any portion of the current period expense which might relate to prior period sales would be the result of adjustments to factors used in estimating the provision. The Company believes such adjustments are not material in relation to the current period expense.

The Company sells products to wholesalers, who in turn sell these products to pharmacies and hospitals. The hospitals or state Medicaid agencies are the entities which submit requests for VA chargebacks or Medicaid rebates to the Company. The Company believes it is not practical and may not even be possible to determine when the hospital or state Medicaid agency purchased product from the wholesaler, and correspondingly when that wholesaler purchased that product from the Company. Therefore, it is not possible for the Company to match VA chargebacks or Medicaid rebates with sales made during a particular fiscal year.

Product returns can be identified with a particular product lot, however, such lots are not sold within discrete fiscal years. Therefore, it is not possible for the Company to match returns with sales made during a particular fiscal year.

f. Staff Comment No. 1f: In your discussion of results of operations for the period to period revenue comparisons, discuss the amount of and reason for fluctuations for each type of reduction of gross revenue, i.e. product returns, customer rebates and other discounts and allowances, including the effect that changes in your estimates of these items had on your revenues and operations.

Company Response: The Company believes that the amounts of the reduction of gross revenue related to sales reserve accruals are not individually material in relation to gross product sales for either 2003 or 2004, with the exception of the reserve for product returns under the credit memoranda policy, which is disclosed in Item 7, Management's Discussion and Analysis, Results of Operations, on page 32 of Form 10-K. The Company's response to Staff Comment No. 1a presents the relative values of the expenses related to sales reserve accruals in relation to gross product sales.

The Company believes that changes in the assumptions used to estimate the sales reserves have not produced a material effect on revenues and results of operations between the fiscal years presented.

#### **Results of Operations, pages 31-41**

2. Staff Comment No. 2: Please revise the comparison of years to discuss and quantify the reasons for each significant factor that resulted in significant increases or decreases in line items on your financial statements. Refer to Financial Reporting Codification Section 501.04. Based on your existing disclosures, it appears that you could have better quantified your discussion regarding your revenue items.

Company Response: In accordance with the Staff's comment, the Company proposes to revise its discussion of results of operations to expand the discussion and quantification of significant revenue items. Exhibit A attached herewith presents the Company's proposed revisions to Form 10-K, Item 7, Management's Discussion and Analysis, Results of Operations, for the fiscal year ended December 31, 2004.

3 Staff Comment No. 3: Notwithstanding the preceding, it would also appear based upon existing disclosures that a material amount of the fluctuations within the current year were the result of the change in the return policy. Please disclose the amount of the fluctuation due to the change in the return policy for net product sales, cost of product sales and gross margin.

Company Response: The Company disclosed the amount of the fluctuation of net product sales due to the credit memoranda return policy in Form 10-K, Item 7, Management's Discussion and Analysis, Results of Operations, page 32, in the sentence "During fiscal year 2004, reserves for credit memoranda for Acthar and Nascobal totaling \$1,054,000 were recorded as a reduction to gross revenue."

In accordance with the Staff's comment, the Company proposes to disclose the amount of the fluctuation of cost of product sales due to the change from the product exchange policy to the credit memoranda policy. Exhibit A attached herewith presents the Company's proposed revision to Form 10-K, Item 7, Management's Discussion and Analysis, Cost of Product Sales, for the fiscal year ended December 31, 2004.

In accordance with the Staff's comment No. 4 (as noted below), the Company proposes to delete the discussion of gross margin from Results of Operations on pages 34 and 39 of Form 10-K. Exhibit A attached herewith presents the Company's proposed revision to Form 10-K, Item 7, Management's Discussion and Analysis, Results of Operations, for the fiscal year ended December 31, 2004.

#### **Consolidated Financial Statements**

## Consolidated Statements of Operations, page 58

4. Staff Comment No. 4: It appears that amortization of purchased technology is classified as an operating cost and expense. We believe amortization related to purchased technology should be included in cost of product sales. Alternatively, include a parenthetical disclosure after the caption 'cost of product sales' indicating omission of amortization of purchased technology and disclose the amount of amortization and impairment of purchased technology excluded in the notes. Please refer to SAB Topic 11:B. Please note, discussion of gross margin excluding amortization and impairment of purchased technology should be avoided.

Company Response: The Company classifies amortization of purchased technology as an operating cost and expense, as the Company does not report product gross margin on the Consolidated Statement of Operations. The Company has disclosed the amount and classification of amortization of purchased technology in Note 7 to the Consolidated Financial Statements on page 69 of Form 10-K. In accordance with the Staff's comment, the Company proposes to provide a parenthetical disclosure after the caption 'cost of product sales' on the Consolidated Statements of Operations to indicate the absence of amortization of purchased technology from this line item of the statement. Exhibit B attached herewith presents the Company's proposed revision to Form 10-K, Consolidated Statements of Operations, for the fiscal year ended December 31, 2004.

In accordance with the Staff's comment, the Company proposes to delete the discussion of gross margin from Results of Operations on pages 34 and 39 of Form 10-K. Exhibit A attached herewith presents the Company's proposed revision to Form 10-K, Item 7, Management's Discussion and Analysis, Results of Operations, for the fiscal year ended December 31, 2004.

#### **Note to Consolidated Financial Statements**

# General

5. Staff Comment No. 5: It does not appear that you have provided the disclosure required by paragraph 37 of FAS 131. Provide revenue by product or groups of similar products such as therapeutic category.

