## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# Form 10-K

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

For the Fiscal Year ended December 31, 2003

or

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

Commission file number 0-20772

# **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  $\square$ 

The aggregate market value of the voting and non-voting Common Stock held by non-affiliates of the Registrant was approximately \$31,217,565 as of June 30, 2003, 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 13,051,037 shares held by directors, officers and stockholders whose ownership exceeds five percent of the Registrant's outstanding Common Stock as of June 30, 2003. 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 22, 2004 the Registrant had 50,923,101 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 Registrants Definitive Proxy Statement filed with the Commission pursuant to Regulation 14A in connection with the 2004 Annual Meeting of Shareholders are incorporated by reference into Part III of this Report.

# FOR THE FISCAL YEAR ENDED DECEMBER 31, 2003

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#### PART I

#### Item 1. Business of Questcor

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 of Questcor," 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, markets and sells brand name prescription drugs through our U.S. direct sales force and international commercialization partners. We focus on the treatment of central nervous system ("CNS") diseases and gastroenterological disorders, which are served by a concentrated group of physicians such as neurologists and gastroenterologists. Our strategy is to acquire pharmaceutical products that we believe have sales growth potential, are promotionally responsive to a focused and targeted sales and marketing effort, and complement our existing products. In addition, through corporate collaborations, we intend to develop new patented intranasal formulations of medications previously approved by the Food and Drug Administration ("FDA"). For the year ended December 31, 2003, our total revenues were \$14.1 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 biotech companies that do not have the capabilities to effectively market and sell FDA approved products will also be sources of products. In 2003 we acquired an FDA approved product from Nastech.

Since 1995, we have introduced 7 products and currently market 5 products in the United States. We promote certain of our products through our nationwide sales and marketing force of approximately 30 professionals, targeting high-prescribing acute care and specialty physicians such as gastroenterologists and neurologists. We contract with third parties for the manufacture of all our products as well as the warehousing and distribution of our products.

Our current products are: HP 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; Glofil®-125, an injectable agent that assesses how well the kidney is working by measuring glomerular filtration rate, or kidney function; and VSL#3, a patented probiotic marketed as a dietary supplement to promote normal gastrointestinal function. Probiotics are living organisms in food and dietary supplements, which, upon ingestion in certain numbers, improve the health of the host beyond their inherent basic nutrition. Due to minimal demand and increasing production costs, we discontinued marketing and selling Inulin in September 2003 and Neoflo in 2001.

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, 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.

Consistent with our efforts to focus on sales and marketing, our spending on research and development activities is minimal. 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"), 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 partnered with Rigel Pharmaceuticals, Inc. ("Rigel") of South San Francisco, California for our antiviral drug discovery program, and partnered with Dainippon Pharmaceuticals Co., Ltd. ("Dainippon") of Osaka, Japan for our antibacterial program.

We have rights to the following registered trademarks: HP Acthar® Gel, Ethamolin®, Nascobal® and Glofil®-125. We also have the following unregistered trademarks: Migrastat<sup>TM</sup>, Emitasol<sup>TM</sup>, Hypnostat<sup>TM</sup> and Panistat<sup>TM</sup>. VSL#3® is owned by VSL Pharmaceuticals, Inc. 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 and acquire brand name products and our ability to increase our sales and improve our marketing infrastructure 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 organization that includes approximately 30 professionals. Our current target audience for Nascobal are 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 brand name prescription products. We seek to acquire the rights to brand name 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. There is no assurance we will be able to acquire such products or, if acquired, that they will produce attractive gross margins. We intend to purchase products with cash generated from operations, if any, or from capital raised through the sale of equity on terms acceptable to us.
- Acquire companies that sell products that complement our current products and sales strategy. We regularly review opportunities to acquire companies that sell products that complement the current products that we sell and target the physicians to whom we promote our products. We intend to acquire companies using our common stock, if such stock is at acceptable levels, or cash generated from operations, if any, or from capital raised through the sale of equity on terms acceptable to us.

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

Our marketed products as of December 31, 2003 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, which we acquired the rights to market and sell pursuant to a Promotion Agreement effective January 2002.

Acthar. HP Acthar Gel ("Acthar") is a natural source, highly purified preparation of the adrenal corticotropin hormone ("ACTH"). Unlike 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.

In July 2001, we signed an agreement with Aventis to acquire the worldwide rights to Acthar. Due to limited distribution of Acthar prior to our acquisition of the product from Aventis, drug wholesalers did not have access to Acthar. We began shipping Acthar to drug wholesalers at the end of the third quarter of 2001. As part of our agreement with Aventis, Aventis agreed to manufacture and supply Acthar for us through July 2002 at a fixed price per vial. Aventis produced their final batch of Acthar for us in July 2002 which had a January 2004 expiration date. Under our agreement with Aventis, we purchased the active pharmaceutical ingredient (the "API") and other inventory residing at Aventis. We produced our first batch of finished Acthar vials using the API from Aventis at our contract manufacturer, Chesapeake Biological Laboratories, Inc., and commenced shipment of finished product during 2003. We have also made plans to produce our first batch of the API at our new contract manufacturer during 2004 and we expect to use the API for the production of finished vials for commercial use during 2005. Based on internal sales forecasts, our existing inventory of the API, previously manufactured for us by Aventis, should be adequate to supply the annual demand for Acthar through 2006. However, there can be no assurance that the existing inventory of the API will be sufficient to meet our demand through 2006 or that our third party manufacturers will be able to supply Acthar. Additionally, under our prior arrangement, Aventis supplied Acthar at a fixed price per vial through July 2002. The transfer of manufacturing from Aventis to new third party manufacturers will likely result in higher unit costs, which would result in a decrease of our gross margins on sales of Acthar. Acthar gross margins were 78% for the year ended December 31, 2003.

Acthar is used in a wide variety of conditions, including the treatment of infantile spasm ("IS"), periodic flare associated with MS, and various forms of arthritis, collectively called joint pain. Although the FDA approved package labeling does not include 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 age of 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 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 point.

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*. 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 will initially focus our promotional efforts on patients who through surgery or as a result of disease cannot readily absorb Vitamin B-12. The initial promotional efforts will focus on patients who are susceptible to a Vitamin B-12 deficiency caused by Crohn's disease, gastric bypass surgery or multiple sclerosis.

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 2003, it is estimated that 90,000 gastric bypass surgeries were performed and the number of procedures is expected to increase to 140,000 in 2004.

A study of multiple sclerosis ("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.

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 was filed by Nastech with the FDA in December 2003.

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.

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 TM (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, 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. 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. The main reason for this is because routine testing with Glofil-125 requires dedicated laboratory facilities and trained technicians. Due to the lack of strategic fit, as well as the acquisition and growth potential of Nascobal, the promotional efforts on Glofil-125 will be limited to supporting existing users.

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 Tc-DTPA, manufactured by Mallinckrodt, Inc., 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 believe the emerging role for probiotics in the management of patients with Inflammatory Bowel Disease ("IBD") offers an attractive market opportunity for VSL#3 which at the same time effectively complements our current promotion of Nascobal to this same group of gastroenterologists. IBD is one of the most common chronic gastrointestinal illnesses and consists mainly of two conditions — ulcerative colitis and Crohn's disease. It is estimated that almost one million Americans have IBD, with roughly 50% due to ulcerative colitis and 50% due to Crohn's disease. About 25 to 40% of ulcerative colitis patients eventually

must have their colon removed because of massive bleeding, severe illness, rupture of the colon, or risk of cancer. A number of surgeries may be performed for ulcerative colitis. One such procedure, which is becoming increasingly common for ulcerative colitis, is ileal pouch anal anastomosis surgery. This operation allows the patient to have relatively normal bowel movements because it preserves part of the rectum. A major long-term complication that occurs as a result of this surgery is pouchitis. Pouchitis is the non-specific inflammation of the ileal reservoir that appears to be associated with bacterial overgrowth and dysbiosis. Published clinical trials have reported that VSL#3 is effective in maintaining remission of pouchitis and in preventing pouchitis.

VSL#3 has received Orphan Drug designation from the Office of Orphan Products Development at the FDA for two indications: (1) the treatment of active chronic pouchitis; and (2) the prevention of disease relapse in patients with chronic pouchitis. Orphan Drug designation applies to diseases and disease states with a prevalence of less than 200,000 patients in the United States. Orphan Drug designation confers certain protection such as market exclusivity for seven years once the product has been approved. For VSL Pharmaceuticals, Inc. and us to take advantage of this designation, VSL#3 would have to be approved as a new biological prescription product by the FDA. We do not control the clinical or product development strategy for VSL#3. There can be no assurance that VSL#3 will ever be approved as a new biological product by the FDA or that it will ever enjoy the benefits of this Orphan Drug designation.

Effective January 1, 2004, VSL Pharmaceuticals, Inc. assigned the promotion agreement for VSL#3 to Sigma Tau Pharmaceuticals, Inc. and its affiliates ("Sigma Tau"). Sigma Tau entered into a promotion agreement with InKine Pharmaceutical Company, Inc. ("InKine"). Under the terms of the agreement, Sigma Tau will pay to InKine a fixed fee to promote VSL#3 to gastroenterologists as a second detail. In the short term, we could benefit from this increased promotion effort in that we are responsible for taking orders and shipping VSL#3 directly to customers. As such, we recognize the revenues for the sales of VSL#3 in the United States regardless of which company promotes the product. We are currently in discussion with Sigma Tau about an extension or renewal of the promotion agreement. There is no assurance that our promotion agreement will be renewed, or if it is renewed, that the terms of the agreement will not be substantially different than the current terms of the agreement. If the agreement is not renewed, we will not recognize any revenue from VSL#3 sales once the agreement expires in January 2005.

Virtually any number of manufacturers of probiotics may be considered competitors to VSL#3. Among the most notable are Culturelle<sup>TM</sup> by ConAgra and Probiotica by Johnson & Johnson.

*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 NDA for Inulin.

#### **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. Metoclopramide is an approved antiemetic and is available in both 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 being developed and marketed in certain countries throughout the world through corporate partners. It is approved in Italy as Pramidin, and during 2002 was distributed by sirton under our existing license agreement in Italy for the treatment of a variety of gastrointestinal disorders and emesis. For the year ended December 31, 2002, sirton distributed approximately 15,592 units of Pramidin in Italy. 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. Prior to 2003, there were no drugs specifically approved to treat delayed onset emesis. However, on March 26, 2003, the FDA approved Merck's Emend (aprepitant) with 5-HT3 antagonist for various indications, including delayed onset emesis. On July 25, 2003, the FDA also approved MGI Pharma's Aloxi (palonsetron hydrochloride) for the prevention of acute nausea and vomiting associated with chemotherapy and the prevention of delayed nausea and vomiting associated with chemotherapy. Given these recent approvals, our potential to develop Emitasol for delayed onset emesis has diminished. We will continue to partner or to seek funding for the development of Emitasol on a limited basis. If we are not successful in finding a development partner or in obtaining funding for the development of Emitasol, we plan to abandon our Emitasol project.

#### 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. We received a milestone payment from Fabre-Kramer of \$250,000 in the first quarter of fiscal year 2003, 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.

Fabre Kramer is developing Hypnostat for the short-term treatment of insomnia. We believe that Hypnostat, when given intranasally, may be effective in treating insomnia. Advantages of Hypnostat as compared to alternatives may include ease of administration, an increased level of efficacy, cost effectiveness, and possibly reduced side effects. The potential advantages of Hypnostat are significant in light of the fact that thirty to forty million Americans suffer from serious sleep disorders which are often untreated or inadequately treated. Continued sleep impairment may cause severe health effects. Oral triazolam (Halcion®) has been one of the most successful and most prescribed sleep-inducing agents in the world, with over 11 billion prescriptions filled. Oral triazolam is considered safer in terms of overdose, drug interactions, and addictive potential as compared to barbiturates. In addition, oral triazolam produces less morning grogginess, as compared to other benzodiazepines. Oral triazolam and other benzodiazepines are recommended for short-term use in conservative doses. Zolpidem (Ambien®) and zaleplon (Sonata®) are newer hypnosedative agents that are chemically unrelated to benzodiazepines. However, both zolpidem and zaleplon have similar pharmacokinetic and pharmacodynamic effects and do not differ with respect to efficacy, tolerability, residual effects, memory impairment, rebound insomnia, or abuse potential compared to oral triazolam. Over the counter medications containing diphenhydramine (such as Benadryl® and Sominex®) have been shown to increase the risk of symptoms of delirium including disorganized speech, poor attention level, and altered consciousness in the elderly. Other over the counter medications such as valerian and melatonin may be useful in alleviating mild short-term insomnia, but further clinical trials are required to fully evaluate efficacy and safety.

Prior clinical trials for Hypnostat support that triazolam is absorbed and effective when given intranasally. Phase I trials indicated that the overall amount of triazolam which reaches the plasma is very similar whether the drug is given intranasally or orally. Given the similarity in uptake of the two dosage forms, similarity might also be expected in their clinical performance. The expected similarity in performance is supported for the intranasal dosage form. In a prior Phase II pilot study, Hypnostat at 0.125 mg was superior to oral triazolam at

0.250 mg for time to sleep onset (p=0.008), effective sleep time (p=0.008), and stage two sleep time (p<0.05) and was equivalent to oral triazolam at 0.250 mg for quality of sleep. We therefore anticipate that intranasal triazolam may be effective for treating insomnia. Hypnostat is currently in the Phase II stage of development and Fabre Kramer is conducting the clinical testing. We believe it will be several years, if ever, before Hypnostat is commercially available.

Fabre Kramer intends 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. Advantages of Panistat as compared to alternatives may include ease of administration, an increased level of efficacy, and cost effectiveness.

The potential advantages of Panistat are significant in light of the fact that anxiety disorders are the most common mental disorder in the United States, affecting approximately 19 million people. According to the National Institute of Mental Health, approximately 25% of those affected by anxiety disorders seek treatment. Generalized anxiety disorder is characterized by constant uncontrollable worry. Panic disorder is characterized by acute, spontaneous, and repeated anxiety attacks which involve an intense, terrifying, and unfocused fear in the absence of any external threat. Panic attacks typically last for approximately 20 to 30 minutes and may cause racing heartbeat, chest pains, difficulty breathing, choking sensations, dizziness, and numbness. Panic attacks can occur as often as several times per week or several times per day. Approximately 2.4 million people in the United States suffer from panic disorder, which often progresses into chronic anxiety and agoraphobia.

Early treatment can help keep a panic disorder from progressing. Benzodiazepines, including oral alprazolam (Xanax®), have proven to be safe and effective for treating panic disorder for over 20 years. Benzodiazepines block panic attacks during the first or second day of treatment. Surprisingly low rates of abuse of this and other medicines are reported in persons with panic disorder. Many antidepressants, including doxepin (Sinequan®), sertraline (Zoloft®), fluoxetine (Prozac®), imipramine (Tofranil®), and paroxetine hydrochloride (Paxil®), are useful in treating panic attacks without causing physical dependence. However, successful treatment requires full strength dosage and usually takes four to eight weeks for therapeutic effects to be observed. In addition, antidepressants cause panic attacks to initially increase in approximately half of panic disorder sufferers. Phenelzine sulfate (Nardil®) is effective for panic disorder, but is complicated to use. Although phenelzine sulfate is safe when used by an experienced physician, it is typically reserved for cases where simpler medications have failed or cannot be used. Unsafe elevations of blood pressure for several hours can occur if one does not adhere to diet and medication restrictions. Cognitive-behavioral therapy ("CBT") teaches the patient to anticipate and prepare for situations and bodily sensations that may trigger panic attacks. CBT generally requires at least eight to twelve weeks for the patient to learn the skills and put them into practice. CBT requires a motivated patient and a specially trained therapist. Clinical experience suggests that for many patients with panic disorder, a combination of CBT and medication may be the best treatment. Other treatment options include relaxation, breathing techniques, hypnotherapy, and psychotherapy. 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. Although we have had some preliminary discussions with potential corporate partners regarding the GERI compounds, there can be no assurance that we will enter into a collaboration to fund future research on these compounds. We do not intend to expend any additional resources on these compounds. There can be no assurance that we will be successful in licensing the GERI program or that we will 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. Laboratories 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 2003, the status of this product remains uncertain.

Ahn-Gook Pharmaceutical Co., Ltd. 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. Ahn-Gook began selling Emitasol in the Republic of Korea in the first half of 2003. Through 2003, the sales of the product are 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 will receive an up-front payment and additional royalties upon commercialization of Emitasol in each of these new countries.

#### Manufacturing

We do not currently manufacture any of our acquired products or our products in development. Our commercial products, Acthar, Nascobal, Ethamolin, VSL#3 and Glofil-125, are manufactured for us by approved contract manufacturers.

