#### [QUESTCOR LETTERHEAD]

August 5, 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

Filed March 31, 2005 File No. 1-14758

Dear Mr. Rosenberg:

Questcor Pharmaceuticals, Inc. (the "Company") is in receipt of your letter dated July 5, 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 in that letter 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

- Staff Comment No. 1: We have reviewed your responses to comment 1. Please tell us how you have complied with paragraph 6 of SFAS 48,
  as several statements made in your response would appear to indicate that the price established for your products is neither fixed nor
  determinable, nor can you reasonably estimate the amount of future returns. Specifically, you state:
  - "the Company is unable to predict with certainty when within that six-month period the product returns may occur;"

- "the Company is not privy to its customers' business operating policies and requirement regarding inventory levels;"
- "it is not possible for the Company to match VA chargebacks or Medicaid rebates with sales made during a particular year;"
- "it is not possible for the Company to match returns with sales made during a particular fiscal year."

Company Response: The Company meets all the criteria of paragraph 6 of SFAS 48, which permits the recognition of revenue at the time of sale.

The Company sells three products (Acthar, Ethamolin and Nascobal) which may be returned by the purchaser during a six-month period following the expiration date of the product lot. Through contract manufacturers, the Company manufactures these products and sells to pharmaceutical drug wholesalers. The sale price of the products to all wholesalers is fixed according to a published price list. Therefore, the Company's price to its customers is fixed and determinable at the date of sale.

The wholesalers are required to pay for product purchased on standard 2% net 30 day terms, regardless of whether the wholesaler sells the product to its own customers. The wholesalers are obligated to pay the Company at the time of sale, and such obligation is not contingent on resale of the product.

All responsibility for loss or destruction passes to the drug wholesalers when they receive the products in their warehouse. The Company's terms of sale for Acthar, Ethamolin and Nascobal are FOB Destination. The wholesalers' obligation to pay the Company is not changed if theft or physical destruction or damage occurs subsequent to the wholesalers' receipt of the product.

The largest wholesalers to which the Company sells are Amerisource Bergen, Cardinal, and McKesson, which are large independent companies. These wholesalers have substantial economic substance. The Company also sells to other, smaller wholesalers who are independent and not affiliated with the Company in any way. The Company is not able to control or significantly influence the purchasing patterns of the drug wholesalers who purchase our products. These are sophisticated companies that purchase our products in a manner consistent with their industry practices and perceived business interests.

The Company is not obligated to assist the wholesalers in reselling the Company's product, and has no involvement or obligations in the wholesalers' sale or distribution of products purchased from the Company, other than occasional drop shipments provided as a convenience to the wholesaler. The Company does provide information to physicians who prescribe or are likely to prescribe the Company's products, but such efforts are intended to increase overall prescription demand for the Company's products, and are not obligations

to directly bring about resale of the products by the wholesalers who purchase them from the Company.

The Company's products are manufactured in lots, and as required by FDA regulations, are labeled with a specific identifying lot number. The Company sells from only one lot for each product at one time. Depending on the amount of product sold, a lot could take four to ten months to sell. If, for example, a lot were sold from October 2003 until March 2004, the Company maintains data on how many units were sold from that lot during that time period. However, the Company is unable to determine whether a particular unit which is returned was sold in October 2003 or February 2004. Except in special circumstances, such as manufacturing constraints, the Company ceases selling from each lot four to six months before the expiration date of the lot.

After the expiration date of a lot, the wholesalers may return product from that lot which they have on hand. No returns are accepted after six months past the expiration date of the lot. After the returned product is received and verified, the product is destroyed. Because the product is past its lot expiration date, it is no longer saleable. The Company maintains an historical database of return material requests received on each lot, and compares the number of return material requests with the number of sales from the same lot. This historical database of return rates by product lot enables the Company to reasonably estimate the amount of future returns related to current sales.

There are a limited number of external factors which may affect the historical return rate, such as the number of months from the last shipment date to the lot expiration date, prescription demand and current inventory on hand at wholesalers. These factors are continually assessed, and return rates may be adjusted, if it is apparent that such factors would impact the estimated return rate of a particular lot. For example, if lot 1234 were shipped up to 3 months prior to the lot expiration date due to manufacturing constraints, the estimated return rate for this lot could reasonably be expected to be higher than lots which historically stopped shipping six or more months prior to expiration date.

To date, actual product returns have been consistent with the Company's estimates.

Please refer to the Company's response to Staff Comment No. 3 for information regarding matching government chargebacks and Medicaid rebates with sales during a particular year.

2. Staff Comment No. 2: Refer to your response to comment 1a. Please disclose within your critical accounting estimate that the use of other likely assumptions would not produce results materially different from those which were recorded in the Company's financial statements. Please note it is usually our opinion that materiality should be assessed against net income from operations and net income, not against gross sales. Additionally, please provide to us the amount of the accrual as of each year end and the reduction to gross sales recorded for all years presented for product returns, government chargebacks, Medicaid rebates, and cash discounts separately.

Company Response: In accordance with the Staff's comment, the Company proposes to include the following statement in Management's Discussion and Analysis, Critical Accounting Policies, Sales Reserves, Product Returns, and Rebates:

• "Significant judgment is inherent in the selection of assumptions and the interpretation of historical experience as well as the identification of external and internal factors affecting the estimates of our reserves for product returns, government chargebacks, and Medicaid rebates. We believe that the assumptions used to estimate these sales reserves are the most reasonably likely assumptions considering known facts and circumstances. However, our product return activity, government chargebacks received, and Medicaid rebates paid could differ significantly from our estimates because our analysis of product shipments, prescription trends and the amount of product in the distribution channel may not be accurate. If actual product returns, government chargebacks, and Medicaid rebates are significantly different from our estimates, or if the wholesalers fail to adhere to our product exchange or credit memoranda policy, such differences would be accounted for in the period in which they become known. To date, actual amounts have been consistent with our estimates."

Exhibit B attached herewith presents the Company's proposed revision to Form 10-K for the fiscal year ended December 31, 2004, including the proposed revision set forth above.

The Company understands the Staff's position regarding the use of net income from operations and net income, rather than gross sales, to assess materiality. The Company believes that, because it has a history of recurring operating losses, investors regard the level of and growth in sales as a more relevant indicator of the Company's financial growth. In addition, as the Company moves from net losses to small net income amounts, assessment of materiality against net income becomes more challenging, as nearly all transactions would be deemed material when assessed against a small net income amount. The Company

will consider the Staff's position in evaluating future disclosures and explanations.

As requested by the Staff, Exhibit A attached herewith presents the amounts of accruals for product returns, product replacements, government chargebacks, Medicaid rebates, and cash discounts as of December 31, 2004 and 2003, the reduction in gross sales recorded for 2004, 2003 and 2002 for product returns, government chargebacks, Medicaid rebates, and cash discounts, and the increase to cost of product sales recorded for 2004, 2003 and 2002 for product replacements.

- 3. Staff Comment No. 3: Refer to your response to comment 1e. We maintain our belief that your disclosure related to estimate of product returns is material and could be improved. Schedule II Valuation and Qualifying Accounts does not provide a breakdown of the current provisions nor actual returns or credits by the fiscal year that these items relate to. Please provide to us a roll forward of the liability 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 months and,
  - Ending balance

Company Response: In accordance with the Staff's comment, the Company proposes to provide a schedule presenting roll-forward amounts in the requested format for the reserves for credit memoranda product returns and product exchanges. These reserves represent 75% of the total amount of sales reserves at December 31, 2004. Exhibit B attached herewith presents the Company's proposed revision to Form 10-K, Item 7, Management's Discussion and Analysis, Critical Accounting Policies, for the fiscal year ended December 31, 2004.

For Medicaid rebates and government chargebacks, due to the nature of the Company's sales process, the actual rebates and chargebacks cannot be related to the sales of a specific fiscal year. The Company sells its products to pharmaceutical drug wholesalers. The drug wholesalers maintain an inventory of product consistent with their industry practices and perceived business interests. The drug wholesalers resell their inventory of products to hospitals, pharmacies, and secondary distributors, who may also maintain an inventory of product. The hospitals and pharmacies dispense the product to end users in response to prescriptions written by physicians. Thus, the date on which the Company sold the product to the wholesaler may be months or years different from the date of sale to the end-user government entity or state Medicaid agency. The requests for

rebates and chargebacks do not provide the product lot number, which is the Company's only method of relating product sales to a specific time period.

4. Staff Comment No. 4: Refer to your response to comment 1f. We do not believe assessing materiality against gross product sales is appropriate. Until you demonstrate otherwise, we believe you should discuss the amount of and reason for fluctuations for product returns in your discussion of results of operations.

Company Response: The Company understands the Staff's position regarding the use of net income from operations and net income, rather than gross sales, to assess materiality. The Company believes that, because it has a history of recurring operating losses, investors regard the level of and growth in net sales as a more relevant indicator of the Company's financial growth. In addition, as the Company moves from net losses to small net income amounts, assessment of materiality against net income becomes more challenging, as nearly all transactions would be deemed material when assessed against a small net income amount. The Company will consider the Staff's position in evaluating future disclosures and explanations.

Exhibit B 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. Page 30 discusses the amount of and reason for fluctuations in net product sales due to reserves for credit memoranda product returns.

#### **Consolidated Financial Statements**

#### **Consolidated Statements of Operations**

#### Note to Consolidated Financial Statements, Page 61

#### General

5. Staff Comment No. 5: We have considered your response to comment 5 but continue to believe that your current disclosure does not meet the requirement of paragraph 37 of FAS 131. We believe that the intent of paragraph 37 is to achieve greater disaggregation than total revenue from pharmaceuticals. We believe you should show revenue by product or major product line such as therapeutic category.

Company Response: In accordance with the Staff's comment, the Company proposes to provide information on revenue by therapeutic category in Management's Discussion and Analysis of Results of Operations and Note 1 to Consolidated Financial Statements. Exhibit B

attached herewith presents the Company's proposed revision to Form 10-K, Item 7, Management's Discussion and Analysis, Results of Operations and Note 1 to Consolidated Financial Statements, for the fiscal year ended December 31, 2004.

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

#### Revenue Recognition, page 63-64

6. Staff Comment No. 6: Refer to your response to comment 6. We do not believe that you have adequately justified your compliance with SFAS 48 as it would appear that any estimated costs or losses associated with a product return or replacement should be reported as a reduction of sales revenue. Please provide to us your basis for the current accounting treatment. Please include all relevant citations to the accounting literature relied upon. Additionally, please quantify the amount of costs associated with the Company's product exchange policy, which applied to product lots released prior to June 1, 2004, that was included in cost of goods sold for all periods presented.

Company Response: The Company maintains an historical database of return material requests received from wholesalers (our customers) on each product lot, and compares the number of return material requests with the number of sales from the same lot. This historical database of return rates by product lot enables the Company to reasonably estimate the amount of future replacements related to current sales. The Company's reserve for product returns under the credit memoranda policy is accounted for as a reduction of sales revenue. The Company's reserve for returns under the product exchange policy is accounted for as cost of goods sold.

After the expiration date of a lot, the wholesalers may return product from that lot which they have on hand. No returns are accepted after six months past the expiration date of the lot. After the returned product is received and verified, the product is destroyed. Because the product is past its lot expiration date, it is no longer saleable. Therefore, there is no reduction in cost of product sales at the time of replacement. Replacement product is sent to the wholesaler without any additional receipt of revenue.

The Company believes it is appropriate to record a provision for product exchanges as part of cost of goods sold based on the cost of the replacement product, and such amount can be reasonably estimated at the time of the original sale based on historical return rates. We have considered the guidance in EITF 01-09, paragraph 10 that states "if consideration consists of a free product or service . . . the Task Force reached a consensus that the cost of the consideration should be characterized as an expense (as opposed to a reduction of revenue) when recognized . . . in the income statement." Because the number and cost of replacements can be estimated at the time of sale, based on the Company's historical returns database, the costs of such replacements are recorded as an expense when the corresponding revenue is recognized in the income statement. Effectively revenue is recognized for the invoiced amount of the product sale and the cost of two units is recognized in cost of goods sold (as no additional revenue is received for the product given in exchange for the expired product).

Exhibit A attached herewith presents the amounts of costs associated with the Company's product exchange policy which were included in cost of products sold for the years ended December 31, 2004, 2003 and 2002.

Please feel free to contact the Company's President and CEO, James L. Fares, at (510) 400-0707 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: James L. Fares, Questcor Pharmaceuticals, Inc. David A. Hahn, Esq.

# EXHIBIT A TO QUESTCOR PHARMACEUTICALS' RESPONSE DATED AUGUST 5, 2005

U.S. Securities and Exchange Commission August 5, 2005 Page 9

	Decem	December 31	
	2004	2003	
	(in thou	ısands)	
Reserve for credit memoranda product returns	\$ 1,054	\$ —	
Reserve for product exchanges	213	158	
Reserve for Medicaid rebates	336	271	
Reserve for government chargebacks	80	153	
Total Sales-related reserves	\$ 1,683	\$ 582	
Allowance for discounts	\$ 42	\$ 33	

			Years Ended December 31		
	_	2004	2003 (in thousands)	:	2002
Credit memoranda product returns expense	\$	1,054	\$ —	\$	388
Medicaid rebate expense		785	560		121
Government chargeback expense		322	470		292
Discounts expense		371	255		264
Total Reduction in sales	\$	2,532	\$ 1,285	\$	677
Product exchange expense	\$	117	\$ 188	\$	75

## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## Form 10-K/A

☑ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year ended December 31, 2004

or

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number 001-14758

## **Questcor Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

California

(State or other jurisdiction of incorporation or organization)

33-0476164

(I.R.S. Employer Identification No.)

3260 Whipple Road Union City, California

(Address of principal executive offices)

**94587** (Zip Code)

Registrant's telephone number, including area code: (510) 400-0700

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, no par value

(Title of class)

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

Indicate by check mark whether Registrant is an accelerated filer (as defined in Rule 12B-2 of the Act). Yes o No ☑

The aggregate market value of the voting and non-voting Common Stock held by non-affiliates of the Registrant was approximately \$29,968,055 as of June 30, 2004, based upon the last sales price of the Registrant's Common Stock reported on the American Stock Exchange. The determination of affiliate status for the purposes of this calculation is not necessarily a conclusive determination for other purposes. The calculation excludes approximately 15,854,811 shares held by directors, officers and shareholders whose ownership exceeds five percent of the Registrant's outstanding Common Stock as of June 30, 2004. Exclusion of these shares should not be construed to indicate that such person controls, is controlled by or is under common control with the Registrant.

As of March 18, 2005 the Registrant had 51,216,488 shares of Common Stock outstanding.

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

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement to be filed with the Commission within 120 days after Registrant's fiscal year ended December 31, 2004 are incorporated by reference into Part III of this Report.

# ANNUAL REPORT ON FORM 10-K FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004

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#### PART I

#### Item 1. Business

Except for the historical information contained herein, the following discussion contains forward-looking statements that involve risks and uncertainties. Questcor's actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this Item 1 "Business," including without limitation "Risk Factors," and Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as those discussed in any documents incorporated by reference herein or therein. When used in this Annual Report, the terms "Questcor," "Company," "we," "our," "ours" and "us" refer to Questcor Pharmaceuticals, Inc. and its consolidated subsidiaries.

#### Overview

We are a specialty pharmaceutical company that acquires, develops, markets and sells prescription drugs through our U.S. direct sales force and international distributors. We focus on the treatment of central nervous system ("CNS") diseases and gastroenterological disorders, which are served by a limited group of physicians such as neurologists and gastroenterologists. Our strategy is to acquire or develop pharmaceutical products that we believe have sales growth potential, are promotionally responsive to a focused and targeted sales and marketing effort, complement our existing products and can be acquired at a reasonable valuation relative to our cost of capital. In addition, through corporate collaborations, we intend to develop new medications focused on our target markets. For the year ended December 31, 2004, our total revenues were \$18.4 million.

Large multinational companies dominate the U.S. prescription pharmaceutical market. These companies tend to focus on drugs with annual sales in excess of \$1 billion and often divest products that, as a result of consolidation or lack of strategic fit, do not meet the threshold level of sales required for continued marketing and promotion. Since our inception, we have acquired and licensed products from Aventis Pharmaceuticals, Inc. ("Aventis"), Schwartz Pharma AG, Nastech Pharmaceutical Company Inc. ("Nastech") and other pharmaceutical companies. Smaller drug development or biotechnology companies that do not have the capabilities to effectively market and sell Food and Drug Administration ("FDA") approved products may also be sources of products.

Since 1995, we have introduced seven products and currently market four products in the United States. We promote certain of our products through our nationwide sales and marketing force, targeting high-prescribing specialty physicians such as gastroenterologists, bariatric surgeons, and neurologists, and select primary care physicians. We contract with third parties for the manufacture, warehousing, and distribution of our products.

Our current products are in three therapeutic areas: neurology, gastroenterology and nephrology. Our neurology product is H.P. Acthar® Gel ("Acthar"), an injectable drug that is approved for the treatment of certain CNS disorders with an inflammatory component, including the treatment of flares associated with multiple sclerosis ("MS"), and is also commonly used in treating patients with infantile spasm. Our gastroenterology products are Nascobal®, the only prescription nasal gel used for the treatment of various Vitamin B-12 deficiencies and Ethamolin®, an injectable drug used to treat enlarged weakened blood vessels at the entrance to the stomach that have recently bled, known as esophageal varices. Our nephrology product is Glofil®-125, an injectable agent that assesses how well the kidney is working by measuring glomerular filtration rate, or kidney function.

Consistent with our efforts to focus on sales and marketing, our spending on research and development activities has been modest. We have entered into several agreements with pharmaceutical and biotechnology companies to further the development of certain acquired technology. In June 2002, we signed a definitive License Agreement with Fabre-Kramer Pharmaceuticals, Inc. ("Fabre-Kramer") of Houston, Texas, whereby we granted Fabre-Kramer exclusive worldwide rights to develop and commercialize Hypnostat<sup>TM</sup> (intranasal triazolam for the treatment of insomnia) and Panistat<sup>TM</sup> (intranasal alprazolam for the treatment of panic disorders). We have a development agreement with Rigel Pharmaceuticals, Inc. ("Rigel") of South

San Francisco, California for our antiviral drug discovery program, and a development agreement with Dainippon Pharmaceuticals Co., Ltd. ("Dainippon") of Osaka, Japan for our antibacterial program. In 2004, no revenues were received, and no significant expenses were incurred as a result of these agreements.

We have rights to the following registered trademarks: H.P. Acthar® Gel, Ethamolin®, Nascobal® and Glofil®-125. We also have the following unregistered trademarks: Migrastat™, Emitasol™, Hypnostat™ and Panistat™. Pramidin® is owned by sirton pharmaceuticals S.p.A. ("sirton"). Emitasol is approved in Italy as Pramidin and has been marketed in the past by sirton. Each other trademark, trade name or service mark appearing in this document belongs to its respective holder.

Questcor is the surviving corporation of a merger between Cypros Pharmaceutical Corporation and RiboGene, Inc. ("RiboGene"). The merger was completed on November 17, 1999. Our principal office is located at 3260 Whipple Road, Union City, California 94587 and our telephone number is (510) 400-0700. Our corporate Internet address is www.questcor.com. We do not intend for the information contained on our website to be part of this Annual Report.

#### Strategy

We believe that our ability to market, develop and acquire prescription products and our ability to focus our promotional efforts, product development programs and overall company resources in limited therapeutic areas uniquely positions us to continue to grow.

The key elements of our strategy include:

- Increase sales of products through targeted promotion. We seek to increase sales by promoting certain of our products to high-prescribing specialty physicians through our nationwide sales and marketing force. Our current target audience for Nascobal is gastroenterologists, bariatric surgeons and neurologists, and neurologists for Acthar. Product usage and recommendations by these specialists generally influence usage by primary care physicians.
- Identify and license or acquire prescription products. We seek to acquire the rights to pharmaceutical products that we believe will (i) benefit from increased marketing efforts directed at high-prescribing specialty physicians, (ii) leverage our existing sales infrastructure, and (iii) complement our existing products. Since our inception, we have acquired or licensed seven products. Products to be considered for acquisition would have to be complementary to our existing products, synergistic with promotional efforts currently being undertaken by our sales force, and contribute to our gross margin. We intend to purchase products with cash generated from operations, if any, from debt financings, or from capital raised through the sale of equity on terms acceptable to us.
- Develop and market new or improved formulations of prescription products that complement our target therapeutic areas and sales strategy. We intend to fund development with cash generated from operations, if any, and corporate collaborations.

#### **Marketed Pharmaceutical and Related Healthcare Products**

Our marketed products as of December 31, 2004 include: Acthar, which we acquired in July 2001; Nascobal, which we acquired in June 2003; Ethamolin, which we acquired in November 1996; Glofil-125, which we acquired in August 1995; and VSL#3<sup>®</sup>, which we acquired the rights to market and sell pursuant to a Promotion Agreement effective January 2002. The VSL#3<sup>®</sup> Promotion Agreement expired effective January 2005.

Acthar. H.P. Acthar Gel ("Acthar") is a natural source, highly purified preparation of the adrenal corticotropin hormone ("ACTH"). Unlike synthetic ACTH, Acthar is specially formulated to provide prolonged release after intramuscular or subcutaneous injection. It works by stimulating the adrenal cortex to secrete the natural endogenous corticosteroids, including cortisol, corticosterone, aldosterone, and a number of weakly androgenic substances.

Acthar is used in a wide variety of conditions, including the treatment of infantile spasm ("IS"), periodic flares associated with MS, and various forms of arthritis, collectively called joint pain. Although the FDA-approved package labeling does not mention IS, Acthar has been used to treat this condition. We believe IS is the disease with the most compelling need for Acthar treatment. IS is an epileptic syndrome characterized by the triad of infantile spasm (generalized seizures), hypsarrhythmia and arrest of psychomotor development at seizure onset. We estimate that as many as 2,000 children annually experience bouts of this devastating syndrome in the U.S. In 90% of children with IS, the spasms occur during the first year of life, typically between 3 to 6 months of age. The first onset rarely occurs after the age of two. Patients left untreated or treated inadequately have a poor prognosis for intellectual and functional development. About two-thirds of patients are neurologically impaired prior to the onset of IS, while one-third are otherwise normal. Rapid and aggressive therapy to control the abnormal seizure activity appears to improve the chances that these children will develop to their fullest potential.

The market for IS therapies has not changed much over the last several years. Acthar remains the treatment of choice, however, Acthar's availability in the several years before our acquisition of the drug from Aventis was very restricted. As such, many physicians used synthetic steroids and even sought to obtain vigabatrin from Canada, an unapproved product in the United States. Vigabatrin, an enzyme inhibitor, is marketed under the trade name Sabril® in Canada. A symposium on IS, sponsored by the Child Neurology Society, discussed the fact that there has been no clinical evidence to show that any therapy is better than Acthar for the treatment of IS. The proceedings of that symposium have been made available to all pediatric neurologists as a continuing medical education monograph.

Acthar is indicated for use in acute exacerbations of MS and is prescribed currently for patients that have MS and experience painful, episodic flares. During 2003, we began to promote Acthar as an alternative to intravenous methylprednisolone, a corticosteroid, for the treatment of exacerbations of MS. Intravenous methylprednisolone is currently the treatment of choice for this indication. The primary advantage of Acthar in this setting is that it provides the patient with the freedom and convenience of intramuscular or subcutaneous administration at home, rather than the intravenous administration of methylprednisolone, without sacrificing efficacy or tolerability. Sales promotion of Acthar for joint pain is not anticipated at this time.

Acthar may be challenged by newer agents, such as synthetic corticosteriods, immune system suppressants known as immunosuppressants, and anti-seizure medications (in the case of infantile spasms) and other types of anti-inflammatory products for various autoimmune conditions that have inflammation as a clinical aspect of the disease. Solu-Medrol, the primary competitive product to Acthar for the treatment of MS flare, is now available to patients after an announced shortage in 2003.

*Nascobal.* In June 2003, we acquired Nascobal, an FDA approved nasal gel formulation of Cyanocobalamin USP (Vitamin B-12), from Nastech, a leading formulation science company. We began distributing Nascobal in July 2003. We are marketing Nascobal for patients with MS and Crohn's Disease, as well as for patients who have undergone bariatric surgery, since these patients are at high risk of developing severe deficiencies of Vitamin B-12 due to a compromised ability to absorb Vitamin B-12 through the gastrointestinal system.

Cyanocobalamin is one of the B-12 (cobalamin) class of vitamins. Cyanocobalamin is the principal member of the class, and the most widely employed in medicine in the United States. It is currently commercially available over the counter in an oral formulation and by prescription in injectable and nasal formulations.

The diets of most adult Americans provide the recommended intake of Vitamin B-12, but deficiency can still occur. Vitamin B-12 deficiency has a number of causes, including malabsorption of Vitamin B-12 resulting from structural or functional damage to the gastrointestinal system, caused by surgery or various disease states. Vitamin B-12 deficiency of this type has traditionally been treated with an intramuscular injection of Vitamin B-12. Most individuals who develop a Vitamin B-12 deficiency resulting from structural or functional damage to the gastrointestinal system have an underlying stomach or intestinal disorder that limits the absorption of Vitamin B-12. Characteristic signs of Vitamin B-12 deficiency include fatigue,

weakness, nausea, constipation, flatulence (gas), loss of appetite and weight loss. Deficiency also can lead to neurological changes such as numbness and tingling in the hands and feet. Additional symptoms of Vitamin B-12 deficiency are difficulty in maintaining balance, depression, confusion, poor memory and soreness of the mouth or tongue. Sometimes the only symptom of these intestinal disorders is anemia resulting from Vitamin B-12 deficiency. Dietary deficiency of Vitamin B-12 has also been seen in strict vegetarians but this type of deficiency can be treated with oral Vitamin B-12 supplements.

Currently in the United States approximately 37 million injection dosages of Vitamin B-12 are prescribed annually to address all causes of Vitamin B-12 deficiency. Although the potential market for the use of Nascobal is large, we have initially focused our promotional efforts on patients who through surgery or as a result of disease cannot readily absorb Vitamin B-12, including patients susceptible to a Vitamin B-12 deficiency caused by Crohn's disease, gastric bypass surgery or MS.

People with Crohn's disease may have difficulty absorbing Vitamin B-12 because of intestinal inflammation. Crohn's patients who have had both a primary and secondary surgical resection of their small bowel may develop Vitamin B-12 deficiency. Vitamin B-12 deficiency can also predate surgery in Crohn's patients. A study in patients with Crohn's disease found that up to 60% of those who had not had surgery showed signs of Vitamin B-12 deficiency, probably due to the malabsorption caused by the disease itself. Surgical procedures of the gastrointestinal tract, such as surgery to remove all or part of the stomach, often result in a loss of cells that secrete stomach acid and intrinsic factor, a substance normally present in the stomach. Surgical removal of the distal ileum, a section of the intestines, also can result in the inability to absorb Vitamin B-12. Individuals who have had either of these surgeries usually require lifelong supplemental Vitamin B-12 to prevent a deficiency. In the U.S. alone there are approximately 500,000 Crohn's patients, of which approximately 175,000 are candidates for Vitamin B-12 therapy.

Gastric bypass surgery is a surgical procedure performed on morbidly obese patients. Obesity is a major health problem in the United States and it is estimated that over 12 million Americans are classified as morbidly obese. To assist with weight loss, bariatric surgeons perform a variety of surgical procedures on the stomach and intestines designed to restrict or limit the intake of food. As a result of these procedures, the absorption of Vitamin B-12 through diet is extremely limited. In fact, approximately 50% of patients two years after surgery had significant vitamin and mineral deficiency. In 2004, it is estimated that 110,000 gastric bypass surgeries were performed and the number of procedures is expected to increase in 2005.

A study of MS patients found that over 20% had abnormally low serum Vitamin B-12 levels. Cerebral spinal fluid levels of Vitamin B-12 were also reduced in patients with MS. It is speculated that Vitamin B-12 associated transmethylation may be an important component in the demyelination that is characteristic of MS. Over 350,000 people in the U.S. have MS.

Vitamin B-12 deficiency may also result from a variety of disease states. It is estimated that 1% of the U.S. population (approximately 2,750,000 people) will develop pernicious anemia in their lifetime. Pernicious anemia is a rare blood disorder characterized by the inability of the body to properly utilize Vitamin B-12. Pernicious anemia occurs when there is an absence of intrinsic factor, a substance normally present in the stomach. Vitamin B-12 deficiency is found in up to 10% of patients over 60 years old. Another study suggests that approximately half of Americans over 65 can not absorb the Vitamin B-12 contained in their food. Among the estimated 800,000 HIV and AIDS patients in the U.S., 10 to 20% (or approximately 80,000-160,000 people) are Vitamin B-12 deficient.

Current maintenance treatment for Vitamin B-12 deficiency calls for injections of Vitamin B-12 once per month for life. This chronic need for Vitamin B-12 replacement therapy often requires frequent trips to a health care professional's office or visits by a home health care professional to receive injections.

Nascobal gel is the only intranasal Vitamin B-12 available, and is the only non-injectable prescription Vitamin B-12 therapy. It is administered once a week which can enhance compliance and provide more consistent blood levels than monthly injections of Vitamin B-12. Nascobal is covered by most major pharmaceutical benefit programs.

In September 2003, the FDA approved our request to have Nascobal labeled for first-line use for all Vitamin B-12 deficiencies except pernicious anemia. Previously, the approved Nascobal labeling required the initial stabilization of Vitamin B-12 levels with injectable Vitamin B-12 before switching to Nascobal.

Nascobal is manufactured for us by Nastech under a long-term supply agreement. The purchase price is adjusted annually based on increases in Nastech's raw materials costs and the Producer Price Index for Pharmaceutical Preparations. As part of our acquisition of Nascobal, we also acquired the rights to Nascobal nasal spray, a new dosage form, for which a New Drug Application ("NDA") was filed by Nastech with the FDA in December 2003. The FDA approved the NDA for Nascobal nasal spray in February 2005.

Nascobal competes in the market for Vitamin B-12 replacement therapy. This market on a unit basis is dominated by inexpensive generic Vitamin B-12 injections. The Vitamin B-12 injection requires the additional expense of a doctor's office visit once a month. Some patients may also receive over-the-counter Vitamin B-12 tablets or sublingual formulations of Vitamin B-12; however, the effectiveness of tablets and sublingual formulation is questionable in the patients for whom Nascobal is marketed.

Ethamolin. End-stage liver disease, also known as hepatic cirrhosis, results in approximately 26,000 deaths annually in the United States. Hepatic cirrhosis promotes the formation of enlarged weakened blood vessels at the entrance to the stomach that have recently bled, known as esophageal varices, through development of portal hypertension. When portal venous blood pressure rises, the varicosities that develop may cause life threatening upper gastrointestinal hemorrhage and are associated with a high mortality rate. At least 33,000 patients in the United States have either actively bleeding esophageal varices or esophageal varices that are at imminent risk of bleeding.

Early and effective treatment of esophageal varices to achieve hemostasis is essential to a favorable outcome in a bleeding patient. The most common pharmaceutical treatment protocol involves the injection of a sclerosing agent into the varix, achieving clot formation and obliteration of the varix. Sclerotherapy agents are chemicals that are injected into varicose veins that damage and scar the inside of the vein, causing it to close. This form of hemostasis is called sclerotherapy and usually requires multiple treatment sessions. Ethamolin is the only sclerotherapy agent approved by the FDA for the treatment of esophageal varices that have recently bled. However, there is strong competition from band ligation, a form of surgery that is becoming the treatment of choice for this emergent clinical condition. At the present time, we are not actively promoting Ethamolin.

Ethamolin is manufactured for us by Ben Venue Laboratories ("Ben Venue") on a purchase order basis. The purchase price is based on Ben Venue's costs at the time of manufacture.

Several companies may offer less expensive sclerotherapy agents that compete with Ethamolin. However, Ethamolin is the only product which is FDA approved for treating esophageal varices. Other competitive agents include Scleromate<sup>TM</sup> (an injectable agent used to treat varicose veins and spider veins), Rubber Band Ligation methods (procedures in which bleeding esophageal varices are tied off at their base with rubber bands, cutting off the blood flow) such as the Multi-band Superview manufactured by Boston-Scientific, the Multi-band Six Shooter manufactured by Wilson-Cook Medical Inc., and the Multi-band Ligator manufactured by Bard. Other products may reduce the number of bleeding esophageal varices by lowering portal hypertension, such as Sandostatin® manufactured by Novartis. The competition to market FDA-approved active bleeding esophageal varices therapies is intense.

Glofil-125. Glofil-125 is approved by the FDA for measuring glomerular filtration rate ("GFR"), a measurement of kidney function. Nephrology, transplant, oncology and nuclear medicine departments at major medical centers are the primary users of Glofil-125. Glofil-125 is an injectable radioisotope diagnostic agent, which provides rapid information on GFR with great accuracy. Radioisotopes have very short half-lives and require special handling. Present diagnostic procedures for measuring kidney function include serum creatinine and creatinine clearance tests. These two tests are the most commonly performed methods of measuring kidney function because of their low cost. However, both methods may significantly overestimate kidney function in the estimated 700,000 patients with severe renal disease. The utility of Glofil-125 has been established in published clinical studies as being a more direct and accurate measure of kidney function

yielding much more reliable results than serum creatinine or creatinine clearance tests. This improved accuracy can be essential in monitoring disease progression, implementing appropriate interventions and assessing the degree of success of kidney grafts, post transplant. However, most early stage patients are not deemed to require this degree of accuracy in the determination of renal function.