Company Response: The Company believes that it operates in one reportable operating segment, and that its products constitute a group of similar products. The nature of the Company's products is similar, in that each is a therapeutic pharmaceutical drug. Each product is distributed in a similar manner, and is sold to the same type or class of customer, with the exception of VSL#3. The nature

of the regulatory environment for the Company's products is similar, with the exception of VSL#3.

VSL#3 was sold directly to consumers, whereas the Company's other products are sold to wholesalers, who in turn sell these products to pharmacies and hospitals. VSL#3 does not require a prescription to purchase, unlike the Company's other products. However, VSL#3 net sales in fiscal year 2004 represented approximately 8% of total net sales, and the Company believes that revenue from VSL#3 may be included with other product revenue based on materiality.

The Company believes that its products and the revenue generated by those products are similar, and that its disclosures are in accordance with paragraph 37 of FAS 131.

## Note 1. Organization and Summary of Significant Accounting Policies

#### **Revenue Recognition, page 63**

6. Staff Comment No. 6: We note your accounting policies for returns received for product lots released prior to June 1, 2004 of recording costs for such exchanges, including actual product material costs and related shipping charges, within cost of products sales. Please tell us how this policy complies with paragraph 7 of FAS 48 that requires that you reduce sales and cost of sales reported in the income statement to reflect estimated returns.

Company Response: The Company's product exchange policy, which applies to product lots released prior to June 1, 2004, allows customers to return expired product for exchange during the six month period following the product's expiration date. The return period may occur anywhere from six months to two years or more after the sale of the product, depending on the expiration date of the product being sold. The Company records the cost of replacing product returned after expiration in accordance with FAS 5. At the time of sale, it is probable that a certain proportion of the product sold will be replaced in accordance with the product exchange policy, and costs associated with the product replaced can be reasonably estimated based on current costs and historical returns experience. The Company believes it is appropriate to match the cost of the replaced product with sales in the period of the sale to which the replaced product relates. The replaced product is issued with no additional or subsequent sale recorded. As the cost of replacement represents an ongoing cost of providing the product, rather than a reduction or adjustment of the sales price of the product, the Company believes that such cost, including the related shipping charges, is appropriately included in cost of goods sold.

Note 2. Development and Collaboration Agreements, pages 66-67

7. Staff Comment No. 7: We note that you pay quarterly access fees to Sigma-Tau Pharmaceuticals which vary based upon sales and costs incurred. Please provide to us additional information regarding this arrangement including each parties responsibilities under the agreement, how the access fee is specifically calculated, where these amounts are classified in the Consolidated Statement of Operations, and your basis for the current accounting treatment. Please make specific references to any GAAP literature relied upon to support your current accounting treatment.

Company Response: Under the terms of the promotion agreement and amendments to the promotion agreement with Sigma-Tau Pharmaceuticals (formerly VSL Pharmaceuticals), the Company agreed to purchase VSL#3 product from Sigma-Tau Pharmaceuticals at a stated price, and also agreed to promote, sell, warehouse and distribute the VSL#3 product directly to customers at its cost and expense. These responsibilities of the Company are described in Note 2 to the Consolidated Financial Statements, on pages 66 and 67 of Form 10-K. The responsibilities of Sigma-Tau Pharmaceuticals, which are not specifically described in Form 10-K, were to manufacture or acquire VSL#3 and maintain all required insurance and regulatory approvals and compliance.

As described in Note 2, the Company paid a quarterly access fee which varied based upon sales and costs incurred by the Company during that period. Specifically, the access fee was calculated as net sales less: i) a specified percentage of net sales depending upon total net sales for the year; ii) the greater of 20% of net sales or the fully burdened cost of engaging in all of the Company's obligations under the agreement; and iii) amounts paid by the Company for the purchase of product. All sales of VSL#3 were to third parties, unrelated to the Company or Sigma-Tau Pharmaceuticals.

As described in Note 13 to the Consolidated Financial Statements on page 82 of Form 10-K, the access fee is included in Selling, General and Administrative expense, as an expense of marketing and promoting the product.

#### **Acknowledgements**

The undersigned, on behalf of the Company, acknowledges the following:

- The Company is responsible for the adequacy and accuracy of the disclosure in the filings;
- The Staff's comments or changes to disclosure in response to Staff comments in the filings reviewed by the Staff do not foreclose the United States Securities and Exchange Commission (the "Commission") from taking any action with respect to the filing; and

• The Company may not assert Staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Please feel free to contact the undersigned at (510) 400-0728 should you have any questions and/or comments to this response.

Very truly yours,
/s/ Barbara J. McKee
Barbara J. McKee
Director of Finance and Principal
Accounting Officer

Cc: David A. Hahn, Esq.

#### Exhibit A

## **Results of Operations**

## Year Ended December 31, 2004 Compared to the Year Ended December 31, 2003

Total Revenues

			s Ended nber 31,				
	20	2004 2003			In (D (In \$000's)	%	
Net product sales	\$ 1	18,404	\$	13,655	\$	4,749	35%
Contract research, grant and royalty revenue		_		58		(58)	(100)%
Technology revenue		_		350		(350)	(100)%
Total revenues	\$ 1	18,404	\$	14,063	\$	4,341	<u>31</u> %

Total revenues for the year ended December 31, 2004 increased \$4,341,000, or 31%, from the year ended December 31, 2003 due to increases in net product sales, as explained below.