As part of our agreement with Aventis to acquire Acthar, Aventis agreed to manufacture the finished goods from existing inventory of the active pharmaceutical ingredient (the "API") through July 2002. Aventis produced its final batch of finished Acthar in July 2002. The production of Acthar requires the production of the API and the production of the finished product. The API is an extraction from porcine pituitary glands. Although the extraction process is well known by individuals within Aventis, the extraction may be difficult to reproduce at a new vendor. Under our agreement with Aventis, we purchased the API and other inventory residing at Aventis. Based on internal sales forecasts, our existing inventory of the API, previously manufactured for us by Aventis, should be adequate to supply the annual demand for Acthar through 2006. We are transferring the manufacturing process of the API to a new third party manufacturer, BioVectra, dcl ("BioVectra"). 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 the first batch of API is scheduled to begin in 2004. We have contracted with a third party manufacturer, Chesapeake Biological Laboratories, Inc., for Acthar finished product. During 2003 our first batch of Acthar vials were produced by Chesapeake Biological Laboratories, Inc. using API from Aventis and shipment to customers commenced in September 2003. The production of the API and the finished product 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 will be required through the transfer process. On November 4, 2002, we met with the FDA to discuss our manufacturing transfer plan for Acthar. In connection with that meeting, 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 released an Acthar lot with 18 month dating in 2003. The transfer of manufacturing of Acthar from Aventis to new third party manufacturers will result in higher unit costs.

We have experienced delays and cost overruns in the validation of the potency release assay being transferred from Aventis to our new third party contract laboratory. Beginning in January 2004, we initiated a plan designed to assist with the successful transfer of this assay. There are no assurances that we will be successful in transferring this assay to a third party contract laboratory. If we are unable to efficiently and timely validate the potency release assay prior to the date when Aventis can no longer conduct this assay, we will not be able to release both API and finished goods and therefore we may not be able to meet the expected demand for Acthar. We anticipate that Aventis will continue to conduct this assay through the end of 2004.

The Acthar site transfer process has numerous risks that could have a materially adverse impact on our financial results in future years. Such risks include the ability of the new independent third party contractors to produce qualified API and finished goods in sufficient quantities, on a timely basis and at an acceptable cost, that the production facilities and the processes will be approved by the FDA and that the API and finished product will be similar in potency and efficacy as the Aventis API and finished product historically produced

by Aventis. Although we believe we have adequate time and resources to ensure that the site transfer of Acthar will occur timely and correctly with minimal impact on future revenues, there can be no assurance that the site transfer will occur timely and correctly and that the transfer will not have a materially adverse impact on the company in the future.

Nascobal is manufactured by Nastech under a long-term supply agreement at a fixed price per unit, under which Nastech will continue to manufacture Nascobal at its FDA approved, current good manufacturing practice ("cGMP") manufacturing facility in Hauppauge, New York. Nastech plans on transferring Nascobal manufacturing in 2005 to a new facility in Bothell, Washington.

During 2002, we successfully transferred the manufacturing of Ethamolin from Schering Plough to Ben Venue Laboratories ("Ben Venue"). We obtained full 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.

We obtain VSL#3 from Sigma Tau Pharmaceuticals, Inc. ("Sigma Tau") under our promotion agreement with them. However, we have no experience with manufacturing VSL#3, and we are relying completely on Sigma Tau to supply us with the product. Due to our lack of experience with VSL#3 and our reliance on Sigma Tau, we can provide no assurances as to the timely manufacture of this product.

Our manufacturer of Glofil-125 was subject to an inspection by the FDA in July 2003. As a result of this inspection, our manufacturer received notification that several items required attention in order to comply with FDA regulations. We are working with our manufacturer on addressing any outstanding issues resulting from the FDA inspection. Based on the information available, we believe that the manufacture of Glofil-125 will not be affected.

There can be no assurance that any of our bulk 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 complete the production of Acthar API, 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 bulk 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, 2003, we have hired, trained and deployed a total of 24 product specialists and marketing personnel to support the commercialization of our primary promoted products, Acthar, Nascobal and VSL#3. Our current strategic focus is neurology and gastroenterology. Our promotion and educational efforts of 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), and neurologists (MS, dementia). 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 market VSL#3 to gastroenterologists. 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. 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 Pharmaceuticals, Ltd. in 2003 were \$78,000.

#### **IDIS Limited**

In November 2003, we signed an agreement with IDIS Limited 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, UK, where Acthar is sold through Beacon Pharmaceuticals, Ltd., and Israel where Nascobal is sold through a distributor.

#### 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 will target. There are products and treatments on the market that compete with Acthar, Nascobal, Ethamolin, Glofil-125 and VSL#3. 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 of products.

Most of our competitors are larger than us and have substantially greater financial, marketing and technical resources than we have. In addition, many of these competitors have substantially greater experience than we do in acquiring, developing, testing and obtaining FDA and other approvals of pharmaceuticals. 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. Our competitive position will also depend upon our ability to attract and retain qualified personnel and to secure sufficient capital resources for product acquisition and commercialization of products.

# **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 non-complying 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 through our partners 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 prior to commercialization. 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 or our 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.

#### VSL#3

We are marketing VSL#3 as a dietary supplement. If approval of VSL#3 as a biological product is pursued by Sigma Tau at a later date, the regulatory hurdles discussed above will apply.

The manufacturing, distribution, and sale of dietary supplements and medical foods are subject to regulation by one or more federal agencies, principally the FDA and the Federal Trade Commission (the "FTC"). Our activities are also regulated by various governmental agencies for the states and localities in which VSL#3 is distributed and sold. Among other matters, the FDA and FTC are concerned with product safety and claims that refer to a product's ability to provide dietary support for health-related conditions.

The regulation of dietary supplements is principally governed by the Dietary Supplement Health and Education Act ("DSHEA"), which was enacted in 1994, amending the FDCA. DSHEA establishes a statutory class of "dietary supplements," which includes vitamins, minerals, herbs, amino acids and other dietary ingredients for human use to supplement the diet. Dietary ingredients that were not on the market as of October 15, 1994 require the submission by the manufacturer or distributor to the FDA of evidence of a history of use or other evidence of safety establishing that the ingredient will reasonably be expected to be safe. Among other things, DSHEA prevents the further regulation of dietary ingredients as "food additives" and allows the use of statements of nutritional support on product labels. The FDA has issued proposed and final regulations in this area and indicates that further guidance and regulations are forthcoming.

In November 1998, the FTC Bureau of Consumer Protection announced its new advertising guidelines for the dietary supplement industry, which it labeled "Dietary Supplements: An Advertising Guide for Industry." These guidelines reiterate many of the policies the FTC has announced over the years, including requirements for substantiation of claims made in advertising about dietary supplements.

The FDA has announced its intent to issue cGMP regulations for the dietary supplement industry. The FDA has published an advance notice of proposed rulemaking, and on March 13, 2003 published proposed regulations. This rule is not yet final. The comment period on the proposed cGMP regulations (Federal Register Docket No. 96N-0417) was extended from June 11, 2003 to August 11, 2003. Comments have been received by the FDA and the regulation is in revision. We are evaluating the proposed cGMP regulations and will assess the impact of the final cGMP rules on our operations.

#### **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 or have licensed a total of thirty-four issued U.S. and foreign patents covering all formulations of Nascobal, eighteen issued U.S. and foreign patents covering Emitasol, and nine issued U.S. and foreign patents covering our other technology. We also hold the right to a patent application for a new and improved spray formulation of Nascobal. However, we may not be renewing our foreign patents relating to Nascobal, since Nascobal is only approved in Sweden and our current plans do not include seeking approval in additional foreign countries.

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 have also filed several other patent applications in the U.S. and abroad on our various products and expect to file additional applications in the future.

#### **Employees**

At December 31, 2003, we had 39 full-time employees (as compared to 52 full-time employees at December 31, 2002).

Our success will depend in large part on our ability to attract and retain key employees. At December 31, 2003, we had 24 employees engaged directly in the marketing and selling of our on-market 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, 2003 is \$82.9 million, of which \$5.9 million represented the net loss applicable to common stockholders for the twelve months ended December 31, 2003, \$2.8 million represented the net loss for the year ended December 31, 2002, and \$8.7 million represented the net loss for the year ended December 31, 2001. Operating losses are expected to continue at least through the end of 2004. 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. 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:

- increase sales of current products,
- · finance and acquire additional marketed products,
- finance the future growth of our sales/marketing and customer service organization,
- finance operations with external capital until consistent positive cash flows are achieved,
- properly and timely complete the transfer of the manufacturing of Acthar API to the new contract manufacturer and the transfer of the release assay to a third party laboratory including receiving the appropriate approvals from the FDA and other regulatory authorities,
- 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. Acthar revenues comprised 58%, 65% and 41% of our total net product revenues for the years ended December 31, 2003, 2002 and 2001 (sales of Acthar began in September 2001), respectively. Nascobal sales comprised 15% of net product revenues for the year ended December 31, 2003 (sales of Nascobal began in July 2003, while promotion began in October 2003). We anticipate that as a percentage of our total sales, Nascobal will increase and Acthar will decrease. 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 in 2004. We expect that Acthar and Nascobal will continue to constitute a significant portion of our revenues in 2004. 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.

Effective January 1, 2004, VSL Pharmaceuticals, Inc. assigned the VSL#3 promotion agreement to Sigma Tau. Sigma Tau entered into a promotion agreement with InKine Pharmaceutical Company, Inc. ("InKine"). Under the terms of the agreement, Sigma Tau will pay to InKine a fixed fee to promote VSL#3 to gastroenterologists as a second detail. In the short term, we could benefit from this increased promotion effort in that we are responsible for taking orders and shipping VSL#3 directly to customers. As such, we recognize the revenues for the sale of VSL#3 in the United States regardless of which company promotes the product. There is no assurance that our promotion agreement will be renewed or if it is renewed that the terms of the agreement will not be substantially different than the current terms of the agreement. If the agreement is not renewed, we will not recognize any revenue from VSL#3 sales once the agreement expires in January 2005.

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

Any delays or problems associated with the site transfer of the manufacturers or third party contract laboratories for testing of Acthar could reduce the amount of the product that will be available for sale and adversely affect our operating results. Under our agreement with Aventis Pharmaceuticals, Inc. ("Aventis"), Aventis manufactured and supplied Acthar through July 2002. During 2003, we signed a definitive agreement with Chesapeake Biological Laboratories ("CBL"), a contract manufacturer for Acthar finished product, and transferred the final fill and packaging process from Aventis to CBL. Under our agreement with Aventis, we purchased the active pharmaceutical ingredient ("API") and other inventory residing at Aventis. We believe that this API should be sufficient to meet our forecasted demand through 2006. CBL, the new final fill manufacturer, began supplying to us finished product during 2003 using the API manufactured by Aventis.

We have selected a new contract laboratory to perform various bioassays associated with the release of API and finished product. These assays have been performed and are continuing to be performed by Aventis. However, we have experienced delays and cost overruns in the validation of the potency bioassay from Aventis to our new third party contract laboratory. Beginning in 2004, we will resume the testing necessary to transfer the assay to a new contact laboratory. 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 date when Aventis can no longer conduct this assay, 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.

As described above, the process of manufacturing Acthar is complex and we may encounter problems associated with the site transfer. Once the site transfer to our new API manufacturer, BioVectra, has been completed and the bioassays have been validated and they begin supplying released API to us, the cost of the product is expected to increase which may cause our gross margins to decline. In addition, if the site transfer and the corresponding approval by the FDA and other regulatory authorities do not occur on a timely basis at the appropriate costs to us, we will lose sales. Moreover, contract manufacturers that we may 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 exchange policy and/or demand that we implement a return policy, our revenues would be significantly impacted.

We have an exchange policy in which we will ship replacement product for expired product returned to us within six months after expiration. This policy is not commonplace in the industry as the standard policy is to issue credit memoranda in exchange for expired product that is returned. Our customers have expressed dissatisfaction with our exchange policy and, although they have complied to date, have suggested that they may choose not to adhere to it in the future. Since we sell a majority of our products to the three largest distributors and no viable alternatives exist, we may be forced to change our current policy to a return policy in which credit memoranda are issued. In the event this occurred, the negative financial impact on our revenues, operations and cash position would be substantial in the near term.

In December 2002, we noted that certain of our customers were not complying with our expired product exchange policy. These customers were deducting from amounts owed to us the full price of expired Acthar they planned to return to us. While we reached an agreement with these customers to pay these short-remittances ("returns receivable") upon their receipt of replacement product for the Acthar that expired in November 2002 and May 2003, customers have continued to deduct from amounts owed to us the full price of expired Acthar they return to us. Additionally, certain customers received an administration fee from us for the expired product that was exchanged. Certain of our customers continued to short-remit for expired product returns in 2003. As of December 31, 2003, the returns receivable amount is \$420,000. A majority of returns of expired product, which in turn has created this returns receivable, have been replaced in accordance with our exchange policy, and we are in the process of seeking reimbursement. The next batches of Acthar expire in January 2004 and December 2004, the next batches of Ethamolin expire in January and February 2004 and the next Nascobal batch expires in February 2005. We expect that our customers will continue to short remit us in the future as these batches expire and our customers seek to return expired product. Should our customers not reimburse us for the returns receivable upon shipment of replacement product, the negative impact on our cash and operations would be substantial.

In 2002 and 2001, the Acthar vials we sold had a one year shelf life and, in the first quarter of 2003, we began shipping product which expired in January 2004. In November 2002, the shelf life of Acthar was increased to 18 months. Due to the short shelf life of Acthar, significant quantities could expire at the wholesale or pharmacy level, which could then be returned for replacement product under our exchange 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 Conditions and Results of Operations for further discussion of our exchange policy.

#### 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. Our three largest customers represented over 75% of our net product sales for fiscal year 2003. While we attempt to estimate inventory levels of our products at our major wholesale customers using inventory data obtained from these customers, historical prescription information and historical purchase patterns, this process is inherently imprecise. We rely solely upon our wholesale customers to effect the distribution allocation of our products. There can be no assurance that these customers will adequately manage their local and regional inventories to avoid outages or inventory build-ups. We noted in the second quarter of 2003 that one of our major customers had purchased Ethamolin units in excess of what we estimated their historical demand to be. This build-up of inventory adversely impacted Ethamolin sales in 2003 and may adversely impact future sales of Ethamolin.

Our therapeutic pharmaceutical products have expiration dates that range from 18 to 36 months from date of manufacture. We will generally accept for exchange pharmaceutical products that have reached the expiration date. We establish reserves for these exchanges at the time of sale. There can be no assurance that we will be able to accurately forecast the reserve requirement that will be needed 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. The actual amounts could be different from the estimates and differences are accounted for in the period in which they become known.

We do not control or significantly influence the purchasing patterns of wholesale customers. These are highly sophisticated customers 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 our major customers, 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 inventory are based on an analysis of expected future sales that will occur before the inventory on hand will expire. Judgment is required in estimating reserves for excess inventories. The actual amounts of required reserves could be different from the estimates and differences are accounted for in the period in which they become known.

#### We have limited experience marketing Nascobal and may be unsuccessful in doing so.

In June 2003, we acquired Nascobal, a nasal gel used for the treatment of various Vitamin B-12 deficiencies. We currently have limited sales and marketing experience with respect to Nascobal. We also cannot predict what the demand for Nascobal will be. If the demand for Nascobal is less than we anticipate, or if we are unsuccessful in marketing Nascobal, our revenues from the sale of Nascobal will be less than we are currently anticipating. As part of the acquisition, Questcor also acquired the rights to Nascobal nasal spray, a new dosage form, for which an NDA was filed with the FDA by Nastech in December 2003. Subject to the approval of the NDA for the new Nascobal nasal spray dosage form by the FDA, we will make a \$2 million payment to Nastech for the transfer of the NDA from Nastech to Questcor. Further, subject to the approval of the NDA by the FDA for the new Nascobal nasal spray dosage form and upon issuance of a pending U.S. patent for the new Nascobal nasal spray dosage form, we will make a second \$2 million payment to Nastech. We need to generate revenues from sales of Nascobal in order to raise the necessary funds to make these payments. If we are not successful in marketing Nascobal, we may need to seek other sources of cash to make such payments or to fund operations. Moreover, if the amount of Nascobal inventory at the wholesale level at the time that we purchased Nascobal was higher than we anticipated, this may also affect the demand for Nascobal in the near term.