Due to its high degree of accuracy, Glofil-125 has also been used in clinical trials administered by the National Institutes of Health ("NIH"). Use of Glofil-125 in clinical trials can provide the trial administrators with an accurate measure of kidney function and illustrate the effects of the drug being studied on normal kidney function.

The biggest impediment to future growth in the sales of Glofil-125 is the current lack of availability of the test to practicing clinicians, because routine testing with Glofil-125 requires dedicated laboratory facilities and trained technicians. Due to the lack of strategic fit, the promotional efforts on Glofil-125 are limited to supporting existing users.

Glofil-125 is manufactured for us by ISO-Tex Diagnostics, Inc. ("ISO-Tex") from whom we purchase on a lot by lot basis. The purchase price is based on ISO-Tex's costs at the time of manufacture.

There are numerous products that may be viewed as competitors to Glofil-125. These include intrinsic tests, such as serum creatinine tests and creatinine clearance tests, both of which are used to measure how quickly the kidneys are able to clear creatinine, an endogenously produced chemical from the blood. Extrinsic tests use such products as Omnipaque® (an injectable contrast media agent), manufactured by Sanofi, a division of Sanofi-Synthelabo, and Conray®-iothalamate meglumine (another injectable contrast medium), manufactured by Mallinckrodt, Inc. There is intense competition among both FDA and non-FDA approved products to measure kidney function.

VSL#3. We acquired U.S. promotion rights from VSL Pharmaceuticals, Inc. for VSL#3 under an agreement effective January 2002. VSL#3 is a patented over-the-counter probiotic preparation of eight live freeze-dried lactic acid bacterial species. Probiotics are living organisms in foods and dietary supplements, which, upon ingestion in certain numbers, improve the health of the host beyond their inherent basic nutrition. We formally launched VSL#3 to the market as a dietary supplement to promote normal gastrointestinal ("GI") function at the annual Digestive Disease Week meeting in May 2002. We purchased VSL#3 products from Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau Pharmaceuticals") at a fixed price.

Effective January 1, 2004, VSL Pharmaceuticals, Inc. assigned the promotion agreement for VSL#3 to Sigma-Tau Pharmaceuticals. 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. In 2004, we may have benefited from this increased promotion effort in that we were responsible for taking orders and shipping VSL#3 directly to customers. As such, we recognized the revenues for the sales of VSL#3 in the United States regardless of which company promoted the product. The promotion agreement expired in January 2005 in accordance with its terms, as Sigma-Tau Pharmaceuticals has chosen to assume promotional efforts for VSL#3.

*Inulin*. Due to minimal demand, increasing production costs and lack of strategic fit, we discontinued marketing and selling Inulin in September 2003. In December 2003 we sold the Inulin product and marketing rights.

#### **Drug Development**

Our development stage products include the intranasal drugs Emitasol, Hypnostat and Panistat.

## **Intranasal Drugs**

Emitasol

Through our merger with RiboGene, we acquired Emitasol, an intranasal form of metoclopramide, which is an approved antiemetic available in oral and intravenous forms to treat diabetic gastroparesis and to prevent acute chemotherapy-induced emesis. We, through future strategic partners, may also choose to investigate

Emitasol for the treatment of diabetic gastroparesis and delayed onset emesis (nausea and vomiting) associated with cancer chemotherapy.

Emitasol was developed and marketed in certain countries throughout the world through corporate partners. It is approved in Italy as Pramidin, and during 2002 approximately 15,600 units were distributed by sirton under our license agreement in Italy for the treatment of a variety of gastrointestinal disorders and emesis. This agreement expired in accordance with terms in June 2002. We entered into a marketing agreement in December 2000 with Ahn-Gook Pharmaceuticals ("Ahn-Gook"), for intranasal metoclopramide, to be marketed under the trade name Emitasol, in Korea. Ahn-Gook also signed an agreement with sirton to obtain the intranasal metoclopramide finished product. Emitasol has been approved in Korea, and is distributed by Ahn-Gook in Korea for the treatment of gastrointestinal disorders and emesis, on a hospital by hospital basis. In the United States, Emitasol could be proposed as a method to control diabetic gastroparesis and to prevent delayed onset emesis associated with cancer chemotherapy. In 2003, the FDA approved Merck's Emend (aprepitant) with 5-HT3 antagonist for various indications, including delayed onset emesis, and MGI Pharma's Aloxi (palonsetron hydrochloride) for the prevention of acute and delayed nausea and vomiting associated with chemotherapy. Given these approvals, our potential to develop Emitasol for delayed onset emesis has diminished. At the present time, due to high development costs, we have no plans to investigate or develop further uses of Emitasol.

#### Hypnostat and Panistat

Through our merger with RiboGene, we acquired Hypnostat, an intranasal form of triazolam for the treatment of insomnia, and Panistat, an intranasal alprazolam for the treatment of panic disorders. In June 2002, we signed a definitive License Agreement with Fabre-Kramer, whereby we granted Fabre-Kramer exclusive worldwide rights to develop and commercialize Hypnostat and Panistat. Immediately after the License Agreement was signed, we received a cash payment of \$250,000 for the transfer of all technology related to the products. We are entitled to future payments from Fabre-Kramer when specific developmental milestones are met. In 2003 we received a milestone payment from Fabre-Kramer of \$250,000, which we recognized as revenue as there were no continuing obligations. We will also receive a milestone payment upon the acceptance of a New Drug Application and the approval of a New Drug Application for Hypnostat and Panistat, provided Fabre-Kramer has not entered into an agreement prior to these events. If Fabre-Kramer has entered into an agreement, we will share the payments received by them under the agreement. In addition, we are entitled to a share of future worldwide product-related Fabre-Kramer revenues, based on a percentage of total revenues. No further payments have been received and Fabre-Kramer has informed us that development efforts have ceased.

Fabre-Kramer intended to develop Panistat for the management of panic disorder or the short-term relief of anxiety symptoms. We believe that Panistat, when given intranasally, may be effective in treating panic disorders. To date, no clinical work has been performed on Panistat. We believe it will be several years, if ever, before Panistat is commercially available.

#### Glial Excitotoxin Release Inhibitors ("GERIs")

The GERIs are neuroprotective compounds that may prevent ischemic brain damage originating from astrocytes (astroglial cells). Astrocytes serve important metabolic functions and are thought to be responsible for the bulk of brain swelling following stroke or injury. The GERI compounds were being funded by a Small Business Innovation Research ("SBIR") grant from the NIH. The grant was terminated on July 31, 2003. We do not intend to expend any additional resources on these compounds nor do we expect to realize license fees or revenues from such programs.

## Other Strategic Alliances and Collaborations

### The Dainippon Agreement

We have an exclusive, worldwide license agreement with Dainippon to use our antibacterial peptide deformylase and ppGpp degradase technology for the research, development and commercialization of

pharmaceutical products. We have retained the right to co-promote, in Europe and the United States, certain products resulting from the arrangement. We will be entitled to receive potential milestone payments upon the achievement of clinical and regulatory milestones up to the amount of \$5.0 million in Japan and \$5.0 million in one other major market. The first milestone payment will occur upon the initiation of a human clinical trial using a compound included in the agreement. We will receive a potential royalty on net sales that will range from 5% to 10%, depending on sales volume and territory.

Dainippon has been conducting research on two specific bacterial targets, peptide deformylase and ppGpp degradase. To date, Dainippon has focused most of their efforts on the deformylase project. Their efforts on the ppGpp degradase project have ended. Several compounds have been synthesized and tested in vivo against drug resistant bacteria. Although the compounds have shown good in vivo activity, Dainippon has not selected any compounds for clinical studies in animals. There can be no assurance that Dainippon will ever select any compounds for preclinical studies or if selected that these compounds will eventually be approved as drugs. There can also be no assurance that we will ever receive any milestone payments or royalties under our agreement with Dainippon.

#### The Rigel Pharmaceuticals Agreement

We have an exclusive agreement with Rigel Pharmaceuticals, Inc. ("Rigel") to use our antiviral technology. Under the agreement, we have assigned to Rigel certain antiviral technology, including our Hepatitis C virus internal ribosome entry site and NS5A drug discovery technology, for the research, development and commercialization of pharmaceutical products. We will be entitled to potential future milestone payments upon the achievement of certain clinical and regulatory milestones, including the selection of a compound developed under the agreement for submission as an Investigational New Drug, and royalty payments on sales. The status of this project is on-going at Rigel. There can also be no assurance that we will ever receive any milestone payments or royalties under our agreement with Rigel.

#### **Licenses and Distribution Agreements**

CSC Pharmaceuticals Handels GmbH ("CSC"). In April 1997, RiboGene entered into an agreement with CSC which was assigned to us upon our merger with RiboGene. The agreement grants CSC an exclusive license to market and sell Emitasol in Austria, Poland, the Czech Republic, Bulgaria, Russia, Hungary, the Slovak Republic, Romania, and the remaining Community of Independent States and eight other eastern European countries. CSC has agreed to pay us a royalty based on net sales within the countries listed above. The agreement will expire on a country-by-country basis 10 years after the first commercial sale in that country. Although we can terminate the license if CSC did not obtain approval in any country contained in the agreement by April 16, 1999, we have not done so, since CSC has filed for regulatory approval in Austria, Russia, Hungary and the Slovak Republic. In 2001, CSC received approval to market Emitasol in Poland and the Czech Republic and has no immediate plans to do so. It is difficult to predict when, if ever, CSC will begin to market Emitasol in their approved territories.

Laboratorios Silesia SA. In December 1999, we signed a license agreement with Laboratorios Silesia SA for marketing intranasal metoclopramide, to be marketed under the trade name Emitasol, in Chile. Laboratorios Silesia SA also signed an agreement with sirton to obtain the intranasal metoclopramide finished product under the trade name Pramidin. This product is marketed as Pramidin in Italy. We received a small up-front payment and will receive royalties on net sales, if any, of Emitasol in this territory. The product was submitted for approval in Chile and was rejected. As of December 2004, the status of this product remains uncertain.

Ahn-Gook Pharmaceutical Co., Ltd. ("Ahn-Gook"). We entered into a license agreement in December 2000 and amended in December 2002 with Ahn-Gook for marketing intranasal metoclopramide, to be marketed in Korea under the trade name Emitasol. Ahn-Gook received government approval to market Emitasol in 2002 and began selling in the Republic of Korea in the first half of 2003. Through 2004, the sales of the product have been minimal. Ahn-Gook intends to manufacture Emitasol in Korea. We received an up-

front cash payment of \$50,000 in 2000 and a milestone payment of \$150,000 in 2002 upon transfer of technology and will earn future royalties based on actual sales in Korea. In December 2002, we expanded the license agreement to include twelve additional countries in Asia and since we have no future obligations, we recognized \$200,000 in revenues related to the up-front cash payment and milestone payment under the agreement. We did not receive payments or royalties under this agreement in 2003 or 2004.

## Manufacturing

We do not currently manufacture any of our acquired products. Our commercial products, Acthar, Nascobal, Ethamolin and Glofil-125, are manufactured for us by approved contract manufacturers.

In 2003, we transferred the Acthar final fill and packaging process from Aventis to our contract manufacturer, Chesapeake Biological Laboratories, Inc. ("CBL"), and produced our first lot of Acthar finished vials using active pharmaceutical ingredient ("API") purchased from Aventis ("Aventis API"). We began shipping this lot to customers in September 2003. We have now produced a total of three commercial Acthar lots at CBL using Aventis API.

In 2004, we transferred the Acthar API manufacturing process from Aventis to our contract manufacturer, BioVectra dcl ("BioVectra"), and produced the first BioVectra API lot. In late 2004, we filed an NDA Supplement with the FDA seeking approval for the API manufacturing site transfer. The FDA has approved our use of Aventis API in the production of Acthar finished vials until the API manufacturing site transfer is approved. We expect to use the BioVectra API in 2005 to produce finished Acthar product for commercial use once the FDA approves the API manufacturing site transfer. Based on internal sales forecasts, our existing inventory of the Aventis API should be adequate to supply the annual demand for Acthar through 2006. We have signed an agreement with BioVectra, which requires minimum production totaling \$1.7 million during the term of the agreement. The agreement terminates on December 31, 2007 and includes two one-year extension options.

The production of Acthar API and finished vials are subject to inspection and ultimate approval by the FDA. While we have reviewed our plans and progress to date with the FDA, and received a positive response, additional approvals are required. The FDA approved our Supplemental New Drug Application filed on September 27, 2002 to extend the labeled shelf life of Acthar from twelve months to 18 months from the date of manufacture.

We have 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. ZLB Behring ("ZLB") has agreed to support Questcor through 2006 by continuing to conduct the two bioassays until we receive FDA approval, and conduct the potency testing and assist us on the potency assay transfer. Work on the potency assay transfer is planned to restart by mid-2005. There are no assurances that we will be successful in transferring this assay. If we are unable to efficiently and timely validate the potency assay prior to the end of 2006, we will not be able to release both API and finished vials, and therefore we may not be able to meet the expected demand for Acthar.

The transfer of manufacturing from Aventis to our new contract manufacturers results in higher unit costs than the fixed-price manufacturing agreement with Aventis, which decreases our gross margins on sales of Acthar.

Nascobal is manufactured for us by Nastech under a long-term supply agreement. The purchase price is adjusted annually based on increases in Nastech's raw materials costs and the Producer Price Index for Pharmaceutical Preparations. Nastech manufactures Nascobal at its FDA approved, current good manufacturing practice ("cGMP") manufacturing facility in Hauppauge, New York.

During 2002, we successfully transferred the manufacturing of Ethamolin from Schering Plough to Ben Venue. We obtained FDA approval for the transfer to Ben Venue in September 2002. Ben Venue manufactures Ethamolin for us on a purchase order basis. We believe we have sufficient product on hand to cover demand through late 2005. A new lot of Ethamolin is scheduled to be manufactured by mid-2005.

Our manufacturer of Glofil-125 was subject to an FDA inspection in June 2004. As a result of this inspection, the FDA placed our manufacturer back onto a normal two year inspection cycle. The FDA had previously placed the manufacturer on a yearly inspection cycle as a result of FDA inspections conducted prior to 2004.

There can be no assurance that any of our API or finished goods contract manufacturers will continue to meet our requirements for quality, quantity and timeliness or the FDA's cGMP requirements. Also, there can be no assurance that we will be able to obtain FDA approval for the Acthar API manufacturing site transfer, nor that our contract manufacturers will be able to meet all cGMP requirements, nor that lots will not have to be recalled with the attendant financial consequences to us.

Our dependence upon others for the manufacture of API or finished forms of our products may adversely affect the future profit margin on the sale of those products and our ability to develop and deliver products on a timely and competitive basis. We do not have substitute suppliers for any of our products although we strive to plan appropriately and maintain safety stocks of product to cover unforeseen events at manufacturing sites. In the event we are unable to manufacture our products, either directly or indirectly through others or on commercially acceptable terms, if at all, we may not be able to commercialize our products as planned.

#### Sales and Marketing

As of December 31, 2004, we have hired, trained and deployed a total of 17 product specialists and 10 sales and marketing personnel to support the commercialization of our primary promoted products, Acthar and Nascobal. Our strategic focus in 2004 was neurology and gastroenterology. Our promotion and educational efforts for Acthar are focused on pediatric neurologists and on a subset of high potential neurologists dedicated to the treatment of multiple sclerosis in adults. We market Nascobal to physicians who treat patients at high risk of developing deficiencies of Vitamin B-12. Our priority targets for Nascobal are gastroenterologists (Crohn's disease), bariatric surgeons (gastric bypass surgery), neurologists (MS, dementia) and a select number of primary care physicians. Each of these physician specialists sees a high number of patients with a compromised ability to absorb Vitamin B-12 through the gastrointestinal system. We are not actively marketing Ethamolin and Glofil-125 at this time.

### **International Distribution Agreements**

#### Beacon Pharmaceuticals, Ltd.

In October 2002 we signed an agreement with Beacon Pharmaceuticals, Ltd. ("Beacon") of Tunbridge Wells, Kent, UK, for the exclusive marketing and distribution of Acthar in the United Kingdom on a named patient basis. Sales to Beacon were \$135,000, \$78,000 and \$64,000 in 2004, 2003 and 2002, respectively.

#### **IDIS** Limited

In November 2003, we signed an agreement with IDIS Limited ("IDIS") of Sirbiton, Surrey, UK for the exclusive distribution of Acthar, Ethamolin and Nascobal on a named patient basis. The agreement covers all countries of the world except: the United States; Australia and New Zealand where Acthar and Ethamolin are sold through a distributor and the UK where Acthar is sold through Beacon. Sales to IDIS in 2004 were \$78,000. There were no sales to IDIS in 2003.

## Competition

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological change. A number of companies are pursuing the development of pharmaceuticals and products that target the same diseases and conditions that we target. There are products and treatments on the market that compete with Acthar, Nascobal, Ethamolin and Glofil-125. Moreover, technology controlled by third parties that may be advantageous to our business may be acquired or licensed by our competitors, which may prevent us from obtaining this technology on favorable terms, or at all.

Our ability to compete will depend on our ability to acquire and commercialize pharmaceutical products that address critical medical needs, as well as our ability to attract and retain qualified personnel, and secure sufficient capital resources for the acquisition and commercialization of products.

Most of our competitors are larger than us and have substantially greater financial, marketing and technical resources than we have. Furthermore, if we commence commercial sales of products that are currently in the development stage, when they are approved, we will also be competing with respect to manufacturing efficiency and marketing capabilities, areas in which we have limited experience. If any of the competitors develop new products that are superior to our products, our ability to expand into the pharmaceutical markets may be materially and adversely affected.

Competition among products will be based, among other things, on product efficacy, safety, reliability, availability, price and patent position. An important factor will be the timing of market introduction of our or our competitors' products. Accordingly, the relative speed with which we can acquire products and supply commercial quantities of the products to the market is expected to be an important competitive factor.

### **Government Regulation**

#### **Marketed Pharmaceutical Products**

The processes carried out in the production of pharmaceutical products by pharmaceutical firms, including manufacturers from whom we purchase products, are subject to regulation by the FDA. Any restrictions or prohibitions applicable to sales of products we market could materially and adversely affect our business.

We market prescription drug products that have been approved by the FDA. The FDA has the authority to revoke existing approvals if new information reveals that they are not safe or effective. The FDA also regulates the promotion, including advertisement, of prescription drugs.

Drug products must be manufactured, packaged, and labeled in accordance with their approvals and in conformity with cGMP standards and other requirements. Drug manufacturing facilities must be registered with and approved by the FDA and must list with the FDA the drug products they intend to manufacture or distribute. The manufacturer is subject to inspections by the FDA and periodic inspections by other regulatory agencies. The FDA has extensive enforcement powers over the activities of pharmaceutical manufacturers, including authority to seize and prohibit the sale of unapproved or noncomplying products, and to halt manufacturing operations that are not in compliance with current cGMPs. The FDA may impose criminal penalties arising from non-compliance with applicable regulations.

## **Drugs in Development**

Our products in development are subject to extensive regulation by the U.S., principally under the Federal Food, Drug and Cosmetic Act ("FDCA") and the Public Health Service Act, and foreign governmental authorities. In particular, drugs and biological products are subject to rigorous preclinical and clinical testing and other approval requirements by the FDA, state and local authorities and comparable foreign regulatory authorities. The process for obtaining the required regulatory approvals from the FDA and other regulatory authorities takes many years and is very expensive. There can be no assurance that any product developed by us and current or potential development partners will prove to meet all of the applicable standards to receive marketing approval in the U.S. or abroad. There can be no assurance that these approvals will be granted on a timely basis, if at all. Delays and costs in obtaining these approvals and the subsequent compliance with applicable federal, state and local statutes and regulations could materially adversely affect our ability to commercialize our products and our ability to earn sales revenues.

#### **Patents and Proprietary Rights**

Our success may depend in part upon our ability to maintain confidentiality, operate without infringing upon the proprietary rights of third parties, and obtain patent protection for our products. We have obtained patent coverage, either directly or through licenses from third parties, for Nascobal and some of our products

in development or marketed overseas. We currently own one U.S. patent that is scheduled to expire on April 16, 2005, covering certain formulations of Nascobal. We could face increased competition in connection with our Nascobal gel formulation from competitors entering the market after expiration of the U.S. patent on April 16, 2005. We hold the right to have assigned to us two pending patent applications in the U.S. for a new spray formulation of Nascobal and related technology. We own eighteen issued U.S. and foreign patents covering Hypnostat and Panistat, seven issued U.S. and foreign patents covering Emitasol, and eight issued U.S. and foreign patents covering our other technology.

We acquired intellectual property associated with our intranasal program, including Emitasol for diabetic gastroparesis and delayed onset emesis associated with chemotherapy, Migrastat (intranasal propranolol) for migraine treatment, and intranasal benzodiazepines such as Hypnostat and Panistat for various conditions such as anxiety, seizures, panic attacks and sleep disorders. We have licensed rights to intranasal metoclopramide in Italy, Chile, South Korea, Austria, the Russian Federation, Asia (excluding Japan) and certain former Eastern European countries. The former Italian licensee, sirton, received approval to market intranasal metoclopramide (Pramidin) in Italy. The agreement with sirton expired according to terms in June 2002. There can be no assurance that the foreign licensees will obtain the necessary regulatory approvals to market Emitasol, or that, in the event such approvals are obtained, Emitasol will achieve market acceptance in such countries, or that we will ever realize royalties on sales of Emitasol in such countries. We also have a number of patent applications currently pending in Patent Offices around the world on our various products and expect to file additional applications in the future.

#### **Employees**

At December 31, 2004, we had 41 full-time employees (as compared to 39 full-time employees at December 31, 2003). We experienced several executive transitions in 2004 and early 2005. On February 18, 2005, Mr. James L. Fares was named President and Chief Executive Officer, succeeding Mr. Charles J. Casamento who resigned on August 5, 2004. Mr. Timothy E. Morris resigned as Senior Vice President of Finance and Administration and Chief Financial Officer effective November 9, 2004. Ms. Barbara J. McKee joined the Company as Director of Finance on February 28, 2005 and was named Principal Accounting Officer on March 21, 2005. On March 8, 2005, Mr. Steve Cartt joined Questcor as Executive Vice President of Commercial Development. Mr. R. Jerald Beers resigned as Vice President, Sales and Marketing on March 3, 2005.

Our success will depend in large part on our ability to attract and retain key employees. At December 31, 2004, we had 27 employees engaged directly in the marketing and selling of our products. We believe that our relationship with our employees is good. None of our employees are represented by a collective bargaining agreement, nor have we experienced work stoppages.

#### **Website Address**

Our website address is www.questcor.com. We make available free of charge through our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to these reports as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC, by providing a hyperlink to the SEC's website directly to such reports.

#### RISK FACTORS

We have a history of operating losses and may never generate sufficient revenue to achieve profitability.

We have a history of recurring operating losses. Our accumulated deficit through December 31, 2004 was \$84.4 million, of which \$1.5 million represented the net loss applicable to common shareholders for the twelve months ended December 31, 2004, \$5.9 million represented the net loss applicable to common shareholders for the year ended December 31, 2003, and \$2.8 million represented the net loss applicable to common shareholders for the year ended December 31, 2002. Operating losses are expected to continue at least through the end of 2005. To date, our revenues have been generated principally from sales of Acthar, Nascobal,

Ethamolin, Glofil-125, Inulin and VSL#3. In July 2003, we began selling Nascobal, a product that we acquired in June 2003. We discontinued selling Inulin in September 2003. The promotion agreement for VSL#3 expired in January 2005 and we will no longer be selling VSL#3. We do not expect Emitasol, Hypnostat or Panistat to be commercially available for a number of years, if at all.

Our ability to achieve a consistent, profitable level of operations will be dependent in large part upon our ability to:

- develop, finance and implement an effective promotional strategy for current products,
- finance and acquire additional marketed products,
- finance operations with external capital until consistent positive cash flows are achieved,
- obtain FDA approval for the Acthar API manufacturing site transfer and the transfer of the Acthar bioassays,
- continue to receive products from our sole-source contract manufacturers on a timely basis and at acceptable costs,
- continue to control our operating expenses, and
- ensure customers' compliance with our sales and exchange policies.

If we are unable to generate sufficient revenues from the sale of our products, or if we are unable to contain costs and expenses, we may not achieve profitability and may ultimately be unable to fund our operations.

### If our revenues from product sales decline or fail to grow, we may not have sufficient revenues to fund our operations.

We rely heavily on sales of Acthar and Nascobal. We expect to continue to rely on sales of these products in 2005. We review external data sources to estimate customer demand for our products. In the event that demand for our products is less than our sales to wholesalers, excess inventory may result at the wholesaler level, which may impact future product sales. If the supply of Acthar or Nascobal available at the wholesale level exceeds the future demand, our future revenues from the sales of Acthar or Nascobal may be affected adversely.

We monitor the amount of Acthar and Nascobal at the wholesale level as well as prescription data obtained from third party sources to help assess product demand. Although our goal is to actively promote Acthar and Nascobal, and we have no reason to believe that our promotion of Acthar and Nascobal will not be successful, we cannot predict whether the demand for Acthar and Nascobal will continue in the future or that we will continue to generate significant revenues from sales of Acthar and Nascobal. We may choose, in the future, to reallocate our sales and promotion efforts for Acthar and Nascobal which may result in a decrease in revenues from one or both of the products. If the demand for Acthar or Nascobal declines, or if we are forced to reduce the prices, or if exchanges of expired products are higher than anticipated, or if we are forced to re-negotiate contracts or terms, or if our customers do not comply with our existing policies, our revenues from the sale of Acthar or Nascobal would decline. If the cost to produce Acthar increases, and we are unable to raise the price correspondingly, our gross margins on the sale of Acthar would decline. If our revenues from the sale of Acthar or Nascobal decline or fail to grow, our total revenues, gross margins and operating results would be harmed and we may not have sufficient revenues to fund our operations.

## If we are unsuccessful in completing the Acthar manufacturing site transfer, we may be unable to meet the demand for Acthar and lose potential revenues.

Any delays or problems associated with obtaining FDA approval for the Acthar API manufacturing site transfer or the transfer of the three bioassays (including potency) to a new contract laboratory could reduce the amount of the product that will be available for sale and adversely affect our operating results. In 2003, we signed an agreement with CBL, a contract manufacturer for Acthar finished product, and transferred the final

fill and packaging process from Aventis to CBL. We also produced our first lot of Acthar finished vials using the Aventis API in 2003. We have now produced a total of three commercial Acthar lots at CBL using Aventis API.

In 2004, we transferred the Acthar API manufacturing process from Aventis to our contract manufacturer, BioVectra, and produced the first BioVectra API lot. In late 2004, we filed an NDA Supplement with the FDA seeking approval for the API manufacturing site transfer. The FDA has approved our use of Aventis API in the production of Acthar finished vials until the API manufacturing site transfer is approved. Use of Aventis API is conditioned on the results of yearly re-testing meeting current API specifications. We expect to use the BioVectra API in 2005 to produce finished Acthar product for commercial use once the FDA approves the API manufacturing site transfer. Based on internal sales forecasts, our existing inventory of the Aventis API should be adequate to supply the annual demand for Acthar through 2006. However, if demand exceeds our forecasts, if FDA approval of the Acthar API manufacturing site transfer is delayed, or if the Aventis API yearly re-testing results fail to meet current API specifications, we could be unable to meet demand and we could lose potential revenues.

The production of Acthar API and finished vials are subject to inspection and ultimate approval by the FDA. While we have reviewed our plans and progress to date with the FDA, and received a positive response, additional approvals are required. The Acthar API manufacturing site transfer has several risks that could have a materially adverse impact on our financial results in future years. Such risks include the ability of the new contractors to produce API in sufficient quantities, on a timely basis, at an acceptable cost, that meet the potency specification, and the possibility that the production facility and the process will be not be approved by the FDA. Although we believe that the Acthar API manufacturing site transfer will be successful, there can be no assurance that the manufacturing site transfer will be approved by the FDA and that the transfer will not have a materially adverse impact on the company in the future.

We have 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. ZLB has agreed to support Questcor through 2006 by continuing to conduct the two bioassays until we receive FDA approval, and conduct the potency testing and assist us on the potency assay transfer. Work on this assay transfer is planned to restart by mid-2005. There can be no assurances that we will be successful in transferring this assay. If this laboratory is unable to validate this specific assay, we may be forced to find a new contractor to complete this work, which in turn could increase our costs substantially. If we are unable to efficiently and timely validate the potency assay before the end of 2006, we will not be able to release API and finished goods and therefore we may not be able to meet the expected demand for Acthar.

Once the FDA approves the Acthar API manufacturing site transfer, the cost of the product will increase which will cause our gross margins to decline. In addition, if the approvals by the FDA do not occur on a timely basis, we could lose sales. Moreover, contract manufacturers that we use must continually adhere to current good manufacturing practices regulations enforced by the FDA. If the facilities of these manufacturers cannot pass an inspection, we may lose the FDA approval of our products. Failure to obtain products for sale for any reason may result in an inability to meet product demand and a loss of potential revenues.

If our customers do not comply with our product exchange policy or demand that we implement a credit memoranda return policy for product lots covered by our product exchange policy, our revenues would be significantly impacted.

Our product exchange policy is applicable to production lots released prior to June 1, 2004, under which we ship replacement product for expired product returned to us within six months after expiration. The standard policy in the industry is to issue credit memoranda in exchange for expired product. The three largest wholesalers to which we sell have expressed dissatisfaction with our product exchange policy and, although they have complied to date, our ability to enforce this policy on wholesalers whose influence within the pharmaceutical industry and resources are far greater than ours may prove to be difficult. Since we sell a

majority of our products to the three largest wholesalers and no viable alternatives currently exist, we may be forced to change our product exchange policy to a credit memoranda return policy in which credit memoranda are issued for all returns currently subject to the product exchange policy. In the event this occurred, the negative financial impact on our revenues, operations and cash position would be substantial in the near term.

During the second quarter of 2004, we implemented a transition plan for expired product returns from the product exchange policy to a credit memoranda return policy for the return of expired product within six months beyond the expiration date. Expired product returned from lots released after May 31, 2004 are subject to this credit memoranda return policy in which a credit memoranda will be issued for the original purchase price of the returned product.

Should this transition plan to a credit memoranda return policy not be adhered to and we are forced to issue credit memoranda for all returns currently subject to the product exchange policy, the reserves for credit memoranda would be significantly increased, with an offset to gross product sales at the time of the policy change. This change in policy would have a significant negative financial impact at the time of the change, reducing gross product sales by the amount of the estimated future credit memoranda to be issued, offset by a reduction in cost of product sales for the elimination of the reserve for product replacement.

Due to the short shelf life of Acthar (18 months), significant quantities could expire at the wholesale or pharmacy level, which could then be returned for replacement product under our product exchange policy, or credit memoranda under our credit memoranda return policy. We are actively monitoring inventory levels at the wholesalers and have implemented a plan designed to minimize the amount of returns of expired product. However there can be no assurance that our actions will be effective in reducing the return of expired product or minimizing the negative impact on receivables and future sales. Such shipment of replacement product may displace future sales.

See the Critical Accounting Policies section in the Management Discussion and Analysis of Financial Condition for further discussion of our product exchange and credit memoranda return policies.

## If our customers do not comply with the terms on which we extend them credit, our cash flows and ability to fund operations may be adversely impacted.

Certain wholesalers are not complying with our product exchange policy. These wholesalers are deducting from amounts owed to us the full price of expired Acthar they plan to return. While we reached an agreement with the three largest wholesalers to pay these short-remittances ("returns receivable") upon their receipt of replacement product for the Acthar that expired in November 2002, May 2003 and December 2004, these wholesalers have continued to deduct from amounts owed to us the full price of expired Acthar they return to us. Additionally, certain wholesalers received an administration fee from us for the expired product that was exchanged. Certain wholesalers have continued to short-remit for expired product returns in 2003 and 2004. As of December 31, 2004, the returns receivable amount is \$162,000. As of December 31, 2004, replacement units have been shipped with respect to approximately 11% of the amounts owing to us and we are seeking reimbursement from these wholesalers. The next Acthar lot expires in May 2005, the next Ethamolin lot expires in January 2005 and the next Nascobal lot expires in February 2005. We expect that the wholesalers will continue to short-remit us in the future as these lots and other lots expire and they seek to return expired product. Should these wholesalers not reimburse us for the returns receivable upon shipment of replacement product, the negative impact on our cash and operations would be substantial.

Most of our revenues, and consequently our receivables, are derived from the three largest U.S. drug wholesalers. As of December 31, 2004, 88% of our accounts receivable (excluding allowances) was attributable to these three wholesalers. Consequently, our cash flows and ability to fund operations are highly dependent on these wholesalers' financial ability and willingness to pay amounts due on a timely basis. Should these wholesalers in particular not reimburse us for returns receivable upon shipment of replacement product, or not pay us amounts due on a timely basis for any reason, the negative impact on our cash and operations would be substantial.

#### We have little or no control over our wholesalers' buying patterns, which may impact future revenues, exchanges and excess inventory.

We sell our products primarily through major drug wholesalers located in the United States. Consistent with the pharmaceutical industry, most of our revenues are derived from the three largest drug wholesalers. These wholesalers represented over 81% of our gross product sales for fiscal year 2004. While we attempt to estimate inventory levels of our products at the three largest wholesalers using inventory data obtained from them, historical prescription information and historical purchase patterns, this process is inherently imprecise. We rely solely upon the wholesalers to effect the distribution allocation of our products. There can be no assurance that these wholesalers will adequately manage their local and regional inventories to avoid outages or inventory build-ups. On occasion we note that the wholesalers buy quantities of product in excess of the quantities being sold by them, resulting in increasing inventories.