For the year ended December 31, 2004, net product sales increased by \$4,749,000, or 35%, from the year ended December 31, 2003. The increase in net product sales is primarily the result of revenue from a full year of sales of Nascobal, which was acquired in June 2003, and also reflects higher net product sales of Acthar, Ethamolin and VSL#3. In addition, net product sales for fiscal year 2004 include \$325,000 of shipments to wholesalers in January 2004 for orders received in December 2003. We expect quarterly fluctuations in the net sales of all our products due to the timing of shipments, changes in wholesaler inventory levels, expiration dates of products sold, the timing of replacement units shipped under our exchange policy, the impact of reserves provided for under our credit memoranda return policy and the reallocation of promotional efforts for each product.

#### Acthar

For the year ended December 31, 2004, net product sales of Acthar increased 2% or \$196,000 from the year ended December 31, 2003. Increased Acthar net product sales resulted from a higher average selling price and increased demand in the fourth quarter of 2004 as compared to fiscal year 2003. The average selling price of Acthar for the year ended December 31, 2004 increased approximately 7% as compared to the year ended December 31, 2003. This increase in the average selling price contributed approximately 70% of the increase in Acthar gross product sales as compared to the prior year. These increases were offset in part by reserves recorded under our credit memoranda return policy initiated in the second quarter of 2004. During fiscal year 2004, reserves for credit memoranda for Acthar and Nascobal totaling \$1,054,000 were recorded as a reduction to gross revenue.

The estimated demand for Acthar as measured by prescriptions reported from an independent source increased by 7% in 2004 as compared to 2003. The demand for Acthar increased significantly in the fourth quarter of 2004 as compared to each of the previous three quarters in 2004. The higher level of volume in the fourth quarter of 2004 did not continue beyond February 2005.

Our product exchange policy for expired product remains in effect for lots of Acthar released prior to June 1, 2004. During fiscal year 2004, under our product exchange policy we replaced vials of Acthar with an estimated sales value of \$980,000 calculated using the unit prices in effect at December 31, 2004. The Acthar returns which were replaced were from lots which expired in May 2003 and January 2004. As of December 31, 2004, customers have requested the replacement under our product exchange policy of expired Acthar with a gross sales value of approximately \$490,000 which we have not yet replaced. The replacement of expired product, at no cost to the customers, displaced sales in fiscal year 2004 and is expected to continue to displace sales as product expires and is subsequently replaced. We have recorded reserves for future replacements at the estimated cost of such exchanges. In addition, until the transition from our product exchange policy to a

credit memoranda return policy is complete in 2006, both the product exchange policy and the credit memoranda return policy will be in effect at the same time. This will result in lower revenues than historically experienced due to the additional impact of displacement of future sales from the product exchange policy and reduction of gross product sales for the reserves under the credit memoranda return policy.

The next lot of Acthar expires in May 2005 and replacements for the expired Acthar relating to this lot, and the lot that expired in December 2004, will occur in fiscal year 2005. During fiscal year 2003, under our product exchange policy we shipped replacement units of expired products with an estimated sales value of \$2.3 million calculated using the unit prices in effect at December 31, 2003. In fiscal year 2002 and fiscal year 2001, our Acthar vials sold had a one year shelf life and in the first quarter fiscal year 2003 we began shipping Acthar with an 18 month shelf life. Due to the short shelf life of Acthar, significant quantities could expire at the wholesaler or pharmacy level, which would then be returned for replacement product under our product exchange policy, or for credit under our credit memoranda return policy.

#### Nascobal

Nascobal was acquired in June 2003, and sales commenced in July 2003. Net product sales of Nascobal for the year ended December 31, 2004 increased 193% or \$4,047,000 from the year ended December 31, 2003. The increase in net product sales was due to increased volume of sales and was primarily the result of a full year of sales for 2004 and expanded promotional efforts focused on this product in 2004.

The increase in Nascobal net sales in fiscal year 2004 was partially reduced by the reserves recorded under our credit memoranda return policy. We commenced shipments of a new lot of Nascobal in July 2004, which are subject to the credit memoranda return policy. During fiscal year 2004, reserves for credit memoranda for Nascobal and Acthar totaling \$1,054,000 were recorded as a reduction to gross product sales.

#### Ethamolin

For the year ended December 31, 2004, net product sales of Ethamolin increased 10% or \$156,000 from the year ended December 31, 2003. The increase in fiscal year 2004 is primarily a result of increased demand for Ethamolin. Total unit sales of Ethamolin for the year ended December 31, 2004 increased by approximately 9% as compared to the year ended December 31, 2003. The increase was also partially the result of lower shipments in the first quarter of 2003 resulting from the impact of advanced buying by wholesalers in mid-2002 after we pre-announced a price increase. From the date of notification of the price increase through June 30, 2002, we received \$1,560,000 of Ethamolin orders, which we believe were in excess of actual prescription needs and negatively impacted sales in the remainder of fiscal year 2002 and fiscal year 2003. The demand for all sclerosing agents as measured by total prescriptions increased in fiscal year 2004 by approximately 14% from fiscal year 2003, and the increase in demand for Ethamolin was approximately 25%. In fiscal year 2004 we did not actively promote Ethamolin and we do not expect to actively promote the product in fiscal year 2005.

During the year ended December 31, 2004, under our product exchange policy we replaced units of Ethamolin at no cost having a sales value of approximately \$251,000 calculated using the unit prices in effect at December 31, 2004. As of December 31, 2004, customers have requested the replacement under our product exchange policy of expired Ethamolin with a gross sales value of approximately \$320,000. During fiscal year 2004, the Ethamolin lots shipped were not subject to the credit memoranda return policy.