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

While 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, 2004, unless a substantial portion of our cash is used for product acquisition or our fiscal year 2004 revenues are less than we expect. If Nastech is successful in obtaining approval for the NDA covering the nasal spray formulation, and if the patent covering this formulation issues after the approval of the NDA, we would be required to pay \$4 million to Nastech. If we experience unanticipated cash requirements, or if revenues fail to grow, or we are required to make the milestone payments to Nastech, we could be required to raise additional funds. Regardless, we may seek additional funds, before the end of 2004, through public or private equity financing or from other sources to potentially avoid the payment of additional dividends of 6% under our Series B Convertible Preferred Stock, to

acquire additional products, to expand our operations or to meet future obligations. 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.

In order to conduct our operating activities, we may require substantial additional capital resources in order to acquire new products, increase sales of existing products, and maintain our operations. In addition, if revenues from product sales do not significantly increase or if further capital investments do not materialize, or if such investments cannot be completed at attractive terms to us, or if we are unable to receive any additional capital investments at all, 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,
- · cost maintenance and potential future expansion of our sales force,
- 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 additional products.

We anticipate obtaining 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 shareholders. 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, product acquisition or manufacturing efforts.

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

We will rely on third party contract manufacturers to produce our marketed products, Acthar, Nascobal, Ethamolin, Glofil and VSL#3, and other products that we may develop, commercialize or acquire in the future. Third party manufacturers may not be able to meet our needs with respect to timing, cost, quantity or quality. All of our manufacturers are sole-source manufacturers and no currently qualified alternative suppliers exist.

Ethamolin is currently being manufactured by Ben Venue Laboratories ("Ben Venue"). We do not have a formal Ethamolin manufacturing contract in place with Ben Venue, rather 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 is manufactured by ISO-Tex Diagnostics, Inc. from whom we purchase on a lot by lot basis. Nascobal is manufactured by Nastech under a long-term supply agreement. VSL#3 is supplied by Sigma Tau Pharmaceuticals under a promotion agreement we have with them. Sigma Tau Pharmaceuticals has the sole responsibility for manufacturing and/or acquiring the VSL#3 product.

See "If we are unsuccessful in completing the Acthar site transfer, we may be unable to meet the demand for Acthar and lose potential revenues" for discussion of third party 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 site transfer and the corresponding approval by the FDA and other regulatory authorities does not occur on a timely basis at the appropriate costs to us, 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 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 third party distributors are unable to distribute our products, we will lose potential revenues.

We currently outsource certain functions previously performed in our Carlsbad, California distribution center, including, but not limited to, warehousing, shipping and quality control studies. The outsourcing of these functions is complex, and we may experience difficulties at the third party contractor level that could result in the non-shipment of our products. We have transferred the distribution of Acthar, Nascobal, Ethamolin and Glofil to third party distributors, and we distribute VSL#3 from our Union City facility. If we encounter problems with the distribution of these products at the third party distribution level the products could become unavailable and we could lose revenues, or the costs to distribute these products could become higher than we anticipated.

#### If we lose the services of certain key personnel or are unable to hire skilled personnel in the future, our business will be harmed.

We are highly dependent on the services of our Chairman, President, and Chief Executive Officer, Mr. Charles J. Casamento, our Senior Vice President of Finance and Administration and Chief Financial Officer, Mr. Timothy E. Morris, and our Vice President of Sales and Marketing, Mr. R. Jerald Beers. If we were to lose Mr. Casamento, Mr. Morris or Mr. Beers as employees, our business could be harmed. Moreover, 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 only minor increases in staffing levels are expected during 2004, recruiting and retaining management and operational personnel to perform sales and marketing, 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 shareholders, who in the future could attempt to take over control of our management and operations or exercise voting power to advance their own best interests and not necessarily those of other shareholders.

Sigma-Tau Finanziaria S.p.A. and its affiliates, or Sigma-Tau, beneficially own, directly or indirectly, approximately 26% 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 22, 2004. Additionally, as reported on Amendment No. 1 to Schedule 13D, filed with the SEC on February 13, 2004, Corporate Opportunities Fund, L.P. and its affiliates and Montreux Equity Partners II SBIC, L.P. and its affiliates beneficially own approximately 11% of our voting capital stock. Accordingly, these shareholders, 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 shareholders 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, Glofil-125, and VSL#3. 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 are developing, our technology and future drugs may be rendered obsolete and noncompetitive. 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 development of our licensed products progress 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.

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 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 pre-clinical 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 pre-clinical 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,
- diminish any competitive advantages that we or our corporate partners may attain, and
- 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. For example, successful late stage Phase III clinical trials for such potentially important treatments such as diabetic gastroparesis and delayed onset emesis may require the enrollment of many patients. Together, the costs of these trials, if funded solely by us, could exceed our current financial resources.

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. Because of VSL#3's non-prescription status, it is not widely covered by third party payors. 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 its 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 Medicaid Services. As a result, we pay quarterly rebates consistent with the utilization of our products by individual states. We also must 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 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 \$0.60 to \$2.18 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/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, 2003, we lease four 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, distribution of VSL#3, 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 has 30,000 square feet of laboratory and office space under a master lease that expires in November 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 a 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 three month periods.

In May 2001, we closed our Neoflo manufacturing facility located in Lee's Summit, Missouri. The lease period ends in December 2004 and, during 2003, we subleased the space through December 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, 2003.

## PART II

## Item 5. Market for Registrant's Common Equity and Related Shareholder Matters

We are listed on the American Stock Exchange, Inc. From January 1998 to November 1999 we were traded under the symbol "CYP." On November 17, 1999, we changed our name to Questcor Pharmaceuticals, Inc. and 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, 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	
December 31, 2002	1.16	0.90	
September 30, 2002	1.35	0.89	
June 30, 2002	2.01	1.28	
March 31, 2002	2.18	1.29	

The last sale price of our common stock on March 22, 2004 was \$0.93. As of March 22, 2004 there were approximately 296 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,				Five Months Ended December 31,	Year Ended July 31,
	2003	2002(2)	2001	2000	1999(1)	1999
			(In thous	ands, except per share da	ta)	
Consolidated Statement of Operations			`	, <b>.</b> .	,	
Data:						
Net product sales	\$13,655	\$13,819	\$ 5,196	\$ 2,134	\$ 624	\$ 2,518
Total revenues	14,063	14,677	5,667	3,594	956	2,569
Total operating costs and expenses	17,397	17,080	15,050	17,752	23,257	10,026
Loss from operations	(3,334)	(2,403)	(9,383)	(14,158)	(22,301)	(7,457)
Net loss	(3,791)	(2,785)	(8,697)	(13,762)	(22,210)	(6,784)
Net loss applicable to common						
stockholders	(5,947)	(2,785)	(8,697)	(13,762)	(22,210)	(6,784)
Net loss per common share applicable to common stockholders — basic						
and diluted	(0.14)	(0.07)	(0.28)	(0.56)	(1.22)	(0.43)
Shares used in computing net loss per common share applicable to common stockholders — basic and diluted	41,884	38,407	31,425	24,722	18,240	15,712
				December 31,		
		2003	2002	2001	2000	1999
Consolidated Balance Sheet Data:				(In thousands)		
Consolidated Balance Sheet Data:  Cash, cash equivalents and short-	tama					
investments (includes \$5 millio compensating balance at Decer	n					
2000 and 1999)		\$ 3,220	\$ 7,506	\$ 10,571	\$ 8,151	\$ 21,699
Working capital		4,352	7,018	2,659	1,261	16,943
Total assets		22,929	12,766	14,946	14,848	32,221
Long-term obligations		3,402	2,908	122	548	6,078
Preferred stock, Series A		5,081	5,081	5,081	5,081	5,081
Preferred stock, Series B		8,278	_	_	· <del>-</del>	· <del>_</del>
Common stock		85,232	77,528	74,018	66,152	65,423
Accumulated deficit		(82,915)	(76,968)	(74,183)	(65,486)	(51,724)
Total stockholders' equity (defici	t)	10,578	496	(300)	927	13,626

<sup>(1)</sup> Includes the results of operations of RiboGene, Inc. from November 17, 1999 through December 31, 1999, including a one-time charge for restructuring costs of \$1.5 million and a charge of \$15.2 million for acquired in process research and development costs.

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)**

09/30/03	06/30/03	03/31/03
n thousands, excer	ot per share data)	

	12/31/03	09/30/03	06/30/03	03/31/03
		(In thousands, ex	cept per share 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 stockholders	129	(776)	(2,062)	(3,238)
Net income (loss) per share applicable to common stockholders	0.00	(0.02)	(0.05)	(80.0)

#### **Ouarter Ended**

Quarter Ended

	12/31/02	09/30/02	06/30/02	03/31/02
		(In thousands, exc	ept per share data)	
Net product sales	\$2,934	\$3,772	\$ 3,307	\$3,806
Total revenues	3,234	3,848	3,741	3,854
Cost of product sales	651	829	708	634
Net income (loss)	(355)	(995)	(1,103)	(332)
Net loss applicable to common stockholders	(355)	(995)	(1,103)	(332)
Net loss per share applicable to common stockholders	(0.01)	(0.03)	(0.03)	(0.01)

Certain amounts have been reclassified to conform with current year presentation of annual financial statements. The amounts reclassified from Research and Development to Cost of Product Sales totaled, in the aggregate, \$443,000 for the quarters ended March 31, 2002, June 30, 2002, and September 30, 2002. The amounts reclassified from Cost of Product Sales to Selling, General and Administrative totaled, in the aggregate, \$110,000 for the quarters ended June 30, 2002, September 30, 2002 and December 31, 2002.

#### 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, markets and sells brand name prescription drugs through our U.S. direct sales force and international commercialization partners. We focus on the treatment of central nervous system ("CNS") diseases and gastroenterological disorders which are served by a concentrated group of physicians such as neurologists and gastroenterologists. Our strategy is to acquire pharmaceutical products that we believe have sales growth potential, are promotionally responsive to a focused and targeted sales and marketing effort and complement our existing products. We currently market five products in the United States:

- HP 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;
- Glofil®-125, an injectable agent that assesses how well the kidney is working by measuring glomerular filtration rate, or kidney function; and
- VSL#3®, a patented probiotic marketed as a dietary supplement to promote normal gastrointestinal function. Probiotics are living organisms in food and dietary supplements, which, upon ingestion in certain numbers, improve the health of the host beyond their inherent basic nutrition.

Due to minimal demand and increasing production costs, we discontinued marketing and selling Inulin in September 2003.

In June 2003, we acquired Nascobal®, an 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 Crohn's Disease and MS, 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 malabsorbtive state.

Consistent with our focus on sales and marketing, our spending on research and development activities is minimal. 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 agreements with pharmaceutical and biotechnology companies to further the development of certain acquired technology.

We have incurred an accumulated deficit of \$82.9 million at December 31, 2003. At December 31, 2003, we had \$3.2 million in cash, cash equivalents and short-term investments, and in January 2004 we raised an additional \$2.4 million through the private placement of common stock for cash and the surrender of warrants.

Results of operations may vary significantly from quarter to quarter depending on, among other factors, the results of our sales efforts, timing of expiration of our products and the resulting shipment of replacement product under our exchange policy, the availability of finished goods from our sole-source manufacturers, the

timing of certain expenses including the Acthar site transfer costs, the acquisition of marketed products, the establishment of strategic alliances and corporate partnering, 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 product returns, sales allowances, bad debts, inventories, investments, 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.

#### Product Returns, Rebates and Sales Allowances

We have estimated allowances for product returns from wholesalers and pharmacies, government chargebacks for goods purchased by certain Federal government organizations including the Veterans Administration, Medicaid rebates from all states for goods purchased by patients covered by Medicaid, and cash discounts for prompt payment. We estimate our allowances by utilizing historical information for existing products and data obtained from external sources. For new products, we estimate our allowances for product returns, government chargebacks and rebates on specific terms for product returns, chargebacks and rebates, and our experience with similar products.

Effective August 12, 2002, we changed our return goods policy such that we no longer issue credit memorandums for returns, rather returns are exchanged for replacement product ("Exchange Policy"). 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 in the distribution channel, and the remaining shelf life of that inventory (ranging from 18 months to 3 years for all products except Glofil), and (iii) changes in demand measured by prescriptions as provided by an independent third party source and our internal estimates. For Glofil, we accept no returns for expired product. We continually assess our historical experience including customers' compliance with the Exchange Policy, and we adjust our allowances as appropriate.

In December 2002, we noted that certain customers were not complying with our Exchange Policy. These customers were deducting from amounts owed to us the full price of expired Acthar they planned to return to us. We reached an agreement with these customers to reverse these short-remittances and to accept replacement product for the Acthar expiring in November 2002 and May 2003. Certain customers received an administration fee from us. It remains our customers' standard practice to deduct from payments to us the amount of the sales value of expired product ("returns receivable") that they have requested for return. The returns receivable of \$420,000 at December 31, 2003 was an increase of \$344,000 from the December 31, 2002 balance of \$76,000 primarily due to the expiration of batches of Acthar in November 2002 and May 2003. Customers have indicated that they will reimburse us for these deductions upon the replacement of expired units in accordance with our Exchange Policy, however, our experience has been the timing of such reimbursements is slower than the collection of our normal trade receivables. As of December 31, 2003, replacement units have been shipped relating to over two thirds of the amounts owing to us and we are seeking reimbursement from these customers. As long as our customer's standard practice is to deduct amounts related to the return of expired product, a returns receivable will arise. Should our customers not comply with

our Exchange Policy, the amounts deducted by them for returns may not be collectible, and we would increase our allowance for bad debts.

Our Exchange Policy is not commonplace in the pharmaceutical industry as the standard policy is to issue credit memorandums in exchange for expired product that is returned. Our customers have expressed dissatisfaction with our Exchange Policy, and although they have complied to date, our ability to enforce this policy on customers whose influence and resources are far greater than ours, is extremely limited. If our customers do not comply with our policies, our options are limited. We could either not sell our products to them (see Wholesalers' buying patterns, in the Risk Factor Section) or we could be forced to change our policy to allow for the issuance of credit memoranda in exchange for returned expired products. Under such a policy, we would no longer issue replacement product. The issuance of credit memoranda would negatively impact cash flow in the short-term but may increase future sales as shipment of replacement product at no cost would no longer occur.

Should we be forced to change to a returns policy in which credit memoranda are issued in exchange for expired product, an allowance for returns (credit memorandums) would be necessary and would be recorded with an offset to net product sales at the time of the policy change. The allowance would be based on an estimate of the future credit memorandums to be issued based upon historical return rates by product, applied to the quantity of product sold that has not yet expired. Further, if such a policy change were made the currently recorded allowance for product exchanges would be eliminated resulting in a reduction of cost of product sales. On Acthar, the historical return rate has been approximately 18 to 20% due to the short shelf life of the product and the nature of the disease for which it is presented. A change in our business policy to a return for credit memoranda basis would have a significant negative financial impact at the time of the change. Using historical return rates for each product, if we adopted a policy of issuing credit memorandums for expired product, allowances of up to \$2 million to \$3 million might be needed. A change in the business policy to issuing credit memorandums for expired product would be considered a change in accounting estimate and would be accounted for on a prospective basis. The impact of a change to a return for credit memoranda policy would be to reduce net 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 allowance for product replacement.

In March 2004, one of our three largest customers communicated to us that they do not want to continue with the Exchange Policy but desire a policy of issuing credit memoranda for expired product. We will be meeting with this customer to attempt to maintain our Exchange Policy but in the event we are unsuccessful, we may be forced to change to a return for credit memoranda policy.

In estimating Medicaid rebates, we match the actual rebates to the actual sales 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 current period sales to arrive at the rebate expense (allowance) for the period. In particular, we consider allowable prices by Medicaid. In estimating government chargeback allowances, we analyze actual chargeback amounts by product and apply historical chargeback rates to sales to which chargebacks apply, typically sales to the Veterans Administration and other U.S. government organizations. We continually assess our experience with Medicaid rebates and government chargebacks and adjust the allowances accordingly.

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

If actual product returns, government chargebacks, Medicaid rebates and cash discounts are greater than our estimates, or if our customers fail to adhere to our Exchange Policy, additional allowances may be required. To date, the actual amounts have approximated our estimates.

#### Inventories

We maintain inventory reserves primarily for obsolescence (due to the expiration of shelf life). In estimating inventory 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 inventory obsolescence. 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.

During fiscal year 2003, we acquired from Aventis for \$470,000 various materials (including Acthar API) which are needed to produce both Acthar final product and API. As of December 31, 2003, there was \$320,000 of the Aventis raw materials remaining in our inventory. The FDA approved our use of Aventis API in the production of Acthar final product until we have successfully transferred the production of API to a new contract manufacturer. This approval is conditioned on yearly testing of the API and the results meeting the current API specification. In the future, if we are successful in transferring the API production to our new contract manufacturer, BioVectra, we may write off certain of the remaining raw materials as excess inventory.