Our therapeutic pharmaceutical products have expiration dates that range from 18 to 36 months from date of manufacture. We will generally accept for exchange or credit pharmaceutical products returned within the six month period following the expiration date. We establish reserves for these exchanges or credit memoranda at the time of sale. There can be no assurance that we will be able to accurately forecast the reserve requirements needed to provide for exchanges or credit memoranda issued in the future. Although our estimates are reviewed quarterly for reasonableness, our product return activity could differ significantly from our estimates because our analysis of product shipments, prescription trends and the amount of product in the distribution channel may not be accurate. Judgment is required in estimating these reserves. Actual amounts could be significantly different from the estimates and such differences are accounted for in the period in which they become known.

We do not control or significantly influence the purchasing patterns of the drug wholesalers who purchase our products. These are sophisticated companies that purchase our products in a manner consistent with their industry practices and perceived business interests. Our sales are subject to the purchase requirements of the major wholesalers, which, presumably, are based upon their projected demand levels. Purchases by any customer, during any period, may be above or below actual prescription volumes of one or more of our products during the same period, resulting in increases or decreases in product inventory existing in the distribution channel.

We provide reserves for potentially excess, dated or otherwise impaired inventory. Reserves for excess finished goods and work-in-process inventories are based on an analysis of expected future sales that will occur before the inventory on hand expires. Reserves for raw material inventories are based on viability and projected future use. Judgment is required in estimating reserves for excess or impaired inventories. Actual amounts of required reserves could be different from the estimates and such differences are accounted for in the period in which they become known.

#### Our inability to secure additional funding could lead to a loss of your investment.

We raised gross proceeds of \$10 million through a private placement of Series B Preferred Stock in January 2003, \$5 million through a private placement of common stock in June 2003, and \$2.4 million and the surrender of outstanding warrants through a private placement of common stock in January 2004. We anticipate that our capital resources based on our internal forecasts and projections will be adequate to fund operations and capital expenditures through at least December 31, 2005, unless our fiscal year 2005 revenues are less than we expect. In February 2005, Nastech was successful in obtaining approval for the NDA covering the nasal spray formulation and in February 2005, \$2 million was paid to Nastech. If the patent covering the nasal spray formulation issues after the approval of the NDA, we would be required to pay an additional \$2 million to Nastech. On April 15, 2005, we will be required to redeem our 8% convertible debentures, which have a face value of \$4.0 million, for cash, or a combination of \$2.0 million in cash and the remainder in common stock. If we experience unanticipated cash requirements, or if revenues are less than we expect, or we are required to make the milestone payment to Nastech before December 31, 2005, we could be required to raise additional funds. Regardless, we may seek additional funds before the end of 2005, through public or private equity financing or from other sources. Additionally, we may seek to raise capital whenever conditions

in the financial markets are favorable, even if we do not have an immediate need for additional cash at that time. There can be no assurance that additional funds can be obtained on desirable terms or at all.

If revenues from product sales are less than we expect or if further capital resources are not available, or if such resources cannot be obtained on attractive terms to us, this may further limit our ability to fund operations. Our future capital requirements will depend on many factors, including the following:

- existing product sales performance,
- the cost and timing of the Acthar site transfer,
- · achieving better operating efficiencies,
- maintaining customer compliance with our policies,
- obtaining product from our sole-source contract manufacturers and completing the site transfer to new contract manufacturers, and
- acquiring or developing additional products.

We may obtain additional financing through public or private debt or equity financings. However, additional financing may not be available to us on acceptable terms, if at all. Further, additional equity financings will be dilutive to our stockholders. If sufficient capital is not available, then we may be required to reduce our operations or to delay, reduce the scope of, eliminate or divest one or more of our products or manufacturing efforts.

## If we are unable to contract with third party contract manufacturers, we may be unable to meet the demand for our products and lose potential revenues.

We rely on contract manufacturers to produce our marketed products, Acthar, Nascobal, Ethamolin, and Glofil-125 and other products that we may develop, commercialize or acquire in the future. Contract manufacturers may not be able to meet our needs with respect to timing, cost, quantity or quality. All our manufacturers are sole-source manufacturers and no currently qualified alternative suppliers exist.

Ethamolin is currently manufactured by Ben Venue. We do not have a formal Ethamolin manufacturing contract with Ben Venue, however we have an agreement on terms and conditions, and we purchase product on a purchase order basis under these agreed-upon terms and conditions. Glofil-125 is manufactured by ISO-Tex from whom we purchase on a lot by lot basis. Nascobal is manufactured by Nastech under a long-term supply agreement.

See "If we are unsuccessful in completing the Acthar manufacturing site transfer, we may be unable to meet the demand for Acthar and lose potential revenues" for discussion of third party contract manufacturers of Acthar.

If we are unable to contract for a sufficient supply of our required products and services on acceptable terms, or if we should encounter delays or difficulties in our relationships with our manufacturers, or if the required approvals by the FDA and other regulatory authorities do not occur on a timely basis, we will lose sales. Moreover, contract manufacturers that we may use must continually adhere to current good manufacturing practices enforced by the FDA. If the facilities of these manufacturers cannot pass an inspection, we may lose FDA approval of our products. Failure to obtain products for sale for any reason may result in an inability to meet product demand and a loss of potential revenues.

## If our third party distributors are unable to distribute our products or the costs to distribute our products increase substantially, we will lose potential revenues and profits.

We transferred certain product distribution functions, including warehousing, shipping and quality control studies, to third party distributors. The outsourcing of these functions is complex, and we may experience difficulties at the third party contractor level that could reduce, delay or stop shipments of our products. If we

encounter such distribution problems, our products could become unavailable and we could lose revenues, or the costs to distribute these products could become higher than we anticipated.

In fiscal year 2004, 81% of our gross product sales were derived from the three largest drug wholesalers. Two of these three wholesalers instituted a 5% distribution fee for handling our products during 2004. As a result, our distribution costs increased by \$251,000. If other wholesalers institute similar fees, or if such fees increase in magnitude in the future, our costs to distribute products will increase, and our gross profit margins will decline.

#### The Company has experienced changes in key personnel which will have an uncertain impact on future operations.

On February 18, 2005, Mr. James L. Fares was named President and Chief Executive Officer, succeeding Mr. Charles J. Casamento who resigned as Chairman, President and Chief Executive Officer on August 5, 2004. On March 8, 2005, Mr. Steve Cartt was named Executive Vice President of Commercial Development. On March 21, 2005, Ms. Barbara J. McKee was named Principal Accounting Officer. Mr. Timothy Morris resigned as Senior Vice President of Finance and Administration and Chief Financial Officer effective November 9, 2004. On March 3, 2005, Mr. R. Jerald Beers resigned as Vice President, Sales and Marketing. If the transition to a new executive team is unsuccessful, our business could be harmed. We are highly dependent on the services of our President and Chief Executive Officer, Mr. James L. Fares and our Executive Vice President of Commercial Development, Mr. Steve Cartt. If we were to lose Mr. Fares or Mr. Cartt, as employees, our business could be harmed.

We do not carry key person life insurance for our senior management or other personnel. Additionally, the future potential growth and expansion of our business is expected to place increased demands on our management skills and resources. Although some changes in staffing levels are expected during 2005, recruiting and retaining management and operational personnel to perform sales and marketing, financial operations, business development, regulatory affairs, quality assurance, medical affairs and contract manufacturing in the future will also be critical to our success. We do not know if we will be able to attract and retain skilled and experienced management and operational personnel in the future on acceptable terms given the intense competition among numerous pharmaceutical and biotechnology companies for such personnel. If we are unable to hire necessary skilled personnel in the future, our business could be harmed.

## Our commercial products and our products in the development stage may not be accepted by the market, which may result in lower future revenues as well as a decline in our competitive positioning.

Our commercial products and any products that we successfully develop, if approved for marketing, may never achieve market acceptance. These products, if successfully developed, will compete with drugs and therapies manufactured and marketed by major pharmaceutical and other biotechnology companies. Physicians, patients or the medical community in general may not accept and utilize the products that we may develop or that our corporate partners may develop.

The degree of market acceptance of our commercial products and any products that we successfully develop will depend on a number of factors, including:

- · The establishment and demonstration of the clinical efficacy and safety of the product candidates,
- Their potential advantage over alternative treatment methods and competing products,
- Reimbursement policies of government and third party payers, and
- Our ability to market and promote the products effectively.

The failure of our products to achieve market acceptance may result in lower future revenues as well as a decline in our competitive positioning.

A large percentage of our voting stock is beneficially owned by a small number of stockholders, who in the future could attempt to take control of our management and operations or exercise voting power to advance their own best interests and not necessarily those of other stockholders.

Sigma-Tau Finanziaria SpA and its affiliates ("Sigma-Tau") beneficially own, directly or indirectly, approximately 23% of the voting power of our outstanding voting capital stock, and they beneficially own, including shares of our common stock issuable upon conversion of a convertible debenture, approximately 28% of our outstanding common stock, as of March 18, 2005. Additionally, as reported on Amendment No. 3 to Schedule 13D filed with the SEC on May 21, 2004, Corporate Opportunities Fund, L.P. and its affiliates beneficially own approximately 5.7% of our voting capital stock and, as reported on Amendment No. 3 to Schedule 13D filed with the SEC on May 27, 2004, Montreux Equity Partners II SBIC, L.P. and its affiliates beneficially own approximately 5.2% of our voting capital stock. Accordingly, these stockholders, acting individually or together, could control the outcome of certain shareholder votes, including votes concerning the election of directors, the adoption or amendment of provisions in our Articles of Incorporation, and the approval of mergers and other significant corporate transactions. This level of concentrated ownership may, at a minimum, have the effect of delaying or preventing a change in the management or voting control of us by a third party. It may also place us in the position of having these large stockholders take control of us and having new management inserted and new objectives adopted.

#### If competitors develop and market products that are more effective than ours, our commercial opportunity will be reduced or eliminated.

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological change. A number of companies are pursuing the development of pharmaceuticals and products that target the same diseases and conditions that we target. For example, there are products on the market that compete with Acthar, Nascobal, Ethamolin, and Glofil-125. Moreover, technology controlled by third parties that may be advantageous to our business may be acquired or licensed by competitors of ours, preventing us from obtaining this technology on favorable terms, or at all.

Our ability to compete will depend on our ability to create and maintain scientifically advanced technology, and to develop, acquire and commercialize pharmaceutical products based on this technology, as well as our ability to attract and retain qualified personnel, obtain patent protection, or otherwise develop proprietary technology or processes, and secure sufficient capital resources for the expected substantial time period between technological conception and commercial sales of products based upon our technology.

Many of the companies developing competing technologies and products have significantly greater financial resources and expertise in development, manufacturing, obtaining regulatory approvals, and marketing than we do. Other smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Academic institutions, government agencies and other public and private research organizations may also seek patent protection and establish collaborative arrangements for clinical development, manufacturing, and marketing of products similar to ours. These companies and institutions will compete with us in recruiting and retaining qualified sales and marketing and management personnel, as well as in acquiring technologies complementary to our programs. We will face competition with respect to:

- product efficacy and safety,
- the timing and scope of regulatory approvals,
- availability of resources,
- price, and
- patent position, including potentially dominant patent positions of others.

If our competitors succeed in developing technologies and drugs that are more effective or less costly than any that we develop or acquire, our technology and future drugs may be rendered obsolete and noncompeti-

tive. In addition, our competitors may succeed in obtaining the approval of the FDA or other regulatory approvals for drug candidates more rapidly than we will. Companies that complete clinical trials, obtain required regulatory agency approvals and commence commercial sale of their drugs before their competitors may achieve a significant competitive advantage, including patent and FDA marketing exclusivity rights that would delay our ability to market specific products. We do not know if drugs resulting from the joint efforts of our existing or future collaborative partners will be able to compete successfully with our competitors' existing products or products under development or whether we will obtain regulatory approval in the U.S. or elsewhere.

## If we fail to maintain or enter into new contracts related to collaborations and in-licensed or acquired technology and products, our product development and commercialization could be delayed.

Our business model has been dependent on our ability to enter into licensing and acquisition arrangements with commercial or academic entities to obtain technology for commercialization or marketed products. If we are unable to enter into any new agreements in the future, our development and commercialization efforts will be delayed. Disputes may arise regarding the inventorship and corresponding rights in inventions and know-how resulting from the joint creation or use of intellectual property by us and our licensors or scientific collaborators. We may not be able to negotiate additional license and acquisition agreements in the future on acceptable terms, if at all. In addition, current license and acquisition agreements may be terminated, and we may not be able to maintain the exclusivity of our exclusive licenses.

If collaborators do not commit sufficient development resources, technology, regulatory expertise, manufacturing, marketing and other resources towards developing, promoting and commercializing products incorporating our discoveries, the progress of our licensed products development will be stalled. Further, competitive conflicts may arise among these third parties that could prevent them from working cooperatively with us. The amount and timing of resources devoted to these activities by the parties could depend on the achievement of milestones by us and otherwise generally may be controlled by other parties. In addition, we expect that our agreements with future collaborators will likely permit the collaborators to terminate their agreements upon written notice to us. This type of termination would substantially reduce the likelihood that the applicable research program or any lead candidate or candidates would be developed into a drug candidate, would obtain regulatory approvals and would be manufactured and successfully commercialized.

If none of our collaborations are successful in developing and commercializing products, or if we do not receive milestone payments or generate revenues from royalties sufficient to offset our significant investment in product development and other costs, then our business could be harmed. Disagreements with our collaborators could lead to delays or interruptions in, or termination of, development and commercialization of certain potential products or could require or result in litigation or arbitration, which could be time-consuming and expensive and may result in lost revenues and substantial legal costs which could negatively impact our results from operations. In addition, if we are unable to acquire new marketed products on a timely basis at an appropriate purchase price and terms, we may not reach profitability and may not generate sufficient cash to fund operations.

### If we are unable to protect our proprietary rights, we may lose our competitive position and future revenues.

Our success will depend in part on our ability to:

- obtain patents for our products and technologies,
- protect trade secrets,
- operate without infringing upon the proprietary rights of others, and
- prevent others from infringing on our proprietary rights.

We will only be able to protect our proprietary rights from unauthorized use by third parties to the extent that these rights are covered by valid and enforceable patents or are effectively maintained as trade secrets and

are otherwise protectable under applicable law. We will attempt to protect our proprietary position by filing U.S. and foreign patent applications related to our proprietary products, technology, inventions and improvements that are important to the development of our business.

We currently own one U.S. patent that is scheduled to expire on April 16, 2005, covering certain formulations of Nascobal. We could face increased competition in connection with our Nascobal gel formulation from competitors entering the market after expiration of the U.S. patent on April 16, 2005.

The patent positions of biotechnology and biopharmaceutical companies involve complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from third parties may not provide any protection against competitors. Pending patent applications we may file in the future, or those we may license from third parties, may not result in patents being issued. Also, patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed or we will develop. The laws of some foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States.

In addition to patents, we rely on trade secrets and proprietary know-how. We currently seek protection, in part, through confidentiality and proprietary information agreements. These agreements may not provide meaningful protection or adequate remedies for proprietary technology in the event of unauthorized use or disclosure of confidential and proprietary information. The parties may not comply with or may breach these agreements. Furthermore, our trade secrets may otherwise become known to, or be independently developed by competitors.

Our success will further depend, in part, on our ability to operate without infringing the proprietary rights of others. If our activities infringe on patents owned by others, we could incur substantial costs in defending ourselves in suits brought against a licensor or us. Should our products or technologies be found to infringe on patents issued to third parties, the manufacture, use and sale of our products could be enjoined, and we could be required to pay substantial damages. In addition, we, in connection with the development and use of our products and technologies, may be required to obtain licenses to patents or other proprietary rights of third parties, which may not be made available on terms acceptable to us, if at all.

Since we must obtain regulatory approval to market our products in the United States and in foreign jurisdictions, we cannot predict whether or when we will be permitted to commercialize our products.

Any products that we develop are subject to regulation by federal, state and local governmental authorities in the United States, including the FDA, and by similar agencies in other countries. Any product that we develop must receive all relevant regulatory approvals or clearances before it may be marketed in a particular country. The regulatory process, which includes extensive preclinical studies and clinical trials of each product to establish its safety and efficacy, is uncertain, can take many years, and requires the expenditure of substantial resources. Data obtained from preclinical and clinical activities are susceptible to varying interpretations that could delay, limit or prevent regulatory approval or clearance. In addition, delays or rejections may be encountered based upon changes in regulatory policy during the period of product development and the period of review of any application for regulatory approval or clearance for a product. Delays in obtaining regulatory approvals or clearances could:

- stall the marketing, selling and distribution of any products that our corporate partners or we develop,
- impose significant additional costs on our corporate partners and us,
- $\bullet$  diminish any competitive advantages that we or our corporate partners may attain, and
- $\bullet$  decrease our ability to receive royalties and generate revenues and profits.

Regulatory approval, if granted, may entail limitations on the indicated uses for which a new product may be marketed that could limit the potential market for the product. Product approvals, once granted, may be withdrawn if problems occur after initial marketing. Furthermore, manufacturers of approved products are

subject to pervasive review, including compliance with detailed regulations governing FDA good manufacturing practices. The FDA periodically revises the good manufacturing practices regulations. Failure to comply with applicable regulatory requirements can result in warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to grant marketing applications and criminal prosecution.

In addition, we cannot predict the extent of government regulations or the impact of new governmental regulations that may result in a delay in the development, production and marketing of our products. As such, we may be required to incur significant costs to comply with current or future laws or regulations.

## Our ability to generate revenues is affected by the availability of reimbursement on our products, and our ability to generate revenues will be diminished if we fail to obtain an adequate level of reimbursement for our products from third party payors.

In both domestic and foreign markets, sales of our products will depend in part on the availability of reimbursement from third party payors such as state and federal governments (for example, under Medicare and Medicaid programs in the United States) and private insurance plans. In certain foreign markets, the pricing and profitability of our products generally are subject to government controls. In the United States, there have been, and we expect there will continue to be, a number of state and federal proposals that limit the amount that state or federal governments will pay to reimburse the cost of drugs. We believe the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of our products, which may also impact product sales. Further, when a new therapeutic is approved, the reimbursement status and rate of such a product is uncertain. In addition, current reimbursement policies for existing products may change at any time. Changes in reimbursement or our failure to obtain reimbursement for our products may reduce the demand for, or the price of, our products, which could result in lower product sales or revenues, thereby weakening our competitive position and negatively impacting our results of operations.

In the United States, proposals have called for substantial changes in the Medicare and Medicaid programs. Any such changes enacted may require significant reductions from currently projected government expenditures for these programs. The Medicare Prescription Drug Improvement Act, enacted in December 2003, provides for, among other things, an immediate reduction in the Medicare reimbursement rates for many drugs administered in a physician's office. The Medicare Act, as well as other changes in government legislation or regulation or in private third party payors' policies toward reimbursement for our products, may reduce or eliminate reimbursement of our products' costs. Driven by budget concerns, Medicaid managed care systems have been implemented in several states and local metropolitan areas. If the Medicare and Medicaid programs implement changes that restrict the access of a significant population of patients to innovative medicines, the market acceptance of these products may be reduced. We are unable to predict what impact the Medicare Act or other future legislation, if any, relating to third party reimbursement, will have on our product sales.

To facilitate the availability of our products for Medicaid patients, we have contracted with the Center for Medicare and Medicaid Services. As a result, we pay quarterly rebates consistent with the utilization of our products by individual states. We also give discounts under contract on purchases or reimbursements of pharmaceutical products by certain other federal and state agencies and programs. If these discounts and rebates become burdensome to us and we are not able to sell our products through these channels, our net sales could decline.

## Our business is subject to changing regulation of corporate governance and public disclosure that has increased both our costs and the risk of noncompliance.

Because our common stock is publicly traded, we are subject to certain rules and regulations of federal, state and financial market exchange entities charged with the protection of investors and the oversight of companies whose securities are publicly traded. These entities, including the Public Company Accounting Oversight Board, the SEC and the American Stock Exchange, have recently issued new requirements and

regulations and continue developing additional regulations and requirements in response to recent corporate scandals and laws enacted by Congress, most notably the Sarbanes-Oxley Act of 2002. Our efforts to comply with these new regulations have resulted in, and are likely to continue resulting in, increased general and administrative expenses and diversion of management time and attention from revenue-generating activities to compliance activities.

In particular, our efforts to prepare to comply with Section 404 of the Sarbanes-Oxley Act and related regulations for fiscal years ending on or after July 15, 2006 regarding our management's required assessment of our internal control over financial reporting and our independent auditors' attestation of that assessment will require the commitment of significant financial and managerial resources. Although management believes that ongoing efforts to assess our internal control over financial reporting will enable management to provide the required report, and our independent auditors to provide the required attestation, under Section 404, we can give no assurance that such efforts will be completed on a timely and successful basis to enable our management and independent auditors to provide the required report and attestation in order to comply with SEC rules effective for us.

Moreover, because the new and changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices.

#### Our stock price has a history of volatility, and an investment in our stock could decline in value.

The price of our common stock, like that of other specialty pharmaceutical companies, is subject to significant volatility. Our stock price has ranged in value from \$0.38 to \$1.34 over the last two years. Any number of events, both internal and external to us, may continue to affect our stock price. These include, without limitation, the quarterly and yearly revenues and earnings or losses; our ability to acquire and market appropriate pharmaceuticals; announcement by us or our competitors regarding product development efforts, including the status of regulatory approval applications; the outcome of legal proceedings, including claims filed by us against third parties to enforce our patents and claims filed by third parties against us relating to patents held by the third parties; the launch of competing products; our ability to obtain product from our contract manufacturers; the resolution of (or failure to resolve) disputes with collaboration partners and corporate restructuring by us.

If product liability lawsuits are successfully brought against us or we become subject to other forms of litigation, we may incur substantial liabilities and costs and may be required to limit commercialization of our products.

Our business will expose us to potential liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products. The use of any drug candidates ultimately developed by us or our collaborators in clinical trials may expose us to product liability claims and possible adverse publicity. These risks will expand for any of our drug candidates that receive regulatory approval for commercial sale and for those products we currently market. Product liability insurance for the pharmaceutical industry is generally expensive, if available at all. We currently have product liability insurance for claims up to \$10,000,000. However, if we are unable to maintain insurance coverage at acceptable costs, in a sufficient amount, or at all, or if we become subject to a product liability claim, our reputation, stock price and ability to devote the necessary resources to the commercialization of our products could be negatively impacted.

#### Item 2. Properties

At December 31, 2004, we lease three buildings. We lease our 23,000 square foot headquarters in Union City, California under a lease agreement that expires in 2011. Our headquarters is currently occupied by the Executive, Finance and Administration, Sales and Marketing, Medical and Regulatory Affairs, Contract Manufacturing, Quality Control and Quality Assurance departments.

We are subleasing 100% of a building in Hayward, California under a sublease agreement that expires in 2006. The Hayward premises have 30,000 square feet of laboratory and office space under a master lease that expires in 2012. While we anticipate that our sublessee will fulfill the term of the sublease agreement, if they were to default, it would have a negative impact on us as we would still be obligated to make rent payments on the Hayward facility under the master lease agreement.

We lease an 8,203 square foot facility in Carlsbad, California under a lease that expires January 2006. During 2003, we subleased 100% of the space under two separate subleases expiring in January 2006 and January 2005. The sublease expiring in January 2005 includes a renewal option to extend the term for four three-month periods. To date, one option period has been exercised and will expire April 30, 2005.

In May 2001, we closed our Neoflo manufacturing facility located in Lee's Summit, Missouri. During 2003 we subleased the space. The lease period and the sublease expired on December 31, 2004.

#### Item 3. Legal Proceedings

None.

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

No matters were submitted to a vote of security holders for the quarter ended December 31, 2004.

#### **PART II**

## Item 5. Market for Registrant's Common Equity and Related Shareholder Matters and Issuer Purchases of Equity Securities

Our common stock is traded on the American Stock Exchange, Inc. From January 1998 to November 1999 the stock was traded under the symbol "CYP." On November 17, 1999, we changed our name to Questcor Pharmaceuticals, Inc. and the stock began trading under the symbol "QSC."

The following table sets forth, for the periods presented, the high and low closing price per share of our common stock.

		Common Stock Closing Price				
Quarter Ended	High	Low				
December 31, 2004	\$ 0.57	\$ 0.40				
September 30, 2004	0.84	0.38				
June 30, 2004	0.95	0.77				
March 31, 2004	1.09	0.70				
December 31, 2003	0.92	0.60				
September 30, 2003	1.00	0.75				
June 30, 2003	1.20	0.75				
March 31, 2003	1.34	0.78				

The last sale price of our common stock on March 18, 2005 was \$0.50. As of March 18, 2005 there were approximately 283 holders of record of our common stock.

We have never paid a cash dividend on our common stock. Our dividend policy is to retain our earnings, if we achieve positive earnings, and to support the expansion of our operations. Our Board of Directors does not intend to pay cash dividends on our common stock in the foreseeable future. Any future cash dividends will depend on future earnings, capital requirements, our financial condition and other factors deemed relevant by our Board of Directors.

## Item 6. Selected Consolidated Financial Data

The following table sets forth certain financial data with respect to our business. The selected consolidated financial data should be read in conjunction with our Consolidated Financial Statements and related Notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other information contained elsewhere in this Form 10-K.

	Years Ended December 31,									
	2004	2003	2002(1)	2001	2000					
		(In thousands, except per share data)								
Consolidated Statement of Operations Data:										
Net product sales	\$ 18,404	\$ 13,655	\$ 13,819	\$ 5,196	\$ 2,134					
Total revenues	18,404	14,063	14,677	5,667	3,594					
Total operating costs and expenses	18,670	17,397	17,080	15,050	17,752					
Loss from operations	(266)	(3,334)	(2,403)	(9,383)	(14,158)					
Net loss	(832)	(3,791)	(2,785)	(8,697)	(13,762)					
Net loss applicable to common shareholders	(1,508)	(5,947)	(2,785)	(8,697)	(13,762)					
Net loss per common share applicable to common										
shareholders — basic and diluted	(0.03)	(0.14)	(0.07)	(0.28)	(0.56)					
Shares used in computing net loss per common share										
applicable to common shareholders — basic and diluted	50,844	41,884	38,407	31,425	24,722					

			De	cember 31,		
	2004	2003		2002	 2001	2000
			(In	thousands)		
Consolidated Balance Sheet Data:						
Cash, cash equivalents and short-term investments						
(includes \$5 million compensating balance at						
December 31, 2001 and 2000)	\$ 8,729	\$ 3,220	\$	7,506	\$ 10,571	\$ 8,151
Working capital	5,082	4,352		7,018	2,659	1,261
Total assets	28,173	22,929		12,766	14,946	14,848
Long-term obligations	2,021	3,402		2,908	122	548
Preferred stock, Series A	5,081	5,081		5,081	5,081	5,081
Preferred stock, Series B	7,578	8,278		_	_	_
Common stock	88,436	85,232		77,528	74,018	66,152
Accumulated deficit	(84,423)	(82,915)		(76,968)	(74,183)	(65,486)
Total shareholders' equity (deficit)	11,581	10,578		496	(300)	927

<sup>(1)</sup> Effective January 1, 2002, we adopted Statement of Financial Accounting Standards, or SFAS, No. 141 "Business Combinations" and SFAS No. 142, "Goodwill and Other Intangible Assets." See Note 1 to the Consolidated Financial Statements.

#### QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

	Quarter Ended							
	12/31/04		0	09/30/04		06/30/04		3/31/04
			(In	thousands, exce				
Net product sales	\$	5,297	\$	3,869	\$	4,090	\$	5,148
Total revenues		5,297		3,869		4,090		5,148
Cost of product sales		1,070		843		961		856
Net income (loss)		511		(1,366)		(247)		270
Net income (loss) applicable to common shareholders		343		(1,534)		(415)		98
Net income (loss) per share applicable to common shareholders — basic		0.01		(0.03)		(0.01)		0.00
Net income (loss) per share applicable to common shareholders —								
diluted		0.01		(0.03)		(0.01)		0.00

		Quarter Ended								
	12/31/03			09/30/03		06/30/03		3/31/03		
			(1	in thousands, exc	ept per sh	are data)				
Net product sales	\$	4,470	\$	3,943	\$	2,880	\$	2,362		
Total revenues		4,570		3,967		2,905		2,621		
Cost of product sales		953		796		1,149		675		
Net income (loss)		324		(576)		(1,769)		(1,770)		
Net income (loss) applicable to common shareholders		129		(776)		(2,062)		(3,238)		
Net income (loss) per share applicable to common shareholders —				(0.00)		(0.0 <del>-</del> )		(0.00)		
basic and diluted		0.00		(0.02)		(0.05)		(80.0)		

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

Except for the historical information contained herein, the following discussion contains forward-looking statements that involve risks and uncertainties, including statements regarding the period of time during which our existing capital resources and income from various sources will be adequate to satisfy our capital requirements. Our actual results could differ materially from those discussed herein. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this section, as well as Item 1, "Business of Questcor," including without limitation "Risk Factors," as well as those discussed in any documents incorporated by reference herein or therein.

We are a specialty pharmaceutical company that acquires, develops, markets and sells prescription drugs through our U.S. direct sales force and international distributors. We focus on the treatment of central nervous system ("CNS") diseases and gastroenterological disorders, which are served by a limited group of physicians such as neurologists and gastroenterologists. Our strategy is to acquire or develop pharmaceutical products that we believe have sales growth potential, are promotionally responsive to a focused and targeted sales and marketing effort, complement our existing products and can be acquired at a reasonable valuation relative to our cost of capital. We currently market four products in the United States:

- H.P. Acthar® Gel ("Acthar"), an injectable drug that is approved for the treatment of certain CNS disorders with an inflammatory component, including the treatment of flares associated with multiple sclerosis ("MS"), and is also commonly used in treating patients with infantile spasm;
- Nascobal®, the only prescription nasal gel used for the treatment of various Vitamin B-12 deficiencies, including Vitamin B-12 deficiencies associated with Crohn's disease, gastric bypass surgery and MS;

- Ethamolin®, an injectable drug used to treat enlarged weakened blood vessels at the entrance to the stomach that have recently bled, known as esophageal varices; and
- Glofil®-125, an injectable agent that assesses how well the kidney is working by measuring glomerular filtration rate, or kidney function.

We have also marketed VSL#3 and Inulin. Our promotion agreement for VSL#3 expired in January 2005 in accordance with its terms. VSL#3 will be promoted in the future by Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau Pharmaceuticals"), an affiliate of Sigma-Tau Finanziaria SpA ("Sigma-Tau"), a significant shareholder and affiliate of the Company. Due to minimal demand, increasing production costs and lack of strategic fit, we discontinued marketing and selling Inulin in September 2003.

In June 2003 we acquired Nascobal, a Food and Drug Administration ("FDA") approved nasal gel formulation of Cyanocobalamin USP (Vitamin B-12), from Nastech Pharmaceutical Company Inc. ("Nastech") for \$14.2 million. We began distributing Nascobal in July 2003. We are marketing Nascobal for patients with MS and Crohn's Disease, and patients who are at high risk of developing severe deficiencies of Vitamin B-12 due to a compromised ability to absorb Vitamin B-12 through the gastrointestinal system. We are also marketing Nascobal for patients who have undergone gastric bypass surgery or other conditions that lead to a malabsorptive state.

Consistent with our focus on sales and marketing, our spending on research and development activities has been modest. Expenses incurred for the Acthar manufacturing site transfer and medical and regulatory affairs are classified as Research and Development Expenses in the accompanying Consolidated Statements of Operations. We have entered into several agreements with pharmaceutical and biotechnology companies to further the development of certain acquired technology.

We have incurred an accumulated deficit of \$84.4 million at December 31, 2004. At December 31, 2004, we had \$8.7 million in cash and cash equivalents. Results of operations may vary significantly from quarter to quarter depending on, among other factors, the results of our sales efforts, demand for our products by patients and consumers, inventory levels of our products at wholesalers, timing of expiration of our products and the resulting shipment of replacement product under our product exchange policy, future credit memoranda to be issued under our credit memoranda return policy, the availability of finished goods from our sole-source manufacturers, the timing of certain expenses, the acquisition of marketed products, the establishment of strategic alliances and collaborative arrangements and the receipt of milestone payments.

#### **Critical Accounting Policies**

Our management's discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures. On an on-going basis, we evaluate our estimates, including those related to sales reserves, product returns, bad debts, inventories, and intangible assets. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances; the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

## Sales Reserves, Product Returns, and Rebates

We have estimated reserves for product returns from wholesalers, hospitals and pharmacies, government chargebacks for goods purchased by certain Federal government organizations including the Veterans Administration, Medicaid rebates to all states for products purchased by patients covered by Medicaid, and cash discounts for prompt payment. We estimate our reserves by utilizing historical information for existing

products and data obtained from external sources. For new products, we estimate our reserves for product returns, government chargebacks and rebates on specific terms for product returns, chargebacks and rebates, and our experience with similar products.