#### VSL#3

For the year ended December 31, 2004, net product sales of VSL#3 increased 48% or \$474,000 from the year ended December 31, 2003. The increase in net sales was attributed primarily to increased promotion efforts focused on VSL#3 during fiscal year 2004. Sigma-Tau Pharmaceuticals entered into a promotion agreement with InKine Pharmaceutical Company, Inc. ("InKine"). Under the terms of the agreement, Sigma-Tau Pharmaceuticals paid InKine a fixed fee to promote VSL#3 to gastroenterologists. We may have benefited from this increased promotion effort in fiscal year 2004 in that we were responsible for taking orders

and shipping VSL#3 directly to customers. We recognized the revenues for the sales of VSL#3 in the United States regardless of which company promoted the product.

In January 2005, our VSL#3 promotion agreement expired in accordance with its terms. The product will be promoted in the future by Sigma-Tau Pharmaceuticals.

Glofil-125

For the year ended December 31, 2004, net product sales of Glofil-125 decreased by 6% or \$52,000 from the year ended December 31, 2003. In fiscal year 2004, we did not actively promote Glofil-125 and do not intend to actively promote it in the future.

Inulin

For the year ended December 31, 2004, sales of Inulin decreased by 97% or \$73,000 from the year ended December 31, 2003. Due to minimal demand, increasing cost of production and lack of strategic fit, we discontinued marketing and selling Inulin in September 2003. During the year ended December 31, 2004, we sold our remaining Inulin inventory for \$2,000.

#### **Contract Research, Grant and Royalty Revenue**

We did not recognize any contract research, grant and royalty revenue for the year ended December 31, 2004. Contract research, grant and royalty revenue of \$58,000 in fiscal year 2003 represented reimbursement under our Small Business Innovation Research ("SBIR") grant related to our Glial Excitotoxin Release Inhibitors ("GERI") compound research project. Our SBIR grant terminated in July 2003.

#### **Technology Revenue**

We did not recognize any technology revenue for the year ended December 31, 2004. For the year ended December 31, 2003, we recognized \$350,000 in technology revenue primarily from our License Agreement with Fabre-Kramer Pharmaceuticals, Inc. ("Fabre-Kramer") and the sale of certain patents.

#### **Cost of Product Sales**

Cost of product sales increased \$157,000, or 4%, to \$3,730,000 for the year ended December 31, 2004 from \$3,573,000 for the year ended December 31, 2003. Cost of product sales includes material cost, packaging, warehousing and distribution, product liability insurance, royalties, quality control, quality assurance and estimated provision for excess or obsolete inventory. The increase in cost of product sales is primarily due to increases in material costs as a result of higher volume of product sales in fiscal year 2004, increases in product stability testing costs of \$256,000, and increases in distribution costs of \$350,000. During fiscal year 2004, two of the largest wholesalers began charging a fee for distribution services provided to us. These increases were partially offset by a decrease of approximately \$467,000 in inventory obsolescence expense in fiscal year 2004 as compared to fiscal year 2003. In fiscal year 2003, write-offs and allowances related to the discontinuation of sales of Inulin and the short shelf life of Acthar were recorded. Stability testing is required on each production lot of Acthar and Ethamolin and is conducted at third party laboratories at periodic intervals subsequent to manufacturing. Stability testing costs are expensed as incurred and are expected to increase as more lots of Acthar and Ethamolin are produced and become subject to testing. We expect per unit material costs for Acthar to increase in the future due to higher contract manufacturing and laboratory costs.

In the second quarter of 2004, we initiated a credit memoranda return policy for all product lots released after May 31, 2004. If our product exchange policy had been in effect for all product lots shipped during 2004, we estimate that cost of product sales would have been approximately \$50,000 higher.

Cost of product sales as a percentage of net product sales decreased to 20% for the year ended December 31, 2004 from 26% for the year ended December 31, 2003. A change in the mix of products we sold contributed to this decrease. In April 2003, we decided to outsource certain functions previously performed in

our Carlsbad, California distribution center, including, but not limited to, warehousing, shipping and quality control studies. We have entered into agreements with various vendors to distribute Acthar, Nascobal, Ethamolin and Glofil-125, and we distributed VSL#3 from our Union City facility. The decision to outsource these functions and close the Carlsbad facility resulted in reduced expense in fiscal year 2004.

## Selling, General and Administrative

Selling, general and administrative expense Percentage of total revenue

Years Decem	Ended ber 31,				
2004		2003	Ir	ıcrease	%
		(In \$000	)'s)		
\$ 11,551	\$	10,400	\$	1,151	<u>11</u> %
63%		74%			

Selling, general and administrative expenses for the year ended December 31, 2004 increased \$1,151,000 or 11% from the year ended December 31, 2003. As a percentage of revenue, selling, general and administrative expenses decreased to 63% for the year ended December 31, 2004 from 74% for the year ended December 31, 2003. The increase in dollars is primarily due to approximately \$920,000 in severance and related expenses associated with the departure of our former CEO in the third quarter of 2004, the write-off of \$180,000 related to the impairment of assembled workforce, increases in sales commissions of \$119,000 and access fees to Sigma-Tau Pharmaceuticals of \$296,000 due to higher product sales, and an increase of \$145,000 in Board of Director fees due to increased oversight activities related to executive transitions during fiscal year 2004. These increases were partially offset by decreases in legal, consulting and investor relations expenses of approximately \$365,000 and bad debt expense of \$59,000, as compared to the year ended December 31, 2003.