## Intangible Assets

We have intangible assets related to purchased technology, goodwill and other acquired intangibles. The determination of related estimated useful lives and whether or not these assets are impaired involves significant judgment. Changes in strategy and/or market conditions could significantly impact these judgments and require adjustments to recorded asset balances. In accordance with SFAS 144, 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 142, we review goodwill and other intangible assets with no definitive lives for impairment on an annual basis, using the two-step approach. To date, no impairment has been determined.

## **Results of Operations**

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

Total Revenues

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

Voore Ended

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 explained below.

#### Net Product Sales

		Years Ended December 31,		
	2003	2002	Increase/ (Decrease)	%
		(in \$000's)		
HP Acthar® Gel	\$ 7,973	\$ 9,009	\$(1,036)	(11)%
Nascobal®	2,099	_	2,099	100%
Ethamolin®	1,629	3,527	(1,898)	(54)%
VSL#3®	992	523	469	90%
Glofil®-125	887	732	155	21%
Inulin	75	28	47	167%
Total Net Product Sales	\$13,655	\$13,819	\$ (164)	(1)%

Net Product Sales by product as a percentage of total net product sales:

		Years Ended December 31,	
	2003	2002	
H.P. Acthar® Gel	58%	65%	
Nascobal®	15%	_	
Ethamolin®	12%	26%	
VSL#3®	7%	4%	
Glofil®-125	7%	5%	
Inulin	1%	_	
	<del></del>		
	100%	100%	
	_	_	

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

#### Acthar

For the year ended December 31, 2003, net product sales of Acthar decreased 11% from the year ended December 31, 2002. The lower sales of Acthar in fiscal year 2003 was partially the result of the replacement of expired vials of Acthar at no cost under our 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 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 and is expected to continue to displace sales as product expires and is subsequently replaced. 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 Exchange Policy for expired product, during fiscal year 2003 we replaced vials of Acthar which expired in November 2002 and May 2003. The next batches of Acthar expire in January 2004 and December 2004 and replacements for the expired Acthar relating to these batches will occur in fiscal year 2004 and fiscal year 2005. During fiscal year 2002 under our 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 a 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 Exchange Policy. The shipment of replacement product, at no cost to the customers, displaces future sales.

In fiscal year 2004, due to a continued shift in promotional efforts toward Nascobal and the return of supply of a preferred competing product for Acthar, we expect prescriptions for Acthar to drop below fiscal year 2003 levels. Our Acthar promotional efforts will be designed to support current prescribers of Acthar in neurology.

#### Nascobal

Nascobal sales commenced in July 2003. Based on the positive prescription trends of Nascobal in the fourth quarter of fiscal year 2003, we intend to add promotional resources to this product. As such, we expect revenue from Nascobal to increase in fiscal year 2004 and become a larger percentage of our total sales. We anticipate that as a percentage of total sales, Nascobal will increase and Acthar will decrease.

#### Ethamolin

For the year ended December 31, 2003, net product sales of Ethamolin decreased 54% from the year ended December 31, 2002, which was primarily the result of the large purchase of Ethamolin by wholesalers in anticipation of the price increase in June 2002 and shipment of backorders existing at December 31, 2001. Effective June 24, 2002, we increased our list price for Ethamolin. From the date of the notification of the price increase through June 30, 2002, we received \$1,560,000 of Ethamolin orders, which we believe were in excess of actual prescription needs and negatively impacted sales in the remainder of fiscal year 2002 and fiscal year 2003. The decrease of 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%. In fiscal year 2003 we did not actively promote Ethamolin and we do not expect to promote the product in fiscal year 2004.

## VSL#3

For the year ended December 31, 2003, net product sales of VSL#3 increased by \$469,000, to \$992,000, from \$523,000 for the year ended December 31, 2002. The increase was attributed to a full year of sales since VSL#3 was launched in May 2002.

## Glofil-125

For the year ended December 31, 2003, net product sales of Glofil-125 increased by \$155,000, to \$887,000, from net product sales of \$732,000 for the year ended December 31, 2002. The increase in net product sales was due in part to the CRIC study that began in 2003. The CRIC study is 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 and do not intend to actively promote it in the future.

Inulin

For the year ended December 31, 2003, sales of Inulin increased by \$47,000, to \$75,000, from \$28,000 for the year ended December 31, 2002. However, due to minimal demand and increasing cost of production, we discontinued marketing and selling Inulin in September 2003.

We are reviewing the amount of inventory at the wholesale level in order to help assess the demand for Acthar, Ethamolin and Nascobal in fiscal year 2004. Quarterly revenues will fluctuate based on buying patterns of the wholesalers, expiration dates of product sold and timing of shipment of replacement product under our Exchange Policy.

#### 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. 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 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. Cost of product sales includes material cost, packaging, warehousing and distribution, product liability insurance, royalties, quality control, quality assurance and write-offs of excess inventory. 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. We expect per unit material costs for Acthar to increase in the future due to higher contract manufacturing and laboratory costs. 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. A change in the mix of products we sold contributed to this change in the percentage of costs of product sales to net product sales. 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 distribute VSL#3 from our Union City facility. The decision to outsource these functions and close the Carlsbad facility resulted in reduced expense in the second half of 2003.

#### **Gross Margins**

	Years Ei Decembe	
Gross Margins	2003	2002
HP Acthar Gel	78%	83%
Nascobal	86%	_
Ethamolin	73%	81%
VSL#3	52%	61%
Glofil	50%	49%
Inulin	(88)%	(29)%
All products	74%	80%

Acthar and Ethamolin gross margins decreased due to the periodic stability testing required subsequent to manufacturing and the write-off and allowances from excessive inventory. The transfer of the manufacturing of Acthar from Aventis to new third party manufacturers will likely result in higher unit costs, which would result in a decrease of our gross margin on sales of Acthar. We commenced sales of Nascobal in July 2003. Inulin's gross margins decreased as a result of the write-off of inventory upon termination of the product offering. 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 greater quantities of Acthar and Ethamolin are produced and become subject to testing. Total gross margins have declined based upon the mix of products and the reduction of margins on some individual products. Gross margins do not include any allocation of the amortization of purchased technology for the related project. The amortization is included in the depreciation and amortization line item in operating expenses.

### Selling, General and Administrative

	Years Ended December 31,			
	2003	2002	Decrease	%
Selling, general and administrative expense	\$10,400	(in \$000's) \$10,825	\$(425)	(4)%
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 newer products Acthar, Nascobal and VSL#3 totaling approximately \$385,000 and other general and administrative costs. In addition, we had a headcount of 24 individuals to support the commercial sales of our five products as of December 31, 2003, compared to a headcount of 30 individuals to support the commercial sales of our five products as of December 31, 2002.

## **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. The costs included in research and development relate primarily to our manufacturing site transfers and medical and regulatory affairs compliance activities. In the year ended December 31, 2003, a third party contract laboratory performed several tests as part of our Acthar manufacturing site transfer. To date, this laboratory has been unsuccessful in validating the assay in order to

complete the transfer. Based in part on the results of these tests, we were not able to complete the transfer of the assay to a new contract laboratory. In the fourth quarter of fiscal 2003, we temporarily suspended the testing and instead completed a review of the results achieved to date. We performed an analysis of the variables involved that may have affected the validation of the assay. Beginning in fiscal year 2004, we will resume the testing necessary to transfer the assay to a new contract laboratory. 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. The costs related to the Acthar site transfer may fluctuate depending on the timing of work performed and the costs related to such 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 recorded to Research and Development.

In fiscal years 2003 and 2002, our spending on research and development programs was limited and will continue to be minimal in the future. As such, we are seeking to out-license the development of Emitasol (intransal 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 will be controlled by Fabre Kramer. The future development of Emitasol will be dependent 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 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 the 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 Ended December 31,			
	2003	2002	Increase/ (Decrease)	<b>%</b>
		(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% shareholders. 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. 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, 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 Stockholders 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 Stockholders waiving certain covenants until January 31, 2004, at which time we were in compliance.

Preferred Stock dividends of \$762,000 represent the 8% cash dividends paid to the Series B Preferred Stockholders. These dividends are required to be paid in cash quarterly. The Series B Preferred Stock was issued in January 2003.

## **Net Loss Applicable to Common Shareholders**

For the year ended December 31, 2003, we incurred a net loss applicable to common stockholders of \$5,947,000, or \$.14 per share, as compared to a net loss applicable to common stockholders 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 stockholders.

## Year Ended December 31, 2002 Compared to the Year Ended December 31, 2001

Total Revenues

	Year E Decemb			
	2002	2001	Increase/ (Decrease)	%
		(in \$000's)		
Net product sales	\$13,819	\$5,196	\$8,623	166%
Contract research, grant and royalty revenue	208	381	(173)	(45)%
Technology revenue	450	90	360	400%
Services revenue from a related party	200	_	200	_
Total revenues	\$14,677	\$5,667	\$9,010	159%

Total revenues for the year ended December 31, 2002 increased 159% from total revenues for the year ended December 31, 2001, primarily due to increases of 166% for net product sales and increases in technology revenue and services revenue from a related party as described below.

Net Product Sales

		Years Ended December 31,		
	2002	2001	Increase/ (Decrease)	%
		(in \$000's)		
HP Acthar® Gel	\$ 9,009	\$2,141	\$6,868	321%
Ethamolin®	\$ 3,527	\$1,695	1,832	108%
VSL#3®	523	_	523	_
Glofil®-125	732	982	(250)	(25)%
Inulin	28	317	(289)	(91)%
$Neoflo^{TM}$		61	(61)	_
Total Net Product Sales	\$13,819	\$5,196	\$8,623	166%

Net Product Sales by product as a percentage of total net product sales:

		rs Ended ember 31,
	2002	2001
H.P. Acthar® Gel	65%	41%
Ethamolin®	26%	33%
VSL#3®	4%	<u> </u>
Glofil®-125	5%	19%
Inulin	_	6%
Neoflo <sup>TM</sup>	_	1%
	_	
	100%	100%
	_	

For the year ended December 31, 2002, net product sales increased by \$8,623,000, or 166%, to \$13,819,000 from \$5,196,000 for the year ended December 31, 2001. The increase in net product sales was due primarily to increased unit sales of Ethamolin and a full year of sales of Acthar, which was introduced in the third quarter of 2001.

During 2002 under our Exchange Policy we shipped replacement units for expired product with an estimated sales value of \$123,000 calculated using unit prices in effect at December 31, 2002.

#### **Acthar**

Acthar net product sales increased by \$6.9 million in fiscal year 2002, from the net product sales in fiscal year 2001. The increase was primarily the result of a full year of Acthar sales in fiscal year 2002 as the product was introduced in the third quarter of fiscal year 2001. The increase of unit sales over the prior year was also partially due to a shipment in early 2002 of backorders outstanding as of December 31, 2001 totaling \$334,000.

#### **Ethamolin**

Ethamolin net product sales increased by \$1.8 million, or 108%, in fiscal year 2002 as compared to fiscal year 2001. The increase was primarily due to the strategic buying by our customers in June 2002. 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. The increase of unit sales over the prior year was also partially due to a shipment in early 2002 of backorders outstanding as of December 31, 2001, totaling \$408,000.

#### VSL#3

We commenced sales of VSL#3 in May 2002, and thus there were no sales in fiscal year 2001.

#### Glofil-125

Glofil-125 net product sales decreased 25% in fiscal year 2002, as compared to fiscal year 2001.

#### Inulin

Inulin net product sales decreased 91% in fiscal year 2002 as compared to fiscal year 2001. Due to manufacturing issues that developed in fiscal year 2002, Inulin was not available for sale for part of fiscal year 2002 resulting in the decrease in sales from fiscal year 2001.

#### Neoflo

Neoflo was discontinued as a product in fiscal year 2001.

## Contract Research, Royalty and Grant Revenue

Contract research, royalty and grant revenue decreased by \$173,000, or 45%, to \$208,000 for the year ended December 31, 2002 from \$381,000 for the year ended December 31, 2001. This decrease was primarily the result of receiving less reimbursement under our SBIR grant due to a decrease in activity with our GERI compound research project during the year ended December 31, 2002.

## Technology Revenues and Services Revenue from a Related Party

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. For the year ended December 31, 2001, we recognized \$90,000 in technology revenue related to a payment under our license agreement with Tularik, Inc. for the sale of our antifungal drug discovery program. This license agreement expired in accordance with its terms in June 2002. 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 for certain promotional activities we undertook to support the launch of VSL#3.

# **Cost of Product Sales**

Cost of product sales increased to \$2,822,000, or 43%, for the year ended December 31, 2002 from \$1,978,000 for the year ended December 31, 2001. This increase was primarily a result of greater material costs due to higher product sales for the current period. However, cost of product sales as a percentage of net

product sales decreased to 20% for the year ended December 31, 2002 from 38% for the year ended December 31, 2001, primarily due to a change in product mix.

#### **Gross Margins**

		Years Ended December 31,	
Gross	Margins 2002	2 2001	
HP Acthar® Gel	83	3% 73%	
Ethamolin®	81	1% 71%	
VSL#3®	61	1% —	
Glofil®-125	49	9% 49%	
Inulin	(29	9)% 48%	
Total all products	80	0% 62%	

Gross margins for the products other than VSL#3 and Inulin improved as a result of increased sales volume and product price increases in fiscal year 2002. Inulin's gross margin decreased as a result of low sales volume coupled with increased cost of product. VSL#3 was formally launched in May 2002.

#### Selling, General and Administrative

	Years Ended December 31,			
	2002	2001	Increase	%
Selling, general and administrative	\$10,825	(in \$000's) \$7,836	\$2,989	38%
Percent of total revenues	74%	138%		_

Selling, general and administrative expenses for the year ended December 31, 2002 increased 38% from the year ended December 31, 2001. However, as a percentage of revenue, selling, general and administrative expenses decreased to 74% for the year ended December 31, 2002 from 138% for the year ended December 31, 2001. The increase in dollars is primarily due to increased salary and other costs of \$1,361,000 associated with the expansion of our sales and marketing departments, increased marketing costs of \$1,151,000 to support our newer products, Acthar and VSL#3, and increased general and administrative costs. We had a headcount of 30 individuals to support the commercial sales of our five products as of December 31, 2002, compared to a headcount of 20 individuals to support the commercial sales of our four products as of December 31, 2001. The percentage of selling, general and administrative expenses for the year ended December 31, 2002 decreased to 74% of total revenues due to the increase overall in revenues discussed above.

## Research and Development

Research and development expenses, which are limited to manufacturing, regulatory and medical affairs compliance activities, for the year ended December 31, 2002 were \$2,295,000, which represents a decrease of \$57,000, or 2%, as compared to \$2,352,000 for the year ended December 31, 2001. The decrease was primarily due to lower salary and associated expenses related to our research and development activities, offset by increased manufacturing site development costs related to the Acthar site transfer. The manufacturing site development costs incurred for the year ended December 31, 2002 relate primarily to site transfer and validation costs for Acthar.

#### **Depreciation and Amortization**

Depreciation and amortization expense decreased by 48% to \$1,138,000 for the year ended December 31, 2002 from \$2,207,000 for the year ended December 31, 2001, primarily due to minimal purchases made in fiscal year 2002, as well as assets becoming fully depreciated in the period and a portion of purchased technology becoming fully amortized in fiscal year 2002.

#### Other Income and Expense Items

		Ended ber 31,		
	2002	2001	Increase/ (Decrease)	%
		(in \$000's	)	
Non-cash amortization of deemed discount on convertible				
debentures	\$(415)	\$ —	\$ 415	_
Interest income	307	520	(213)	(41)%
Interest expense	(315)	(465)	(150)	(32)%
Other income	120	29	91	314%
Other expense	(361)	(10)	351	3,510%
Rental income, net	282	612	(330)	(54)%

Non-cash amortization of deemed discount on convertible debentures for the year ended December 31, 2002 was \$415,000 pertaining to amortization of the deemed discount related to the convertible debentures. There was no similar expense in the year ended December 31, 2001.

Interest income for the year ended December 31, 2002 decreased by 41% from the year ended December 31, 2001, primarily due to a lower return on invested cash. Interest expense decreased by 32% for the year ended December 31, 2002 as compared to the year ended December 31, 2001 due to lower debt levels.

Other income for the year ended December 31, 2002 increased by \$91,000 from the year ended December 31, 2001. 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% shareholders. Other expense increased by \$351,000 for the year ended December 31, 2002 as compared to the year ended December 31, 2001, primarily due to a \$367,000 other-than-temporary loss taken on our Rigel equity securities investment.

Rental income, net, for the year ended December 31, 2002 decreased \$330,000 from the year ended December 31, 2001. The decrease was primarily due to the receipt in 2001 of a sublease termination fee of \$130,000 by the former sublessor of our Carlsbad facility and a \$250,000 payment receipt for vacating our Hayward facility in May 2001.