Significant judgment is inherent in the selection of assumptions and the interpretation of historical experience as well as the identification of external and internal factors affecting the estimates of our reserves for product returns, government chargebacks, and Medicaid rebates. We believe that the assumptions used to estimate these sales reserves are the most reasonably likely assumptions considering known facts and circumstances. However, our product return activity, government chargebacks received, and Medicaid rebates paid could differ significantly from our estimates because our analysis of product shipments, prescription trends and the amount of product in the distribution channel may not be accurate. If actual product returns, government chargebacks, and Medicaid rebates are significantly different from our estimates, or if the wholesalers fail to adhere to our product exchange or credit memoranda policy, such differences would be accounted for in the period in which they become known. To date, actual amounts have been consistent with our estimates.

We have a product exchange policy in which we will ship replacement product for expired product returned to us within six months after expiration. The estimated costs for such potential exchanges, which include actual product costs and related shipping charges, are included in cost of product sales. In estimating returns for each product, we analyze (i) historical returns and sales patterns, (ii) current inventory on hand at wholesalers and the remaining shelf life of that inventory (ranging from 18 months to 3 years for all products except Glofil-125 and VSL#3, which are not subject to our product exchange policy), and (iii) changes in demand measured by prescriptions or other data as provided by an independent third party source and our internal estimates. We believe that the information obtained from wholesalers regarding inventory levels and from independent third parties regarding prescription demand is reliable, but we are unable to independently verify the accuracy of such data. For Glofil-125 and VSL#3, we accept no returns for expired product. We routinely assess our historical experience including customers' compliance with our product exchange policy, and we adjust our reserves as appropriate.

Our product exchange policy is not commonplace in the pharmaceutical industry. The standard policy in the industry is to issue credit memoranda in exchange for expired product. The three largest wholesalers to which we sell have expressed dissatisfaction with our product exchange policy. During the second quarter of 2004 we implemented a transition plan for expired product returns from the product exchange policy to a credit memoranda return policy for the return of expired product within six months beyond the expiration date. Expired product returned from production lots released prior to June 1, 2004 continues to be subject to the product exchange policy. Expired product returned from lots released after May 31, 2004 are subject to the credit memoranda return policy in which a credit memoranda will be issued for the original purchase price of the returned product.

We commenced shipping a new lot of Acthar in June 2004 and a new lot of Nascobal in July 2004, which are subject to the credit memoranda policy. 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 with a corresponding reduction in gross product sales. This reserve reflects an estimate of future credit memoranda to be issued for Acthar and Nascobal, applied to the quantity of product shipped from lots subject to the credit memoranda return policy. The reserve will be reduced as future credit memoranda are issued, with an offset to accounts receivable. In estimating the return rate for expired product subject to credit memoranda, we analyze (i) historical returns and sales patterns, (ii) current inventory on hand at wholesalers and the remaining shelf life of that inventory, and (iii) changes in demand measured by prescriptions and other data as provided by an independent third party source and our internal estimates. We believe that the information obtained from wholesalers regarding inventory levels and from independent third parties regarding prescription demand is reliable, but we are unable to independently verify the accuracy of such data. A new lot of Ethamolin is not expected to be released until late 2005, at which time a reserve for credit memoranda will be estimated and recorded as a reduction of gross product sales based upon the quantity of product shipped. This will reduce the future amount recorded as net product sales.

A transition period will extend through 2006 between the existing product exchange policy, applicable to product lots released prior to June 1, 2004, and the new credit memoranda return policy, applicable to product lots released after May 31, 2004. The product exchange policy will continue through the return period (six months after expiration) for all product lots released prior to June 1, 2004. These return periods end as follows: Acthar, June 2005; Nascobal, May 2006; Ethamolin, October 2006. The credit memoranda return policy commenced with the actual release of product lots of Acthar in June 2004 and Nascobal in July 2004, and will apply to the actual release of an Ethamolin lot currently planned for late 2005. Planned releases of products are subject to change. Reserves for the estimated credit memoranda applicable to future returns related to sales from these product lots will be recorded as shipments occur, and will reduce gross product sales. Until the transition from our product exchange policy to a credit memoranda return policy for expired product is complete in 2006, both the product exchange policy and the credit memoranda return policy will be in effect at the same time, which 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.

At December 31, 2004 and 2003, sales-related reserves for product returns under the credit memoranda and product exchange policies were as follows:

		Years Ended December 31,					
	2	2004		2003	2	2002	
				(In \$000's)			
Balance, beginning of year	\$	158	\$	150	\$	169	
Actual returns in current year related to sales from prior years		(62)		(162)		(482)	
Actual returns in current year related to sales from current year		_		(18)		_	
Current provision related to sales made in prior years		30		32		107	
Current provision related to sales made in current year		1,141		156		356	
Balance, end of year	\$	1,267	\$	158	\$	150	

The increase in the provision relates to the change from the product exchange policy to the credit memoranda return policy. The provision related to sales made in prior years reflects adjustments to the estimated rate of product returns and to the cost of product replacements.

If our transition to a credit memoranda policy for returns is not adhered to, our options may be limited. We could either not sell our products to wholesalers or we could be forced to issue credit memoranda for all returns currently subject to the product exchange policy. If we are forced to issue credit memoranda for all returns currently subject to the product exchange policy, the reserves for credit memoranda would be significantly increased, with an offset to gross product sales at the time of the policy change. The reserve would be based on an estimate of the future credit memoranda to be issued based upon historical return rates by product, applied to the quantity of product sold that has not yet expired. In the event this occurred, the negative impact on our revenues, operations and cash position would be substantial in the near term. Further, if such a policy change were made, the currently recorded reserve for product replacements would be eliminated resulting in a reduction of cost of product sales.

Certain wholesalers have deducted the full price of expired product which they planned to return from the amounts owed to us ("returns receivable"). We reached an agreement with the three largest wholesalers to accept replacement product and pay the amounts previously deducted in return for an administration fee, however it remains their standard practice to deduct from payments to us the sales value of expired product that they have requested authorization to return. As of December 31, 2004, our returns receivable is \$162,000, primarily due to return materials authorization requests for expired product from Acthar lots that expired in May 2003 and January 2004 and Ethamolin lots that expired in October 2003, January 2004 and February 2004. Wholesalers have indicated that they will reimburse us for these deductions upon the replacement of expired units in accordance with our product exchange policy; however, in our experience the timing of such reimbursements is slower than the collection of our normal trade receivables. As of December 31, 2004, replacement units have been shipped with respect to approximately 11% of the amounts owing to us and we

are seeking reimbursement from these wholesalers. As long as the wholesalers' standard practice is to deduct amounts related to the return of expired product, a returns receivable will arise. Should the wholesalers not comply with our product exchange policy, the amounts deducted by them for returns may not be collectible, and we would need to increase our allowance for bad debts.

In estimating Medicaid rebates, we match the actual rebates to the quantity of product sold by pharmacies on a product-by-product basis to arrive at an actual rebate percentage. This historical percentage is used to estimate a rebate percentage that is applied to the sales to which the rebates apply to arrive at the rebate expense (reserve) for the period. In particular, we consider allowable prices by Medicaid. In estimating government chargeback reserves, we analyze actual chargeback amounts by product and apply historical chargeback rates to sales to which chargebacks apply. We routinely assess our experience with Medicaid rebates and government chargebacks and adjust the reserves accordingly.

For qualified customers, we grant payment terms of 2%, net 30 days. Allowances for cash discounts are estimated based upon the amount of trade accounts receivable subject to the cash discounts.

#### Inventories

We maintain inventory reserves primarily for excess and obsolete inventory (due to the expiration of shelf life of a product). In estimating inventory excess and obsolescence reserves, we analyze on a product-by-product basis (i) the expiration date, (ii) our sales forecasts, and (iii) historical demand. Judgment is required in determining whether the forecasted sales information is sufficiently reliable to enable us to reasonably estimate excess and obsolete inventory. If actual future usage and demand for our products are less favorable than those projected by our management, additional inventory write-offs may be required in the future.

As part of our agreement with Aventis Pharmaceuticals, Inc. ("Aventis") to acquire Acthar, in fiscal year 2003 we purchased for approximately \$470,000 the Acthar active pharmaceutical ingredient ("API") and other raw material ingredients owned by Aventis. As of December 31, 2004, there was approximately \$144,000 of Aventis API remaining in our inventory. The FDA approved our use of Aventis API in the production of Acthar finished vials until the API manufacturing site transfer is approved. Use of Aventis API is conditioned on the results of yearly re-testing meeting current API specifications. We filed a New Drug Application ("NDA") Supplement with the FDA seeking approval for the API manufacturing site transfer, and if approval is obtained, we may write off the Aventis API as excess inventory.

#### **Intangible Assets**

We have intangible assets related to purchased technology and goodwill. The determination of related estimated useful lives and whether or not these assets are impaired involves significant judgment. Changes in strategy or market conditions could significantly impact these judgments and require adjustments to recorded asset balances. In accordance with Statement of Financial Accounting Standards ("SFAS") No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, we review intangible assets, as well as other long-lived assets, for impairment whenever events or circumstances indicate that the carrying amount may not be fully recoverable. In accordance with SFAS No. 142, Goodwill and Other Intangible Assets, we review goodwill and other intangible assets with no definitive lives for impairment on an annual basis, using the two-step approach.

For the year ended December 31, 2004, we tested the recorded goodwill (including assembled workforce) for impairment. The assembled workforce was generated from the merger with RiboGene Inc., and represented the value of the employees that we retained subsequent to the merger. The carrying value of the assembled workforce at the time of the merger was based upon the cost to replace the retained employees. In evaluating the assembled workforce, we determined that the cost to replace the remaining employees would be minimal. Hence, we concluded that the remaining assembled workforce was impaired and the carrying value of \$180,000 related to the assembled workforce was written off in the fourth quarter of 2004. The impairment loss is included in Selling, General and Administrative in the accompanying Consolidated Statements of

Operations. We will continue to monitor the carrying value of the remaining goodwill through the annual impairment tests.

#### **Results of Operations**

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

Total Revenues

		ears Ended ecember 31,		
	2004			
Net product sales	\$ 18,404		(In \$000's) \$ 4,749	35%
Contract research, grant and royalty revenue	_	58	(58)	(100)%
Technology revenue	_	350	(350)	(100)%
Total revenues	\$ 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.

Net product sales by therapeutic area:

	Years Decen					
	 2004			Increase/ (Decrease) (In \$000's)		%
Neurology	\$ 8,168	\$	7,973	\$	195	2%
Gastroenterology	9,399		4,721		4,678	99%
Nephrology	837		961		(124)	(13)%
Total net product sales	\$ 18,404	\$	13,655	\$	4,749	35%

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 increased revenue from gastroenterology products, due to a full year of sales of Nascobal, which was acquired in June 2003, and also reflects slightly higher net product sales of neurology products. 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.

Neurology Net Product Sales

For the years ended December 31, 2004 and 2003, neurology net product sales were comprised of Acthar net product sales. For the year ended December 31, 2004, neurology net product sales increased \$195,000 or

2% from the year ended December 31, 2003. Increased neurology net product sales resulted from a higher average selling price of Acthar and increased demand for Acthar 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 neurology products totaling \$928,000 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 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. 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. The next lot of Acthar expired in December 2004, and replacements relating to this lot will occur in fiscal year 2005. 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.

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.

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.

## Gastroenterology Net Product Sales

For the year ended December 31, 2004, gastroenterology net product sales increased \$4,678,000 or 99% from the year ended December 31, 2003. For the years ended December 31, 2004 and 2003, gastroenterology net product sales were comprised of revenues from the sale of Nascobal, Ethamolin and VSL#3. The increase is due primarily to a full year of sales of Nascobal and expanded promotional efforts focused on Nascobal in 2004. Nascobal was acquired in June 2003, and sales commenced in July 2003.

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 gastroenterology products totaling \$126,000 were recorded as a reduction to gross product sales.

Net product sales of Ethamolin in fiscal year 2004 were higher as compared to fiscal year 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.

Increased net product sales of VSL#3 also contributed to the increase of gastroenterology net product sales. The increase in VSL#3 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 and sold in the future by Sigma-Tau Pharmaceuticals.

#### Nephrology Net Product Sales

For the year ended December 31, 2004, nephrology net product sales decreased by \$124,000 or 13% from the year ended December 31, 2003. In fiscal year 2004, nephrology net product sales were comprised of revenues from the sale of Glofil-125. In fiscal year 2003, nephrology net product sales were comprised of revenue from Glofil-125 and Inulin. 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. In fiscal year 2004, we did not actively promote Glofil-125 and do not intend to actively promote it in the future.

#### 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

	Years Ei Decembe			
	2004	2003	Increase	%
		(In \$000	0's)	
Selling, general and administrative expense	\$ 11,551	\$ 10,400	\$ 1,151	11%
Percentage of total revenue	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 Ended December 31,		
	2004	2003	Increase/ (Decrease) (In \$000's)	<u>%</u>
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

		Years Ended December 31,			_		
	:	2003		2002 (n \$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)	<u>(4)</u> %

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.

Net product sales by therapeutic area:

		Ended ber 31,					
	 2003		2002 (In \$000's)		Increase/ Decrease)		
Neurology	\$ 7,973	\$	9,009	\$	(1,036)	(11)%	
Gastroenterology	4,721		4,050		671	17%	
Nephrology	961		760		201	26%	
Total net product sales	\$ 13,655	\$	13,819	\$	(164)	(1)%	

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 neurology net product sales offset by increased gastroenterology and nephrology net product sales.

During the year ended December 31, 2002 we shipped backorders outstanding at December 31, 2001 totaling \$742,000. 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.

#### Neurology Net Product Sales

For the year ended December 31, 2003, neurology net product sales decreased by \$1,036,000 or 11% from the year ended December 31, 2002. The decrease in neurology net product sales 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.

#### Gastroenterology Net Product Sales

For the year ended December 31, 2003, gastroenterology net product sales increased by \$671,000 or 17% from the year ended December 31, 2002. In fiscal year 2003, gastroenterology net product sales were comprised of revenues from the sale of Nascobal, Ethamolin and VSL#3. The increase in gastroenterology net product sales is due to sales of Nascobal, which was acquired in June 2003. Sales of Nascobal commenced in July 2003.

For the year ended December 31, 2003, the increase in gastroenterology net product sales from Nascobal was offset by a decrease in net product sales of Ethamolin. This decrease 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.

Increased net product sales of VSL#3 also contributed to the increase of gastroenterology net product sales. The increase in VSL#3 net product sales was attributed to a full year of sales since we began selling VSL#3 in May 2002.

#### Nephrology Net Product Sales

For the year ended December 31, 2003, nephrology net product sales, which were comprised of revenues from Glofil-125 and Inulin, increased \$202,000 or 27% from the year ended December 31, 2002. An increase in Glofil-125 net product sales, due in part to a Chronic Renal Insufficiency Cohort ("CRIC") study that began in 2003, contributed to the higher nephrology net product sales. 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.

Increased net product sales of Inulin also contributed to the higher nephrology net product sales in fiscal year 2003. 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 E Decemb				
	2003	2002	Decrease	<u>%</u>	
		(In \$000's	i)		
Selling, general and administrative expense	\$ 10,400	\$ 10,825	\$ (425)	<u>(4</u> )%	
Percentage of total revenue	74%	74%		·	

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 Decemi				
	2003	2002	Incre (Decr (In \$000's)		
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.

#### **Liquidity and Capital Resources**

We have principally funded our activities to date through various issuances of equity securities and debt. Through March 21, 2005, we have raised total net proceeds of \$63.1 million through various issuances of equity securities. As of December 31, 2004 our outstanding debt consists of convertible debentures with a face value of \$4.0 million and a promissory note in the amount of \$2.2 million.

		As	of December 31,		
Liquidity and Capital Resources	 2004		2003	<u></u>	2002
			(In \$000's)		
Cash, cash equivalents and short-term investments	\$ 8,729	\$	3,220	\$	7,506
Working capital	\$ 5,082	\$	4,352	\$	7,018
Cash provided by/(used in):					
Operating activities	\$ 1,758	\$	(3,346)	\$	(1,836)
Investing activities	\$ (233)	\$	(13,273)	\$	(1,423)
Financing activities	\$ 3,984	\$	13,683	\$	(768)

At December 31, 2004, we had cash and cash equivalents of \$8,729,000 compared to \$3,220,000 at December 31, 2003. At December 31, 2004, our working capital was \$5,082,000 compared to \$4,352,000 at December 31, 2003. The increase in our working capital was principally due to proceeds of \$2.2 million received from a secured promissory note issued in July 2004, net proceeds of \$2.4 million received in our private placement in January 2004 and funds provided by operations, partially offset by the reclassification of \$3,897,000 of convertible debentures to current liabilities during the first quarter of 2004.

We used cash generated from product sales, proceeds from the January 2004 private placement and matured short-term investments, and cash on hand at the beginning of the year to fund operations and for capital expenditures during fiscal year 2004.

#### **Net Cash Used In Operating Activities**

During fiscal year 2004 net cash of \$1.8 million was provided by operating activities. Sales reserves increased \$1,101,000 primarily as a result of the new credit memoranda policy implemented during fiscal year

2004. Accrued compensation increased \$616,000 primarily due to accrued severance related to the resignation of our former CEO. A major use of cash was the increase in inventory of \$719,000 primarily due to the purchase of Acthar raw materials. The net cash provided by operations funded the net loss of \$832,000.

Net cash of \$3.3 million was used to fund operating activities during fiscal year 2003. Major uses of cash in addition to the funding of the net loss of \$3.8 million were increases in accounts receivable of \$571,000 and inventory of \$596,000. Accounts receivable increased primarily as a result of the increase in returns receivable for expired product of \$344,000 and inventory increased primarily due to the purchase of Acthar raw materials from Aventis for \$470,000.

During fiscal year 2002 net cash of \$1.8 million was used to fund operating activities. Major uses of cash in addition to the funding of the net loss of \$2.8 million were increases in accounts receivable of \$932,000, increases in inventory of \$295,000 and increases in prepaid expenses and other current assets of \$509,000. Accounts receivable increased primarily as a result of the increasing sales in 2002 over 2001. Inventory increased primarily due to the purchase of Acthar finished goods in fiscal year 2002. Prepaid expenses and other current assets increased due to FDA regulatory fees and prepaid financing costs which did not exist in fiscal year 2001.

#### **Net Cash Used in Investing Activities**

Net cash used in investing activities for fiscal year 2004 was \$233,000, primarily the result of cash paid for purchases of property, plant and equipment of \$220,000.

Net cash used in investing activities was \$13.3 million for fiscal year 2003, primarily the result of cash paid of \$14.3 million for the purchase of Nascobal and the purchase of property plant and equipment of \$334,000 offset by the net proceeds of \$1.3 million from maturity of short-term investments, net of purchases.

Net cash used in investing activities was \$1.4 million for fiscal year 2002, primarily the result of \$1.3 million for the purchase of short-term investments and \$355,000 in purchases of property, plant and equipment, offset by \$142,000 increase in deposits and other assets.

#### **Net Cash Provided from Financing Activities**

Net cash provided from financing activities was \$4.0 million for fiscal year 2004. This was primarily the result of net proceeds from the issuance of common stock and the surrender of outstanding warrants of \$2.4 million, proceeds from a secured promissory note payable of \$2.2 million, and short-term borrowings of \$516,000, offset by the payment of dividends on the Series B preferred stock of \$672,000, and the repayment of short-term debt and capital lease obligations of \$530,000.

In July 2004, we issued a \$2.2 million secured promissory note to Defiante Farmaceutica Lda ("Defiante"). A majority of the proceeds from the note funded the \$2 million payment made to Nastech Pharmaceutical Company Inc. in February 2005 upon approval of the NDA for the spray formulation of Nascobal. The note is secured by the Nascobal intellectual property including the NDA for the spray formulation upon its approval.

Net cash provided from financing activities was \$13.7 million for fiscal year 2003. This was primarily the result of net proceeds from the issuance of Series B convertible preferred stock of \$9.4 million, net proceeds from a private placement of common stock of \$5 million and short-term borrowings of \$587,000 offset by the payment of dividends on the Series B preferred stock of \$749,000 and the repayment of short-term and long-term debt and capital lease obligations of \$665,000.

Net cash of \$768,000 was used in financing activities for fiscal year 2002. This was primarily the result of net proceeds from the issuance of convertible debentures of \$4 million, short term borrowing of \$1,251,000 and issuance of common stock of \$560,000 offset by repayment of a note payable to a bank of \$5 million and the repayment of short-term and long-term debt and capital lease obligations of \$1,579,000.

#### Cash and cash equivalents at December 31, 2004

Total net cash flows for fiscal year 2004 resulted in a net increase of cash and cash equivalents of \$5.5 million for fiscal year 2004. The cash and cash equivalents at December 31, 2004 are \$8.7 million. In February 2005, we made a payment of \$2.0 million to Nastech upon FDA approval of the NDA for the spray formulation of Nascobal.

#### **Contractual Obligations**

			Pa	yments	Due by Period			
	 <u> Fotal</u>	1 Year or Less		1 to 3	er Than <u>3 Years</u> ousands)	_	4 to 5 Years	After Years
Short-term debt(1)	\$ 128	\$ 128		\$		\$		\$ _
Convertible debentures, including interest(2)	4,067	4,067			_		_	_
Secured promissory note, including interest(3)	2,675	426			1,687		562	_
Operating leases(4)	10,623	1,654			2,767		2,810	3,392
Contingent milestone payments for Nascobal spray(5)	4,000	2,000			2,000		_	_
Minimum payments remaining under supply agreement								
with BioVectra(6)	1,137	569			568		_	_
Capital leases(7)	56	12			24		20	_
Purchase orders(8)	42	42			_		_	_
Total contractual cash obligations	\$ 22,728	\$ 8,898		\$	7,046	\$	3,392	\$ 3,392

- (1) Short-term debt is principally notes payable related to our product liability and property and liability insurance policies which require monthly payments and will be paid in full during 2005.
- (2) In March 2002, we issued \$4.0 million of 8% convertible debentures to an institutional investor and Defiante, a wholly-owned subsidiary of Sigma-Tau. We pay interest on the debentures at a rate of 8% per annum on a quarterly basis. The debentures are convertible into shares of our common stock at a fixed conversion price of \$1.58 per share (subject to adjustment for stock splits and reclassifications). In March 2005, we entered into amendments to the debentures whereby the maturity date of the debentures was extended from March 15, 2005 to April 15, 2005. As a result of this extension we expect to pay an additional \$27,000 in interest which is not reflected in the table above.
  - We may redeem the debentures for cash prior to maturity after March 15, 2003, provided the average of the closing sale price of our common stock for the twenty (20) consecutive trading days prior to the delivery of the optional prepayment notice to the holders of the debentures is equal to or greater than \$3.16 per share, and we have satisfied certain equity conditions. At the end of the term of the debentures, under certain circumstances, we may redeem any outstanding debentures for stock. We may redeem the institutional investor's debentures for stock at maturity, provided the total aggregate number of shares of our common stock issued to them (including shares issuable upon conversion of the debenture and shares issuable upon exercise of their warrant) does not exceed 7,645,219 shares (representing 19.999% of the total number of issued and outstanding shares of our common stock as of March 15, 2002). We may redeem Defiante's debenture for stock at maturity, provided the market price of our common stock at the time of redemption is greater than \$1.50 per share (representing the five day average closing sale price of our common stock immediately prior to March 15, 2002).
- (3) In July 2004, we issued a \$2,200,000 secured promissory note to Defiante. The interest rate on the note is 9.83% per annum. Repayment of the note consists of interest only for the first twelve months, with monthly principal and interest payments thereafter through August 2008. The note is secured by the

Nascobal intellectual property including the NDA for the spray formulation, which was approved in February 2005.

(4) We lease three buildings with lease terms expiring in 2006 to 2012. Annual rent expense for all of our facilities, equipment and automobile leases in fiscal year 2004 was approximately \$1,543,000. We lease our headquarters in Union City, California, with 23,000 square feet of office space under a lease agreement that expires in 2011. Our headquarters is currently occupied by our Executive, Finance and Administration, Sales and Marketing, Medical and Regulatory Affairs, Contract Manufacturing, and Quality Control and Quality Assurance departments. Annual rent payments for fiscal year 2005 for this facility are \$506,000.

We lease a facility of 8,203 square feet in Carlsbad, California under a lease that expires in January 2006. During fiscal year 2003, the Carlsbad facility was vacated and our warehousing and distribution for all products, except VSL#3, were outsourced to third party contractors. VSL#3 was distributed from our Union City facility through January 2005, when the VSL#3 promotion agreement expired. During 2003, we subleased 100% of the space under two separate subleases expiring in January 2006 and January 2005. The sublease expiring in January 2005 includes a renewal option to extend the term for three month periods. To date, one option period has been exercised and will expire April 30, 2005. We anticipate that we will receive \$173,000 in fiscal year 2005 as sublease income to be used to pay the annual rent of \$238,000.

We have subleased laboratory space in Hayward, California for a term of six years and anticipate that we will receive \$1,095,000 in fiscal year 2005 as sublease income to be used to pay the annual rental expense of \$724,000. This sublease expires in July 2006. Our facility in Lee's Summit, Missouri was closed in May 2001 and this facility was subleased through December 31, 2004 when both the lease period and the sublease expired. Lease payments for the facility in Lee's Summit, Missouri were \$189,000 for fiscal year 2004 and we received \$57,000 as sublease income to be used to pay the annual rental expense. We have also entered into various office equipment leases and automobile leases for our sales representatives, the terms of which are typically three years.

- (5) In connection with our acquisition of Nascobal, we acquired rights to Nascobal nasal spray, an improved dosage form, for which an NDA was filed by Nastech with the FDA in December 2003. Upon approval of the NDA for the new Nascobal nasal spray dosage form by the FDA in February 2005, we made a \$2.0 million payment for the transfer of the NDA from Nastech to us. Further, upon issuance of a U.S. patent for the new Nascobal nasal spray dosage form, which is anticipated to occur in the first fiscal quarter of 2006, we will be required to make a second \$2.0 million payment. A provisional patent application for Nascobal nasal spray has been filed.
- (6) We have signed an agreement with BioVectra to produce the API used in Acthar. The agreement requires minimum production totaling \$1.7 million during the term. During fiscal years 2004 and 2003, we paid \$468,000 and \$115,000, respectively, under this agreement. The agreement terminates in December 2007 and includes two one-year extension options.
- (7) In August 2004, we entered into a capital lease for certain office equipment with a lease term expiring in August 2009. Annual lease payments under this lease are \$12,000.
- (8) As of December 31, 2004, we issued purchase orders totaling \$42,000 for which the goods have not yet been received or the services have not yet been rendered.

At December 31, 2004 Mr. R. Jerald Beers, Vice President of Sales and Marketing, was a party to an agreement that would provide certain benefits upon a change in control of the Company. In the event a change in control occurs and the employee's employment with the Company is terminated involuntarily other than for cause, the employee will be entitled to receive a lump sum severance benefit in the amount equal to the sum of: (i) twelve months of base salary, and (ii) the employee's pro-rated maximum bonus opportunity for the fiscal year of the Company in which the termination of his employment occurs. In addition, Mr. Beers would be entitled to receive Company paid insurance coverage for 12 months and coverage at their election and expense for an additional 15 months. On March 3, 2005, Mr. Beers resigned as Vice President, Sales and Marketing, of the Company. Under the separation agreement entered into by the Company and Mr. Beers, the

Company is obligated to continue to (i) pay Mr. Beers his regular monthly base salary of \$19,583 for six months, and (ii) maintain Mr. Beers' participation in the Company's employee benefit plans under COBRA for six months. Although certain payments will be paid on a monthly basis over the six months, Mr. Beers is not performing further services for the Company. The separation agreement may be revoked by Mr. Beers through April 2, 2005.

Messrs. James. L. Fares, Steve Cartt and Reinhard Koenig are each party to agreements that would provide certain benefits upon a change in control of the Company. Mr. Koenig's agreement provides that all of the employee's stock options under any plan of the Company that are then outstanding shall become vested and exercisable immediately prior to a change in control of the Company (and such employee would have a period of ninety days following the later of termination of employment or expiration of any lock-up agreement to exercise such options). Also, Mr. Koenig's agreement provides that in the event a change in control occurs and the employee's employment with the Company is terminated involuntarily other than for cause, the employee's bonus from the prior fiscal year of the Company in which the termination of his employment occurs. In addition, Mr. Koenig would be entitled to receive Company paid insurance coverage for six months and coverage at his election and expense for an additional 15 months. Messrs. Fares' and Cartt's agreements provide that in the event a change in control occurs and the employee's employment with the Company is terminated involuntarily other than for cause, fifty percent of such employee's stock options under any plan of the Company that are then outstanding shall become vested and exercisable immediately prior to a change in control of the Company.

#### **Equity Transactions**

#### Equity Transactions in Year Ended December 31, 2002

In March 2002, in two separate transactions, we issued \$4.0 million of 8% convertible debentures to an institutional investor and Sigma-Tau. We pay interest on the debentures at a rate of 8% per annum on a quarterly basis. The debentures are convertible into shares of our common stock at a fixed conversion price of \$1.58 per share (subject to adjustment for stock splits and reclassifications). At the end of the term of the debenture, under certain circumstances, we have the option to repay the principal in stock and, under certain circumstances, we can also redeem the debenture for cash prior to maturity. In conjunction with this transaction, we issued warrants to both the institutional investor and Sigma-Tau to acquire an aggregate of 1,518,987 shares of common stock at an exercise price of \$1.70 per share. In January 2004 the warrants to purchase 759,493 shares of common stock held by Sigma-Tau were surrendered as consideration, along with cash for the issuance of 759,493 shares of common stock. The remaining warrants held by the institutional investor expire on March 15, 2006. In connection with the issuance of the debentures and warrants, we recorded a deferred expense related to a beneficial conversion feature of \$1,484,000. This amount is amortized to interest expense over the term of the debentures. In March 2005, we entered into amendments to the debentures whereby the maturity date of the debentures was extended from March 15, 2005 to April 15, 2005.

#### Equity Transactions in Year Ended December 31, 2003

In January 2003, we completed a private placement of Series B Convertible Preferred Stock and warrants to purchase common stock to various institutional healthcare investors. Our gross proceeds from the private placement were \$10 million. The Series B Preferred Stock had an aggregate stated value of \$10 million and is entitled to a quarterly dividend at an initial rate of 8% per year, which rate will increase to 10% per year on and after January 1, 2006, and to 12% on and after January 1, 2008. In addition, on the occurrence of designated events the dividend rate will increase by an additional 6% per year. The Series B Preferred Stock is entitled to a liquidation preference over our common stock and Series A Preferred Stock upon a liquidation, dissolution or winding up of Questcor. The Series B Preferred Stock is convertible at the option of the holder into our common stock at a conversion price of \$0.9412 per share, subject to certain anti-dilution adjustments. In December 2003, Series B Preferred Stock having a stated value of \$900,000 and accrued and unpaid dividends of \$13,000 was converted into 976,770 shares of common stock. In January 2004, Series B Preferred Stock with a stated value of \$600,000 plus accrued and unpaid dividends of \$2,000 was converted into 640,147 shares

of common stock. In March 2004, Series B Preferred Stock with a stated value of \$100,000 plus accrued and unpaid dividends of \$1,600 was converted into 107,995 shares of common stock. As of December 31, 2004, the stated value of the Series B Preferred Stock is \$8.4 million. We have the right commencing on January 1, 2006 (assuming specified conditions are met) to redeem the Series B Preferred Stock at a price of 110% of stated value, together with all accrued and unpaid dividends and arrearage interest. In addition, upon the occurrence of designated Optional Redemption Events, the holders have the right to require us to redeem the Series B Preferred Stock at 100% of stated value, together with all accrued and unpaid dividends and accrued interest. The terms of the Series B Preferred Stock contain a variety of affirmative and restrictive covenants, including limitations on indebtedness and liens. Each share of Series B Preferred Stock is generally entitled to a number of votes equal to 0.875 times the number of shares of common stock issuable upon conversion of such share of Series B Preferred Stock. The purchasers of the Series B Preferred Stock also received for no additional consideration warrants exercisable for an aggregate of 3,399,911 shares of our common stock at an exercise price of \$1.0824 per share, subject to certain anti-dilution adjustments. The warrants expire in January 2007. In June 2003, the exercise price of the warrants was adjusted to \$0.9412 per share. In January 2004 warrants to purchase 373,990 shares of common stock were surrendered as consideration, along with cash, for the issuance of 373,990 shares of common stock.

In June 2003, we entered into agreements with the holders of record of our Series B Preferred Stock, whereby the holders of Series B Preferred Stock waived certain covenants and rights to receive additional dividends as provided in the Certificate of Determination, which may have been triggered as a result of our acquisition of Nascobal and the use of our cash resources to pay the purchase price (the "Acquisition"). Specifically, the holders of Series B Preferred Stock waived their right to receive an additional aggregate six percent dividend in the event that the Acquisition resulted in our being unable to satisfy the test set forth in Sections 500 and 501 of the California Corporations Code to allow for us to redeem all of the issued and outstanding shares of Series B Preferred Stock. Such waiver was granted through the earlier of (i) December 31, 2003 and (ii) the date on which (A) our assets (exclusive of goodwill, capitalized research and development expenses and deferred charges) equal less than 125% of our liabilities (not including deferred taxes, deferred income and other deferred credits) or (B) our current assets equal less than 80% of our current liabilities. Additionally, the holders of Series B Preferred Stock waived their right to receive an additional aggregate six percent dividend in the event that the Acquisition resulted in our being unable to maintain Net Cash, Cash Equivalents and Eligible Investment Balances (as defined in the Certificate of Determination) in an amount equal to \$5 million. Such waiver was granted through the earlier of (i) December 31, 2003 and (ii) the date on which we fail to maintain Net Cash, Cash Equivalents and Eligible Investment Balances in an amount equal to at least \$2.5 million. The holders of Series B Preferred Stock also agreed that: (i) the Acquisition would not constitute a breach of the covenant in the Certificate of Determination requiring us to use our best efforts to maintain compliance with Sections 500 and 501 of the California Corporations Code to be able to pay dividends on and to redeem all of the issued and outstanding shares of Series B Preferred Stock; and (ii) the incurrence by us of contingent obligations to pay additional amounts to Nastech of \$5,183,333 and the granting of a security interest in the acquired Nascobal product would not constitute a breach of the covenants in the Certificate of Determination restricting our ability to incur indebtedness and create liens. In consideration of such agreements, we agreed to adjust the exercise price of warrants to purchase 3,399,911 shares of our common stock previously issued by us to the holders of Series B Preferred Stock from \$1.0824 per share to \$0.9412 per share. On December 23, 2003, a new waiver was signed by the holders of Series B Preferred Stock which waived the Net Cash, Cash Equivalents and Eligible Investment Balances among other requirements until January 31, 2004 at which time we were in compliance.