#### **Research and Development**

Research and development expenses for the year ended December 31, 2004 were \$2,181,000, a decrease of \$86,000, as compared to \$2,267,000 for the year ended December 31, 2003. The costs included in research and development relate primarily to our manufacturing site transfers and medical and regulatory affairs compliance activities. The decrease primarily resulted from the closure costs incurred in the third quarter of 2003 when we ceased use of our Carlsbad distribution facility and recorded charges associated with the closure, offset by increased regulatory fees related to Nascobal, which we introduced in July 2003.

For the year ended December 31, 2004, we incurred approximately \$580,000 of Acthar site transfer costs, a decrease of approximately \$70,000 as compared to the year ended December 31, 2003. In 2003, we transferred the Acthar final fill and packaging process to our contract manufacturer, Chesapeake Biological Laboratories Inc. ("CBL"), and produced our first lot of Acthar finished vials. In 2004, we transferred the Acthar API manufacturing process to our contract manufacturer, BioVectra dcl ("BioVectra"), and produced the first BioVectra API lot. We also selected a new contract laboratory to perform three bioassays associated with the release of API and finished vials. Two of these bioassays have been successfully transferred to the contract laboratory, and we are awaiting FDA approval of these two transfers. We have experienced delays and cost overruns in the validation of the third assay, potency. In 2004, we conducted additional studies aimed at identifying critical differences in the way the potency assay is performed at the contract laboratory as compared with the previous laboratory. Some differences were identified and corrected, however results were still not acceptable. Work on this assay transfer is planned to restart by mid-2005. In fiscal year 2005, the costs which we plan to incur related to the API manufacturing site transfer and the bioassay transfers are expected to be less than the costs incurred in 2004.

In fiscal years 2004 and 2003, our spending on research and development programs was modest. We are seeking to out-license the development of Emitasol (intranasal metoclopramide), a product that is approved in Italy and Korea as an anti-emetic. The development of Hypnostat for the treatment of sleep disorders and Panistat for the treatment of panic disorders is controlled by Fabre-Kramer. The future development of Emitasol will depend in part on our ability to enter into a partnership arrangement. As we rely on current and

future strategic partners to develop and fund our non-commercial projects, we are unable to project estimated completion dates. We have limited control, if any, over these programs due to our reliance on partners for their development. Accordingly our ability to disclose historical and future costs associated with these projects is limited.

#### **Depreciation and Amortization**

Depreciation and amortization expense increased by 4% to \$1,208,000 for the year ended December 31, 2004 from \$1,157,000 for the year ended December 31, 2003. This increase was due primarily to the amortization of the purchased technology related to the Nascobal product acquisition for \$14.2 million in June 2003. The increase was partially offset by decreased amortization expense related to the Ethamolin purchased technology, which was fully amortized in fiscal year 2003. The Nascobal purchased technology is being amortized over 15 years. In February 2005, we paid an additional \$2 million to Nastech upon the approval of the NDA for Nascobal nasal spray. This additional amount will be amortized over the remaining life of the Nascobal purchased technology.

#### Other Income and Expense Items

	Years I Deceml			
	2004	2003	Increase/ (Decrease) (In \$000's)	
Non-cash amortization of deemed discount on convertible debentures	\$ (522)	\$ (522)	\$ —	_
Interest income	78	229	(151)	(66)%
Interest expense	(420)	(333)	87	26%
Other income	21	1	20	2000%
Other expense	_	(92)	(92)	(100)%
Rental income, net	277	260	17	7%

Non-cash amortization of deemed discount on convertible debentures was \$522,000 for the year ended December 31, 2004 which was consistent with the year ended December 31, 2003. The convertible debentures were issued in March 2002.

Interest income for the year ended December 31, 2004 decreased by \$151,000 or 66% from the year ended December 31, 2003. The decrease was due in part to interest earned in 2003 on a financing lease of equipment. Interest expense increased by 26% for the year ended December 31, 2004 as compared to the year ended December 31, 2003. The increase was primarily due to interest expense related to the \$2.2 million promissory note issued to Sigma-Tau in July 2004.

Other income for the year ended December 31, 2004 increased by \$20,000 from the year ended December 31, 2003. The increase was primarily due to proceeds from the sale of miscellaneous equipment no longer used by us. There was no other expense for the year ended December 31, 2004. Other expense for the year ended December 31, 2003 resulted in part from our investment in the common stock of Rigel Pharmaceuticals, Inc. We liquidated our investment in Rigel common stock in the second quarter of fiscal year 2003. For the year ended December 31, 2003 we recorded an other-than-temporary loss of \$51,000 and realized losses of \$14,000 related to the common stock investment.

Rental income, net, for the year ended December 31, 2004 increased by \$17,000 or 7% from the year ended December 31, 2003. Rental income, net, primarily arises from the lease and sublease of our former headquarters facility in Hayward, California. Although the current rental income from the sublessee exceeds the current rental expense on the Hayward facility, there can be no assurance our sublessee will not default on the sublease agreement, and if they were to do so, we would still be obligated to pay rent on this property.

#### Net Loss

For the year ended December 31, 2004, we incurred a net loss of \$832,000, as compared to a net loss of \$3,791,000 for the year ended December 31, 2003, a decrease of \$2,959,000, or 78%. The decreased net loss for fiscal year 2004 compared to fiscal year 2003 was primarily the result of higher net product sales.