## **Net Loss and Net Loss Applicable to Common Shareholders**

For the year ended December 31, 2002, we incurred a net loss applicable to common stockholders of \$2,785,000 or \$0.07 per share, as compared to a net loss applicable to common stockholders of \$8,697,000 or \$0.28 per share for the year ended December 31, 2001, a decrease of \$5,912,000 or 68%. As there were no dividends payable in fiscal year 2002 or fiscal year 2001 the net loss applicable to common stockholders is the same as the net loss for those years. The lower net loss is primarily the result of higher total revenues offset by increased operating costs and expenses.

### **Liquidity and Capital Resources**

We have principally funded our activities to date through various issuances of equity securities. Through March 22, 2004, we have raised total net proceeds of \$63.0 million through various issuances of equity securities.

		As of December 31,		
Liquidity and Capital Resources	2003	2002	2001	
		(in \$000's)		
Cash, cash equivalents and short-term investments (includes				
compensating balances of \$5,000,000 at December 31, 2001)	\$ 3,220	\$ 7,506	\$10,571	
Working capital	\$ 4,352	\$ 7,018	\$ 2,659	
Cash provided by/(used in):				
Operating activities	\$ (3,346)	\$(1,836)	\$ (4,966)	
Investing activities	\$(13,273)	\$(1,423)	\$ 551	
Financing activities	\$ 13,683	\$ (768)	\$ 7,780	

At December 31, 2003, we had cash, cash equivalents and short-term investments of \$3,220,000 compared to \$7,506,000 at December 31, 2002. In January 2004, we raised an additional \$2.4 million through the private placement of common stock for cash and the surrender of outstanding warrants. At December 31, 2003, our working capital was \$4,352,000 compared to \$7,018,000 at December 31, 2002. The decrease in working capital was primarily due to the \$14.3 million we paid in fiscal year 2003 for the purchase of Nascobal and funds used in operations, offset by net proceeds from the issuance of \$10 million of Series B Convertible Preferred Stock in January 2003 and a \$5 million private placement of common stock and warrants in June 2003.

We used cash generated from product sales and other revenue, proceeds from stock issuances and matured short-term investments, and cash and short-term investments on hand at the beginning of the year to fund operations, acquire Nascobal, acquire short-term investments and for capital expenditures during fiscal year 2003.

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

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 "short remittances" for expired product of \$344,000 and inventory increased primarily due to the purchase of Acthar raw materials from Aventis for \$470,000. Our goal is to increase net product sales in fiscal year 2004 over fiscal year 2003 levels while maintaining operating costs and expenses at a level that is consistent with that of 2003.

The operating loss in fiscal year 2003 included cash outlays for the Acthar manufacturing site transfer We expect to incur substantial future cash outlays for the Acthar site transfer. The site transfer process is not complete and may require substantial cash outlays for the work performed, capital expenditures and inventory, prior to the transfer being complete.

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.

During fiscal year 2001 net cash of \$5.0 million was used to fund operating activities. The major use of cash was the funding of the net loss of \$8.7 million. Also contributing to the use of cash was the increase in accounts receivables due to higher sales in fiscal year 2001 compared to fiscal year 2000, reduction of accrued

development costs offset by increasing liabilities at December 31, 2001 including higher accounts payable and accrued compensation.

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

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 investing activities was \$551,000 for fiscal year 2001, primarily the result of proceeds from sales of short-term investments of \$499,000 and increases in deposits and other assets offset by purchases of property, equipment and leasehold improvements of \$183,000.

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

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 repayments of short-term and long-term debt of \$664,000.

Net cash was used in financing activities of \$768,000 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 of \$1,522,000.

Net cash was provided from financing activities of \$7.8 million for fiscal year 2001. This was primarily the result of net proceeds from the issuance of common stock and warrants of \$7.3 million and the net proceeds of \$960,000 from common stock to be issued offset by repayments of short-term debt, long-term debt and capital lease obligations of \$470,000.

## Cash and cash equivalents at December 31, 2003

Total net cash flows for fiscal year 2003 resulted in a net decrease of cash and cash equivalents of \$2.9 million for fiscal year 2003. The cash and cash equivalents at December 31, 2003 are \$3.2 million. In January 2004, we entered into agreements with existing shareholders to issue common stock in exchange for \$2.4 million and the surrender of outstanding warrants.

#### **Contractual Obligations**

			Payments Due by Period	l	
	Total	1 Year or Less	Greater than 1 to 3 Years	4 to 5 Years	After 5 Years
			(In thousands)		
Short-term debt(1)	\$ 140	\$ 140	\$ —	\$ —	\$ —
Convertible debentures(2)	4,000	_	4,000	_	_
Operating leases(3)	12,193	1,747	2,868	2,709	4,869
Contingent milestone payments for Nascobal spray(4)	4,000	_	4,000	_	_
Minimum payments remaining under supply agreement					
with BioVectra(5)	1,605	458	1,147	_	_
Annual employment agreement with CEO(6)	458	458	_	_	_
Purchase orders(7)	203	203	_	_	_
Total contractual cash obligations	\$22,599	\$3,006	\$12,015	\$2,709	\$4,869

- (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 2004.
- (2) In March 2002, we issued \$4.0 million of 8% convertible debentures to an institutional investor and Defiante Farmaceutica Unipessoal L.D.A. ("Defiante"), a wholly-owned subsidiary of Sigma-Tau Finanzaria S.p.A. ("Sigma-Tau"). We will pay interest on the debentures at a rate of 8% per annum on a quarterly basis. The debentures are convertible into 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). The debentures mature on March 15, 2005.

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) We lease four buildings with lease terms expiring in 2004 to 2012. Annual rent expense for all of our facilities, equipment and automobile leases in fiscal year 2003 were approximately \$1,885,000. We lease our headquarters in Union City, California, with 23,000 square feet of office space under a lease agreement that expires in 2012. Our headquarters is currently occupied by our Executive, Finance and Administration, Sales and Marketing, Medical and Regulatory Affairs, distribution of VSL#3, Contract Manufacturing, and Quality Control and Quality Assurance departments. Annual rent payments for fiscal year 2004 for this facility are \$485,000.

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 is now distributed from our Union City facility. During fiscal year 2003, we subleased 100% of the Carlsbad facility under two separate subleases expiring in January 2006 and January 2005. We anticipate that we will receive \$149,000 in fiscal year 2004 as sublease income to be used to pay the annual rent of \$228,000.

We have subleased laboratory space in Hayward, California for a term of six years and anticipate that we will receive \$1,048,000 in fiscal year 2004 as sublease income to be used to pay the annual rental expense of \$697,000. Our facility in Lee's Summit, Missouri was closed in May 2001 and this facility has been subleased. Lease payments for the facility in Lee's Summit, Missouri are \$138,000 for fiscal year 2004 and we anticipate \$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.

- (4) In connection with our acquisition of Nascobal, we are also acquiring rights to Nascobal nasal spray, an improved dosage form, for which an NDA was filed by Nastech with the FDA in December 2003. Subject to the approval of the NDA for the new Nascobal nasal spray dosage form by the FDA, we will be required to make a \$2 million payment for the transfer of the NDA from Nastech to us. We understand that the FDA's target for review and action on NDA applications is ten months from the date of submission. Hence the NDA could be approved as early as the fourth quarter of 2004; however, we believe that the final approval is more likely to occur in the first half of fiscal year 2005. Further, subject to the approval of the NDA for the new Nascobal nasal spray dosage form and upon issuance of a U.S. patent for the new Nascobal nasal spray dosage form, we will be required to make a second \$2 million payment. A provisional patent application for Nascobal nasal spray has been filed.
- (5) We have signed an agreement with BioVectra dcl to produce the API used in Acthar. The agreement requires minimum production totaling \$1.7 million during the term. During fiscal year 2003, we paid \$115,000 under this agreement. The agreement terminates in December 2007 and includes two one-year extension options. The production of the first batch of API is scheduled to begin in 2004.
- (6) In August 1999, we entered into an employment agreement with Charles J. Casamento, our Chairman, President and Chief Executive Officer. The agreement automatically renews annually. The agreement provides for an annual base salary of \$341,250 prior to January 1, 2000, and an annual base salary of not less than \$375,000 thereafter, subject to annual review and increases. In January 2003, Mr. Casamento's annual base salary was increased to \$458,500. The Employment Agreement provides Mr. Casamento with the opportunity to receive an additional annual bonus for each fiscal year with us. The amount of the bonus opportunity is 50% of the annual rate of base salary, and our Board of Directors determines the objectives which Mr. Casamento must achieve to receive all or a portion of this bonus opportunity for each fiscal year with us. The employment agreement also provides that, in the event Mr. Casamento's employment is terminated without cause, he will receive, as severance, continued payment of his then base salary for twenty four months and a pro-rated portion of his annual bonus following such termination. In addition, Mr. Casamento would be entitled to receive Questcor paid insurance coverage for 24 months and coverage at his election and expense for an additional 24 months thereafter.
- (7) Purchase orders issued as of December 31, 2003 for which the goods have not yet been received or the services not yet rendered.

Messrs. Morris and Beers are each party to agreements 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, such employees would be entitled to receive Company paid insurance coverage for 12 months and coverage at their election and expense for an additional 15 months. In the event Mr. Morris is terminated other than for cause without a change in control, he would receive a lump sum severance payment equal to nine months base salary and the continuation of health and medical benefits for nine months.

As of December 31, 2003 we had an agreement with a bank for a revolving accounts receivable line of credit for a maximum of \$3,000,000 secured by a blanket lien on all of our assets including intellectual property. There were no borrowings under the line of credit during 2003 and in January 2004 we terminated the agreement and the blanket lien was released.

#### **Equity Transactions**

#### Equity Transactions in Year Ended December 31, 2001

In April 2001, we entered into a Stock and Warrant Purchase Agreement with Sigma-Tau Finance Holding S.A. ("Sigma-Tau") pursuant to which Sigma-Tau purchased (i) an aggregate of 2,873,563 shares of common stock at a purchase price of \$0.52 per share, for an aggregate purchase price of \$1,500,000, and (ii) a warrant to purchase an additional 2,873,563 shares of common stock at a purchase price of \$0.52 per share. In May 2001, as required under the rules of AMEX, we sought and received shareholder approval to allow for full exercise of the warrant. In July 2001, Sigma-Tau assigned the warrant to Paolo Cavazza and Claudio Cavazza, the principal shareholders of Sigma-Tau, who exercised the warrant in full, purchasing 2,873,563 shares of common stock at a purchase price of \$0.52 per share, resulting in aggregate proceeds to us of \$1,500,000 (including the \$100,000 originally paid by Sigma-Tau to acquire the warrant).

In April 2001, we closed a financing with various accredited investors which totaled \$442,000. This investment came from a group of individual investors. We 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 equal to \$0.64 per share. The warrants are exercisable from the date of issuance until the close of business on April 30, 2006.

In July 2001, concurrent with our agreement to acquire Acthar from Aventis, we entered into a Stock Purchase Agreement with Sigma-Tau pursuant to which Sigma-Tau purchased 5,279,034 shares of common stock at a purchase price of \$0.66 per share, for an aggregate purchase price of \$3,500,000.

In December 2001, we entered into a Promotion Agreement effective in January 2002 with VSL Pharmaceuticals, Inc., 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. In connection with this Promotion Agreement, we 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 our 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 before December 1, 2003. The warrants expired on December 1, 2003 without exercise. We issued the common stock related to this transaction in February 2002.

#### 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. The debentures mature on March 15, 2005. 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. Assuming the conversion of the abovementioned debenture by Sigma-Tau, Sigma-Tau would own approximately 28% of our outstanding voting capital stock as of March 22, 2004.

#### 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 antidilution 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. 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 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 Subsequent to December 31, 2003

In January 2004 we entered into agreements with existing shareholders to issue 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 warrants surrendered represented approximately 46% of the warrants outstanding as of December 31, 2003. The warrants surrendered were included as consideration at their 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 for the five trading days prior to the agreement to the terms of the transaction.

#### **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, 2003, together with the \$2.4 million of cash raised in our January 2004 private placement of common stock, and the net cash flows generated from operations, will be sufficient to fund operations through at least December 31, 2004, unless a substantial portion of our cash is used for product acquisition or our 2004 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 payments to Nastech relating to 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 are unable to maintain compliance with certain covenants and thus avoid the payment of additional dividends of 6% to the holders of the Series B Convertible Preferred Stock, or we do not have sufficient funds to make the contingent payments, if, and when due to Nastech for 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 in addition to the equity financing raised in January 2004. However, traditional asset based financing does not appear to be available at this time. 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, 2003, we had federal and state net operating loss carryforwards of approximately \$98 million and \$27 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 2004 through 2023, if not utilized.

## **Recently Issued Accounting Standards**

In May 2003, the Financial Accounting Standards Board (the "FASB") issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." This Statement establishes new standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). This Statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS No. 150 on July 1, 2003 did not have a material impact on our results of operations or financial position as of December 31, 2003.

In January 2003, the FASB issued Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities." FIN 46 requires that if an entity has a controlling financial interest in a variable interest entity, the assets, liabilities and results of activities of the variable interest entity should be included in the consolidated financial statements of the entity. FIN 46 as amended must be applied for interim or annual reporting periods ending after March 15, 2004, and is effective immediately for all new variable interest entities created or acquired after January 31, 2003. The adoption of FIN 46 did not impact our results of operations or financial position as of December 31, 2003, as we are not a party to any variable interest entities.

In July 2002, the FASB issued Statement of Financial Accounting Standards No. 146 ("SFAS No. 146"), "Accounting for Costs Associated with Exit or Disposal Activities." SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies EITF Issue No. 94-3 ("EITF 94-3"), "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)". The principal difference between SFAS No. 146 and EITF 94-3 relates to SFAS No. 146's timing for recognition of a liability for a cost associated with an exit or disposal activity. SFAS No. 146 requires that a liability for an exit cost associated with an exit or disposal activity be recognized when the liability is incurred. Under EITF 94-3 a liability for an exit cost, as generally defined in EITF 94-3, was recognized at the date of an entity's commitment to an exit plan. SFAS No. 146 is effective for exit or disposal activities that are initiated after December 31, 2002. During the year ended December 31, 2003, we transferred certain functions previously performed at our Carlsbad, California facility (distribution, quality control and quality assurance) to third party contractors or to our Union City headquarters. Consequently, during fiscal year 2003, we entered into sublease agreements with two sublessees for the Carlsbad facility. We recognized losses relating to the lease totaling \$171,000 in fiscal year 2003. The loss associated with the Carlsbad leases is included in research and development in our consolidated statements of operations.

## 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 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, 2003 and 2002.

	2003	Total	Fair Value 12/31/03
	(In thou except ir rate	iterest	
ASSETS			
Cash and cash equivalents	\$3,220	\$3,220	\$3,220
Average interest rate	1.13%	_	_
LIABILITIES			
Notes payable — short-term	\$ 140	\$ 140	\$ 140
Average interest rate	7.64%		_
Convertible debentures	\$4,000	\$4,000	\$4,000
Average interest rate	8%	_	_
	2002	Total	Fair Value 12/31/02
	(In thou except in rate	iterest	
ASSETS		,	
Cash and cash equivalents	\$7,506	\$7,506	\$7,506
Average interest rate	1.63%	_	_
LIABILITIES			
Notes payable — short-term	\$ 218	\$ 218	\$ 218
Average interest rate	10.31%	_	_
Convertible debentures	\$4,000	\$4,000	\$4,000
Average interest rate	8%		_

#### 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 Chief Financial 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 Chief Financial 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 Chief Financial 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.

## PART III.

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

The information required is hereby incorporated by reference from the information contained in our definitive proxy statement (the "Proxy Statement") with respect to our 2004 Annual Meeting of Shareholders, filed with the Commission pursuant to Regulation 14A under the headings "Nominees," "Company Management," "Code of Business Conduct and Ethics" and "Section 16(A) Beneficial Ownership Reporting Compliance."

## Item 11. Executive Compensation

The information required by this item is hereby incorporated by reference from information contained in the Proxy Statement under the heading "Compensation of Directors and Executive Officers."

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

The information required by this item is hereby incorporated by reference from information contained in the Proxy Statement under the heading of "Security Ownership of Certain Beneficial Owners and Management."

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

The information required by this item is hereby incorporated by reference from information contained in the Proxy Statement under the heading "Certain Relationships and Related Transactions" and "Executive Compensation."

## Item 14. Principal Accountant Fees and Services

The information required by this item is hereby incorporated by reference from information contained in the Proxy Statement under the heading "Ratification of Selection of Independent Auditors."