Also in June 2003, we consummated a private placement of our common stock and warrants to purchase common stock. We issued 4,979,360 shares of common stock in the private placement at \$1.01 per share, which was the volume weighted average price of the common stock for the five days prior to and including the close of the private placement. Gross proceeds to us from the private placement were approximately \$5.0 million. The purchasers of our common stock also received for no additional consideration warrants exercisable for an aggregate of 2,987,616 shares of common stock at an exercise price of \$1.26 per share, which represented a 25% premium to the volume weighted average price of the common stock for the five days

prior to and including the close of the private placement. The warrants expire in June 2008. In January 2004 warrants to purchase 2,512,368 shares of common stock were surrendered as consideration, along with cash, for the issuance of 2,512,368 shares of common stock.

#### Equity Transactions in the Year Ended December 31, 2004

In January 2004, we entered into agreements with some of our existing investors and issued 4,878,201 shares of common stock in exchange for \$2,399,050 in cash and the surrender of outstanding warrants to purchase 3,878,201 shares of common stock. The offer to issue common stock for cash and the surrender of warrants was made to all warrant holders. The warrants retired represented approximately 46% of the warrants outstanding as of December 31, 2003. The warrants surrendered were included as consideration at their aggregate fair value of \$743,000 which was determined using a Black-Scholes valuation method. The purchase price of the common stock, which was payable in cash and surrender of outstanding warrants, was \$0.644 per share, which was the volume weighted average price of our common stock in December 2003 for the five trading days prior to the agreement to the terms of the transaction. Sigma-Tau, a related party, participated in the transaction, purchasing 759,493 shares of common stock for aggregate consideration of \$489,000 in cash and the surrender of 759,493 warrants with a fair value of \$53,000 to purchase common stock.

#### Equity Transactions Subsequent to December 31, 2004

On March 29, 2005, the Company and all of the holders of the outstanding shares of Series B Preferred Stock of the Company entered into a Series B Preferred Shareholder Agreement and Waiver. The agreement provides that (i) the holders shall waive certain rights to receive additional dividends through March 31, 2006, (ii) the holders will, with respect to dividends payable on April 1, 2005, July 1, 2005, October 1, 2005 and January 1, 2006, accept as full and complete payment of all such dividend payments the issuance by the Company to them in a private placement of shares of the Company's common stock having an aggregate value equal to the dividends otherwise payable on those dates, with the shares of common stock so issued valued at fair market value based upon a ten-day weighted average trading price formula through March 29, 2005, and (iii) the expiration date of the warrants to purchase shares of the Company's common stock held by the holders shall be extended for one year, until January 15, 2008.

## **American Stock Exchange Listing Standards**

In August 2002, we were notified by the American Stock Exchange ("AMEX") that certain of our financial measures fell below certain of AMEX's continued listing standards and we had therefore become subject to possible delisting. On October 15, 2003, AMEX notified us that it had completed its review of Questcor and determined that we had regained compliance with AMEX's applicable continued listing standards at that date.

#### **Cash Requirements**

Based on our internal forecasts and projections, we believe that our cash on hand at December 31, 2004, and the net cash flows generated from operations, will be sufficient to fund operations through at least December 31, 2005, unless a substantial portion of our cash is used for product acquisition or our 2005 revenues are less than we expect.

Our future funding requirements will depend on many factors, including: the timing and extent of product sales; returns of expired product; the acquisition and licensing of products, technologies or compounds, if any; our ability to manage growth; timing of the payment to Nastech relating to the patent approvals for the nasal spray formulation of Nascobal; competing technological and market developments; costs involved in filing, prosecuting, defending and enforcing patent and intellectual property claims; the receipt of licensing or milestone fees from current or future collaborative and license agreements, if established; the timing of regulatory approvals; the timing and successful completion of the Acthar site transfer; payment of dividends

and compliance to prevent additional dividend events; any expansion or acceleration of our development programs or optional redemption events, and other factors.

If our revenues do not grow and provide cash flow from operations in an amount sufficient to meet our obligations, or if we do not have sufficient funds to redeem the convertible debentures, which have a face value of \$4 million, for cash, or a combination of cash and stock, upon maturity in April 2005, or if we are unable to maintain compliance with certain covenants and thus avoid the payment of additional dividends of 6% to the holders of our Series B Convertible Preferred Stock, or we do not have sufficient funds to make the contingent payment, if, and when due to Nastech for the patent approvals of the new nasal spray form of Nascobal, or if we have insufficient funds to acquire additional products or expand our operations, we will seek to raise additional capital through public or private equity financing or from other sources. However, traditional asset based debt financing has not been available on acceptable terms. Additionally, we may seek to raise additional capital whenever conditions in the financial markets are favorable, even if we do not have an immediate need for additional cash at that time. There can be no assurance that we will be able to obtain additional funds on desirable terms or at all.

#### **Income Taxes**

As of December 31, 2004, we had federal and state net operating loss carryforwards of approximately \$99 million and \$30 million, respectively. We also had federal and California research and development tax credits of approximately \$2 million and \$1 million, respectively. The federal and state net operating loss carryforwards and the federal credit carryforwards expire at various dates beginning in the years 2005 through 2024, if not utilized.

#### **Recently Issued Accounting Standard**

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123R, "Share-Based Payment," a revision to SFAS No. 123, "Accounting for Stock-Based Compensation." SFAS No. 123R eliminates our ability to use the intrinsic value method of accounting under APB Opinion 25, "Accounting for Stock Issued to Employees," and generally requires a public entity to reflect on its income statement, instead of pro forma disclosures in its financial footnotes, the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. The grant-date fair value will be estimated using option-pricing models adjusted for the unique characteristics of those equity instruments. SFAS No. 123R is effective generally for public companies as of the beginning of the first interim or annual reporting period that begins after June 15, 2005. SFAS No. 123R applies to all awards granted after the required effective date, to awards that are unvested as of the effective date, and to awards modified, repurchased, or cancelled after that date. As of the required effective date, all public entities that used the fair-value-based method for either recognition or disclosure under the original SFAS No. 123 will apply this revised statement. Under SFAS No. 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include modified prospective and modified retrospective adoption options. Under the modified prospective method, compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS No. 123R for all share-based payments granted after the effective date and (b) based on the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date. The modified retrospective method includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS No. 123 for purposes of pro forma disclosures, either (a) all prior periods presented or (b) prior interim periods of the year of adoption. We are currently evaluating the requirements of SFAS No. 123R and will adopt this statement at the effective date. We expect that the adoption of this statement will have a material effect on our financial statements.

## Item 7A. Quantitative and Qualitative Disclosures about Market Risk

#### **Market Rate Risk**

Our exposure to market rate risk for changes in interest rates relates primarily to our investment portfolio. We do not use derivative financial instruments in our investment portfolio. We place our investments with high quality issuers and follow internally developed guidelines to limit the amount of credit exposure to any one issuer. Additionally, in an attempt to limit interest rate risk, we follow guidelines to limit the average and longest single maturity dates. We are adverse to principal loss and aim to ensure the safety and preservation of our invested funds by limiting default, market and reinvestment risk. Our investments include money market accounts, commercial paper and corporate bonds. The table below presents the amounts and related interest rates of our investment portfolio and interest-bearing liabilities as of December 31, 2004 and 2003. Our interest-bearing liabilities are at fixed rates, thus limiting our liability exposure to market rate risk.

			2004		ir Value 2/31/04
		_	(In thou inter	t	
	ASSETS				
Cash and cash equivalents		\$	8,729	\$	8,729
Average interest rate			1.09%		_
	LIABILITIES				
Notes payable — short-term		\$	128	\$	128
Average interest rate			6.18%		_
Convertible debentures		\$	4,000	\$	4,000
Average interest rate			8.00%		_
Secured promissory note		\$	2,200	\$	2,200
Average interest rate			9.83%		_
Capital lease		\$	42	\$	42
Average interest rate			12.47%		_

(In these			
(In thousands, except interest rates)			
	,		
\$ 3,220	\$	3,220	
1.13%		_	
\$ 140	\$	140	
7.64%		_	
\$ 4,000	\$	4,000	
8.00%		—	
\$	\$ 3,220 1.13% \$ 140 7.64% \$ 4,000	\$ 3,220 \$ 1.13% \$ 140 \$ 7.64% \$ 4,000 \$	

## Item 8. Financial Statements and Supplementary Data

## QUESTCOR PHARMACEUTICALS, INC.

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#### Item 9. Changes In and Disagreements with Accountants on Accounting and Financial Disclosure

Not Applicable.

#### Item 9A. Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Principal Accounting Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Principal Accounting Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Principal Accounting Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

There has been no change in our internal controls over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

#### Item 9B. Other Information

Not Applicable.

#### PART III

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

The information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission in connection with the Annual Meeting of our Shareholders (the "Proxy Statement"), which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2004, and is incorporated in this report by reference.

#### Item 11. Executive Compensation

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

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

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

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

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

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

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

#### PART IV

## Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K

- (a) The following documents are filed as part of this Report:
- 1. *Financial Statements*. Our financial statements and the Report of Independent Registered Public Accounting Firm are included in Part IV of this Report on the pages indicated:

	Page
Report of Independent Registered Public Accounting Firm	56
Consolidated Balance Sheets	57
Consolidated Statements of Operations	58
Consolidated Statement of Preferred Stock and Shareholders' Equity	59
Consolidated Statements of Cash Flows	60
Notes to Financial Statements	61

- 2. Financial Statement Schedules. The following financial statement schedule is included in Item 15(a)(2): Valuation and Qualifying Accounts.
- (b) Reports on Form 8-K
- On November 1, 2004, we filed on Form 8-K, under Item 5, a press release announcing the appointment of our Chairman and Acting CEO and the departure of our Chief Financial Officer.
  - On November 4, 2004, we furnished on Form 8-K, under Item 2, a press release of our results for the quarter ended September 30, 2004.
  - (c) Exhibits

Exhibit Number	Description
2.1(1)	Merger agreement entered into August 4, 1999, by and among Cyprus Pharmaceutical Corporation, a California corporation ("Parent"), Cyprus Acquisition Corporation, a Delaware corporation and a wholly owned subsidiary of Parent, and RiboGene, Inc., a Delaware corporation.
3.1(2)	Amended and Restated Articles of Incorporation of the Company.
3.2(3)	Certificate of Determination of Series B Convertible Preferred Stock of the Company.
3.3(4)	Certificate of Determination of Series C Junior Participating Preferred Stock of the Company.
3.4(5)	Bylaws of the Company.
4.1(6)	Convertible Debenture between the Company and SF Capital Partners Ltd. dated March 15, 2002.
4.2(6)	Convertible Debenture between the Company and Defiante Farmaceutica Unipessoal Lda dated March 15, 2002.
10.1(7)	Forms of Incentive Stock Option and Non-statutory Stock Option.
10.2(8)	1992 Employee Stock Option Plan, as amended.
10.3(9)	1993 Non-employee Directors' Equity Incentive Plan, as amended and related form of Nonstatutory Stock Option.
10.5(10)	2000 Employee Stock Purchase Plan.
10.6(11)	Asset Purchase Agreement dated July 27, 2001 between the Company and Aventis Pharmaceuticals Products, Inc.†
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Exhibit Number	Description
10.7(11)	First Amendment to Asset Purchase Agreement dated January 29, 2002, between the Company and Aventis Pharmaceuticals Products, Inc.†
10.10(12)	Stock Purchase Agreement dated July 31, 2001 between Registrant and Sigma-Tau Finance Holding S.A.
10.11(13)	Warrant dated December 1, 2001 between the Company and Paolo Cavazza.
10.12(13)	Warrant dated December 1, 2001 between the Company and Claudio Cavazza.
10.13(6)	Securities Purchase Agreement between the Company and SF Capital Partners Ltd. dated March 15, 2002.
10.14(6)	Registration Rights Agreement between the Company and SF Capital Partners Ltd. dated March 15, 2002.
10.15(6)	Warrant between the Company and SF Capital Partners Ltd. dated March 15, 2002.
10.16(6)	Securities Purchase Agreement between the Company and Defiante Farmaceutica Unipessoal Lda dated March 15, 2002.
10.17(6)	Registration Rights Agreement between the Company and Defiante Farmaceutica Unipessoal Lda dated March 15, 2002.
10.18(6)	Warrant between the Company and Defiante Farmaceutica Unipessoal Lda dated March 15, 2002.
10.19(3)	Form of Common Stock Purchase Warrant dated January 15, 2003 issued by the Company to purchasers of Series B Convertible Preferred Stock.
10.21(4)	Rights Agreement, dated as of February 11, 2003, between the Company and Computershare Trust Company, Inc.
10.22(3)	Form of Subscription Agreement dated as of December 29, 2002 by and between the Company and purchasers of Series B Convertible Preferred Stock and Common Stock Purchase Warrants.
10.28(14)	Letter Agreement dated September 2, 2003 between the Company and R. Jerald Beers.
10.29(14)	Amendment to Letter Agreement dated November 6, 2003 between the Company and R. Jerald Beers.
10.30(14)	Supply Agreement dated April 1, 2003 between the Company and BioVectra, dcl.
10.33(15)	Separation Agreement dated August 5, 2004 between the Company and Charles J. Casamento.
10.34(16)	Secured Promissory Note and Security Agreement dated July 31, 2004 between the Company and Defiante Farmaceutica Lda.
10.35(17)	Letter Agreement between the Company and James L. Fares dated February 17, 2005.
10.36(18)	Amendment dated March 8, 2005 to the 8% Convertible Debenture dated March 15, 2002 issued by Questcor Pharmaceuticals, Inc. in favor of Defiante Farmaceutica Lda.
10.37(18)	Amendment dated March 10, 2005 to the 8% Convertible Debenture dated March 15, 2002 issued by Questcor Pharmaceuticals, Inc. in favor of SF Capital Partners Ltd.
10.38(19)	2004 Non-Employee Directors' Equity Incentive Plan.
10.39*	Letter Agreement between the Company and Reinhard Koenig dated September 30, 2004.
10.40*	Letter Agreement between the Company and James L. Fares dated February 18, 2005.
10.41*	Letter Agreement between the Company and Steve Cartt dated March 7, 2005.
10.42*	Letter Agreement between the Company and Steve Cartt dated March 8, 2005.
10.43*	Letter Agreement between the Company and Reinhard Koenig dated February 3, 2004.
10.44*	Letter Agreement between the Company and Barbara J. McKee dated February 9, 2005.
10.45*	Separation Agreement and Release dated March 3, 2005 between the Company and R. Jerald Beers.
10.46*	Series B Preferred Shareholder Agreement and Waiver dated March 29, 2005 by and between the Company and all of the holders of the outstanding shares of Series B Preferred Stock of the Company.

Number	<b>Description</b>
23.1*	Consent of Independent Registered Public Accounting Firm.
31*	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32*	Certification pursuant to Section 906 of the Public Company Accounting Reform and Investor Act of 2002.

\* Filed herewith.

Exhibit

- (1) Filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 1999, and incorporated herein by reference.
- (2) Filed as an exhibit to the Company's Registration Statement on Form S-8, Registration Statement No. 333-30558, filed on February 16, 2000, and incorporated herein by reference.
- (3) Filed as an exhibit to the Company's Current Report on Form 8-K filed on January 16, 2003, and incorporated herein by reference.
- (4) Filed as an exhibit to the Company's Current Report on Form 8-K filed on February 14, 2003, and incorporated herein by reference.
- (5) Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002, and incorporated herein by reference.
- (6) Filed as an exhibit to the Company's Registration Statement on Form S-3, Registration No. 333-85160, filed on March 28, 2002, and incorporated herein by reference.
- (7) Filed as an exhibit to the Company's Registration Statement on Form S-1, Registration No. 33-51682, and incorporated herein by reference.
- (8) Filed as an exhibit to the Company's Proxy Statement for the 2002 Annual Meeting of Shareholders, filed on March 28, 2002, and incorporated herein by reference.
- (9) Filed as an exhibit to the Company's Registration Statement Form S-4, Registration Statement No. 333-87611, filed on September 23, 1999, and incorporated herein by reference.
- (10) Filed as an exhibit to the Company's Registration Statement on Form S-8, Registration Statement No. 333-46990, filed on September 29, 2000, and incorporated herein by reference.
- (11) Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, and incorporated herein by reference.
- (12) Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001, and incorporated herein by reference.
- (13) Filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2001, and incorporated herein by reference.
- (14) Filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, and incorporated herein by reference.
- (15) Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, and incorporated herein by reference.
- (16) Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004, and incorporated herein by reference.
- (17) Filed as an exhibit to the Company's Current Report on Form 8-K filed on February 23, 2005, and incorporated herein by reference.
- (18) Filed as an exhibit to the Company's Current Report on Form 8-K filed on March 14, 2005, and incorporated herein by reference.
- (19) Filed as an exhibit to the Company's Proxy Statement for the 2004 Annual Meeting of Stockholders, filed on March 29, 2004, and incorporated herein by reference.
- † The Company has requested confidential treatment with respect to portions of this exhibit.

#### **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

QUESTCOR PHARMACEUTICALS, INC.

By /s/JAMES L. FARES

James L. Fares
President and Chief Executive Officer

Dated: March 31, 2005

#### POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints James L. Fares and Barbara J. McKee, and each of them, his attorney-in-fact, each with the power of substitution, for him in any and all capacities, to sign any amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ JAMES L. FARES	President and Chief Executive Officer and Director	March 31, 2005
James L. Fares	(Principal Executive Officer)	
/s/ BARBARA J. McKEE	Director of Finance	March 31, 2005
Barbara J. McKee	(Principal Accounting Officer)	
/s/ ALBERT HANSEN	Chairman	March 31, 2005
Albert Hansen	<del></del>	
/s/ NEAL C. BRADSHER	Director	March 31, 2005
Neal C. Bradsher	<del></del>	
/s/ HOWARD D. PALEFSKY	Director	March 31, 2005
Howard D. Palefsky	<del></del>	
/s/ JON S. SAXE	Director	March 31, 2005
Jon S. Saxe	<del></del>	
/s/ ROGER G. STOLL	Director	March 31, 2005
Roger G. Stoll, Ph.D.		
/s/ VIRGIL D. THOMPSON	Director	March 31, 2005
Virgil D. Thompson		
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#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders Questcor Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Questcor Pharmaceuticals, Inc. as of December 31, 2004 and 2003, and the related consolidated statements of operations, preferred stock and shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2004. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Questcor Pharmaceuticals, Inc. at December 31, 2004 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ Ernst & Young LLP

Palo Alto, California February 18, 2005 except for Note 17, as to which the date is March 29, 2005

# QUESTCOR PHARMACEUTICALS, INC. CONSOLIDATED BALANCE SHEETS

		December 31,			
		2004 2003  (In thousands, except share amounts)			
ASSETS		Silui e C			
Current assets:					
Cash and cash equivalents	\$	8,729	\$	3,220	
Accounts receivable, net of allowance for doubtful accounts of \$40 and \$60 at December 31, 2004					
and 2003, respectively		2,349		2,161	
Inventories		1,769		1,050	
Prepaid expenses and other current assets		839		873	
Total current assets		13,686		7,304	
Property and equipment, net		614		609	
Purchased technology, net		12,758		13,709	
Goodwill and other indefinite-lived intangible assets		299		479	
Deposits and other assets		816		828	
Total assets	\$	28,173	\$	22,929	
			===		
LIABILITIES AND SHAREHOLDERS' EQUITY	Y				
Current liabilities:					
Accounts payable	\$	1,103	\$	1,402	
Accrued compensation		974		358	
Sales-related reserves		1,683		582	
Other accrued liabilities		598		470	
Short-term debt and current portion of long-term debt and capital lease obligation		349		140	
Convertible debentures (face amount of \$4,000), net of deemed discount of \$103		3,897		_	
Total current liabilities		8,604		2,952	
Long-term debt and long-term portion of capital lease obligation		2,021		_	
Convertible debentures, (face amount of \$4,000), net of deemed discount of \$598		_		3,402	
Other non-current liabilities		886		916	
Commitments and contingencies:					
Preferred stock, no par value, 7,500,000 shares authorized; 2,155,715 Series A shares issued and					
outstanding at December 31, 2004 and 2003 (aggregate liquidation preference of \$10,000 at					
December 31, 2004 and 2003)		5,081		5,081	
Shareholders' equity:					
Preferred stock, no par value, 8,400 and 9,100 Series B shares issued and outstanding at December 31,					
2004 and 2003, respectively, net of issuance costs (aggregate liquidation preference of \$8,400 and					
\$9,100 at December 31, 2004 and 2003, respectively)		7,578		8,278	
Common stock, no par value, 105,000,000 shares authorized; 51,216,488 and 45,387,802 shares issued					
and outstanding at December 31, 2004 and 2003, respectively		88,436		85,232	
Deferred compensation		(10)		(17)	
Accumulated deficit		(84,423)		(82,915)	
Total shareholders' equity		11,581		10,578	
Total liabilities and shareholders' equity	\$	28,173	\$	22,929	

## QUESTCOR PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS

		Years Ended December 31,					
	2	2004 2003			2002		
			(In thousands, except per share amounts)				
Revenues:			per on	are amounts,			
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	<u></u>	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		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		<u> </u>	
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	
			_		_		

## QUESTCOR PHARMACEUTICALS, INC.

## CONSOLIDATED STATEMENTS OF PREFERRED STOCK AND SHAREHOLDERS' EQUITY

	Preferred Stock									
	Serie	s A	Seri	es B	Common	Common Stock Deferred		Accumulated	Accumulated Other Comprehensive	Total Shareholders'
	Shares	Amount	Shares	Amount		Amount thousands, e	Compensation xcept shares)	Deficit	Gain/(Loss)	Equity
Balances at December 31, 2001 Deemed discount on convertible	2,155,715	\$5,081	_	_	37,389,603	\$74,018	\$(20)	\$(74,183)	\$(115)	\$ (300)
debentures Stock compensation for options	_	_	_	_	_	1,484	_	_	_	1,484
and warrants granted to consultants	_	_	_	_	_	405	_	_	_	405
Deferred compensation Amortization of deferred	_	_	_	_	_	19	(19)	_	_	_
compensation	_	_	_	_	_	_	17	_	_	17
Issuance of shares pursuant to employee stock purchase plan	_	_	_	_	313,114	146	_	_	_	146
Issuance of common stock to investors	_	_	_	_	640,000	960	_	_	_	960
Issuance of common stock upon exercise of stock options	_	_	_	_	355,432	414	_	_	_	414
Cancellation of shares			_	_	(21,557)	_	_	_		
Warrant issuances associated with convertible debentures	_	_	_	_	_	82	_	_	_	82
Comprehensive income (loss): Other-than-temporary loss on										
investments	_	_	_	_	_	_	_	_	367	367
Net unrealized loss on investments	_	_	_	_	_	_	_	_	(294)	(294)
Net loss	_	_	_	_	_	_	_	(2,785)	_	(2,785)
Total comprehensive loss	2,155,715	<u> </u>			38,676,592	77.530	(22)	(70,000)		(2,712)
Balances at December 31, 2002 Stock compensation for options	2,155,/15	5,081			38,070,392	77,528	(22)	(76,968)	(42)	496
and warrants granted to consultants and employees						50				50
Deferred compensation		_	_	_	_	15	(15)		_	<del></del>
Amortization of deferred compensation	_	_	_	_	_	_	20	_	_	20
Issuance of shares pursuant to	_			_			20			
employee stock purchase plan Issuance of common stock to		_	_	_	93,123	68	_	_	_	68
investors	_	_	_	_	4,979,360	4,826	_	_	_	4,826
Issuance of common stock upon cashless exercise of warrant	_	_	_	_	387,995	_	_	_	_	_
Issuance of common stock upon						242				242
exercise of stock options Issuance of Series B preferred	_	_	_	_	273,962	212	_	_	_	212
stock, net of issuance costs		_	10,000	9,404	_	_		_	_	9,404
Warrants issued on Series B preferred stock	_	_	_	(1,620)	_	1,620	_	_	_	_
Issuance of common stock upon conversion of										
Series B preferred stock	_	_	(900)	(900)	956,225	900	_	_	_	_
Issuance of common stock upon conversion of accrued dividends										
for Series B preferred stock Deemed dividends on Series B			_	_	20,545	13			_	13
preferred stock	_	_	_	1,394	_	_	_	(1,394)	_	_
Dividends recorded Comprehensive income (loss):		_	_	_		_	_	(762)	_	(762)
Other-than-temporary loss on investments									51	51
Reclassification of net		_	_	_		_	_		31	51
unrealized loss on investments into realized										
loss	_	_	_	_	_	_	_	_	(9)	(9)
Net loss Total comprehensive loss	_			_	_		_	(3,791)	_	(3,791) (3,749)
Balances at December 31, 2003	2,155,715	5,081	9,100	8,278	45,387,802	85,232	(17)	(82,915)	_	10,578
Stock compensation for options and warrants granted to consultants						21				21
Stock compensation from			_	_		21	_			21
modification of employee stock options	_	_	_	_	_	9	_	_	_	9
Amortization of deferred						, i	_			
compensation Issuance of shares pursuant to	_	_	_	_	_	_	7	_	_	7
employee stock purchase plan Issuance of common stock to	_	_	_	_	182,267	90		_		90
investors, net of issuance costs	_	_	_	_	1,000,000	610	_	_	_	610
Issuance of common stock upon surrender of warrants	_	_	_	_	3,878,201	1,755	_	_	_	1,755
Issuance of common stock upon										
exercise of stock options Issuance of common stock upon	_	_	_	_	20,076	15	_	_	_	15
conversion of Series B preferred stock	_	_	(700)	(700)	743,732	700	_	_	_	_
Issuance of common stock upon			(. 30)	(. 20)	,,	. 50				
conversion of accrued dividends for Series B preferred stock	_	_	_	_	4,410	4	_	_	_	4
Dividends payable Net loss and comprehensive loss	_	_	_	_	_	_		(676) (832)		(676) (832)
Balances at December 31, 2004	2,155,715	\$ <u>5,081</u>	8,400	\$ 7,578	51,216,488	\$88,436	\$ <u>(10)</u>	\$ <u>(84,423)</u>	\$ <u> </u>	\$ <u>11,581</u>
				_=						