#### Series B Preferred Stock Dividends

Preferred stock dividends of \$676,000 for the year ended December 31, 2004 and \$762,000 for the year ended December 31, 2003, represent the 8% cash dividends paid by us to the Series B preferred shareholders. These dividends are required to be paid in cash quarterly. The Series B preferred stock was issued in January 2003.

Non-cash deemed dividends of \$1,394,000 at December 31, 2003 are related to the beneficial conversion feature in connection with the Series B preferred stock and warrants issued in January 2003. A beneficial conversion feature was recorded because the effective conversion price of the Series B preferred stock was less than the fair value of the common stock on the commitment date. In addition, in June 2003, we obtained a letter from our Series B preferred shareholders whereby certain covenants were waived until December 31, 2003. In exchange for such waiver, the exercise price of the warrants was reduced. The beneficial conversion feature was revalued using the new exercise price and the increase in value was recorded as a dividend.

# **Net Loss Applicable to Common Shareholders**

For the year ended December 31, 2004, we incurred a net loss applicable to common shareholders of \$1,508,000, or \$0.03 per share, as compared to a net loss applicable to common shareholders of \$5,947,000, or \$0.14 per share for the year ended December 31, 2003, a decrease of \$4,439,000. In fiscal year 2004 dividends on Series B preferred stock of \$676,000 were recorded in arriving at the net loss applicable to common shareholders. In fiscal year 2003 dividends on Series B preferred stock of \$762,000 and non-cash deemed dividends related to the beneficial conversion feature of Series B Preferred Stock of \$1,394,000 were recorded in arriving at the net loss applicable to common shareholders.

## Year Ended December 31, 2003 Compared to the Year Ended December 31, 2002

Total Revenues

		s Ended nber 31,		
	2003	2002	Increase/ (Decrease)	<u>%</u>
			(In \$000's)	
Net product sales	\$ 13,655	\$ 13,819	\$ (164)	(1)%
Contract research, grant and royalty revenue	58	208	(150)	(72)%
Technology revenue	350	450	(100)	(22)%
Service revenue from a related party		200	(200)	_
Total revenues	\$ 14,063	\$ 14,677	\$ (614)	(4)%

Total revenues for the year ended December 31, 2003 decreased \$614,000, or 4%, from the year ended December 31, 2002 due to decreases in net product sales, contract research, grant and royalty revenue, technology revenue and service revenue from a related party as described below.

For the year ended December 31, 2003, net product sales decreased by \$164,000, or 1%, from the year ended December 31, 2002. The decrease in net product sales is primarily the result of lower revenues from Acthar and Ethamolin offset by the commencement of sales of Nascobal in July 2003. During the year ended December 31, 2002 we shipped backorders outstanding at December 31, 2001 amounting to \$334,000 for Acthar and \$408,000 for Ethamolin. Without these backorders, product revenues would have been \$13,077,000 in the year ended December 31, 2002. As of December 31, 2003, we had orders from customers totaling \$325,000 that were not shipped until January 2004.

#### Acthar

For the year ended December 31, 2003, net product sales of Acthar decreased 11% or \$1,036,000 from the year ended December 31, 2002. The lower sales of Acthar in fiscal year 2003 was partially the result of the replacement of expired vials of Acthar at no cost under our product exchange policy, and the decision in the first quarter of fiscal year 2003 to briefly limit shipments of Acthar to critical care and emergency care situations due to the relatively short dating of our inventories and inventories at the wholesale level. During fiscal year 2003, under our product exchange policy we replaced vials of Acthar with an estimated sales value of \$2.3 million calculated using the unit prices in effect at December 31, 2003. The replacement of expired product displaced sales in fiscal year 2003. The decrease of unit sales over the prior year was also partially due to a shipment in early fiscal year 2002 of backorders totaling \$334,000 outstanding as of December 31, 2001. The estimated demand as measured by prescriptions reported from an independent source increased by 6% in 2003 as compared to 2002.

Under our product exchange policy for expired product, during fiscal year 2003 we replaced vials of Acthar which expired in November 2002 and May 2003. During fiscal year 2002 under our product exchange policy we shipped replacement units for expired product with an estimated sales value of \$116,000 calculated using unit sales prices in effect at December 31, 2002. In fiscal year 2002 and fiscal year 2001, our Acthar vials sold had a one year shelf life and in the first quarter fiscal year 2003 we began shipping Acthar with an 18 month shelf life. The shipment of replacement product, at no cost to the customers, displaces future sales.

## Nascobal

For the year ended December 31, 2003, net product sales of Nascobal were \$2,099,000. We commenced sales of Nascobal in July 2003, and thus there were no sales in fiscal year 2002.

#### Ethamolin

For the year ended December 31, 2003, net product sales of Ethamolin decreased 54% or \$1,898,000 from the year ended December 31, 2002, which was primarily the result of the large purchase of Ethamolin by wholesalers in anticipation of the price increase in June 2002 and shipment of backorders existing at December 31, 2001. Effective June 24, 2002, we increased our list price for Ethamolin. From the date of the notification of the price increase through June 30, 2002, we received \$1,560,000 of Ethamolin orders, which we believe were in excess of actual prescription needs and negatively impacted sales in the remainder of fiscal year 2002 and fiscal year 2003. The decrease in sales of Ethamolin in fiscal year 2003 over the prior year was also partially due to a shipment in early 2002 of backorders totaling \$408,000 outstanding as of December 31, 2001. The demand for all sclerosing agents as measured by total prescriptions decreased in fiscal year 2003 by approximately 36%, from fiscal year 2002, and the decrease in demand for Ethamolin was approximately 37%. We did not actively promote Ethamolin in fiscal year 2003.