## 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 Ernst & Young LLP, Independent Auditors, are included in Part IV of this Report on the pages indicated:

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Consolidated Statement of Stockholders' Equity	62
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- 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 October 21, 2003, we furnished on Form 8-K, under Item 9, our press release of our results for the quarter ended September 30, 2003.

# (c) Exhibits

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.,
	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.

Exhibit Number	Description
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 L.D.A. 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.
10.4(9)	Employment Agreement dated as of August 4, 1999 between the Company and Charles J. Casamento.
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.†
10.8(11)	Promotion Agreement dated December 1, 2001 between the Company and VSL Pharmaceuticals, Inc.†
10.9(11)	First Amendment to Promotion Agreement dated June 27, 2002 between the Company and VSL Pharmaceuticals, 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 L.D.A. dated March 15, 2002.
10.17(6)	Registration Rights Agreement between the Company and Defiante Farmaceutica Unipessoal L.D.A. dated March 15, 2002.
10.18(6)	Warrant between the Company and Defiante Farmaceutica Unipessoal L.D.A. 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.
10.20(14)	Amendment to Employment Agreement between the Company and Charles J. Casamento dated March 21, 2003.
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.
10.23(14)	Letter Agreement dated May 2, 2000 between the Company and Kenneth R. Greathouse.
10.24(14)	Amendment to Letter Agreement dated March 21, 2003 between the Company and Kenneth R. Greathouse.
10.25(14)	Letter Agreement dated August 24, 2001 between the Company and Timothy E. Morris.
10.26(14)	Amendment to Letter Agreement dated November 7, 2001 between the Company and Timothy E. Morris.
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Exhibit Number	Description
10.27(14)	Amendment to Letter Agreement dated March 21, 2003 between the Company and Timothy E. Morris.
10.28*	Letter Agreement dated September 2, 2003 between the Company and R. Jerald Beers.
10.29*	Amendment to Letter Agreement dated November 6, 2003 between the Company and R. Jerald Beers.
10.30*	Supply Agreement dated April 1, 2003 between the Company and BioVectra, dcl.
23.1*	Consent of Ernst & Young LLP, Independent Auditors.
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.

- (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, 2002, 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.

By

QUESTCOR PHARMACEUTICALS, INC.

/s/ CHARLES J. CASAMENTO

Charles J. Casamento
Chairman, President and Chief Executive Officer

Dated: March 30, 2004

#### **POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Charles J. Casamento and Timothy E. Morris, 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/ CHARLES J. CASAMENTO	Chairman, President and Chief Executive Officer and Director (Principal Executive Officer)	March 30, 2004
Charles J. Casamento	,	
/s/ TIMOTHY E. MORRIS	Senior Vice President, Finance & Administration and Chief Financial Officer (Principal Financial and	March 30, 2004
Timothy E. Morris	Accounting Officer)	
/s/ NEAL C. BRADSHER	Director	March 30, 2004
Neal C. Bradsher		
/s/ BRIAN C. CUNNINGHAM	Director	March 30, 2004
Brian C. Cunningham		
/s/ FRANK J. SASINOWSKI	Director	March 30, 2004
Frank J. Sasinowski		
/s/ JON S. SAXE	Director	March 30, 2004
Jon S. Saxe		
/s/ ROGER G. STOLL	Director	March 30, 2004
Roger G. Stoll, Ph.D.		
/s/ VIRGIL D. THOMPSON	Director	March 30, 2004
Virgil D. Thompson		
	58	

#### REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Stockholders

Questcor Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Questcor Pharmaceuticals, Inc. as of December 31, 2003 and 2002, and the related consolidated statements of operations, preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2003. 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 auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Questcor Pharmaceuticals, Inc. at December 31, 2003 and 2002, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States. 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.

As discussed in Note 1 to the consolidated financial statements, in 2002 the Company changed its method of accounting for goodwill and other intangible assets.

/s/ Ernst & Young LLP

Palo Alto, California

February 12, 2004

# CONSOLIDATED BALANCE SHEETS

	Decem	iber 31,
	2003	2002
		nds, except
ASSETS	share a	mounts)
Current assets:		
Cash and cash equivalents	\$ 3,220	\$ 6,156
Short-term investments	_	1,350
Accounts receivable, net of allowance for doubtful accounts of \$60		
and \$20 at December 31, 2003 and 2002, respectively	2,161	1,590
Inventories	1,050	391
Prepaid expenses and other current assets	873	979
Total current assets	7,304	10,466
Property and equipment, net	609	585
Purchased technology, net	13,709	382
Goodwill and other indefinite lived intangible assets	479	479
Deposits and other assets	828	854
Total assets	\$ 22,929	\$ 12,766
		<b>4</b> ==,: 00
LIABILITIES AND STOCKHOLDERS' I Current liabilities:	EQUITY	
Accounts payable	\$ 1,402	\$ 1,230
Accrued compensation	358	794
Other accrued liabilities	1,052	1,205
Short-term debt and current portion of long-term debt	140	218
Current portion of capital lease obligations		1
Current portion of capital rease obligations		
Total current liabilities	2,952	3,448
Convertible debentures, (face amount of \$4,000), net of deemed		
discount of \$598 and \$1,092 at December 31, 2003 and 2002,		
respectively	3,402	2,908
Other non-current liabilities	916	833
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, 2003 and 2002 (aggregate liquidation preference of \$10,000 at December 31,		
2003 and 2002)	5,081	5,081
Stockholders' equity:		
Preferred stock, no par value, 9,100 Series B shares issued and		
outstanding, net of issuance costs (aggregate liquidation preference of \$9,100) at December 31, 2003	8,278	
Common stock, no par value, 105,000,000 shares authorized;	0,270	
45,387,802 and 38,676,592 shares issued and outstanding at		
December 31, 2003 and 2002, respectively	85,232	77,528
Deferred compensation	(17)	(22
Accumulated deficit	(82,915)	(76,968
Accumulated other comprehensive loss	_	(42
Total stockholders' equity	10,578	496
Total liabilities and stockholders' equity	\$ 22,929	\$ 12,766
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See accompanying notes.

# CONSOLIDATED STATEMENTS OF OPERATIONS

 -	 Docom	~ -	

2001
are
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See accompanying notes.

# CONSOLIDATED STATEMENTS OF PREFERRED STOCK

# AND STOCKHOLDER'S EQUITY

## Preferred Stock

				C			Accumulated Other Comprehensive Gain/(Loss)	Total Stockholders Equity/(Deficit)		
	Serie Shares	Series A Series B es Amount Shares Amount		Common	Common Stock  ———— Deferred  Shares Amount Compensation					
						n thousands.	except shares)			
Balances at December 31, 2000	2,155,715	\$5,081	_	s —	25,303,091	\$66,152	\$(71)	\$(65,486)	\$ 332	\$ 927
Deferred compensation offset by cancellation of unvested options to a director	2,135,713	ψ3,001		Ψ	23,303,031	(26)	26	\$(03,400)	\$ 332	Ψ 32/
Stock compensation for options and warrants	_	_	_	_	_		20	_	_	_
granted to consultants Amortization of deferred compensation	_	_	_	_	_	601	— 25	_	_	601
Issuance of shares pursuant to employee stock		_	_	_			23	_	_	
purchase plan Issuance of common stock to investors, net of issuance	_	_	_	_	193,214	112	_	_	_	112
costs Issuance of common stock	_	_	_	_	8,969,397	5,270	_	_	_	5,270
upon exercise of warrant Issuance of common stock	_	_	_	_	2,873,563	1,500	_	_	_	1,500
upon exercise of stock options Warrant issuances for cash	_	_	_	_	50,338 —	58 351	_	_	_	58 351
Comprehensive income (loss) Net unrealized loss on						301				
investments Net loss	_	_	_	_	_ _	_	_ _	(8,697)	(447) —	(447) (8,697)
Total comprehensive loss:	_	_	_	_	_	_	_	_	_	(9,144)
Balances at December 31,	2.455.545				27 200 602		(20)	(74.402)	(445)	(200)
2001 Deemed discount on	2,155,715	5,081			37,389,603	74,018	(20)	(74,183)	(115)	(300)
convertible debentures Stock compensation for options and warrants		_	_	_	_	1,484	_	_	_	1,484
granted to consultants Deferred compensation	_	_			_	405 19	— (19)			405
Amortization of deferred compensation	_	_	_	_	_		17	_	_	17
Issuance of shares pursuant to employee stock purchase plan		_	_		313,114	146	17	_	_	146
Issuance of common stock to										
investors Issuance of common stock upon exercise of stock options	_				640,000 355,432	960			_	960 414
Cancellation of shares Warrant issuances associated with convertible				=	(21,557)	_	_	_		717
debentures Comprehensive income (loss)	_	_	_	_	_	82	_	_	_	82
Other-than-temporary loss on investments	_	_	_	_	_	_	_	_	367	367
Net unrealized loss on investments	_	_	_	_	_	_	_	_	(294)	(294)
Net loss  Total comprehensive	_	_	_	_	_	_	_	(2,785)	_	(2,785)
loss:							_		_	(2,712)
Balances at December 31, 2002	2,155,715	5,081	_	_	38,676,592	77,528	(22)	(76,968)	(42)	496
Stock compensation for options and warrants granted to consultants and employees	_	_	_	_	_	50	_	_	_	50
Deferred compensation Amortization of deferred	_	_	_	_	_	15	(15)	_	_	_
compensation Issuance of shares pursuant	_	_	_	_	_	_	20	_	_	20
to employee stock purchase plan Issuance of common stock to	_	_	_	_	93,123	68	_	_	_	68
investors Issuance of common stock upon cashless exercise of	_	_	_	_	4,979,360	4,826	_	_	_	4,826
warrant Issuance of common stock upon exercise of stock			_	_	387,995	_	_	_	_	_
options	_	_	_	_	273,962	212	_	_	_	212

Issuance of Series B preferred 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			(000)		056 005					
Series B preferred stock Issuance of common stock upon conversion of accrued dividends for	_	_	(900)	(900)	956,225	900	_	_	_	_
Series B preferred stock	_	_	_	_	20,545	13	_	_	_	13
Deemed dividends on Series B preferred stock	_	_	_	1,394	_	_	_	(1,394)	_	_
Dividends recorded	_	_	_	/- <u>-</u>	_	_	_	(762)	_	(762)
Comprehensive income (loss)										
Other-than-temporary loss on investments	_	_	_	_	_	_	_	_	51	51
Reclassification of net unrealized loss on investments into										
realized loss	_	_	_	_	_	_	_	_	(9)	(9)
Net loss	_	_	_	_	_	_	_	(3,791)	_	(3,791)
Total comprehensive loss:	_	_	_	_	_	_	_			(3,749)
										<u> </u>
Balances at December 31, 2003	2,155,715	\$5,081	9,100	\$ 8,278	45,387,802	\$85,232	<b>\$</b> (17)	\$(82,915)	\$ —	\$10,578
									_	

See accompanying notes.

# CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,			
	2003	2002	2001	
		(In thousands)		
Cash Flows Used in Operating Activities	ф. (D. 704)	# (D EOE)	# (O. COT)	
Net loss	\$ (3,791)	\$ (2,785)	\$ (8,697)	
Adjustments to reconcile net loss to net cash used in operating activities:	75	201	CO1	
Stock-based compensation expense  Amortization of deemed discount on convertible debentures	75 522	381 415	601	
Amortization of deferred compensation	20	17	25	
Depreciation and amortization	1,157	1,138	2,207	
Other-than-temporary loss on investment	51	367	2,207	
Loss (gain) on the sale/disposal of equipment	26	(37)	43	
Loss (gain) on the sale of investment	14	(37)	43	
Loss on discontinued product line	14	<u>—</u>	677	
Write down of licenses and patents	_	_	81	
Changes in operating assets and liabilities:	<del></del>	<u>—</u>	01	
Accounts receivable	(F71)	(022)	(407)	
	(571)	(932)	(487)	
Inventories	(596)	(295)	(40)	
Prepaid expenses and other current assets	81	(509)	112	
Accounts payable	172	135	619	
Accrued compensation	(436)	219	183	
Accrued development costs	<u> </u>		(541)	
Other accrued liabilities	(153)	149	136	
Other non-current liabilities	83	(99)	115	
	(2.2.48)			
Net cash used in operating activities	(3,346)	(1,836)	(4,966)	
Cash flows from Investing Activities				
Acquisition of purchased technology	(14,289)	<del>-</del>	_	
Purchase of short-term investments	(3,009)	(1,261)		
Proceeds from the sale and maturities of short-term investments	4,337		499	
Purchase of property, equipment and leasehold improvements	(334)	(355)	(183)	
Proceeds from the sale of equipment	24	51	44	
Increase (decrease) in deposits and other assets	(2)	142	191	
Net cash (used in) provided by investing activities	(13,273)	(1,423)	551	
Cash Flows from Financing Activities	(13,273)	(1,423)	331	
Issuance of common stock and warrants, net	5,106	560	7 200	
	5,100	300	7,290 960	
Net proceeds from common stock to be issued	9,404	_	900	
Issuance of preferred stock, net Payment of preferred stock dividends	(749)	<del>-</del>	_	
Issuance of convertible debentures	(749)	4 000	_	
	 587	4,000	_	
Short-term borrowings	367	1,251	_	
Repayment of short term and long term daht	(664)	(5,000)	(202)	
Repayment of short-term and long-term debt	(664)	(1,522)	(382)	
Repayments of capital lease obligations	(1)	(57)	(88)	
Net cash provided by (used in) financing activities	13,683	(768)	7,780	
Increase (degreese) in each and each equivalents	(2.026)	(4.027)	2 265	
Increase (decrease) in cash and cash equivalents Cash and cash equivalents at beginning of period	(2,936) 6,156	(4,027) 10,183	3,365 6,818	
Cash and cash equivalents at beginning of period	0,150	10,165	0,010	
Cash and cash equivalents at end of period	\$ 3,220	\$ 6,156	\$10,183	
Supplemental Disclosures of Cash Flow Information:				
Cash paid for interest	\$ 413	\$ 238	\$ 466	
r			÷ 100	
Non-cash Investing and Financing Activities:				
Warrant issued in connection with convertible debentures	_	\$ 82	\$ —	
Common stock issued upon conversion of accrued dividends for Series B	¢ 12	¢	¢	
preferred stock	\$ 13	\$ —	\$ —	

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 1. Organization and Summary of Significant Accounting Policies

## Organization and Business Activity

Questcor Pharmaceuticals, Inc. (the "Company") is a specialty pharmaceutical company that acquires, markets and sells brand name prescription drugs through a U.S. direct sales force and international commercialization partners. The Company focuses on the treatment of central nervous system ("CNS") diseases and gastroenterological disorders which are served by a concentrated group of physicians such as neurologists and gastroenterologists. The Company's strategy is to acquire pharmaceutical products that it believes have sales growth potential, are promotionally responsive to a focused and targeted sales and marketing effort, and complement the Company's existing products. In addition, through corporate collaborations, the Company intends to develop new patented intranasal formulations of medications previously approved by the Food and Drug Administration ("FDA"). The Company currently markets five products in the U.S.: HP 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; Glofil®-125, an injectable agent that assesses how well the kidney is working by measuring glomerular filtration rate, or kidney function; and VSL#3®, a patented probiotic marketed as a dietary supplement to promote normal gastrointestinal function. Probiotics are living organisms in food and dietary supplements, which, upon ingestion in certain numbers, improve the health of the host beyond their inherent basic nutrition. Due to minimal demand and increasing production costs, the Company discontinued marketing and selling Inulin in September 2003.

On June 17, 2003, the Company acquired Nascobal®, a nasal gel formulation of Cyanocobalamin USP (Vitamin B-12), from Nastech Pharmaceutical Company, Inc. ("Nastech"). The Company began distributing Nascobal in July 2003. The Company markets Nascobal for patients with MS and Crohn's Disease, 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. In June 2002, the Company signed a license agreement with Fabre Kramer Pharmaceuticals, Inc., whereby Fabre Kramer will manage and provide funding for the clinical development programs for Hypnostat<sup>TM</sup> (an intranasal triazolam for the treatment of insomnia) and Panistat<sup>TM</sup> (an intranasal alprazolam for the treatment of panic disorders). 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 accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company has incurred significant net losses and negative cash flows from operations since its inception. At December 31, 2003, the Company had an accumulated deficit of \$82.9 million. Management believes that cash on hand at December 31, 2003, together with the \$2.4 million of cash raised in its January 2004 private placement of common stock, and the net cash flows that will be generated from operations, will be sufficient to fund operations through at least December 31, 2004, unless a substantial portion of its cash is used for product acquisition or 2004 revenues are less than expected. If the Company's revenues do not grow and 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, in addition to the equity financing raised in January 2004, if available on terms acceptable to the Company.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## 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 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 stockholders' 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 (expense), net."