# QUESTCOR PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS

Clay 10 (1900)         Color (2000)         (2000)		2004	Years Ended December 31  2003 (In thousands)	2002
Stock-based compensation expense   30	Cash Flows Provided by (Used in) Operating Activities			
Solic based compensation expense	Net loss	\$ (832)	\$ (3,791)	\$ (2,785)
Amontization of deferned compensation         7         20         17           Depreciation and amortization         1,208         1,157         1,138           Obber-than-improral yos on investment         —         26         37           Loss on the sale of investment         —         26         37           Loss on the sale of investment         —         14         —           Witte-off of manighbe assets         —         14         —           Changer         —         180         571         —           Prepaid expenses and other current assets         —         180         571         —         152           Accrued compensation         66         436         —         210         172         153           Accrued compensation         66         436         —         210         4         14         20           Accade propertial passets and flabilities         —         1,01         16         430         2         12         12	Adjustments to reconcile net loss to net cash used in operating activities:			
Annotization of defered compensation         1,7         20         17           Depreciation and amoritazion         1,208         1,157         1,138           Obere-than-temporary loss on investment         -         51         367           Loss (gain) on the sale disposal of equipment         -         16         377           Loss (agin) on the sale of investment         -         180         -         -           Wire-off of intengible assets         180         -         -           Changes in operating assets and liabilities:         -         180         (571)         (932)           Prepaid expenses and other current assets         (18)         (571)         (932)           Accounts payable         (29)         172         135           Accounts payable reserves         (16)         (436)         219           Account payable reserves         1,101         164         207           Other accrued Liabilities         128         317         383           Active developerating activities         1,28         317         383           Ober accrued Liabilities         1,28         317         483         1,29           Ober accrued Liabilities         1,28         417         383         1,29<	Stock-based compensation expense	30	75	381
Deperciation and amortization		522	522	415
Contemp   Cont	Amortization of deferred compensation	7		17
Loss (gain) on the sale/disposal of equipment         —         26         (37)           Loss on the sale/disposal of equipment         180         —         —           Changes in operating assets and liabilities:         —	•	1,208	1,157	1,138
Loss on the sale of investment         —         14         —           White-off of intangible assets         68         5         —           Changes in operating assets and liabilities:         (78)         (59)         (28)           Inventories         (78)         (59)         (28)           Prepaid expenses and other current assets         34         81         (509)           Accounts payable         (29)         172         135           Accounts payable and the current assets         616         (436)         219           Sales-related reserves         1,101         114         207           Other accrued liabilities         128         (317)         (58)           Other non-current liabilities         128         (317)         (58)           Other non-current liabilities         1,78         (3,46)         (1,83)           Net cash provided by (used in) operating activities         1,78         (3,46)         (1,83)           Net cash provided by (used in) operating activities         1,000         (3,009)         (1,621)           Porchase of front term investments         (1,000)         (3,009)         (1,621)           Proceeds front the sale and maturities of short-term investments         (2,00)         (3,41)         <		_	51	367
Write-off of intangible assets         180         —         —           Changes in operating assets and liabilities:         (188)         (571)         (932)           Inventories         (719)         (930)         (252)           Prepaid expenses and other current assets         (299)         172         135           Accrued compensation         (616)         (436)         219           Sales-related reserves         1,101         164         207           Other accrued liabilities         (30)         83         (99)           Net cash provided by (used in) operating activities         1,788         3(36)         (1830)           Net cash provided by (used in) operating activities         1,788         3(36)         (1830)           Provided in Investing Activities         1,788         4(28)         (1830)           Provided in Investing Activities         1,000         4,337            Provides of Short-term investments         1,000         4,337            Provides of Short-term investments         1,000         4,337            Processed from the sale and maturities of short-term investments         1,000         4,337            Processe from the sale of equipment         2         2	Loss (gain) on the sale/disposal of equipment	_	26	(37)
Changes in operating assets and liabilities:         (188)         (571)         (323)           Accounts receivable         (719)         (596)         (295)           Prepaid expenses and oher current assets         34         81         (308)           Accounts payable         (299)         172         135           Account compensation         616         (436)         219           Sales-related reserves         1,101         164         207           Other accrued liabilities         128         (317)         (588)           Other non-current liabilities         1,308         (38)         (99)           Net cash provided by (used in) operating activities         1,758         (3,34)         (1,838)           Other non-current liabilities         (1,000)         (3,009)         (1,630)           Purbase of short-term investing activities         (1,000)         (3,009)         (1,630)           Portage of short-term investing activities         (1,000)         (3,009)         (1,630)           Portage of short-term investing activities         (220)         (344)         (351)           Portage of short-term investing activities in the sale of diepling and other assets         (15)         (2)         142           Net cash provided by Used in Financing Ac	Loss on the sale of investment	_	14	_
Accounts receivable   (188) (571) (532) (525)		180	_	_
Prepaid expenses and other current assets	Changes in operating assets and liabilities:			
Prepaid expenses and other current assets         34         81         (509)           Accounts payable         (299)         172         135           Accounts payable         (299)         172         135           Accounts payable         (616         (436)         219           Sales-related reserves         1,101         164         207           Other accounted liabilities         (30)         83         (99)           Net cash provided by (used in) operating activities         (1,508)         (3,346)         (1,836)           Net cash provided by (used in) operating activities         —         (14,289)         —           Purchase of short-term investments         (1,000)         (3,009)         (1,261)           Proceeds from the sale and maturities of short-term investments         1,000         4,337         —           Proceads from the sale of equipment and leasehold improvements         (220)         (334)         (355)           Proceeds from the sale of equipment and leasehold improvements         (220)         (334)         (352)           Proceeds from the sale of equipment and leasehold improvements         (220)         (334)         (352)           Proceeds from the sale of equipment and leasehold with asset in investing activities         (220)         (350)         <	Accounts receivable	(188)	(571)	(932)
Accounts payable         (299)         172         135           Accounde compensation         616         (436)         219           Sales-related reserves         1,101         164         207           Other accrued liabilities         128         317         (58)           Other concurrent liabilities         300         83         099           Net cash provided by (used in) operating activities         1,758         (3,346)         1,836           Cash Flows Used in Investing Activities         2         (14,289)         -           Cequisition of purchased technology         -         (14,289)         -           Purchase of short-term investments         (1,000)         4,337         -           Proceeds from the sale and maturities of short-term investments         (1,000)         4,337         -           Proceeds from the sale and programment         (200)         (3,34)         (355)           Proceeds from the sale and equipment and leasehold improvements         (200)         (3,34)         (355)           Proceeds from the sale of equipment and leasehold improvements         (200)         (3,34)         (355)           Proceeds from the sale of equipment and leasehold improvements         (200)         (3,24)         (3,24)           Recappose o	Inventories	(719)	(596)	(295)
Accued compensation         6161         (436)         219           Sales-related reserves         1,101         164         207           Other accured liabilities         128         3,17         (58)           Other non-current liabilities         1,20         3,34         (1,808)           Net cash provided by (used in) operating activities	Prepaid expenses and other current assets	34	81	(509)
Seles-related reserves         1,101         164         207           Other accrued liabilities         130         83         70           Other accrued liabilities         3,03         83         69           Net cash provided by (used in) operating activities         1,758         3,346         1,836           Cash Plows Used in Investing Activities         1,758         1,4289         -           Cash Plow Step in Investing Activities         1,000         4,337         -           Purchase of short-term investments         1,000         4,337         -           Proceeds from be sale and maturities of short-term investments         1,000         4,337         -           Proceeds from the sale and equipment         2         2         4         51           Proceeds from the sale and equipment         2         2         4         51           Recease (decrease) in deposits and other assets         1,15         2         1         1           Net cash Used in Investing activities         2         2         4         51           Stank Flows Provided by (Used in) Financing Activities         2         4         51         50         6         50         6         50         6         50         6         50	Accounts payable	(299)	172	135
Other accured liabilities         128         (317)         (58)           Other non-current liabilities         (30)         83         (98)           Net cash provided by (used in) operating activities         1,75         (3,46)         (3,46)           Cast Flows Used in Investings.         -         (14,289)         -           Acquisition of purchased technology         -         (1,000)         (3,009)         (1,261)           Proceads from the sale and maturities of short-term investments         (1,000)         (334)         (355)           Proceeds from the sale of equipment and leasehold improvements         (220)         (334)         (355)           Proceeds from the sale of equipment         (22)         24         51           Increase (decrease) in deposits and other assets         (21)         (22)         142           Net cash used in investing activities         (23)         (1,273)         (1,435)           Net cash used in investing activities         (23)         (516)         560           Resument of common stock and warrants, net         2,470         5,166         560           Suance of common stock and warrants, net         2,470         5,106         560           Suance of convertible debentures         6         6         57         4,0	Accrued compensation	616	(436)	219
Other non-current liabilities         (30)         83         (99)           Net cash provided by (used in) operating activities         1,758         3,340         1,0380           Cash Flows Used in Investing Activities	Sales-related reserves	1,101	164	207
Net cash provided by (used in) operating activities         1,758         (3,346)         (1,836)           Cash Flows Used in Investing         1         (1,289)         —           Acquisition of purchased technology         —         (14,289)         —           Purchase of short-term investments         (1,000)         (3,009)         (1,261)           Proceeds from the sale and maturities of short-term investments         (1,000)         (3,309)         (355)           Proceeds from the sale of equipment and leasehold improvements         (220)         (334)         (355)           Proceeds from the sale of equipment         2         24         51           Increase (decrease) in deposits and other assets         (21)         (22)         (142           Net cash used in investing activities         (23)         (13,273)         (1,420)           Increase (decrease) in deposits and other assets         4         5         10         50           Increase (decrease) in drost dividends         2,470         5,106         50         <	Other accrued liabilities	128	(317)	(58)
Net cash provided by (used in) operating activities         1,758         (3,346)         (1,836)           Cash Flows Used in Investing         1         (1,289)         —           Acquisition of purchased technology         —         (14,289)         —           Purchase of short-term investments         (1,000)         (3,009)         (1,261)           Proceeds from the sale and maturities of short-term investments         (1,000)         (3,309)         (355)           Proceeds from the sale of equipment and leasehold improvements         (220)         (334)         (355)           Proceeds from the sale of equipment         2         24         51           Increase (decrease) in deposits and other assets         (21)         (22)         (142           Net cash used in investing activities         (23)         (13,273)         (1,420)           Increase (decrease) in deposits and other assets         4         5         10         50           Increase (decrease) in drost dividends         2,470         5,106         50         <	Other non-current liabilities	(30)	83	(99)
How Investing Activities         —         (14,89)         —           Acquisition of purchased technology         —         (1,000)         (3,000)         (1,261)           Pruchase of short-term investments         (1,000)         4,337         —           Purchase of property, equipment and leasehold improvements         (220)         (334)         355           Proceeds from the sale of equipment         2         24         51           Increase (decrease) in deposits and other assets         (15)         (20)         142           Net cash used in investing activities         (23)         (13,73)         (1,420)           Net cash used in investing activities         2         24         51           Stance of common stock and warrants, net         2,470         5,106         560           Suance of preferred stock, invited by (Used in) Financing Activities         —         9,404         —           Proceeds from Sigma-Tau note         (672)         (749)         —           Short-term borrowings         5         57         1,215           Repayment of note payable to bank         —         —         —         —           Repayment of short-term and long-term debt and capital lease obligations         (33)         (65)         1,500	Net cash provided by (used in) operating activities		(3.346)	
Acquisition of purchased technology         — (14,289)         — (24,281)           Purchase of short-term investments         (1,000)         (3,009)         (3,606)           Proceeds from the sale and naturities of short-term investments         (200)         (334)         (355)           Proceeds from the sale of equipment and leasehold improvements         (201)         (324)         (355)           Proceeds from the sale of equipment         2         24         51           Increase (decrease) in deposits and other assets         (215)         (202)         (14,287)           Rice cash used in investing activities         (233)         (13,273)         (14,282)           Rice cash used in investing activities         (233)         (13,273)         (14,282)           Rice cash used in investing activities         (233)         (13,273)         (14,282)           Rice cash provided by (Used in) Financing Activities         2,470         5,166         560           Issuance of convertible debentures         6         7,279         4,000           Suance of preferred stock dividends         5         56         1,579           Proceeds from Signal-Tau note         2,200         5,000         1,500           Repayment of short-term and long-term debt and capital lease obligations         (53		_,	(5,5 15)	(=,===)
Purchase of short-term investments         (1,000)         (3,009)         (1,261)           Proceeds from the sale and maturities of short-term investments         1,000         4,337         —           Purchase of property, equipment and leasehold improvements         (220)         (334)         (355)           Proceeds from the sale of equipment         2         2         4         51           Increase (decrease) in deposits and other assets         (230)         (13,207)         (1428)           Net cash used in investing activities         (233)         (13,207)         (1428)           Rest active in investing activities         (233)         (13,207)         (1428)           Issuance of properted stock and warrants, net         2,370         5,106         560           Issuance of preferred stock, net         —         9,404         —           Issuance of preferred stock, dividends         (672)         (749)         —           Issuance of convertible debentures         516         857         1,251           Proceeds from Sigma-Tau note         2,200         —         —         6,500           Repayment of note payable to bank         —         5,500         (5,500)         (655)         (1,579)           Repayment of short-term and long-term debt and capital lease		_	(14.289)	_
Proceeds from the sale and maturities of short-term investments         1,000         4,337         —           Purchase of property, equipment and leasehold improvements         (22)         24         51           Proceeds from the sale of equipment         2         24         51           Increase (decrease) in deposits and other assets         (15)         (2)         142           Net cash used in investing activities         (23)         (13,273         (1,423)           Cash Flows Provided by (Used in) Financing Activities         2,470         5,106         560           Issuance of preferred stock, net         2,470         9,404         —           Payment of preferred stock dividends         (672)         (749)         —           Issuance of preferred stock dividends         (672)         (749)         —           Issuance of preferred stock dividends         516         587         1,251           Issuance of convertible debentures         2         7         4,000           Short-term borrowings         516         587         1,251           Proceeds from Signar-Tau note         2,200         —         6,500           Repayment of note payable to bank         —         —         6,500           Repayment of short-term and long-term debt and capi		(1.000)	, ,	(1.261)
Purchase of property, equipment and leasehold improvements         (220)         (334)         (355)           Proceeds from the sale of equipment         2         24         51           Increase (decrease) in deposits and other assets         (15)         (20)         142           Net cash used in investing activities         (233)         (13,273)         (1,423)           Cash Flows Provided by (Used in) Financing Activities         2,470         5,106         560           Issuance of common stock and warrants, net         -         9,404         -           Issuance of preferred stock, net         -         9,404         -           Payment of preferred stock dividends         (672)         (749)         -           Issuance of convertible debentures         -         -         4,000           Issuance of convertible debentures         -         -         -         -           Issuance of convertible debentures         -				(1,201)
Proceeds from the sale of equipment         2         24         51           Increase (decrease) in deposits and other assets         (15)         (2)         142           Net cash used in investing activities         (23)         (13,273)         (1,423)           Cash Isolate in investing activities           Issuance of common stock and warrants, net         2,470         5,106         560           Issuance of preferred stock, net         -         9,404         -           Payment of preferred stock dividends         (672)         (749)         -           Issuance of convertible debentures         -         4,000         -           Short-term borrowings         516         587         1,251           Proceeds from Sigma-Tau note         2,200         -         -         -           Repayment of note payable to bank         -				(355)
Increase (decrease) in deposits and other assets         (15)         (2)         142           Net cash used in investing activities         (23)         (13,273)         (1,423)           Cash Flows Provided by (Used in) Financing Activities           Issuance of common stock and warrants, net         2,470         5,106         560           Issuance of preferred stock, net         -         9,404         -           Payment of preferred stock dividends         (672)         (749)         -           Issuance of convertible debentures         -         -         4,000           Issuance of convertible debentures         516         587         1,251           Issuance of convertible debentures         516         587         1,251           Issuance of convertible debentures         516         587         1,251           Proceeds from Sigma-Tau note         2,200         -         -         -           Repayment of note payable to bank         539         (665)         1,579           Net cash provided by (used in) financing activities         3,384         13,683         768           Increase (decrease) in cash and cash equivalents at beginning of period         3,220         6,156         10,183           Cash and cash equivalents at end of period		, ,		` ′
Net cash used in investing activities         (233)         (13,273)         (1,423)           Cash Flows Provided by (Used in) Financing Activities         Secondary Common stock and warrants, net         2,470         5,106         560           Issuance of preferred stock, net         —         9,404         —           Payment of preferred stock dividends         (672)         (749)         —           Issuance of convertible debentures         —         —         4,000           Short-term borrowings         516         587         1,251           Proceeds from Sigma-Tau note         2,200         —         —           Repayment of note payable to bank         —         —         —           Repayment of short-term and long-term debt and capital lease obligations         (530)         (665)         (1,579)           Net cash provided by (used in) financing activities         3,984         13,683         (768)           Increase (decrease) in cash and cash equivalents         5,509         (2,936)         (4,027)           Cash and cash equivalents at beginning of period         3,220         6,156         10,183           Cash and cash equivalents at end of period         \$ 8,729         \$ 3,220         6,156           Supplemental Disclosures of Cash Flow Interest         \$ 420				
Cash Flows Provided by (Used in) Financing Activities         Issuance of common stock and warrants, net       2,470       5,106       560         Issuance of preferred stock, net       9,404       —         Payment of preferred stock dividends       (672)       (749)       —         Issuance of convertible debentures       —       4,000       —       4,000         Short-term borrowings       516       587       1,251         Proceeds from Sigma-Tau note       2,200       —       —       (5,000)         Repayment of note payable to bank       —       —       (5,000)       (6,500)       (1,579)         Repayment of short-term and long-term debt and capital lease obligations       (530)       (665)       (1,579)         Net cash provided by (used in) financing activities       3,984       13,683       (768)         Increase (decrease) in cash and cash equivalents       3,220       6,156       10,133         Cash and cash equivalents at beginning of period       3,220       6,156       10,133         Cash and cash equivalents at end of period       \$ 420       413       3 238         Supplemental Disclosures of Cash Flow Information:         Warrant issued in connection with convertible debentures       \$ 42       4 3       3 23 <td>· · · · · ·</td> <td></td> <td></td> <td></td>	· · · · · ·			
Issuance of common stock and warrants, net         2,470         5,106         560           Issuance of preferred stock, net         —         9,404         —           Payment of preferred stock dividends         (672)         (749)         —           Issuance of convertible debentures         —         —         4,000           Short-term borrowings         516         587         1,251           Proceeds from Sigma-Tau note         2,200         —         —           Repayment of short-term and long-term debt and capital lease obligations         (530)         (665)         (1,579)           Net cash provided by (used in) financing activities         3,984         13,683         (768)           Increase (decrease) in cash and cash equivalents         5,509         (2,936)         (4,027)           Cash and cash equivalents at beginning of period         3,220         6,156         10,183           Cash and cash equivalents at end of period         \$ 8,729         \$ 3,220         \$ 6,156           Supplemental Disclosures of Cash Flow Information:           Cash paid for interest         \$ 420         \$ 413         \$ 238           Non-Cash Investing and Financing Activities           Common stock issued upon conversion of Series B preferred stock and accrued dividends for Series B prefe		(233)	(13,273)	(1,423)
Issuance of preferred stock, net         —         9,404         —           Payment of preferred stock dividends         (672)         (749)         —           Issuance of convertible debentures         —         —         4,000           Short-term borrowings         516         587         1,251           Proceeds from Sigma-Tau note         2,200         —         —           Repayment of note payable to bank         —         —         (5,000)           Repayment of short-term and long-term debt and capital lease obligations         (530)         (665)         (1,579)           Net cash provided by (used in) financing activities         3,984         13,683         (768)           Increase (decrease) in cash and cash equivalents         5,509         (2,936)         (4,027)           Cash and cash equivalents at beginning of period         3,220         6,156         10,183           Cash and cash equivalents at end of period         \$ 8,729         3,220         \$ 6,156           Supplemental Disclosures of Cash Flow Information:           Cash paid for interest         \$ 420         413         238           Non-Cash Investing and Financing Activities:           Warrant issued in connection with convertible debentures         \$ -         \$ -         \$ - <td></td> <td>2.470</td> <td>5 106</td> <td>560</td>		2.470	5 106	560
Payment of preferred stock dividends         (672)         (749)         —           Issuance of convertible debentures         —         —         4,000           Short-term borrowings         516         587         1,251           Proceeds from Sigma-Tau note         2,200         —         —           Repayment of note payable to bank         —         —         (5,000)           Repayment of short-term and long-term debt and capital lease obligations         (530)         (665)         (1,579)           Net cash provided by (used in) financing activities         3,984         13,683         (768)           Increase (decrease) in cash and cash equivalents         5,509         (2,936)         (4,027)           Cash and cash equivalents at beginning of period         3,220         6,156         10,183           Cash and cash equivalents at end of period         \$ 8,729         \$ 3,220         \$ 6,156           Supplemental Disclosures of Cash Flow Information:           Cash paid for interest         \$ 420         \$ 413         \$ 238           Non-Cash Investing and Financing Activities:           Warrant issued in connection with convertible debentures         \$ —         \$ —         \$ 8.2           Common stock issued upon conversion of Series B preferred stock and accrued dividends fo	·	2,470	· · · · · · · · · · · · · · · · · · ·	500
Issuance of convertible debentures         —         —         4,000           Short-term borrowings         516         587         1,251           Proceeds from Sigma-Tau note         2,200         —         —           Repayment of note payable to bank         —         —         (5,000)           Repayment of short-term and long-term debt and capital lease obligations         (530)         (665)         (1,579)           Net cash provided by (used in) financing activities         3,984         13,683         (768)           Increase (decrease) in cash and cash equivalents         5,509         (2,936)         (4,027)           Cash and cash equivalents at beginning of period         3,220         6,156         10,183           Cash and cash equivalents at end of period         \$ 8,729         \$ 3,220         \$ 6,156           Supplemental Disclosures of Cash Flow Information:           Cash paid for interest         \$ 420         \$ 413         \$ 238           Non-Cash Investing and Financing Activities:           Warrant issued in connection with convertible debentures         \$ —         \$ —         \$ 82           Common stock issued upon conversion of Series B preferred stock and accrued dividends for Series B preferred stock         \$ 704         \$ 13         \$ —		(672)		
Short-term borrowings         516         587         1,251           Proceeds from Sigma-Tau note         2,200         —         —           Repayment of note payable to bank         —         —         (5,000)           Repayment of short-term and long-term debt and capital lease obligations         (530)         (665)         (1,579)           Net cash provided by (used in) financing activities         3,984         13,683         (768)           Increase (decrease) in cash and cash equivalents         5,509         (2,936)         (4,027)           Cash and cash equivalents at beginning of period         3,220         6,156         10,183           Cash and cash equivalents at end of period         \$ 8,729         \$ 3,220         \$ 6,156           Supplemental Disclosures of Cash Flow Information:           Cash paid for interest         \$ 420         \$ 413         \$ 238           Non-Cash Investing and Financing Activities:           Warrant issued in connection with convertible debentures         \$ —         \$ —         \$ 82           Common stock issued upon conversion of Series B preferred stock and accrued dividends for Series B preferred stock         \$ 704         \$ 13         \$ —		(0/2)	(749)	4 000
Proceeds from Sigma-Tau note         2,200         —         —           Repayment of note payable to bank         —         —         (5,000)           Repayment of short-term and long-term debt and capital lease obligations         (530)         (665)         (1,579)           Net cash provided by (used in) financing activities         3,984         13,683         (768)           Increase (decrease) in cash and cash equivalents         5,509         (2,936)         (4,027)           Cash and cash equivalents at beginning of period         3,220         6,156         10,183           Cash and cash equivalents at end of period         \$ 8,729         3,220         6,156           Supplemental Disclosures of Cash Flow Information:           Cash paid for interest         \$ 420         413         238           Non-Cash Investing and Financing Activities:           Warrant issued in connection with convertible debentures         \$			E97	
Repayment of note payable to bank Repayment of short-term and long-term debt and capital lease obligations  (530) (665) (1,579)  Net cash provided by (used in) financing activities 3,984 13,683 (768)  Increase (decrease) in cash and cash equivalents 5,509 (2,936) (4,027)  Cash and cash equivalents at beginning of period 3,220 6,156 10,183  Cash and cash equivalents at end of period \$8,729 \$3,220 \$6,156 10,183  Cash and cash equivalents at end of period \$8,729 \$3,220 \$6,156  Supplemental Disclosures of Cash Flow Information:  Cash paid for interest  Non-Cash Investing and Financing Activities:  Warrant issued in connection with convertible debentures  \$ 420 \$413 \$238  Common stock issued upon conversion of Series B preferred stock and accrued dividends for Series B preferred stock  \$ 704 \$13 \$ —	<u> </u>			1,251
Repayment of short-term and long-term debt and capital lease obligations (530) (665) (1,579)  Net cash provided by (used in) financing activities 3,984 13,683 (768)  Increase (decrease) in cash and cash equivalents 5,509 (2,936) (4,027)  Cash and cash equivalents at beginning of period 3,220 6,156 10,183  Cash and cash equivalents at end of period \$8,729 \$3,220 \$6,156  Supplemental Disclosures of Cash Flow Information:  Cash paid for interest \$420 \$413 \$238  Non-Cash Investing and Financing Activities:  Warrant issued in connection with convertible debentures \$ \$ \$82  Common stock issued upon conversion of Series B preferred stock and accrued dividends for Series B preferred stock \$ \$ \$ \$ \$ \$ \$ \$				(F 000)
Net cash provided by (used in) financing activities 3,984 13,683 (768) Increase (decrease) in cash and cash equivalents 5,509 (2,936) (4,027) Cash and cash equivalents at beginning of period 3,220 6,156 10,183 Cash and cash equivalents at end of period \$8,729 \$3,220 \$6,156  Supplemental Disclosures of Cash Flow Information: Cash paid for interest \$420 \$413 \$238  Non-Cash Investing and Financing Activities: Warrant issued in connection with convertible debentures \$ \$ \$82  Common stock issued upon conversion of Series B preferred stock and accrued dividends for Series B preferred stock \$ \$ \$ \$ \$ \$ \$ \$				, ,
Increase (decrease) in cash and cash equivalents 5,509 (2,936) (4,027) Cash and cash equivalents at beginning of period 3,220 6,156 10,183 Cash and cash equivalents at end of period \$8,729 \$3,220 \$6,156  Supplemental Disclosures of Cash Flow Information: Cash paid for interest \$420 \$413 \$238  Non-Cash Investing and Financing Activities: Warrant issued in connection with convertible debentures \$ \$ \$82  Common stock issued upon conversion of Series B preferred stock and accrued dividends for Series B preferred stock \$ \$ \$ \$ \$ \$ \$ \$				
Cash and cash equivalents at beginning of period 3,220 6,156 10,183 Cash and cash equivalents at end of period \$8,729 \$3,220 \$6,156  Supplemental Disclosures of Cash Flow Information:  Cash paid for interest \$420 \$413 \$238  Non-Cash Investing and Financing Activities:  Warrant issued in connection with convertible debentures \$ - \$ - \$ 82  Common stock issued upon conversion of Series B preferred stock and accrued dividends for Series B preferred stock \$ 704 \$ 13 \$ - \$ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \				<u>`</u>
Cash and cash equivalents at end of period \$8,729 \$3,220 \$6,156  Supplemental Disclosures of Cash Flow Information:  Cash paid for interest \$420 \$413 \$238  Non-Cash Investing and Financing Activities:  Warrant issued in connection with convertible debentures \$ - \$ - \$ 82  Common stock issued upon conversion of Series B preferred stock and accrued dividends for Series B preferred stock \$ 704 \$ 13 \$ -	. ,			
Supplemental Disclosures of Cash Flow Information:  Cash paid for interest \$ 420 \$ 413 \$ 238  Non-Cash Investing and Financing Activities:  Warrant issued in connection with convertible debentures \$ - \$ - \$ 82  Common stock issued upon conversion of Series B preferred stock and accrued dividends for Series B preferred stock \$ 704 \$ 13 \$ -	Cash and cash equivalents at beginning of period	3,220	6,156	10,183
Cash paid for interest \$ 420 \$ 413 \$ 238  Non-Cash Investing and Financing Activities:  Warrant issued in connection with convertible debentures \$ \$ \$ \$ 82  Common stock issued upon conversion of Series B preferred stock and accrued dividends for Series B preferred stock \$ \$ \$ 13 \$ \$ \$	Cash and cash equivalents at end of period	\$ 8,729	\$ 3,220	\$ 6,156
Cash paid for interest \$ 420 \$ 413 \$ 238  Non-Cash Investing and Financing Activities:  Warrant issued in connection with convertible debentures \$ \$ \$ \$ 82  Common stock issued upon conversion of Series B preferred stock and accrued dividends for Series B preferred stock \$ \$ \$ 13 \$ \$ \$	Supplemental Disclosures of Cash Flow Information:			
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preferred stock <u>\$ 704</u> <u>\$ 13</u> <u>\$ —</u>	Warrant issued in connection with convertible debentures	<u> </u>	<u>\$</u>	\$ 82
·				
Equipment acquired under capital lease \$ 44 \$ —	preferred stock	\$ 704	\$ 13	<u> </u>
	Equipment acquired under capital lease	\$ 44	<u> </u>	<u> </u>

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

# Organization and Summary of Significant Accounting Policies

### **Organization and Business Activity**

Questcor Pharmaceuticals, Inc. (the "Company") is a specialty pharmaceutical company that acquires, develops, markets and sells prescription drugs through a U.S. direct sales force and international distributors. The Company focuses on the treatment of central nervous system ("CNS") diseases and gastroenterological disorders, which are served by a limited group of physicians such as neurologists and gastroenterologists. The Company's strategy is to acquire or develop pharmaceutical products that it believes have sales growth potential, are promotionally responsive to a focused and targeted sales and marketing effort, complement the existing products and can be acquired at a reasonable valuation relative to the Company's cost of capital. In addition, through corporate collaborations, the Company intends to develop new medications focused on the target markets. The Company currently markets four products in the U.S.: H.P. Acthar® Gel ("Acthar"), an injectable drug that is approved for the treatment of certain CNS disorders with an inflammatory component, including the treatment of flares associated with multiple sclerosis ("MS"), and is also commonly used in treating patients with infantile spasm; Nascobal®, the only prescription nasal gel used for the treatment of various Vitamin B-12 deficiencies; Ethamolin®, an injectable drug used to treat enlarged weakened blood vessels at the entrance to the stomach that have recently bled, known as esophageal varices; and Glofil®-125, an injectable agent that assesses how well the kidney is working by measuring glomerular filtration rate, or kidney function. The Company's promotion agreement for VSL#3®, a patented probiotic marketed as a dietary supplement to promote normal gastrointestinal function, expired in January 2005. VSL#3 will be promoted in the future by Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau Pharmaceuticals") an affiliate of Sigma-Tau Finanziaria SpA ("Sigma-Tau"), a significant shareholder and affiliate of the Company. Due to minimal demand, increasing pro

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant inter-company accounts and transactions have been eliminated.

Questcor Pharmaceuticals, Inc. is the surviving corporation of a merger between Cypros Pharmaceutical Corporation and RiboGene, Inc. The merger was completed on November 17, 1999.

### **Need to Raise Additional Capital**

The Company has incurred significant operating losses and negative cash flows from operations since its inception. At December 31, 2004, the Company had an accumulated deficit of \$84.4 million and working capital of \$5.1 million. Management believes that cash on hand at December 31, 2004, and the net cash flows that are projected to be generated from operations in 2005 will be sufficient to fund operations through at least January 1, 2006. If the Company's revenues do not provide cash flows from operations in an amount sufficient to meet its obligations, it will seek to raise additional capital through public or private equity financing or from other sources. Such financing may not be available under acceptable terms, if at all.

### **Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and disclosures made in the accompanying notes to the financial statements. Actual results could differ from those estimates.

#### Cash Equivalents and Short-Term Investments

The Company considers highly liquid investments with maturities from the date of purchase of three months or less to be cash equivalents. The Company determines the appropriate classification of investment

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

securities at the time of purchase and reaffirms such designation as of each balance sheet date. Available-for-sale securities are carried at fair value, with the unrealized gains and losses, if any, reported in a separate component of shareholders' equity. The cost of securities sold is based on the specific identification method. Realized gains and losses, if any, are included in the Statement of Operations, in Other Income.

#### Concentration of Risk

% of Accounts Receivable

Financial instruments which subject the Company to potential credit risk consist of cash, cash equivalents, short-term investments and accounts receivable. The Company invests its cash in high credit quality government and corporate debt instruments and believes the financial risks associated with these instruments are minimal. The Company extends credit to its customers, primarily large drug wholesalers and distributors and certain hospitals and treatment centers, in connection with its product sales. The Company has not experienced significant credit losses on its customer accounts. Three wholesalers accounted for the majority of our accounts receivable and gross product sales as follows:

December 31

2003

2004

M/holosolov A	200/	250/	200/
% of Gross Product Sales	2004	2003	2002
		December 31,	
		Years Ended	
		100%	100%
Other customers		12%	12%
		= : :	
Wholesaler C		25%	14%
Wholesaler B		32%	39%
Wholesaler A		31%	35%

	December 31,				
% of Gross Product Sales	2004	2003	2002		
Wholesaler A	29%	35%	30%		
Wholesaler B	28%	25%	34%		
Wholesaler C	24%	18%	20%		
Other customers	19%	22%	16%		
	100%	100%	100%		

The Company relies on third party sole-source manufacturers to produce its finished goods and raw materials. Third party manufacturers may not be able to meet the Company's needs with respect to timing, quantity or quality. All of the Company's manufacturers are sole-source manufacturers and no alternative suppliers exist.

### **Inventories**

Inventories are stated at the lower of cost (first-in, first-out method) or market value. Inventory reserves are provided for on a product-by-product basis, based upon the expiration date of products, inventory levels in relation to forecasted sales volume, and historical demand for products.

#### **Property and Equipment**

Property and equipment are stated at cost and depreciated over the estimated useful lives of the assets (generally three to eight years) using the straight-line method. Leasehold improvements are amortized over the lesser of the estimated useful lives (five years) or the remaining term of the lease. Amortization of assets under capital leases is included in depreciation expense.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### **Intangible and Other Long-Lived Assets**

Intangible assets consist of goodwill, assembled workforce and purchased technology. The goodwill and other indefinite lived intangible assets were generated from the merger with RiboGene.

Purchased technology associated with the acquisitions of products is stated at cost and amortized over the estimated sales life of the product. The Company periodically reviews the useful lives of its intangible and long-lived assets, which may result in future adjustments to the amortization periods. As of December 31, 2004, the purchased technology only relates to Nascobal which is being amortized over an estimated life of 15 years, as prior purchased technology is fully amortized.

Effective January 1, 2002, goodwill (including the assembled workforce) and intangible assets with indefinite useful lives are no longer amortized, but instead are tested for impairment at least annually. Any impairment loss recognized will be charged to operations. During the quarter ended December 31, 2004, the Company recorded an impairment loss of \$180,000 related to the assembled workforce (see Note 7).

### Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that their carrying amounts may not be recoverable. Recoverability of assets is measured by comparison of the carrying amount of the asset to the net undiscounted future cash flows expected to be generated from the asset. If the future undiscounted cash flows are not sufficient to recover the carrying value of the assets, the assets' carrying value is adjusted to fair value.

### Revenue Recognition

Revenues from product sales are recognized based upon shipping terms, net of estimated reserves for government chargebacks, Medicaid rebates, payment discounts, and after May 31, 2004, returns for credit. Revenue is recognized upon shipment of product, provided the title to the products has been transferred at the point of shipment. If the title to the product transfers at point of receipt by the customer, revenue is recognized upon customer receipt of the shipment. The Company records estimated sales reserves against product revenues for government chargebacks, Medicaid rebates, payment discounts and product returns for credit memoranda. The Company's policy of issuing credit memoranda for expired product, which became effective for product lots released after May 31, 2004, allows customers to return expired product for credit within six months beyond the expiration date. Customers who return expired product from production lots released after May 31, 2004 will be issued credit memoranda equal to the sales value of the product returned, and the estimated amount of such credit memoranda is recorded as a liability with a corresponding reduction in gross product sales. This reserve will be reduced as future credit memoranda are issued, with an offset to accounts receivable. 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 within six months beyond the expiration date. Returns from these product lots are exchanged for replacement product, and estimated costs for such exchanges, which include actual product material costs and related shipping charges, are included in Cost of Product Sales. Returns are subject to inspection prior to acceptance. For Glofil-125 and VSL#3 the Company accepts no returns for expired product.

The Company records estimated sales reserves for expected product exchanges and credit memoranda based upon historical return rates by product, analysis of return merchandise authorizations, returns received, sales patterns, current inventory on hand at wholesalers, changes in prescription demand, and other factors such as shelf life. The Company records estimated sales reserves for Medicaid rebates and government chargebacks by analyzing historical rebate and chargeback percentages, allowable Medicaid prices, and other factors, as required. Significant judgment is inherent in the selection of assumptions and in the interpretation of historical experience as well as the identification of external and internal factors affecting the estimate of

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

reserves for product returns, Medicaid rebates and government chargebacks. The Company routinely assesses the historical returns and other experience including customers' compliance with return goods policy and adjusts its reserves as appropriate.

The Company sells products to wholesalers, who in turn sell these products to pharmacies and hospitals. In the case of VSL#3, the Company sold directly to consumers. The Company does not require collateral from its customers.

Reserves for government chargebacks, Medicaid rebates, product exchanges and product returns for credit memoranda were \$1,683,000 and \$582,000 at December 31, 2004 and 2003, respectively, and are included in Sales-Related Reserves in the Consolidated Balance Sheets. The reserves at December 31, 2004 include \$1,054,000 for estimated product returns for credit memoranda on product lots of Acthar and Nascobal released and shipped after May 31, 2004.

Revenue earned under collaborative research agreements is recognized as the research services are performed. Amounts received in advance of services to be performed are recorded as deferred revenue until the services are performed.

The Company has received government grants that support the Company's research effort in specific research projects. These grants provided for reimbursement of approved costs incurred as defined in the various awards. The Company's Small Business Innovation Research ("SBIR") grant related to Glial Exatotoxin Release Inhibitors ("GERI") compound research terminated in July 2003.

The Company has received payments in exchange for proprietary licenses related to technology and patents. The Company classifies these payments as Technology Revenue. These payments are recognized as revenues upon receipt of cash and the transfer of intellectual property, data and other rights licensed, assuming no continuing material obligations exist.

### **Shipping and Handling Costs**

Shipping and handling costs are included in Cost of Product Sales.

#### Research and Development

The costs included in research and development relate primarily to our manufacturing site transfers and medical and regulatory affairs compliance activities. Research and development expenditures, including direct and allocated expenses, are charged to expense as incurred.

### Net Loss Per Share Applicable to Common Shareholders

Basic and diluted net loss per share applicable to common shareholders is based on net loss applicable to common shareholders for the relevant period, divided by the weighted average number of common shares outstanding during the period. Diluted earnings per share applicable to common shareholders gives effect to all potentially dilutive common shares outstanding during the period such as options, warrants, convertible preferred stock, and contingently issuable shares. Diluted net loss per share applicable to common shareholders has not been presented separately as, due to the Company's net loss position, it is anti-dilutive. Had the Company been in a net income position for the year ended December 31, 2004, the calculation of diluted earnings per share applicable to common shareholders would have included, if dilutive, the effect of the outstanding 5,685,459 stock options, 11,080,492 convertible preferred shares, 2,531,644 shares issuable upon conversion of debentures, placement unit options for 127,676 shares and 4,539,407 warrants. For the year ended December 31, 2003, the calculation of diluted earnings per share applicable to common shareholders would have included, if dilutive, the effect of the outstanding 9,757,502 stock options, 11,824,220 convertible preferred shares, 2,531,646 shares issuable upon conversion of debentures, placement unit options for

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

127,676 shares and 8,437,608 warrants. For the year ended December 31, 2002, the calculation of diluted earnings per share applicable to common shareholders would have included, if dilutive, the effect of the outstanding 8,942,262 stock options, 2,155,715 convertible preferred shares, 2,531,646 shares issuable upon conversion of debentures, placement unit options for 986,898 shares and 4,851,201 warrants.