## VSL#3

For the year ended December 31, 2003, net product sales of VSL#3 increased 90% or \$469,000 from the year ended December 31, 2002. The increase was attributed to a full year of sales since we began selling VSL#3 in May 2002.

# Glofil-125

For the year ended December 31, 2003, net product sales of Glofil-125 increased 21% or \$155,000 from the year ended December 31, 2002. The increase in net product sales was due in part to a Chronic Renal Insufficiency Cohort ("CRIC") study that began in 2003. The CRIC study was to enroll 3,000 people who are at risk for compromised renal function, and follow them for more than five years. The testing using Glofil-125 will occur at the enrollment of the trial and at the end of the trial. In fiscal year 2003, we did not actively promote Glofil-125.

#### Inulin

For the year ended December 31, 2003, sales of Inulin increased by 167% or \$47,000 from the year ended December 31, 2002. Due to minimal demand, increasing cost of production and lack of strategic fit we discontinued marketing and selling Inulin in September 2003.

## Contract Research, Grant and Royalty Revenue

Contract research, grant and royalty revenue decreased by \$150,000, or 72%, to \$58,000 for the year ended December 31, 2003 from \$208,000 for the year ended December 31, 2002. This decrease was primarily the result of receiving less reimbursement under our SBIR grant, which was terminated on July 31, 2003 due to a decrease in activity with our GERI compound research project.

## Technology Revenue and Services Revenue from a Related Party

For the year ended December 31, 2003, we recognized \$350,000 in technology revenue primarily from our License Agreement with Fabre-Kramer and the sale of certain patents. For the year ended December 31, 2002, we recognized \$450,000 in technology revenue related to our License Agreements with Fabre-Kramer and Ahn-Gook Pharmaceutical Co., Ltd. Services revenue from a related party was \$200,000 for the year ended December 31, 2002. This amount represents the recognition of revenue resulting from the \$200,000 payment made by VSL Pharmaceuticals, Inc. for certain promotional activities we undertook to support the launch of VSL#3.

#### **Cost of Product Sales**

Cost of product sales increased \$751,000, or 27%, to \$3,573,000 for the year ended December 31, 2003 from \$2,822,000 for the year ended December 31, 2002. The increase is primarily due to write-offs of excess inventory and increases in our excess inventory allowance, increases in per unit material costs and increases in costs of performing product stability testing. The excess inventory write-offs and allowances are primarily the result of the decision to discontinue production and sales of Inulin and the short shelf life of Acthar. Cost of product sales as a percentage of net product sales increased to 26% for the year ended December 31, 2003 from 20% for the year ended December 31, 2002, primarily due to a change in product mix. In April 2003, we decided to outsource certain functions previously performed in our Carlsbad, California distribution center, including, but not limited to, warehousing, shipping and quality control studies.

## Selling, General and Administrative

	Years Er Decembe				
	2003	2002	Decrease	<u>%</u>	
		(In \$000's	s)		
Selling, general and administrative expense	\$ 10,400	\$ 10,825	\$ (425)	(4)%	
Percentage of total revenue	74%	74%	<u> </u>		

Selling, general and administrative expenses for the year ended December 31, 2003 decreased 4% from the year ended December 31, 2002. As a percentage of revenue, selling, general and administrative expenses remained flat at 74% for the year ended December 31, 2003 from the year ended December 31, 2002. The decrease in dollars is primarily due to lower non-cash charges for stock-based compensation, lower public relations and investor relations expenses and decreases in management bonuses, totaling approximately \$1,036,000, offset by the full year impact of increases to salary and other costs associated with the expansion of our sales and marketing departments in support of our products Acthar, Nascobal and VSL#3 totaling approximately \$385,000 and other general and administrative costs.

#### **Research and Development**

Research and development expenses for the year ended December 31, 2003 were \$2,267,000 as compared to \$2,295,000 for the year ended December 31, 2002. Research and development expenses include our manufacturing site transfers and medical and regulatory affairs compliance activities.

During fiscal year 2003, our Carlsbad facility was vacated and the functions performed there were outsourced to third party contractors or transferred to the Union City headquarters. The entire facility was subleased during fiscal year 2003 and a liability of \$171,000 was recorded for the net present value of future rental payments, net of sublease payments, and the corresponding expense was recorded to Research and Development.

In fiscal years 2003 and 2002, our spending on research and development programs was modest.

#### **Depreciation and Amortization**

Depreciation and amortization expense increased by 2% to \$1,157,000 for the year ended December 31, 2003 from \$1,138,000 for the year ended December 31, 2002. This increase was due primarily to the amortization of purchased technology related to the Nascobal product acquisition for \$14.2 million in June 2003, offset by lower depreciation due to assets becoming fully depreciated in fiscal years 2003 and 2002. The Nascobal purchased technology will be amortized over 15 years. The net remaining balance of purchased technology of \$382,000 at December 31, 2002 was related to Ethamolin and was fully amortized in fiscal year 2003.