#### Concentration of Risk

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, with the exception of the product sales to NutraMax on which the Company wrote off \$29,000 in 2001. Three customers accounted for the majority of our net product sales as follows:

		Years Ended December 31,			
	% of Net Product Sales	2003	2002	2001	
Customer A		35%	30%	22%	
Customer B		25%	34%	27%	
Customer C		18%	20%	21%	
Other customers		22%	16%	30%	
		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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### **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.

#### **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 Nascobal, Glofil-125, Inulin, and Ethamolin is stated at cost and amortized over the estimated sales life of the product (fifteen years for Nascobal and seven years for others). 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, 2003, the purchased technology only relates to Nascobal, as prior purchased technology is fully amortized.

In July 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 141, "Business Combinations", and SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 141 specifies the criteria that intangible assets acquired in a purchase business combination must meet to be recognized and reported apart from goodwill, noting that any purchase price allocable to an assembled workforce may not be accounted for separately. SFAS No. 142 requires, among other things, that the assembled workforce be reclassified to goodwill and that goodwill (including the assembled workforce) and intangible assets with indefinite useful lives no longer be amortized, but instead be tested for impairment at least annually in accordance with SFAS No. 142. The Company adopted the provisions of SFAS No. 141 immediately and SFAS No. 142 effective January 1, 2002.

## 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.

In October 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" which supercedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of." SFAS No. 144 retains the requirements of SFAS No. 121 to (a) recognize an impairment loss only if the carrying amount of a long-lived asset is not recoverable from its undiscounted cash flows and (b) measure an impairment loss as the difference between the carrying amount and the fair value of the asset. SFAS No. 144 excludes goodwill from its scope.

The Company regularly evaluates its long-lived assets for indicators of possible impairment. To date, except for the discontinued product line (see Note 12), no impairment has been recorded.

#### Revenue Recognition

Revenues from product sales of Acthar, Nascobal, Ethamolin, Glofil-125, Inulin and VSL#3 are recognized based upon shipping terms, net of estimated reserves for sales returns, government chargebacks, Medicaid rebates, and payment discounts. Revenue is recognized upon shipment of product, provided the title to the products has been transferred at the point of shipment. If title of product transfers at point of receipt by the customer, revenue is recognized upon customer receipt of the shipment. The Company records estimated sales allowances against product revenues for expected returns, chargebacks, Medicaid rebates and payment

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

discounts based on historical sales returns, chargebacks, and Medicaid rebates, analysis of return merchandise authorizations and other known factors such as shelf life of products, as required. The Company continually assesses the historical returns and other experience including customers' compliance with return goods policy and adjusts its allowances as appropriate. The Company's return policy allows customers to return expired product for exchange within six months beyond the expiration date. Effective August 12, 2002 the Company changed its return goods policy such that it no longer issues credit memorandums for returns. Rather, returns 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 quality assurance reviews prior to acceptance. Allowances for Medicaid rebates, government chargebacks and product returns are \$615,000 and \$447,000 at December 31, 2003 and 2002, respectively, and are included in Other Accrued Liabilities. The Company sells product to wholesalers, who in turn sell its products to pharmacies and hospitals. In the case of VSL#3, the Company sells directly to consumers. The Company does not require collateral from its customers.

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 provide for reimbursement of approved costs incurred as defined in the various awards.

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

Research and development expenditures, including direct and allocated expenses, are charged to expense as incurred.

## Net Loss Per Share Applicable to Common Stockholders

Basic and diluted net loss per share applicable to common stockholders is based on net loss applicable to common stockholders for the relevant period, divided by the weighted average number of common shares outstanding during the period. Diluted earnings per share applicable to common stockholders, 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 stockholders 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, 2003, the calculation of diluted earnings per share applicable to common stockholders 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 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 stockholders 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. For the year ended December 31, 2001, the calculation of diluted

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

earnings per share applicable to common stockholders would have included, if dilutive, the effect of the outstanding 6,878,466 stock options, 2,155,715 convertible preferred shares, placement unit options for 986,898 shares and 3,185,185 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,		
	2003	2002	2001
Net loss applicable to common stockholders, as reported	\$(5,947)	\$(2,785)	\$(8,697)
Add: Stock-based employee compensation expense included in reported			
net loss	58	17	25
Deduct: Total stock-based employee compensation expense determined			
under fair value method for all awards	(1,439)	(1,508)	(1,308)
Net loss applicable to common stockholders, pro forma	\$(7,328)	\$(4,276)	\$(9,980)
•			
Basic and diluted net loss per share applicable to common stockholders:			
As reported	\$ (0.14)	\$ (0.07)	\$ (0.28)
Pro forma	\$ (0.17)	\$ (0.11)	\$ (0.32)

#### 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.

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

### **Segment Information**

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

Net product sales consists of the following:

	Y	Years Ended December 31,		
	2003	2002	2001	
		(in \$000's)		
P Acthar® Gel	\$ 7,973	\$ 9,009	\$2,141	
Vascobal®	2,099	_	_	
thamolin®	1,629	3,527	1,695	
/SL#3®	992	523	_	
Glofil®-125	887	732	982	
nulin	75	28	317	
Ieoflo <sup>TM</sup>	<u> </u>	_	61	
	\$13,655	\$13,819	\$5,196	

### **Recently Issued Accounting Standards**

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." This Statement establishes new standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). This Statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS No. 150 on July 1, 2003 did not have a material impact on the consolidated financial statements as of December 31, 2003.

In January 2003, the FASB issued Interpretation No. 46 ("FIN 46"), Consolidation of Variable Interest Entities. FIN 46 requires that if an entity has a controlling financial interest in a variable interest entity, the assets, liabilities and results of activities of the variable interest entity should be included in the consolidated financial statements of the entity. FIN 46 as amended must be applied for interim or annual reporting periods ending after March 15, 2004, and is effective immediately for all new variable interest entities created or acquired after January 31, 2003. The adoption of FIN 46 did not impact the Company's results of operations or financial position as of December 31, 2003, as it is not a party to any variable interest entities.

In July 2002, the FASB issued Statement of Financial Accounting Standards No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS No. 146"). SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies EITF Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)" ("EITF 94-3"). The principal difference between SFAS No. 146 and EITF 94-3 relates to SFAS No. 146's timing for recognition of a liability for a cost associated with an exit or disposal activity. SFAS No. 146 requires that a liability for an exit cost associated with an exit or disposal activity be recognized when the liability is incurred. Under EITF 94-3 a liability for an exit cost, as generally defined in EITF 94-3, was recognized at the date of an entity's commitment to an exit plan. SFAS No. 146 is effective for exit or disposal activities that are initiated after December 31, 2002. During the year ended December 31, 2003, the Company transferred certain functions previously performed at its Carlsbad, California facility (distribution, quality control and quality assurance) to third party contractors or to its Union City headquarters. Consequently, during 2003, the Company entered into sublease agreements with two sublessees for the Carlsbad facility. The Company recognized losses relating to the leases totaling

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

\$171,000 in fiscal year 2003. The loss associated with the leases is included in Research and Development in the accompanying Consolidated Statements of Operations. In addition, the Company amortized the remaining net book value of the Carlsbad facility leasehold improvements of \$23,000 in 2003.

### Reclassifications

Certain amounts in the prior years' financial statements have been reclassified to conform with the current year presentation. The amount reclassified from Cost of Product Sales to Selling, General and Administrative Expense in the Consolidated Statements of Operations totaled \$110,000 for the year ended December 31, 2002. The amount reclassified from Research and Development to Cost of Product Sales in the Consolidated Statements of Operations totaled \$495,000 for the year ended December 31, 2001. Amounts previously reported as Sales and Marketing, and General and Administrative, have been combined as Selling, General and Administrative.

### 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 shareholders of Sigma Tau. Effective January 1, 2004, the promotion agreement and all amendments were assigned by VSL to Sigma Tau Pharmaceuticals, Inc. As Sigma Tau owns common stock of the Company as of December 31, 2003, VSL and Sigma Tau Pharmaceuticals, Inc. are deemed to be related parties of the Company. On June 27, 2002, the Company signed an amendment to the promotion agreement. Under these agreements, the Company has agreed to purchase VSL#3 from VSL at a stated price, and has also agreed to promote, sell, warehouse and distribute the VSL#3 product direct to customers at its cost and expense. 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 \$992,000 and \$523,000 for the years ended December 31, 2003 and 2002, respectively, and is included in "Net Product Sales." An access fee is paid quarterly to VSL, which varies based upon sales and costs incurred by the Company. Additionally, under these agreements, VSL 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 is three years; however, VSL is entitled to unilaterally terminate the agreement by providing written notice to the Company after the one-year anniversary of the effective date. The VSL#3 product was formally launched on May 23, 2002. As of December 31, 2003 and 2002, the Company owes VSL \$188,000 and \$254,000, respectively, which is included in Accounts Payable in the accompanying Consolidated Balance Sheets.

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

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

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 2003, 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 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, 2003, 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, 2003. 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 July 2001, the Company entered into an Asset Purchase agreement with Aventis Pharmaceuticals Inc. ("Aventis") to acquire the worldwide rights to Acthar as well as inventory and certain assets used to manufacture Acthar. Acthar is a corticotropin product that has been used, as part of a special program administered by the National Organization for Rare Disorders ("NORD"), to treat seriously ill children with a seizure complex, referred to as infantile spasm or West Syndrome, a potentially fatal disorder, and patients with Multiple Sclerosis who experience severe and painful episodes of "flare". The Company paid an upfront fee and has agreed to pay an annual royalty on net sales above a predetermined amount. As part of the agreement, Aventis manufactured the finished goods from existing inventory of the active pharmaceutical ingredient (the "API") through July 2002. The Company began shipping Acthar in the third quarter of 2001

On June 17, 2003, the Company acquired Nascobal, a nasal gel formulation of Cyanocobalamin USP (Vitamin B-12), from Nastech. Under the terms of the Nascobal Asset Purchase Agreement, the Company made an initial cash payment of \$9 million upon the closing of the acquisition, an additional cash payment of \$3 million in the third quarter and an additional \$2.2 million cash payment in December 2003 (a total of \$14.2 million). As part of the acquisition, the Company is also acquiring 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. Subject to the approval of the NDA for the new Nascobal nasal spray dosage form by the FDA, the Company is required to make a \$2 million payment for the transfer of the NDA from Nastech to the Company. Further, subject to the approval of the NDA for the new Nascobal nasal spray dosage form and 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 million payment. 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, cGMP manufacturing facility in Hauppauge, New York.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 \$514,000 for the year ended December 31, 2003. Amortization expense will be approximately \$948,000 per year from 2004 through 2017, and approximately \$434,000 for 2018.

### 4. Investments

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

December 31, 2003	Gross Amortized Cost	Gross Unrealized Loss	Estimated Fair Value
Cash equivalents:			
Money market funds	\$2,301	\$ —	\$2,301
	_	_	_
December 31, 2002	Gross Amortized Cost	Gross Unrealized Loss	Estimated Fair Value
Cash equivalents:			
Money market funds	\$5,400	\$ —	\$5,400
Commercial paper	499	_	499
	\$5,899	\$ —	\$5,899
	_	_	
Short-term investments:			
Commercial paper	\$ 498	\$ —	\$ 498
Corporate bonds	761	_	761
Corporate equity investments	133	(42)	91
	\$1,392	\$(42)	\$1,350
	_	_	

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.

The net realized gains on sales of available for sale investments were not material in fiscal years 2003, 2002 and 2001.

### 5. Inventories

Inventories consist of the following (in thousands):

	December	r 31,
	2003	2002
Raw materials	\$ 534	\$ 70
Work in Process	197	_
Finished goods	660	397
Less allowance for excess and obsolete inventories	(341)	(76)
	\$1,050	\$391

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

### 6. Property and Equipment

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

	Decem	December 31,	
	2003	2002	
Laboratory equipment	\$ 9	\$ 364	
Manufacturing equipment	272	100	
Office equipment, furniture and fixtures	799	1,196	
Leasehold improvements	329	251	
	1,409	1,911	
Less accumulated depreciation and amortization	(800)	(1,326)	
	\$ 609	\$ 585	
	_		

Depreciation and amortization expense for property and equipment totaled \$260,000, \$361,000 and \$580,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

During 2003, the Carlsbad facility was vacated and equipment with a net book value of \$9,000 no longer used, was written off.

### 7. Purchased Technology and Other Intangible Assets

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

	Decemb	er 31,
	2003	2002
Goodwill	\$ 1,023	\$ 1,023
Purchased technology	14,223	3,684
Assembled workforce	616	616
	15,862	5,323
Less accumulated amortization	(1,674)	(4,462)
	\$14,188	\$ 861

Goodwill and assembled workforce no longer subject to amortization amounted to \$479,000 at December 31, 2003 and 2002. Purchased technology at December 31, 2003 includes \$14,223,000 related to the Nascobal acquisition. Purchased technology of \$3,684,000 and \$3,068,000 were fully amortized in 2003 and 2002, respectively, and written off accordingly. Amortization of purchased technology relating to products totaled \$897,000, \$777,000 and \$1,054,000 for the years ended December 31, 2003, 2002, and 2001, respectively, and is included in Depreciation and Amortization in the accompanying Consolidated Statements of Operations. The remaining net balance of \$382,000 at December 31, 2002 relates to purchased technology which was amortized over the estimated sales life of the associated product (seven years), and was amortized in full during 2003, and written off accordingly.

In accordance with SFAS No. 141 and No. 142, the Company discontinued the amortization of goodwill and assembled workforce on January 1, 2002. The Company performed its annual impairment test of goodwill and assembled workforce, which did not result in an impairment charge. The Company will continue to monitor the carrying value of goodwill through the annual impairment tests.

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

A reconciliation of previously reported net loss and net loss per share to the amounts and the basic and diluted net loss per share applicable to common stockholders adjusted for the exclusion of goodwill amortization follows (in thousands, except per share amounts):

	Ye	Years Ended December 31,		
	2003	2002	2001	
Net Loss:				
Reported net loss applicable to common stockholders	\$(5,947)	\$(2,785)	\$(8,697)	
Add back: Goodwill amortization	_	_	546	
Adjusted net loss applicable to common stockholders	\$(5,947)	\$(2,785)	\$(8,151)	
Basic and diluted net loss per share applicable to common				
stockholders:				
Reported net loss per share applicable to common stockholders	\$ (0.14)	\$ (0.07)	\$ (0.28)	
Add back: Goodwill amortization	_	_	0.02	
Adjusted net loss per share applicable to common stockholders	\$ (0.14)	\$ (0.07)	\$ (0.26)	

### 8. Convertible Debentures

In March 2002, the Company issued \$4.0 million of 8% convertible debentures to an institutional investor, and Defiante Farmaceutica Unipessoal L.D.A. ("Defiante"), a wholly-owned subsidiary of Sigma-Tau Finanzaria S.p.A ("Sigma-Tau"). The Company will pay interest on the debentures at a rate of 8% per annum on a quarterly basis. The debentures are convertible into 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). The debentures mature on March 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 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 amounts to \$1,484,000. The beneficial

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

conversion feature and warrant value is amortized over the term of the debentures. The unamortized balance is \$598,000 and \$1,092,000 at December 31, 2003 and December 31, 2002, respectively.

## 9. Long-Term Debt

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

	December 31, 2003	December 31, 2002
Convertible debentures (net of deemed discount of \$598 and \$1,092 at December 31,		
2003 and 2002, respectively) bearing interest of 8%	\$3,402	\$2,908
Notes payable for product liability insurance, bearing interest at 5.25%	82	97
Notes payable for property and liability insurance, bearing interest at 6.43%	58	_
Notes payable for equipment financing	_	121
	3,542	3,126
Less current portion	(140)	(218)
Total	\$3,402	\$2,908

The amounts due for notes payable for product liability and property and liability insurance in 2004 are \$140,000. The convertible debentures are due in March 2005.

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, approximate their respective fair values as of December 31, 2003 and 2002. Interest expense was \$333,000, \$315,000 and \$465,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

On January 2, 2002, the Company entered into a revolving accounts receivable line of credit with Pacific Business Funding, a division of Greater Bay Bancorp, the parent company of Cupertino National Bank. Under the agreement, the Company can borrow up to the lesser of 80% of its eligible accounts receivable balance or \$3,000,000. Interest accrues on outstanding advances at an annual rate equal to prime rate plus four and one-half percent. The term of the agreement is one year and the agreement automatically renews annually, unless terminated by the Company. There were no borrowings under this line of credit as of December 31, 2003. The line of credit is secured by a blanket lien on all assets including intellectual property. As of December 31, 2003, \$1,421,000 was available for borrowing under the line of credit. The Company terminated this line of credit in January 2004 and the associated blanket lien was terminated accordingly.