#### Stock-Based Compensation

The Company generally grants stock options to its employees for a fixed number of shares with an exercise price equal to the fair value of the shares on the date of grant. As allowed under SFAS No. 123, "Accounting for Stock-Based Compensation," the Company has elected to follow Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" and related interpretations in accounting for stock awards to employees. Accordingly, no compensation expense is recognized in the Company's financial statements in connection with stock options granted to employees with exercise prices not less than fair value. Deferred compensation for options granted to employees is determined as the difference between the fair value of the Company's common stock on the date options were granted and the exercise price. For purposes of disclosures pursuant to SFAS No. 123, as amended by SFAS No. 148, "Accounting for Stock-Based Compensation — Transition and Disclosure," the estimated fair value of options is amortized to expense over the options' vesting periods.

Compensation expense for options granted to non-employees has been determined in accordance with SFAS No. 123 and Emerging Issues Task Force ("EITF") 96-18, "Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in conjunction with Selling Goods or Services," as the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. Compensation expense for options granted to non-employees is periodically re-measured as the underlying options vest.

The following table illustrates the effect on net loss per share applicable to common stockholders if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation (in thousands, except per share amounts):

	Years Ended December 31,					
	2004		2003			2002
Net loss applicable to common shareholders, as reported	\$	(1,508)	\$	(5,947)	\$	(2,785)
Add: Stock-based employee compensation expense included in reported net loss		7		58		17
Add: Adjustment to stock-based employee compensation due to forfeitures of unvested						
options, primarily related to officer resignations		488		_		_
Deduct: Total stock-based employee compensation expense determined under fair value						
method for all awards		(720)		(1,439)		(1,508)
Net loss applicable to common shareholders, pro forma	\$	(1,733)	\$	(7,328)	\$	(4,276)
Basic and diluted net loss per share applicable to common shareholders:						
As reported	\$	(0.03)	\$	(0.14)	\$	(0.07)
Pro forma	\$	(0.03)	\$	(0.17)	\$	(0.11)
	=		_	<del></del>	==	

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### Comprehensive Income

SFAS No. 130, "Reporting Comprehensive Income" established standards for the reporting and display of comprehensive income and its components (revenues, expenses, gains and losses) in a full set of general-purpose financial statements. The Company provides the required disclosure in the Consolidated Statements of Preferred Stock and Stockholders' Equity.

#### **Segment Information**

The Company has determined that it operates in one business segment.

Net product sales by therapeutic area:

		Years Ended December 31,								
		2004		2004 20		2004 2003		2003		2002
			(In	\$000's)		<u>.</u>				
Neurology	\$	8,168	\$	7,973	\$	9,009				
Gastroenterology		9,399		4,721		4,050				
Nephrology		837		961		760				
	\$	18,404	\$	13,655	\$	13,819				

#### Recently Issued Accounting Standard

In December 2004, the FASB issued SFAS No. 123R, "Share-Based Payment," a revision to SFAS No. 123, "Accounting for Stock-Based Compensation." SFAS No. 123R eliminates our ability to use the intrinsic value method of accounting under APB Opinion 25, "Accounting for Stock Issued to Employees," and requires a public entity to reflect on its income statement, instead of pro forma disclosures in its financial footnotes, the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. The grant-date fair value will be estimated using option-pricing models adjusted for the unique characteristics of those equity instruments. SFAS No. 123R is effective generally for public companies as of the beginning of the first interim or annual reporting period that begins after June 15, 2005. SFAS No. 123R applies to all awards granted after the required effective date, to awards that are unvested as of the effective date, and to awards modified, repurchased, or cancelled after that date. As of the required effective date, all public entities that used the fair-value-based method for either recognition or disclosure under the original SFAS No. 123 will apply this revised statement. Under SFAS No. 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include modified prospective and modified retrospective adoption options. Under the modified prospective method, compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS No. 123R for all share-based payments granted after the effective date and (b) based on the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date. The modified retrospective method includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS No. 123 for purposes of pro forma disclosures, either (a) all prior periods presented or (b) prior interim periods of the year of adoption. We are currently evaluating the requirements of SFAS No. 123R and will adopt this statement at the effective date. We expect that the adoption of this statement will have a material effect on our financial statements.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### 2. Development and Collaboration Agreements

In June 2002, the Company signed a definitive License Agreement with Fabre-Kramer Pharmaceuticals, Inc. ("Fabre-Kramer") of Houston, TX, for the exclusive worldwide development and commercialization of Hypnostat<sup>TM</sup> (intranasal triazolam) for insomnia and Panistat<sup>TM</sup> (intranasal alprazolam) for panic disorders. Immediately after the agreement was signed, the Company received a cash payment of \$250,000 from Fabre-Kramer for the transfer of all technology related to the products. The Company has no continuing obligations related to the transfer of the technology. The Company is entitled to future payments from Fabre-Kramer when specific developmental milestones are met. In addition, the Company is entitled to a share of future worldwide product-related Fabre-Kramer revenues, based on a percentage of total revenues. This License Agreement is the final result of the Letter of Understanding originally signed in June 2001 and modified in January 2002. Under the License Agreement, Fabre-Kramer assumed the responsibility for the development of Hypnostat<sup>TM</sup> and Panistat<sup>TM</sup>.

In December 2001, the Company entered into a promotion agreement (effective January 2002) with VSL Pharmaceuticals, Inc. ("VSL"), a private company owned in part by the major stockholders of Sigma-Tau. Effective January 1, 2004, the promotion agreement and all amendments were assigned by VSL to Sigma-Tau Pharmaceuticals. As Sigma-Tau owns common stock of the Company as of December 31, 2004, VSL and Sigma-Tau are deemed to be related parties of the Company. In June 2002, the Company signed an amendment to the promotion agreement. Under these agreements, the Company agreed to purchase VSL#3 from Sigma-Tau Pharmaceuticals at a stated price, and also agreed to promote, sell, warehouse and distribute the VSL#3 product direct to customers at its cost and expense. The VSL#3 product was formally launched on May 23, 2002. Revenues from sales of VSL#3 are recognized when product is shipped to the customer. The Company does not accept returns of VSL#3. VSL#3 revenue was \$1,466,000 and \$992,000 for the years ended December 31, 2004 and 2003, respectively, and is included in Net Product Sales. The Company paid a quarterly access fee to Sigma-Tau Pharmaceuticals (formerly VSL Pharmaceuticals, Inc.), which varied based upon sales and costs incurred by the Company. Additionally, under these agreements, Sigma-Tau Pharmaceuticals has paid the Company \$200,000 in exchange for services provided by the Company to launch the VSL#3 product which was recognized in full as of December 31, 2002 and is included in Services Revenue from a Related Party in the Consolidated Statements of Operations. The term of the agreement was three years and the agreement expired in January 2005. Beginning January 2005, the VSL#3 product will be promoted by Sigma-Tau Pharmaceuticals, an affiliate of Sigma-Tau, a significant shareholder and affiliate of the Company. As of December 31, 2004 and 2003, the Company owes Sigma-Tau Pharmaceuticals \$155,000 and \$188,000, respectively, which is included in Accounts Payable in the accompanying Consolidated Balance

The Company entered into a License Agreement in December 2000 with Ahn-Gook Pharmaceutical Co., Ltd ("Ahn-Gook") for marketing intranasal metoclopramide, to be marketed in Korea under the trade name Emitasol. Ahn-Gook intends to manufacture Emitasol in Korea. This product had been sold in the past as Pramidin in Italy. Ahn-Gook received government approval to market Emitasol in 2002. The Company received an up-front cash payment of \$50,000 in December 2000, which was recognized as revenue in 2002 upon completion of the agreement obligation. In addition, the Company received a payment of \$150,000 upon transfer of technology to Ahn-Gook in December 2002 and will earn royalties based on actual sales in Korea. The License Agreement was amended in December 2002 to include twelve additional countries in Asia. The Company will receive an upfront payment and additional royalties upon commercialization of Emitasol in each of these new countries. Ahn-Gook began sales of Emitasol in the Republic of Korea in the first half of 2003. Through 2004, the sales of the product are minimal.

As a result of the merger with RiboGene, the Company assumed an option and license agreement entered into with Roberts Pharmaceutical Corporation, a subsidiary of Shire Pharmaceuticals Ltd. ("Shire"), in July 1998 for the development of Emitasol, an intranasally administered drug being developed for the treatment of

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

diabetic gastroparesis and for the prevention of delayed onset emesis. Under the terms of the agreement, Shire had the option to acquire exclusive North American rights to Emitasol. This option expired in July 2001. Under the collaboration agreement, the Company was obligated to fund one-half of the clinical development expenses for Emitasol up to an aggregate of \$7.0 million. Through December 31, 2004, the Company has made development payments for Emitasol, under the terms of the agreement with Shire, totaling \$4.7 million, consisting of \$4.2 million paid to Shire and approximately \$500,000 paid to other parties for allowable expenses including patent and trademark costs. Shire asserts that the Company owes \$248,000 in development expenses incurred by it under the collaboration agreement prior to the expiration of the option, which the Company has accrued for as of December 31, 2004. The Company had Shire return certain items to the Company, including the transfer of the Investigational New Drug applications relating to Emitasol and the assignment of the intellectual property relating to Emitasol generated in the course of the development program. Shire also holds all 2,155,715 outstanding shares of the Company's Series A preferred stock which it originally acquired from RiboGene for a payment of \$10 million.

### 3. Product Acquisition

In June 2003, the Company acquired Nascobal, a nasal gel formulation of Cyanocobalamin USP (Vitamin B-12), from Nastech Pharmaceuticals, Inc. ("Nastech"). Under the terms of the Nascobal Asset Purchase Agreement, the Company made an initial cash payment of \$9.0 million upon the closing of the acquisition, an additional cash payment of \$3.0 million in the third quarter of 2003 and an additional \$2.2 million cash payment in December 2003 (a total of \$14.2 million). As part of the acquisition, the Company also acquired rights to Nascobal nasal spray, an improved dosage form, for which a New Drug Application ("NDA") was filed by Nastech with the FDA at the end of 2003. Under the terms of the Agreement, subject to the approval of the NDA for the new Nascobal nasal spray dosage form by the FDA, the Company was required to make a \$2.0 million payment for the transfer of the NDA from Nastech to the Company. The NDA for Nascobal spray was approved by the FDA in February 2005, and the Company paid the required \$2.0 million to Nastech in February 2005. Further, upon issuance of a pending U.S. patent for the new Nascobal nasal spray dosage form, the Company is required to make a second \$2.0 million payment. The U.S. patent applications for the Nascobal nasal spray have been filed by Nastech. The Company and Nastech have also entered into a long term supply agreement under which Nastech will continue to manufacture Nascobal for the Company at its FDA-approved, current good manufacturing practice ("cGMP") manufacturing facility in Hauppauge, New York.

The Company accounted for the Nascobal product acquisition as an asset purchase and allocated the purchase price based on the fair value of the assets acquired. Of the purchase cost of \$14.3 million, which includes acquisition costs of \$0.1 million, \$14.2 million was attributed to purchased technology, and \$0.1 million to inventory. Purchased technology will be amortized over the estimated life of 15 years. Amortization expense was \$951,000 and \$514,000 for the years ended December 31, 2004 and 2003, respectively. Amortization expense will be approximately \$1,079,000 for year 2005 and \$1,098,000 per year from 2006 through 2017, and approximately \$503,000 for 2018.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### 4. Investments

Following is a summary of investments, at fair value, based on quoted market prices for these investments (in thousands):

	Gross			Gross realized		timated
December 31, 2004	Amo	rtized Cost		Loss		ir Value
Cash equivalents:						
Money market funds	\$	5,693	\$	_	\$	5,693
Commercial paper		2,245		_		2,245
	\$	7,938	\$		\$	7,938
December 31, 2003	Gross Amortized Cost		Uni	Gross realized Loss		timated ir Value
Cash equivalents:						
Money market funds	\$	2,301	\$		\$	2,301

In 2003, the Company recognized an other-than-temporary loss of \$51,000 and a realized loss of \$14,000 and, in 2002, the Company recognized an other-than-temporary loss of \$367,000 related to its equity investment in Rigel Pharmaceuticals, Inc.

The net realized gains on sales of available-for-sale investments were not material in fiscal years 2004, 2003 and 2002.

### 5. Inventories

Inventories consist of the following (in thousands):

	 December 31,			
	 2004		2003	
Raw materials	\$ 1,239	\$	534	
Work in Process	228		197	
Finished goods	409		660	
Less allowance for excess and obsolete inventories	(107)		(341)	
	\$ 1,769	\$	1,050	

# 6. Property and Equipment

Property and equipment consist of the following (in thousands):

		December 31,			
	2004	2003			
Laboratory equipment	\$	9 \$ 9			
Manufacturing equipment	4	46 272			
Office equipment, furniture and fixtures	8	86 799			
Leasehold improvements	3	29 329			
	1,6	70 1,409			
Less accumulated depreciation and amortization	(1,0	56) (800)			
	\$ 6	\$ 609			

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Depreciation and amortization expense for property and equipment totaled \$257,000, \$260,000, and \$361,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

#### 7. Purchased Technology and Other Intangible Assets

Goodwill and other intangibles consist of the following (in thousands):

	December 31,			
		2004		2003
Goodwill	\$	1,023	\$	1,023
Purchased technology		14,223		14,223
Assembled workforce		_		616
		15,246		15,862
Less accumulated amortization		(2,189)		(1,674)
	\$	13,057	\$	14,188

The net carrying value of goodwill no longer subject to amortization amounted to \$299,000 at December 31, 2004 and 2003. The net carrying value of assembled workforce no longer subject to amortization amounted to nil and \$180,000 at December 31, 2004 and 2003, respectively. Purchased technology at December 31, 2004 and 2003 includes \$14,223,000 related to the Nascobal acquisition. Amortization of purchased technology relating to products totaled \$951,000, \$897,000 and \$777,000 for the years ended December 31, 2004, 2003, and 2002, respectively, and is included in Depreciation and Amortization expense in the accompanying Consolidated Statements of Operations.

For the year ended December 31, 2004, the Company tested its goodwill (including assembled workforce) for impairment. The assembled workforce was generated from the merger with RiboGene, and represented the value of the employees that the Company retained subsequent to the merger based upon the cost to replace the retained employees. In evaluating the assembled workforce, the Company determined that the cost to replace the remaining employees would be minimal. Hence, the Company concluded that the remaining assembled workforce was impaired and the carrying value of \$180,000 related to the assembled workforce was written off in the fourth quarter of 2004. The impairment loss is included in Selling, General and Administrative in the accompanying Consolidated Statements of Operations. The Company will continue to monitor the carrying value of the remaining goodwill and other intangible assets through the annual impairment tests.

#### 8. Convertible Debentures

In March 2002, the Company issued \$4.0 million of 8% convertible debentures to an institutional investor, and Defiante Farmaceutica Unipessoal LDA ("Defiante"), a wholly-owned subsidiary of Sigma-Tau, a significant shareholder and affiliate of the Company. The Company will pay interest on the debentures at a rate of 8% per annum on a quarterly basis. The debentures are convertible into 2,531,644 shares of the Company's common stock at a fixed conversion price of \$1.58 per share (subject to adjustment for stock splits and reclassifications). In March 2005, we entered into amendments to the debentures whereby the maturity date of the debentures was extended from March 15, 2005 to April 15, 2005.

The Company may redeem the debentures for cash prior to maturity after March 15, 2003, provided the average of the closing sale price of the Company's common stock for the twenty (20) consecutive trading days prior to the delivery of the optional prepayment notice to the holders of the debentures is equal to or greater than \$3.16 per share, and the Company has satisfied certain equity conditions. At the end of the term of the debentures, under certain circumstances, the Company may redeem any outstanding debentures for stock. The

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Company may redeem the institutional investor's debentures for stock at maturity, provided the total aggregate number of shares of the Company's common stock issued to them (including shares issuable upon conversion of their debenture and shares issuable upon exercise of their warrant) does not exceed 7,645,219 shares (representing 19.999% of the total number of issued and outstanding shares of the Company's common stock as of March 15, 2002). The Company may redeem Defiante's debenture for stock at maturity, provided the market price of the Company's common stock at the time of redemption is greater than \$1.50 per share (representing the five day average closing sale price of the Company's common stock immediately prior to March 15, 2002).

The Company issued warrants to the institutional investor, Defiante and the placement agent to acquire an aggregate of 1,618,987 shares of common stock at an exercise price of \$1.70 per share. The warrants expire on March 15, 2006. The warrants issued to the institutional investor and Defiante were assigned a value of \$843,000. The warrants issued to the placement agent were assigned a value of \$82,000. The warrants were valued using the Black-Scholes method with the following assumptions: a risk-free interest rate of 5%; an expiration date of March 15, 2006; volatility of 0.72; and a dividend yield of 0%. In connection with the issuance of the debentures and warrants, the Company recorded \$641,000 related to the beneficial conversion feature on the convertible debentures. The total amount of the deemed discount on the convertible debentures as a result of the warrant issuance and the beneficial conversion feature amounted to \$1,484,000. The beneficial conversion feature and warrant value is amortized over the term of the debentures. The unamortized balance is \$103,000 and \$598,000 at December 31, 2004 and December 31, 2003, respectively.

In January 2004 the Company entered into an agreement with Defiante to purchase 759,493 shares of common stock for aggregate consideration of \$489,000 in cash and the surrender of the 759,493 warrants with a fair value of \$53,000 to purchase common stock (see Note 11).

### 9. Long-Term Debt

Long-term debt consists of the following (in thousands):

December 31, 		- /		
\$	3,897	\$	3,402	
	2,200		_	
	81		82	
	47		58	
	6,225		3,542	
	(4,239)		(140)	
\$	1,986	\$	3,402	
		\$ 3,897 2,200 81 47 6,225 (4,239)	\$ 3,897 \$ 2,200 81 47 6,225 (4,239)	2004     2003       \$ 3,897     \$ 3,402       2,200     —       81     82       47     58       6,225     3,542       (4,239)     (140)

The amounts due for notes payable for product liability and property and liability insurance in 2005 are \$128,000. The convertible debentures are due in March 2005. In March 2005, we entered into amendments to the convertible debentures whereby the maturity date of the debentures was extended from March 15, 2005 to April 15, 2005.

On July 31, 2004, the Company issued a \$2,200,000 secured promissory note to Defiante, a wholly-owned subsidiary of Sigma-Tau and an affiliate of the Company. The interest rate on the note is 9.83% per annum. Repayment of the note consists of interest only for the first twelve months, with monthly principal and interest payments thereafter through August 2008. The note is secured by the Nascobal intellectual property including the NDA for the spray formulation, which was approved in February 2005.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The fair value of notes payable is estimated based on current interest rates available to the Company for debt instruments of similar terms, degrees of risk and remaining maturities. The carrying value of these obligations approximates their respective fair values as of December 31, 2004 and 2003. Interest expense was \$420,000, \$333,000, and \$315,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

### 10. Indemnifications, Commitments and Contingencies

#### **Indemnifications**

The Company, as permitted under California law and in accordance with its Bylaws, indemnifies its officers and directors for certain events or occurrences while the officer or director is or was serving at the Company's request in such capacity. The potential future indemnification limit is to the fullest extent permissible under California law; however, the Company has a director and officer insurance policy that limits its exposure and may enable it to recover a portion of any future amounts paid. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has no liabilities recorded for these agreements as of December 31, 2004.

#### Leases

The Company leases its office and distribution facilities under operating lease agreements, the terms of which range from 5 years to 15 years. The Company has also entered into automobile and office equipment leases, the terms of which range from three to five years. The Company also entered into a capital lease for certain office equipment in August 2004. Minimum future obligations under the operating leases as of December 31, 2004 are as follows (in thousands):

Year Ending December 31,	Facility Operating Leases		Sublease Income		Automobile and Office Equipment Leases		Operating Leases Total		ll Leases otal
2005	\$	1,468	\$ (1,268)	\$	186	\$	386	\$	12
2006		1,296	(664)		106		738		12
2007		1,324	_		41		1,365		12
2008		1,375	_		6		1,381		12
2009		1,429	_		_		1,429		8
Thereafter		3,392					3,392		<u> </u>
	\$	10,284	\$ (1,932)	\$	339	\$	8,691	\$	56
Less: amounts representing interest								\$	(14)
Present value of minimum lease payments									42
Current portion of capital lease obligations									7
Long-term capital lease obligations								\$	35

In August 2004, the Company entered into a capital lease for certain office equipment. The net book value of the equipment acquired totaled \$41,000 (net of accumulated amortization of \$3,000) at December 31, 2004.

In July 2000, the Company entered into an agreement to sublease 15,000 square feet of laboratory and office space including subleasing its laboratory equipment for its Hayward, California facility. Due to the termination of the Company's drug discovery programs, the space and equipment were no longer needed. The

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

current sublessee of the Hayward facility subleased and fully occupied the 30,000 square feet facility after the Company's relocation occurred in May 2001. The sublease expires in July 2006.

In October 2000, the Company entered into an agreement to lease a new facility in Union City, California. The initial lease term is for 120 months, with an option for an additional five years. As a condition of this agreement, the Company provided an irrevocable Letter of Credit in the amount of \$659,000, with the face value of the Letter of Credit, subject to certain conditions, declining thereafter. The Company entered into this new lease agreement in order to take advantage of lower rent costs as laboratory space was no longer necessary. The certificate of deposit securing this letter of credit is included in Deposits and Other Assets on the Consolidated Balance Sheets.

In May 2001, we closed our Neoflo manufacturing facility located in Lee's Summit, Missouri. During 2003, we subleased the space. The lease period and the sublease expired on December 31, 2004.

During 2003, the Carlsbad, California facility was vacated and the warehousing and distribution for all products, except VSL#3, were transferred to third party contractors. During 2003, the Company subleased the entire facility under two separate subleases expiring in January 2005 and January 2006. In accordance with SFAS No. 146, the Company recorded a liability of \$171,000 for the net present value of the remaining lease payment net of sublease revenue and the related expense was recorded to Research and Development. The sublease expiring in January 2005 includes a renewal option to extend the term for four three-month periods. To date, one option period has been exercised and will expire April 30, 2005.

Rent expense for facility, equipment and automobile leases totaled \$1,543,000, \$1,885,000 and \$1,771,000 for the years ended December 31, 2004, 2003 and 2002, respectively. Rent expense comprises the cost associated with three buildings leased by the Company including its current headquarters located in Union City, California, its former headquarters in Hayward, California, and its former distribution facility in Carlsbad, California and automobile and office equipment leases. Net rental income totaled \$277,000, \$260,000 and \$282,000 for the years ended December 31, 2004, 2003 and 2002, respectively. The Company has entered into various automobile leases for its sales representatives.

### Contingencies

From time to time, the Company may become involved in claims and other legal matters arising in the ordinary course of business. Management is not currently aware of any matters that will have a material adverse affect on the financial position, results of operations or cash flows of the Company.

#### **Commitments**

We have signed an agreement with BioVectra dcl to produce the active pharmaceutical ingredient ("API") used in Acthar. The agreement requires minimum production totaling \$1.7 million during the term. Under this agreement, the Company paid \$468,000 and \$115,000 during the years ended December 31, 2004 and 2003, respectively. The agreement terminates in December 2007 and includes two one-year extension options. The production of the first batch of API commenced in 2004.

# 11. Preferred Stock and Shareholders' Equity

### Preferred Stock

Pursuant to its Amended and Restated Articles of Incorporation, the Company is authorized to issue up to 7,500,000 shares of Preferred Stock in one or more series and has issued 2,155,715 shares of its Series A Preferred Stock and 10,000 shares of its Series B Preferred Stock as of December 31, 2004. The holders of outstanding shares of Series A Preferred Stock are entitled to receive dividends concurrently with the common stock, if any, as may be declared from time to time by the Board of Directors out of assets legally available

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

therefrom. The holders of Series A Preferred Stock are entitled to the number of votes equal to the number of shares of common stock into which each share of Series A Preferred Stock could be converted on the record date. Each share of Series A Preferred Stock is convertible, at the option of the holder of such share, into one share of common stock, subject to adjustments for stock splits, stock dividends or combinations of outstanding shares of common stock. The Articles of Incorporation authorize the issuance of Preferred Stock in classes, and the Board of Directors may designate and determine the voting rights, redemption rights, conversion rights and other rights relating to such class of Preferred Stock, and to issue such stock in either public or private transactions.

The Series A Preferred Stock has a liquidation preference equal to \$4.64 per share plus all declared and unpaid dividends which is payable upon the occurrence of a liquidation, consolidation, merger or the sale of substantially all of the Company's stock or assets. The Company excluded the Series A Preferred Stock from total shareholders' equity due to the nature of the liquidation preference of the preferred stock.

In January 2003, the Company completed a private placement of Series B Convertible Preferred Stock and warrants to purchase common stock to various investors. Gross proceeds to the Company from the private placement were \$10 million. Net of issuance costs, the proceeds to the Company were \$9.4 million.

The Series B Preferred Stock had an aggregate stated value at the time of issuance of \$10 million and each holder is entitled to a quarterly dividend at an initial rate of 8% per year, which rate will increase to 10% per year on and after January 1, 2006, and to 12% on and after January 1, 2008. The dividends are paid in cash on a quarterly basis. In addition, on the occurrence of designated events, including the failure to maintain Net Cash, Cash Equivalent and Eligible Investment Balances, as defined in the Company's Certificate of Determination of Series B Preferred Stock (the "Certificate of Determination"), of at least 50% of the aggregate stated value of the outstanding shares of Series B Preferred Stock, the dividend rate will increase by an additional 6% per year. The Series B Preferred Stock is entitled to a liquidation preference over the Company's common stock and Series A Preferred Stock upon a liquidation, dissolution or winding up of the Company. The Series B Preferred Stock is convertible at the option of the holder into the Company's common stock at a conversion price of \$0.9412 per share, subject to certain anti-dilution adjustments. To date, Series B Preferred Stock having a stated value of \$1.6 million and accrued and unpaid dividends of \$17,000 has been converted into 1,724,912 shares of common stock. The Company has the right commencing on January 1, 2006 (assuming specified conditions are met) to redeem the Series B Preferred Stock at a price of 110% of stated value, together with all accrued and unpaid dividends and accrued interest. In addition, upon the occurrence of designated Optional Redemption Events (as defined below), the holders have the right to require the Company to redeem the Series B Preferred Stock at 100% of stated value, together with all accrued and unpaid dividends and interest. The Optional Redemption Events include any of the following:

- If the Company consolidates or merges with or into another entity where the shareholders of the Company do not own at least 51% of the surviving entity and such consolidation or merger is approved by the Company's Board of Directors;
- If the Company adopts any amendment to its Amended and Restated Articles of Incorporation which materially and adversely affects the rights of the holders of Series B Preferred Stock in respect of their interests in shares of Common Stock that can be acquired upon conversion of shares of Series B Preferred Stock in a manner different and more adverse than it affects the rights of holders of Common Stock generally;
- If the Company fails to declare or pay dividends in full on the applicable dividend date, other than in circumstances where such declaration or payment would not be permitted by Section 500 or 501 of the California Corporations Code, or fails to pay certain redemption prices on any share of Series B Preferred Stock when due;

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

- If the Company fails to issue shares of Common Stock to any Series B holder upon conversion or upon exercise of warrants when due:
- If the Company commits certain breaches under, or otherwise violates certain terms of, the transaction documents entered into in connection with the issuance of the Series B Preferred Stock;
- If the Company's representations and warranties made in the transaction documents entered into in connection with the issuance of the Series B Preferred Stock are false or misleading in any material way when made or deemed made; and
- If the Company institutes a voluntary bankruptcy or similar proceeding.

The redemption events described above are all within the control of the Company. Therefore, in accordance with EITF Topic D-98, the Company has classified the Series B Preferred Stock in permanent equity. In addition, the Company initially recorded the Series B Preferred Stock at its fair value on the date of issuance. The Company has elected not to adjust the carrying value of the Series B Preferred Stock to the redemption value of such shares, since it is uncertain whether or when the redemption events described above will occur. Subsequent adjustments to increase the carrying value to the redemption value will be made when it becomes probable that such redemption will occur. As of December 31, 2004, the redemption value of the Series B Preferred Stock was \$8.4 million.

The terms of the Series B Preferred Stock contain a variety of affirmative and restrictive covenants, including limitations on indebtedness and liens. Each share of Series B Preferred Stock is generally entitled to a number of votes equal to 0.875 times the number of shares of Common Stock issuable upon conversion of such share of Series B Preferred Stock. In addition, the Company agreed that two of the investors are each entitled to appoint a representative to attend Company Board of Directors meetings in a nonvoting observer capacity.

The purchasers of the Series B Preferred Stock also received for no additional consideration warrants exercisable for an aggregate of 3,399,911 shares of Common Stock at an exercise price of \$1.0824 per share, subject to certain anti-dilution adjustments. The warrants expire in January 2007. The warrants issued to the Series B holders were assigned a value of \$1,527,000 which decreased the carrying value of the preferred stock. The warrants were valued using the Black-Scholes method with the following assumptions: a risk free interest rate of 3%; an expiration date of January 15, 2007; volatility of 82% and a dividend yield of 0%. In connection with the issuance of the Series B Preferred Stock and warrants, the Company recorded \$1,301,000 related to the beneficial conversion feature on the Series B Preferred Stock as a deemed dividend, which increased the carrying value of the preferred stock. A beneficial conversion feature is present 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. For the year ended December 31, 2003, the deemed dividend increased the loss applicable to common shareholders in the calculation of basic and diluted net loss per common share.

In June 2003, the Company entered into agreements with the holders of record of its Series B Preferred Stock, whereby the holders of Series B Preferred Stock waived certain covenants and rights to receive additional dividends as provided in the Certificate of Determination, which may have been triggered as a result of the Nascobal acquisition and the use of the Company's cash resources to pay the purchase price (the "Acquisition"). Specifically, the holders of Series B Preferred Stock waived their right to receive an additional aggregate six percent dividend in the event that the Acquisition resulted in the Company being unable to satisfy the test set forth in Sections 500 and 501 of the California Corporations Code to allow for the Company to redeem all of the issued and outstanding shares of Series B Preferred Stock. Such waiver was granted through the earlier of (i) December 31, 2003 and (ii) the date on which (A) the Company's assets (exclusive of goodwill, capitalized research, and development expenses and deferred charges) equal less than 125% of its liabilities (not including deferred taxes, deferred income and other deferred credits) or (B) the Company's current assets equal less than 80% of its current liabilities. Additionally, the holders of Series B Preferred

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Stock waived their right to receive an additional aggregate six percent dividend in the event that the Acquisition resulted in the Company being unable to maintain Net Cash, Cash Equivalents and Eligible Investment Balances (as defined in the Certificate of Determination) in an amount equal to \$5 million. Such waiver was granted through the earlier of (i) December 31, 2003 and (ii) the date on which the Company fails to maintain Net Cash, Cash Equivalents and Eligible Investment Balances in an amount equal to at least \$2.5 million. The holders of Series B Preferred Stock also agreed that: (i) the Acquisition would not constitute a breach of the covenant in the Certificate of Determination requiring the Company to use its best efforts to maintain compliance with Sections 500 and 501 of the California Corporations Code to be able to pay dividends on and to redeem all of the issued and outstanding shares of Series B Preferred Stock; and (ii) the incurrence by the Company of contingent obligations to pay additional amounts to Nastech of \$5,183,333 and the granting of a security interest in the acquired Nascobal product would not constitute a breach of the covenants in the Certificate of Determination restricting the Company's ability to incur indebtedness and create liens. In consideration of such agreements, the Company agreed to adjust the exercise price of warrants to purchase 3,399,911 shares of Common Stock previously issued by the Company to the holders of Series B Preferred Stock from \$1.0824 per share to \$0.9412 per share. In December 2003 the Company entered into a new waiver agreement with the holders of the Series B Preferred Stock to waive the Net Cash, Cash Equivalents and Eligible Investment Balances among other requirements until January 31, 2004, at which time the Company was in compliance.

As a result of the decrease to the exercise price of the warrants in June 2003, the Company revalued the warrants issued to the Series B Preferred Shareholders, resulting in an incremental value of \$93,000 which decreased the carrying value of the preferred stock. The warrants were valued using the Black-Scholes method with the following assumptions: a risk free interest rate of 1.4%; an expiration date of January 15, 2007; volatility of 70% and a dividend yield of 0%. In connection with the revaluation, the Company recorded \$93,000 related to the beneficial conversion feature on the Series B Preferred Stock as an additional deemed dividend, which increased the carrying value of the Series B Preferred Stock. For the year ended December 31, 2003, the deemed dividend increased the net loss applicable to common shareholders.

### Common Stock

In May 2003, the number of authorized shares of the Company's no par value common stock was increased from 75,000,000 to 105,000,000.

The holders of outstanding shares of the Company's common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by the Board of Directors out of assets legally available therefore, subject to the payment of preferential dividends with respect to any Preferred Stock that may be outstanding. In the event of a liquidation, dissolution and winding-up of the Company, the holders of outstanding common stock are entitled to share ratably in all assets available for distribution to the common stock shareholders after payment of all liabilities of the Company, subject to rights of the Preferred Stock. The holders of the common stock are entitled to one vote per share.