## Other Income and Expense Items

	Years l Deceml				
	2003	2002			
Non-cash amortization of deemed discount on convertible debentures	\$ (522)	\$ (415)	\$	107	26%
Interest income	229	307		(78)	(25)%
Interest expense	(333)	(315)		18	6%
Other income	1	120		(119)	(99)%
Other expense	(92)	(361)		(269)	(75)%
Rental income, net	260	282		(22)	(8)%

Non-cash amortization of deemed discount on convertible debentures increased 26% for the year ended December 31, 2003 as compared to the year ended December 31, 2002. The convertible debentures were issued in March 2002.

Interest income for the year ended December 31, 2003 decreased by 25% from the year ended December 31, 2002, primarily due to lower interest rates in fiscal year 2003 compared to the same period in 2002. Interest expense increased by 6% for the year ended December 31, 2003 as compared to the year ended December 31, 2002. The increase was primarily due to the current period representing a full year's worth of interest expense on the convertible debentures issued in March 2002.

Other income for the year ended December 31, 2003 decreased by 99% from the year ended December 31, 2002. During fiscal year 2002, we recognized other income as a result of receipt of profits arising from short swing stock trades executed by one of our 10% stockholders. Other expense for the year ended December 31, 2003 decreased by 75% from the year ended December 31, 2002. The decrease in other expense is primarily due to a lower amount of loss recognized in fiscal year 2003 related to our investment in the common stock of Rigel Pharmaceuticals as compared to fiscal year 2002. We liquidated our investment in Rigel common stock in the second quarter of fiscal year 2003. As such, for the year ended December 31, 2003 we recorded an other-than-temporary loss of \$51,000 and realized losses of \$14,000 related to the common

stock investment as compared to a \$367,000 other-than-temporary loss recorded on the common stock investment in fiscal year 2002.

Rental income, net, for the year ended December 31, 2003 decreased 8% from the year ended December 31, 2002. Rental income, net, primarily arises from the lease and sublease of our former headquarters facility in Hayward, California.

#### **Net Loss**

For the year ended December 31, 2003, we incurred a net loss of \$3,791,000, as compared to a net loss of \$2,785,000 for the year ended December 31, 2002, an increase of \$1,006,000, or 36%. The increased net loss for fiscal year 2003 compared to fiscal year 2002 was primarily the result of lower total revenues and higher cost of product sales.

#### Series B Preferred Stock Dividends

Non-cash deemed dividends of \$1,394,000 at December 31, 2003 are related to the beneficial conversion feature in connection with the Series B preferred stock and warrants issued in January 2003. A beneficial conversion feature was recorded because the effective conversion price of the Series B preferred stock was less than the fair value of the common stock on the commitment date. In addition, on June 13, 2003, we obtained a letter from our Series B preferred shareholders whereby certain covenants were waived until December 31, 2003. In exchange for such waiver, the exercise price of the warrants was reduced. The beneficial conversion feature was revalued using the new exercise price and the increase in value was recorded as a dividend. In December 2003, a waiver was received from the Series B preferred shareholders waiving certain covenants until January 31, 2004, at which time we were in compliance.

Preferred stock dividends of \$762,000 in fiscal year 2003 represent the 8% cash dividends paid to the Series B preferred shareholders. The Series B preferred stock was issued in January 2003.

## **Net Loss Applicable to Common Stockholders**

For the year ended December 31, 2003, we incurred a net loss applicable to common shareholders of \$5,947,000, or \$0.14 per share, as compared to a net loss applicable to common shareholders of \$2,785,000, or \$0.07 per share for the year ended December 31, 2002, an increase of \$3,162,000. In fiscal year 2003 dividends on Series B preferred stock of \$762,000 and non-cash deemed dividends related to the beneficial conversion feature of Series B preferred stock of \$1,394,000 were recorded in arriving at the net loss applicable to common shareholders.

# QUESTCOR PHARMACEUTICALS, INC.

# CONSOLIDATED STATEMENTS OF OPERATIONS

	 Years Ended December 31,  2004 2003 (In thousands, except per share amounts)		 2002	
Revenues:				
Net product sales	\$ 18,404	\$	13,655	\$ 13,819
Contract research, grant and royalty revenue	_		58	208
Technology revenue	_		350	450
Services revenue from a related party	 		<u> </u>	 200
Total revenues	18,404		14,063	14,677
Operating costs and expenses:				
Cost of product sales (exclusive of amortization of purchased technology)	3,730		3,573	2,822
Selling, general and administrative	11,551		10,400	10,825
Research and development	2,181		2,267	2,295
Depreciation and amortization	1,208		1,157	1,138
Total operating costs and expenses	18,670		17,397	17,080
Loss from operations	(266)		(3,334)	(2,403)
Non-cash amortization of deemed discount on convertible debentures	(522)		(522)	(415)
Interest income	78		229	307
Interest expense	(420)		(333)	(315)
Other income (expense), net	21		(91)	(241)
Rental income, net	277	<u></u>	260	282
Net loss	(832)		(3,791)	(2,785)
Non-cash deemed dividend related to beneficial conversion feature of Series B Preferred Stock	_		1,394	_
Dividends on Series B Preferred Stock	676		762	_
Net loss applicable to common shareholders	\$ (1,508)	\$	(5,947)	\$ (2,785)
Basic and diluted net loss per share applicable to common shareholders	\$ (0.03)	\$	(0.14)	\$ (0.07)
Shares used in computing basic and diluted net loss per share applicable to common shareholders	 50,844	_	41,884	38,407

See accompanying notes.