In January 2004, the Company entered into agreements with some of its existing investors and issued 4,878,201 shares of common stock in exchange for \$2,399,050 in cash and the surrender of outstanding warrants to purchase 3,878,201 shares of common stock. The Company's offer to issue common stock for cash and the surrender of warrants was made to all warrant holders. The warrants retired represented approximately 46% of the Company's warrants outstanding as of December 31, 2003. The warrants surrendered were included as consideration at their aggregate fair value of \$743,000 which was determined using a Black-Scholes valuation method. The purchase price of the common stock, which was payable in cash and surrender of outstanding warrants, was \$0.644 per share, which was the volume weighted average price of the Company's common stock in December 2003 for the five trading days prior to the agreement to the terms of the

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

transaction. Sigma-Tau, a related party, participated in the transaction, purchasing 759,493 shares of common stock for aggregate consideration of \$489,000 in cash and the surrender of 759,493 warrants with a fair value of \$53,000 to purchase common stock.

In June 2003, the Company completed a private placement of its common stock and warrants to purchase common stock. The Company issued 4,979,360 shares of common stock in the private placement at \$1.01 per share, which was the volume weighted average price of the common stock for the five days prior to and including the close of the private placement. Net proceeds to the Company from the private placement were approximately \$4.8 million. The purchasers of common stock also received for no additional consideration warrants exercisable for an aggregate of 2,987,616 shares of common stock for the five days prior to and including the close of the private placement. The warrants expire in June 2008.

In December 2001, the Company entered into a Promotion Agreement (effective January 2002) with VSL, a private company owned in part by the principal shareholders of Sigma-Tau, to promote, sell and distribute the product VSL#3 in the U.S. Effective January 1, 2004, the Promotion Agreement and all amendments were assigned by VSL to Sigma-Tau Pharmaceuticals. The Promotion Agreement expired in January 2005, in accordance with its terms. In connection with this Promotion Agreement, the Company entered into two Stock and Warrant Purchase Agreements, one with Paolo Cavazza and one with Claudio Cavazza, to purchase (i) an aggregate of 640,000 shares of common stock for a purchase price of \$1.50 per share (representing a twenty percent premium to its market price for the five days prior to execution of the Purchase Agreements), for an aggregate purchase price of \$960,000, and (ii) warrants, at an aggregate purchase price of \$300,000, to purchase an additional 1,800,000 shares of common stock at a purchase price of \$1.75 per share which expired on December 1, 2003. The Company issued the common stock related to this transaction in February 2002.

In April 2001, the Company closed a financing which totaled \$442,000. This investment came from a group of individual investors. The Company issued an aggregate of 816,800 shares of common stock and sold warrants to purchase an additional 408,400 shares of common stock with an exercise price of these warrants of \$0.64 per share. The warrants are exercisable from the date of issuance until the close of business on April 30, 2006.

### **Placement Agent Unit Options**

As part of the acquisition of RiboGene, the Company assumed placement agent options from a 1997 offering of preferred stock by RiboGene. At December 31, 2004, options to purchase 127,676 shares of common stock were outstanding at an aggregate exercise price of approximately \$82,000. These options expire in December 2007.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### Warrants

The Company has 4,539,407 warrants outstanding at December 31, 2004 at a weighted average exercise price per share of common stock of \$1.12 and a weighted average remaining contractual life of 2 years. Exercise prices for the warrants outstanding as of December 31, 2004 are as follows:

	Number		Expiration
Exercise Price	Outstanding	Date Issued	Date
\$ 0.64	176,050	4/30/2001	4/30/2006
\$ 0.94	3,025,921	1/15/2003	1/15/2007
\$ 1.26	475,248	6/11/2003	6/11/2008
\$ 1.70	859,494	3/15/2002	3/15/2006
\$31.51	2,694	3/12/1997	3/12/2007
	4,539,407		

In January 2004, the Company entered into agreements with some of its existing investors and issued 4,878,201 shares of common stock in exchange for \$2,399,050 in cash and the surrender of outstanding warrants to purchase 3,878,201 shares of common stock. The Company's offer to issue common stock for cash and the surrender of warrants was made to all warrant holders. The warrants retired represented approximately 46% of the Company's warrants outstanding as of December 31, 2003. The warrants surrendered were included as consideration at their aggregate fair value of \$743,000 which was determined using a Black-Scholes valuation method.

In March 2003, a warrant was exercised through a cashless exercise in accordance with the terms of the warrant, and 315,827 shares of common stock were issued.

In June 2003, a warrant was exercised through a cashless exercise in accordance with the terms of the warrant, and 72,168 shares of common stock were issued.

### **Stock Option Plans**

For the years ended December 31, 2004, 2003 and 2002, the Company recorded amortization of deferred stock compensation of \$7,000, \$20,000 and \$17,000, respectively. As of December 31, 2004 the Company had \$10,000 of remaining unamortized deferred compensation. This amount is included as a deduction of shareholders' equity and is being amortized over the vesting period of the underlying options.

Pro forma information regarding net loss applicable to common shareholders and net loss applicable to common shareholders per share as required by SFAS No. 123 and amended by SFAS No. 148, as disclosed in Note 1, has been determined as if the Company accounted for its employee stock options under the fair value method set forth in SFAS No. 123. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a single

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

reliable measure of the fair value of its employee stock options. For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting periods.

		Years Ended December 31,		
	2004	2003	2002	
Expected stock price volatility	52%	67%	82%	
Risk-free interest rate	3%	3%	5%	
Expected life (in years)	3.8	3.9	4.0	
Expected dividend yield	_	_	_	

In September 2000, the Company adopted the Employee Stock Purchase Plan ("ESPP") and as of December 31, 2002 all shares of common stock had been issued under the original ESPP. In May 2003, the Company's 2003 Employee Stock Purchase Plan (the "2003 ESPP") was approved by the shareholders and 900,000 shares of common stock have been reserved for issuance under the plan. The ESPP provides for payroll deductions for eligible employees to purchase common stock at the lesser of (i) 85% of the fair market value of the common stock on the offering date and (ii) 85% of the fair market value of the common stock on the purchase date. During the year ended December 31, 2002, 313,114 shares were purchased under the ESPP at an average purchase price of \$0.52 per share. During the year ended December 31, 2003, 93,123 shares were purchased under the 2003 ESPP at an average purchase price of \$0.73 per share. During the year ended December 31, 2004, 182,267 shares were purchased under the 2003 ESPP at an average purchase price of \$0.49 per share. As of December 31, 2004, there were 624,610 shares reserved for issuance under the 2003 ESPP.

The aggregate number of shares of common stock authorized for issuance under the 1992 Employee Stock Option Plan (the "1992 Plan") is 13,500,000 shares. The 1992 Plan provides for the grant of incentive and nonstatutory stock options with various vesting periods, generally four years, to employees, directors and consultants. The exercise price of incentive stock options must equal at least the fair market value on the date of grant, and the exercise price of nonstatutory stock options may be no less than 85% of the fair market value on the date of grant. The maximum term of options granted under the 1992 Plan is ten years.

The 1993 Non Employee Directors' Stock Option Plan (the "Directors' Plan") expired in 2003. The maximum term of options granted under the 1993 Directors' Plan is ten years. As of December 31, 2004, 303,000 shares were outstanding under the Directors' Plan.

Prior to the approval of the 2004 Non-Employee Directors' Equity Incentive Plan in May 2004, the Company compensated its non-employee directors for their service on the Board of Directors with a grant of an initial option to purchase 25,000 shares of common stock. Such option grant had an exercise price equal to 85% of the fair market value of the common stock on the date of grant and vests in 48 equal monthly installments commencing on the date of grant, provided that the non-employee director serves continuously on the Board of Directors during such time. In addition, each outside director was granted an option to purchase 10,000 shares of common stock under the 1992 Plan for continuing service as a director. Such option grants had an exercise price equal to 85% of the fair market value of the common stock on the date of grant and vest in 48 equal monthly installments commencing on the date of grant, provided the non-employee director serves continuously on the Board of Directors during such time. For service on a committee of the Board of Directors, members of committees were granted an option to purchase 15,000 shares of common stock and chairmen of committees were granted an additional option to purchase 7,500 shares of common stock under the 1992 Plan. Such option grants had an exercise price equal to the fair market value of the common stock on the date of grant and became fully vested at the time of grant.

In May 2004, shareholders approved the 2004 Non-Employee Directors' Equity Incentive Plan (the "2004 Plan"). Under the terms of the 2004 Plan, 1,250,000 shares of the Company's common stock were

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

authorized for grants of non-qualified stock options to non-employee directors of the Company. The 2004 Plan provides for the granting of 25,000 options to purchase common stock upon appointment as a non-employee director and an additional 15,000 options each January thereafter for continuing service upon reappointment. Such option grants vest over four years. As originally approved by shareholders, such option grants had an option exercise price equal to 85% of the fair market value on the date of grant. However, in May 2004, the Company's Board of Directors approved an amendment to the 2004 Plan to provide that all option grants under the 2004 Plan be made at an exercise price equal to 100% of the fair market value of the Company's common stock on the date of grant. Additionally, the 2004 Plan provides for the annual granting of 10,000 options to members of one or more committees of the Board of Directors and an additional 7,500 options to chairmen of one or more committees. Such option grants will have an exercise price equal to 100% of the fair market value of the Company's common stock on the date of the grant and will become fully vested at the time of grant. The maximum term of the options granted under the 2004 Plan is ten years.

In 2004, the Company's Lead Director, Brian C. Cunningham, received \$18,750 as compensation for service as Lead Director for the period January through May 2004. In May 2004, Neal C. Bradsher was appointed Lead Director. In October 2004, Albert Hansen was appointed as Chairman of the Board of Directors, at which time Mr. Bradsher resigned as Lead Director. Each outside director, other than Mr. Cunningham, received \$2,500 for each Board of Directors' meeting attended during fiscal year 2004, with the Lead Director receiving \$3,500 per meeting. Through July 12, 2004, outside directors received \$1,000 for each committee meeting attended, with the Chairman of each committee receiving \$1,500 per meeting. Commencing July 13, 2004, outside directors received \$1,000 for each telephonic Board meeting, with the Lead Director receiving \$1,250 per meeting, and \$1,000 for each committee meeting attended, with the Chairman of each committee receiving \$1,250 per meeting.

In 2003, the Company's Lead Director received \$3,750 as compensation for services provided during fiscal year 2003. Each other outside director received \$2,500 for each Board of Directors' meeting attended during fiscal year 2003. Members of committees of the Board of Directors, including the Lead Director, received \$1,000 for each committee meeting attended, with committee chairmen receiving \$1,500 per meeting attended. Additionally, the Company's Lead Director was granted an option to purchase 30,000 shares of common stock upon appointment as Lead Director at an exercise price equal to the fair market value of the common stock on the date of the grant, 10,000 shares of which vested immediately, and the remainder of which vest in 48 equal monthly installments commencing on the date of the grant, provided that he serves continuously on the Board of Directors during such time.

For the calendar year 2002, each outside director received \$1,000 for each Board of Directors' meeting attended during fiscal year 2002. Additionally, for service as a director in 2002, each outside director was granted an additional option under the 1992 Plan to purchase 30,000 shares of Common Stock at an exercise price equal to the then fair market value of the Common Stock. Such option grant is now fully vested as to each director.

The Company also reimburses its directors who are not employees for their reasonable expenses incurred in attending meetings. Directors who are officers of the Company receive no additional compensation for Board service.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The following table summarizes stock option activity under the 1992 and 1993 Plans:

	Options Outstanding	ited Average rcise Price
Balance at December 31, 2002	8,942,262	\$ 1.41
Granted	2,170,555	\$ 0.83
Exercised	(273,962)	\$ 0.77
Canceled	(1,081,353)	\$ 1.67
Balance at December 31, 2003	9,757,502	\$ 1.27
Granted	1,388,240	\$ 0.66
Exercised	(20,076)	\$ 0.82
Canceled	(5,440,207)	\$ 1.36
Balance at December 31, 2004	5,685,459	\$ 1.03

At December 31, 2004, 2003 and 2002, options to purchase 3,684,302 shares, 5,308,931 shares, and 4,296,617 shares, respectively, of common stock were exercisable. There were 7,152,011 shares available for future grant under the 1992 Plan, 1,172,500 shares available for grant under the 2004 Plan, and none available for future grant under the 1993 Plan as of December 31, 2004. The weighted average fair values of options granted were \$0.28, \$0.44, and \$0.83 for the years ended December 31, 2004, 2003 and 2002, respectively.

During 2004, 2003 and 2002, there were 40,000, 20,000, and 40,000 options granted to consultants, respectively. These options are re-measured as they vest, using the Black-Scholes pricing model, and the resulting value is recognized as expense over the period of services received. For the years ended December 31, 2004, 2003 and 2002 the Company recorded \$21,000, \$95,000, and \$381,000, respectively, as compensation expense related to these options.

Exercise prices and weighted average remaining contractual life for the options outstanding as of December 31, 2004 are as follows:

	-	Options Outstanding		Options Exercisable									
Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price								Number Exercisable		ited Average rcise Price
\$0.41 - \$0.56	646,000	8.70	\$	0.47	157,080	\$	0.54						
\$0.60 - \$0.64	569,591	8.79	\$	0.60	165,742	\$	0.60						
\$0.67 - \$0.77	721,833	7.64	\$	0.74	466,102	\$	0.73						
\$0.78 - \$0.85	632,291	8.43	\$	0.83	294,784	\$	0.82						
\$0.88 - \$0.99	715,488	8.22	\$	0.95	435,211	\$	0.95						
\$1.00 - \$1.03	586,875	7.37	\$	1.01	461,875	\$	1.01						
\$1.06 - \$1.25	762,433	5.62	\$	1.18	749,515	\$	1.18						
\$1.27 - \$1.65	604,194	5.98	\$	1.49	526,930	\$	1.48						
\$1.69 - \$3.73	441,754	4.08	\$	2.45	422,063	\$	2.48						
\$4.94 - \$4.94	5,000	2.10	\$	4.94	5,000	\$	4.94						
	5,685,459	7.28	\$	1.03	3,684,302	\$	1.19						

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### Reserved Shares

The Company has reserved shares of common stock for future issuance as follows:

	December 31, 2004	
Outstanding options	5,685,459	
Convertible preferred stock issued and outstanding	11,080,492	
Convertible debentures	2,531,644	
Placement agent unit options	127,679	
Common stock warrants	4,539,407	
Reserved for future grant or sale under option and stock purchase plans	8,956,888	
	32,921,569	

#### 12. Income Taxes

As of December 31, 2004, the Company had federal and state net operating loss carryforwards of approximately \$99 million and \$30 million, respectively. The Company also had federal and state research and development tax credits of approximately \$2 million and \$1 million, respectively. The federal and state net operating loss carryforwards and the federal credit carryforwards expire at various dates beginning in the years 2005 through 2024, if not utilized.

Utilization of the Company's net operating loss and credit carryforwards may be subject to substantial annual limitations due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such an annual limitation could result in the expiration of the net operating loss and credit carryforwards before utilization.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets for financial reporting and the amount used for income tax purposes. Significant components of the Company's deferred tax assets for federal and state income taxes are as follows (in thousands):

	December 31, 2004		Dec	ember 31, 2003
Deferred tax liabilities:				
Goodwill and purchased intangibles	\$	100	\$	200
Deferred tax assets:				
Net operating loss carryforwards	\$	35,300	\$	35,000
Research and development credits		1,400		1,400
Capitalized research and development expenses		300		700
Acquired research and development		1,200		1,800
Other, net		1,500		1,000
Total deferred tax assets		39,700		39,900
Valuation allowance		(39,600)		(39,700)
Net deferred taxes	\$	<u> </u>	\$	<u> </u>

Due to the Company's lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance decreased by \$100,000 in 2004, increased by \$2,500,000 in 2003 and decreased by \$300,000 in 2002.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### 13. Other Related Party Transactions

In December 2001, the Company entered into a promotion agreement with VSL, a private company owned in part by the major shareholders of Sigma-Tau. Sigma-Tau beneficially owned approximately 28% of the Company's outstanding common stock as of December 31, 2004. In June 2002, the Company signed an amendment to the promotion agreement. In January 2004, the promotion agreement and all amendments were assigned by VSL to Sigma-Tau Pharmaceuticals. Under these agreements, the Company agreed to purchase VSL#3 from VSL at a stated price, and also agreed to promote, sell, warehouse and distribute the VSL#3 product, direct to customers at its cost and expense, subject to certain expense reimbursements. In January 2005, the promotion agreement expired, in accordance with its terms. Revenues from sales of VSL#3 are recognized when product is shipped to the customer. The Company does not accept returns of VSL#3. VSL#3 revenue for the years ended December 31, 2004, 2003 and 2002 was \$1,466,000, \$992,000 and \$523,000, respectively, and is included in Net Product Sales. Included in Accounts Payable are \$155,000 and \$188,000 for amounts owed to Sigma-Tau Pharmaceuticals (formerly VSL Pharmaceuticals) at December 31, 2004 and 2003, respectively. An access fee to Sigma-Tau Pharmaceuticals is calculated quarterly, which varies based upon sales and costs incurred by the Company subject to reimbursement under certain circumstances. For the years ended December 31, 2004 and 2003 the amount of the access fee was \$355,000 and \$59,000, respectively, and is included in Selling, General and Administrative expense in the accompanying Consolidated Statements of Operations. For the year ended December 31, 2002 the amount of costs incurred by the Company was greater than the amount owing to Sigma-Tau Pharmaceuticals. This net reimbursement to the Company for 2002 was \$107,000 and is included as a deduction in Selling, General and Administrative expense in the Consolidated Statements of Operations, as Sigma-Tau Pharmaceuticals reimbursed the Company for these costs. During the years ended December 31, 2004, 2003 and 2002, the Company paid \$873,000, \$466,000 and \$72,000, respectively, to Sigma-Tau Pharmaceuticals for the purchase of VSL#3 product and access fees.

On July 31, 2004, the Company issued a \$2,200,000 secured promissory note to Defiante, a subsidiary of Sigma-Tau. The interest rate on the note is 9.83% per annum. Repayment of the note consists of interest only for the first twelve months, with monthly principal and interest payments thereafter through August 2008.

Upon the hiring of Reinhard Koenig, MD, PhD, as Vice President, Medical Affairs in February 2004, the Company issued to Dr. Koenig a Promissory Note for \$50,000 at an interest rate of prime plus 1% per annum. Under the terms of the note, the principal and interest is to be forgiven on February 8, 2005 provided that Dr. Koenig continued as a full-time employee through that date. In May 2004, Dr. Koenig was appointed an officer of the Company. Dr. Koenig continued as a full-time employee through the specified date, and the principal and interest were forgiven in February 2005 in accordance with the terms of the note. For accounting purposes, the loan was amortized over the one year service period. As of December 31, 2004, the unamortized portion of the loan is \$4,000 and is included in Prepaid Expenses and Other Current Assets in the Consolidated Balance Sheet.

In January 2002, the Company entered into a royalty agreement with Glenridge Pharmaceuticals LLC ("Glenridge"). Kenneth R. Greathouse, the Company's former Vice President of Commercial Operations, is a part owner of Glenridge. This agreement calls for the payment of royalties on a quarterly basis on the net sales of Acthar. The Company paid Glenridge \$234,000, \$297,000 and \$443,000 in the years ended December 31, 2004, 2003 and 2002, respectively, related to royalties on Acthar® sales. The Company accrued \$105,000, \$69,000 and \$95,000 for royalties earned but unpaid as of December 31, 2004, 2003 and 2002, respectively, which are included in Other Accrued Liabilities on the accompanying Consolidated Balance Sheets. Mr. Greathouse' employment with the Company was terminated in March 2004.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### 14. Defined Contribution Plan

The Company sponsors a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code covering substantially all full-time U.S. employees. Participating employees may contribute up to 60% of their eligible compensation up to the annual Internal Revenue Service contribution limit. The Plan was adopted in 2000. For the year ended December 31, 2004, the Company did not match employee contributions. The Company matched employee contributions according to specified formulas and contributed \$68,000 and \$98,000 for the years ended December 31, 2003 and 2002, respectively. For the year ended December 31, 2003, the Company ceased to match employee contributions halfway through the year.

#### 15. Comprehensive Loss

Comprehensive loss is comprised of net loss and the change in unrealized holding gains and losses on available-for-sale securities.

		Years Ended December 31,				
	2	2004 2003				2002
Net loss	\$	(832)	\$	(3,791)	\$	(2,785)
Change in unrealized gains(losses) on available-for-sale securities				42		73
Comprehensive loss	\$	(832)	\$	(3,749)	\$	(2,712)

#### 16. Shareholders Rights Plan

On February 11, 2003 the Board of Directors of the Company adopted a Shareholder Rights Plan. In connection with the Rights Plan, the Board of Directors declared a dividend of one preferred share purchase right (the "Rights") for each outstanding share of common stock, no par value per share (the "Common Shares"), of the Company outstanding at the close of business on February 21, 2003 (the "Record Date"). Each Right will entitle the registered holder thereof, after the Rights become exercisable and until February 10, 2013 (or the earlier redemption, exchange or termination of the Rights), to purchase from the Company one one-hundredth (1/100th) of a share of Series C Junior Participating Preferred Stock, no par value per share (the "Preferred Shares"), at a price of \$10 per one one-hundredth (1/100th) of a Preferred Share, subject to certain anti-dilution adjustments (the "Purchase Price"). Until the earlier to occur of (i) ten (10) days following a public announcement that a person or group of affiliated or associated persons has acquired, or obtained the right to acquire, beneficial ownership of 15% or more of the Common Shares (an "Acquiring Person") or (ii) ten (10) business days (or such later date as may be determined by action of the Board of Directors prior to such time as any person or group of affiliated persons becomes an Acquiring Person) following the commencement or announcement of an intention to make a tender offer or exchange offer the consummation of which would result in the beneficial ownership by a person or group of 15% or more of the Common Shares (the earlier of (i) and (ii) being called the "Distribution Date"), the Rights will be evidenced, with respect to any of the Common Share certificates outstanding as of the Record Date, by such Common Share certificate. An Acquiring Person does not include any Existing Holder (defined as Sigma-Tau Finanziaria SpA, together with all of its Affiliates and Associates, including, without limitation, Defiante Farmaceutica Lda, Sigma-Tau International S.A., Paolo Cavazza and Claudio Cavazza,), unless and until such time as such Existing Holder shall become the beneficial owner of one or more additional Common Shares of the Company (other than pursuant to a dividend or distribution paid or made by the Company on the outstanding Common Shares in Common Shares or pursuant to a split or subdivision of the outstanding Common Shares), unless, upon becoming the beneficial owner of such additional Common Shares, such Existing Holder is not then the beneficial owner of 15% or more of the Common Shares then outstanding.

In the event that a Person becomes an Acquiring Person or if the Company were the surviving corporation in a merger with an Acquiring Person or any affiliate or associate of an Acquiring Person and the

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Common Shares were not changed or exchanged, each holder of a Right, other than Rights that are or were acquired or beneficially owned by the Acquiring persons (which Rights will thereafter be void), will thereafter have the right to receive upon exercise that number of Common Shares having a market value of two times the then current Purchase Price of one Right. In the event that, after a person has become an Acquiring Person, the Company were acquired in a merger or other business combination transaction or more than 50% of its assets or earning power were sold, proper provision shall be made so that each holder of a Right shall thereafter have the right to receive, upon the exercise thereof at the then current Purchase Price of the Right, that number of shares of common stock of the acquiring company which at the time of such transaction would have a market value of two times the then current purchase price of one Right.

### 17. Subsequent Events

On March 8, 2005, the Company and Defiante entered into an amendment to the Convertible Debenture dated March 15, 2002 issued by the Company in favor of Defiante, extending the maturity date to April 15, 2005.

On March 10, 2005, the Company and SF Capital Partners Ltd. ("SFCP") entered into an amendment to the Convertible Debenture dated March 15, 2002 issued by the Company in favor of SFCP, extending the maturity date to April 15, 2005 and amending certain of the terms of the Company's option to repay the SFCP Debenture in shares of common stock at the maturity date.

On March 29, 2005, the Company and all of the holders of the outstanding shares of Series B Preferred Stock of the Company entered into a Series B Preferred Shareholder Agreement and Waiver. The agreement provides that (i) the holders shall waive certain rights to receive additional dividends through March 31, 2006, (ii) the holders will, with respect to dividends payable on April 1, 2005, July 1, 2005, October 1, 2005 and January 1, 2006, accept as full and complete payment of all such dividend payments the issuance by the Company to them in a private placement of shares of the Company's common stock having an aggregate value equal to the dividends otherwise payable on those dates, with the shares of common stock so issued valued at fair market value based upon a ten-day weighted average trading price formula through March 29, 2005, and (iii) the expiration date of the warrants to purchase shares of the Company's common stock held by the holders shall be extended for one year, until January 15, 2008.

# FINANCIAL STATEMENT SCHEDULES (ITEM 15(a)(2))

# SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS Years Ended December 31, 2004, 2003 and 2002

	Beg	ance at ginning eriod	Additions/ (Deductions) Charged to <u>Income</u>		Deductions and <u>Write-Offs</u>		and		Balance at End of Period	
Reserves for uncollectible accounts				(22-21-						
December 31, 2004	\$	60	\$	(16)	\$	4	\$	40		
December 31, 2003	\$	20	\$	43	\$	3	\$	60		
December 31, 2002	\$	78	\$	(40)	\$	18	\$	20		
Reserves for cash discounts										
December 31, 2004	\$	33	\$	371	\$	362	\$	42		
December 31, 2003	\$	29	\$	255	\$	251	\$	33		
December 31, 2002	\$	9	\$	268	\$	248	\$	29		
Reserves for obsolete and excess inventories										
December 31, 2004	\$	341	\$	(61)	\$	173	\$	107		
December 31, 2003	\$	76	\$	406	\$	141	\$	341		
December 31, 2002	\$	56	\$	72	\$	52	\$	76		
Reserves for sales and product return allowances										
December 31, 2004	\$	582	\$	2,278	\$	1,177	\$	1,683		
December 31, 2003	\$	418	\$	1,217	\$	1,053	\$	582		
December 31, 2002	\$	212	\$	875	\$	669	\$	418		

All other financial statement schedules are omitted because the information described therein is not applicable, not required or is furnished in the financial statements or notes thereto.

### EXHIBIT INDEX

Exhibit Number	Description
2.1(1)	Merger agreement entered into August 4, 1999, by and among Cypros Pharmaceutical Corporation, a California corporation ("Parent"), Cypros Acquisition Corporation, a Delaware corporation and a wholly owned subsidiary of Parent, and RiboGene, Inc., a Delaware corporation.
3.1(2)	Amended and Restated Articles of Incorporation of the Company.
3.2(3)	Certificate of Determination of Series B Convertible Preferred Stock of the Company.
3.3(4)	Certificate of Determination of Series C Junior Participating Preferred Stock of the Company.
3.4(5)	Bylaws of the Company.
4.1(6)	Convertible Debenture between the Company and SF Capital Partners Ltd. dated March 15, 2002.
4.2(6)	Convertible Debenture between the Company and Defiante Farmaceutica Unipessoal LDA dated March 15, 2002.
10.1(7)	Forms of Incentive Stock Option and Non-statutory Stock Option.
10.2(8)	1992 Employee Stock Option Plan, as amended.
10.3(9)	1993 Non-employee Directors' Equity Incentive Plan, as amended and related form of Nonstatutory Stock Option.
10.5(10)	2000 Employee Stock Purchase Plan.
10.6(11)	Asset Purchase Agreement dated July 27, 2001 between the Company and Aventis Pharmaceuticals Products, Inc.†
10.7(11)	First Amendment to Asset Purchase Agreement dated January 29, 2002, between the Company and Aventis Pharmaceuticals Products, Inc.†
10.10(12)	Stock Purchase Agreement dated July 31, 2001 between Registrant and Sigma-Tau Finance Holding S.A.
10.11(13)	Warrant dated December 1, 2001 between the Company and Paolo Cavazza.
10.12(13)	Warrant dated December 1, 2001 between the Company and Claudio Cavazza.
10.13(6)	Securities Purchase Agreement between the Company and SF Capital Partners Ltd. dated March 15, 2002.
10.14(6)	Registration Rights Agreement between the Company and SF Capital Partners Ltd. dated March 15, 2002.
10.15(6)	Warrant between the Company and SF Capital Partners Ltd. dated March 15, 2002.
10.16(6)	Securities Purchase Agreement between the Company and Defiante Farmaceutica Unipessoal Lda dated March 15, 2002.
10.17(6)	Registration Rights Agreement between the Company and Defiante Farmaceutica Unipessoal Lda dated March 15, 2002.
10.18(6)	Warrant between the Company and Defiante Farmaceutica Unipessoal Lda dated March 15, 2002.
10.19(3)	Form of Common Stock Purchase Warrant dated January 15, 2003 issued by the Company to purchasers of Series B Convertible Preferred Stock.
10.21(4)	Rights Agreement, dated as of February 11, 2003, between the Company and Computershare Trust Company, Inc.
10.22(3)	Form of Subscription Agreement dated as of December 29, 2002 by and between the Company and purchasers of Series B Convertible Preferred Stock and Common Stock Purchase Warrants.
10.28(14)	Letter Agreement dated September 2, 2003 between the Company and R. Jerald Beers.
10.29(14)	Amendment to Letter Agreement dated November 6, 2003 between the Company and R. Jerald Beers.
10.30(14)	Supply Agreement dated April 1, 2003 between the Company and BioVectra, dcl.
10.33(15)	Separation Agreement dated August 5, 2004 between the Company and Charles J. Casamento.
10.34(16)	Secured Promissory Note and Security Agreement dated July 31, 2004 between the Company and Defiante Farmaceutica Lda.
10.35(17)	Letter Agreement between the Company and James L. Fares dated February 17, 2005.

Number	Description
10.36(18)	Amendment dated March 8, 2005 to the 8% Convertible Debenture dated March 15, 2002 issued by Questcor Pharmaceuticals, Inc. in favor of Defiante Farmaceutica Lda.
10.37(18)	Amendment dated March 10, 2005 to the 8% Convertible Debenture dated March 15, 2002 issued by Questcor Pharmaceuticals, Inc. in favor of SF Capital Partners Ltd.
10.38(19)	2004 Non-Employee Directors' Equity Incentive Plan.
10.39*	Letter Agreement between the Company and Reinhard Koenig dated September 30, 2004.
10.40*	Letter Agreement between the Company and James L. Fares dated February 18, 2005.
10.41*	Letter Agreement between the Company and Steve Cartt dated March 7, 2005.
10.42*	Letter Agreement between the Company and Steve Cartt dated March 8, 2005.
10.43*	Letter Agreement between the Company and Reinhard Koenig dated February 3, 2004.
10.44*	Letter Agreement between the Company and Barbara J. McKee dated February 9, 2005.
10.45*	Separation Agreement and Release dated March 3, 2005 between the Company and R. Jerald Beers.
10.46*	Series B Preferred Shareholder Agreement and Waiver dated March 29, 2005 by and between the Company and all of the holders of the outstanding shares of Series B Preferred Stock of the Company.
23.1*	Consent of Independent Registered Public Accounting Firm.
31*	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32*	Certification pursuant to Section 906 of the Public Company Accounting Reform and Investor Act of 2002.

\* Filed herewith.

Exhibit

- (1) Filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 1999, and incorporated herein by reference.
- (2) Filed as an exhibit to the Company's Registration Statement on Form S-8, Registration Statement No. 333-30558, filed on February 16, 2000, and incorporated herein by reference.
- (3) Filed as an exhibit to the Company's Current Report on Form 8-K filed on January 16, 2003, and incorporated herein by reference.
- (4) Filed as an exhibit to the Company's Current Report on Form 8-K filed on February 14, 2003, and incorporated herein by reference.
- (5) Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002, and incorporated herein by reference.
- (6) Filed as an exhibit to the Company's Registration Statement on Form S-3, Registration No. 333-85160, filed on March 28, 2002, and incorporated herein by reference.
- (7) Filed as an exhibit to the Company's Registration Statement on Form S-1, Registration No. 33-51682, and incorporated herein by reference.
- (8) Filed as an exhibit to the Company's Proxy Statement for the 2002 Annual Meeting of Shareholders, filed on March 28, 2002, and incorporated herein by reference.
- (9) Filed as an exhibit to the Company's Registration Statement Form S-4, Registration Statement No. 333-87611, filed on September 23, 1999, and incorporated herein by reference.
- (10) Filed as an exhibit to the Company's Registration Statement on Form S-8, Registration Statement No. 333-46990, filed on September 29, 2000, and incorporated herein by reference.
- (11) Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, and incorporated herein by reference.
- (12) Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001, and incorporated herein by reference.
- (13) Filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2001, and incorporated herein by reference.
- (14) Filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, and incorporated herein by reference.

- (15) Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, and incorporated herein by reference.
- (16) Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004, and incorporated herein by reference.
- (17) Filed as an exhibit to the Company's Current Report on Form 8-K filed on February 23, 2005, and incorporated herein by reference.
- (18) Filed as an exhibit to the Company's Current Report on Form 8-K filed on March 14, 2005, and incorporated herein by reference.
- (19) Filed as an exhibit to the Company's Proxy Statement for the 2004 Annual Meeting of Stockholders, filed on March 29, 2004, and incorporated herein by reference.
- † The Company has requested confidential treatment with respect to portions of this exhibit.