### 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, 2003.

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

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.

### 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. Minimum future obligations under the operating leases as of December 31, 2003 are as follows (in thousands):

Year ending December 31,	Facility Operating Leases	Sublease Income	Automobile and Office Equipment Leases	
2004	\$ 1,549	\$(1,254)	\$198	\$ 493
2005	1,466	(1,256)	92	302
2006	1,294	(577)	16	733
2007	1,322	_	8	1,330
2008	1,373	_	6	1,379
Thereafter	4,869	_	_	4,869
	\$11,873	\$(3,087)	\$320	\$9,106

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 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.

On October 26, 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. 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. The lease period ends in December 2004 and during 2003, we subleased the space through December 2004.

During 2003, the Carlsbad 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 December 2004 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.

Rent expense for facility, equipment and automobile leases totaled \$1,885,000, \$1,771,000 and \$1,573,000 for the years ended December 31, 2003, 2002 and 2001, 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 \$260,000, \$282,000 and \$612,000 for the years ended December 31, 2003, 2002 and 2001, respectively. The Company has entered into various automobile leases for its sales representatives.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

### **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 API used in Acthar. The agreement requires minimum production totaling \$1.7 million during the term. During fiscal year 2003, we paid \$115,000 under this agreement. The agreement terminates in December 2007 and includes two one-year extension options. The production of the first batch of API is scheduled to begin in 2004.

### 11. Preferred Stock and Stockholders' 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, 2003. 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 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 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 stockholders' 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. During December 2003 Series B Preferred Stock with a stated value of \$900,000 plus accrued dividends of \$13,000 were converted into 976,770 shares of common stock. The Company has the right commencing on January 1,

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

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;
- 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, 2003, the redemption value of the Series B Preferred Stock was \$9.1 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

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

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. The deemed dividend increased the loss applicable to common stockholders 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 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 we 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 Stockholders, 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. The deemed dividend increased the net loss applicable to common stockholders in the calculation of basic and diluted net loss per common share applicable to common stockholders.

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

#### 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 June 2003, the Company consummated 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. Gross proceeds to the Company from the private placement were approximately \$5 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 Pharmaceuticals, Inc., 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 Pharmaceuticals, Inc. to Sigma-Tau Pharmaceuticals, Inc. 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 July 2001, the Company entered into a Stock Purchase Agreement with Sigma-Tau pursuant to which Sigma-Tau purchased 5,279,034 shares of common stock at a purchase price of \$0.66 per share, for an aggregate purchase price of \$3,500,000.

In April 2001, the Company entered into a Stock and Warrant Purchase Agreement with Sigma-Tau pursuant to which Sigma-Tau purchased (i) an aggregate of 2,873,563 shares of common stock at a purchase price of \$0.52 per share, for an aggregate purchase price of \$1,500,000, and (ii) a warrant to purchase an additional 2,873,563 shares of common stock at a purchase price of \$0.52 per share. In May 2001, as required under the rules of AMEX, the Company sought and received shareholder approval to allow for full exercise of the warrant. In July 2001, Sigma-Tau assigned the warrant to Paolo Cavazza and Claudio Cavazza, the principal shareholders of Sigma-Tau, who exercised the warrant in full, purchasing 2,873,563 shares of common stock at a purchase price of \$0.52 per share, resulting in aggregate proceeds to the Company of \$1,500,000 (including the \$100,000 originally paid by Sigma-Tau to acquire the warrant).

Also, 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.

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

### **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, 2003, 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.

#### Warrants

The Company has 8,437,608 warrants outstanding at December 31, 2003 at a weighted average exercise price per share of common stock of \$1.20 and a weighted average remaining contractual life of 4.5 years. Exercise prices for the warrants outstanding as of December 31, 2003 are as follows:

Exercise Price	Number Outstanding	Date Issued	Expiration Date
\$0.64	408,400	4/30/2001	4/30/2006
\$0.94	3,399,911	1/15/2003	1/15/2007
\$1.26	2,987,616	6/11/2003	6/11/2008
\$1.31	20,000	7/31/2000	5/18/2004
\$1.70	1,618,987	3/15/2002	3/15/2006
\$31.51	2,694	3/12/1997	3/12/2007
	8,437,608		

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, 2003, 2002 and 2001, the Company recorded amortization of deferred stock compensation of \$20,000, \$17,000, and \$25,000, respectively. As of December 31, 2003 the Company had \$17,000 of remaining unamortized deferred compensation. This amount is included as a deduction of stockholders' equity and is being amortized over the vesting period of the underlying options.

Pro forma information regarding net loss applicable to common stockholders and net loss applicable to common stockholders 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,	
	2003	2002	2001
Expected stock price volatility	67%	82%	86%
Risk-free interest rate	3%	5%	5%
Expected life (in years)	3.9	4.0	3.1
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. The first purchase date was December 31, 2000 on which 93,666 shares were purchased at \$0.53 per share. During the year ended December 31, 2001, 193,214 shares were purchased under this plan at an average purchase price of \$0.58 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.

As of December 31, 2001, 12,500,000 shares of common stock were reserved for issuance under the 1992 Employee Stock Option Plan (the "1992 Plan"). In December 2002, the Board of Directors temporarily reduced the number of shares available for grant under the 1992 Plan by 1,220,053 shares. This resulted in 11,279,947 shares of common stock authorized under the 1992 Plan as of December 31, 2002. In 2003, 1,220,053 shares were reinstated to the 1992 Plan resulting in 12,500,000 shares reserved for issuance. In May 2003, the aggregate number of shares of Common Stock authorized for issuance under the 1992 Plan was increased by 1,000,000 shares from 12,500,000 shares to 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.

As of December 31, 2002, 1,250,000 shares of common stock were reserved for issuance under the 1993 Non Employee Directors' Stock Option Plan (the "Directors' Plan"). The maximum term of options granted under the 1993 Directors Plan is ten years. The Director's Plan expired in 2003 (See Note 18, Subsequent Events).

The Company compensates its non-employee directors for their service on the Board of Directors with an initial grant of an option to purchase 25,000 shares of common stock. Such option grant has an exercise price equal to 85% of the fair market value of the common stock on the date of the grant and vests in 48 equal monthly installments commencing on the date of the grant, provided the non-employee director serves continuously on the Board of Directors during such time.

In November 2003, the Board of Directors approved an annual salary of \$45,000 to the Company's Lead Director, Brian C. Cunningham, of which he received \$3,750 as compensation for service as Lead Director 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

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

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 service as a director in 2003 each outside director was granted an option to purchase 10,000 shares of common stock. Such option grants had an exercise price equal to 85% of the fair market value of the common stock on the date of the grant and vest in 48 equal monthly installments commencing on the date of the 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 in 2003, 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. Such option grants had an exercise price equal to 100% of the fair market value of the common stock on the date of the grant and became fully vested at the time of grant.

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. For the calendar year 2001, the Company compensated members of the Board of Directors for attending the Board of Directors meetings, by granting them 30,000 options each to purchase common stock in lieu of the \$2,000 payment per meeting. The options were issued under the 1992 Plan and vest over twelve months.

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.

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

	Options Outstanding	Weighted Average Exercise Price
Balance at December 31, 2001	6,878,466	\$1.65
Granted	3,128,923	\$1.31
Exercised	(355,432)	\$1.16
Canceled	(709,695)	\$3.30
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

At December 31, 2003, 2002 and 2001, options to purchase 5,308,931 shares, 4,296,617 shares and 3,346,440 shares, respectively, of common stock were exercisable and there were 3,080,311 shares available for future grant under the 1992 Plan and none available for future grant under the 1993 Plan as of December 31, 2003. The weighted average fair values of options granted was \$0.44, \$0.83 and \$0.59 for the years ended December 31, 2003, 2002 and 2001, respectively.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

During 2003, 2002 and 2001, there were 20,000, 40,000 and 743,633 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, 2003, 2002 and 2001 the Company recorded \$95,000, \$381,000, and \$601,000, respectively, as compensation expense.

Exercise prices and weighted average remaining contractual life for the options outstanding as of December 31, 2003 are as follows:

### **Options Outstanding**

Options Exercisable	

				· P	
Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.47 — \$0.67	989,453	8.60	\$0.61	320,558	\$0.61
\$0.75 — \$0.82	1,070,729	7.77	\$0.77	549,582	\$0.76
\$0.84 — \$0.94	1,380,000	9.19	\$0.88	263,434	\$0.90
\$0.97 — \$1.02	1,093,727	8.40	\$1.00	432,685	\$1.00
\$1.03 — \$1.24	607,520	7.24	\$1.12	556,285	\$1.12
\$1.24 — \$1.25	1,212,365	5.90	\$1.25	1,075,768	\$1.25
\$1.27 — \$1.48	379,485	7.01	\$1.36	355,108	\$1.36
\$1.50 — \$1.75	2,184,876	7.29	\$1.56	967,277	\$1.61
\$1.78 — \$2.78	406,594	4.74	\$2.24	355,481	\$2.28
\$3.08 — \$4.94	432,753	4.12	\$3.68	432,753	\$3.68
	9,757,502	7.43	\$1.27	5,308,931	\$1.45

### **Reserved Shares**

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

	December 31, 2003
Outstanding options	9,757,502
Convertible preferred stock issued and outstanding	11,824,220
Convertible debentures	2,531,646
Placement agent unit options	127,676
Common stock warrants	8,437,608
Reserved for future grant or sale under option plans	3,080,311
	35,758,963

### 12. Discontinued Product Line

In May 2000, the Company's sole customer for its Neoflo<sup>TM</sup> product, NutraMax Products, Inc., filed a voluntary petition under Chapter 11 of the U.S. Bankruptcy Code. The NutraMax bankruptcy filing had a negative impact on the Company's sales and cash flow during calendar year 2000 and first quarter of 2001. On April 2, 2001, the U.S. Bankruptcy Court granted NutraMax a motion to terminate the Company's supply agreement effective that date. In May 2001, the Company closed its Lee's Summit manufacturing facility where the Neoflo<sup>TM</sup> product was being produced. As of December 31, 2001, there were no definitive purchasers of the Neoflo<sup>TM</sup> product and its related assets, and as a result, the Company recorded a loss on the

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

discontinuance of the Neoflo<sup>TM</sup> product line of \$677,000. The loss of \$677,000 represents a write-down of the assets of approximately \$262,000 consisting mainly of manufacturing equipment directly related to the Neoflo<sup>TM</sup> product line and estimated remaining lease payments of \$415,000 for the Lee's Summit facility.

### 13. Income Taxes

As of December 31, 2003, the Company had federal and state net operating loss carryforwards of approximately \$98 million and \$27 million, respectively. The Company 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 2004 through 2023, 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, 2003	December 31, 2002
Deferred tax liabilities:		
Goodwill and purchased intangibles	\$ 200	\$ 200
Deferred tax assets:		
Net operating loss carryforwards	\$ 35,000	\$ 33,200
Research and development credits	1,400	1,300
Capitalized research and development expenses	700	1,100
Acquired research and development	1,800	800
Other, net	1,000	1,000
Total deferred tax assets	39,900	37,400
Valuation allowance	(39,700)	(37,200)
Net deferred taxes	\$ —	\$ —
		_

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 increased by \$2,500,000 in 2003, decreased by \$300,000 in 2002, and increased by \$200,000 during 2001.

## 14. Other Related Party Transactions

In December 2001, the Company entered into a promotion agreement with VSL Pharmaceuticals Inc. ("VSL"), a private company owned in part by the major shareholders of Sigma Tau. Sigma Tau beneficially owned approximately 31% of the Company's outstanding stock as of December 31, 2003. In June 2002, the Company signed an amendment to the promotion agreement. Effective January 1, 2004, the promotion agreement and all amendments were assigned by VSL to Sigma Tau Pharmaceuticals, Inc. Under these agreements, the Company has agreed to purchase VSL#3 from VSL at a stated price, and has 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. Revenues from sales of VSL#3 are recognized when product is

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

shipped to the customer. The Company does not accept returns of VSL#3. VSL#3 revenue for the years ended December 31, 2003 and 2002 was \$992,000 and \$523,000, respectively, and is included in Net Product Sales. Included in Accounts Payable are \$188,000 and \$254,000 for amounts owed to VSL at December 31, 2003 and 2002, respectively. An access fee to VSL is calculated quarterly, which varies based upon sales and costs incurred by the Company subject to reimbursement under certain circumstances. For the year ended December 31, 2003 the amount of the access fee was \$59,000 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 VSL. 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 VSL reimbursed the Company for these costs. During the years ended December 31, 2003 and 2002, the Company paid \$466,000 and \$72,000, respectively, to VSL for the purchase of VSL#3 product and access fees.

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. As of December 31, 2003, Mr. Greathouse is an employee of Questcor but is no longer a Vice President. This agreement calls for the payment of royalties on a quarterly basis on the net sales of Acthar. The Company paid Glenridge \$297,000 and \$443,000 in the years ended December 31, 2003 and 2002, respectively, related to royalties on Acthar® sales. The Company accrued \$69,000 and \$95,000 for royalties earned but unpaid as of December 31, 2003 and 2002, respectively, which are included in Other Accrued Liabilities on the accompanying Consolidated Balance Sheets.

### 15. 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 15% of their eligible compensation up to the annual Internal Revenue Service contribution limit. The Plan was adopted in 2000. The Company matched employee contributions according to specified formulas and contributed \$68,000, \$98,000 and \$48,000 for the years ended December 31, 2003, 2002, and 2001, respectively. For the year ended December 31, 2003, the Company ceased to match employee contributions halfway through the year.

### 16. Comprehensive Loss

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

	Ye	Years Ended December 31,		
	2003	2002	2001	
Net loss	\$(3,791)	\$(2,785)	\$(8,697)	
Change in unrealized gains(losses) on available-for-sale securities	42	73	(447)	
Comprehensive loss	\$(3,749)	\$(2,712)	\$(9,144)	

## 17. 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

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

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 S.p.A., together with all of its Affiliates and Associates, including, without limitation Defiante Farmaceutica L.D.A., 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 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 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.

### 18. Subsequent Events

### Private Placement of Common Stock

In January 2004 the Company entered into agreements with existing shareholders to issue 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 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 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 for the five trading days prior to the agreement to the terms of the transaction. Sigma-Tau purchased 759,493 shares of common stock through consideration of \$489,000 of cash and the surrender of 759,493 warrants to purchase common shares.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

### 2004 Directors' Stock Option Plan

In February 2004, the Board of Directors adopted the 2004 Non-Employee Directors' Equity Incentive Plan (the "2004 Plan"). The adoption of the 2004 Plan is subject to shareholder approval at the Company's 2004 Annual Meeting of Shareholders. Under the terms of the 2004 Plan, 1,250,000 shares of the Company's common stock would be 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 upon reappointment. Such option grants will vest over four years and the exercise price of the options is 85% of the fair market value on the date of grant. Additionally, the 2004 Plan provides for the annual granting of 10,000 options to members of committees of the Board of Directors and 7,500 options to chairmen of 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.

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

## SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS

## Years Ended December 31, 2003, 2002 and 2001

	Balance at Beginning Period	Additions/ (Deductions) Charged to Income	Deductions and Write-offs	Balance at End of Period
		(In thou	sands)	
Reserves for uncollectible accounts				
December 31, 2003	\$ 20	\$ 43	\$ 3	\$ 60
December 31, 2002	\$ 78	\$ (40)	\$ 18	\$ 20
December 31, 2001	\$ 56	\$ 51	\$ 29	\$ 78
Reserves for obsolete and excess inventories				
December 31, 2003	\$ 76	\$ 406	\$ 141	\$341
December 31, 2002	\$ 56	\$ 72	\$ 52	\$ 76
December 31, 2001	\$ 28	\$ 45	\$ 17	\$ 56
Reserves for sales and product return allowances				
December 31, 2003	\$447	\$1,472	\$1,304	\$615
December 31, 2002	\$221	\$1,143	\$ 917	\$447
December 31, 2001	\$ —	\$ 271	\$ 50	\$221

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 L.D.A. 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.
10.4(9)	Employment Agreement dated as of August 4, 1999 between the Company and Charles J. Casamento.
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.†
10.8(11)	Promotion Agreement dated December 1, 2001 between the Company and VSL Pharmaceuticals, Inc.†
10.9(11)	First Amendment to Promotion Agreement dated June 27, 2002 between the Company and VSL Pharmaceuticals, 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 L.D.A. dated March 15, 2002.
10.17(6)	Registration Rights Agreement between the Company and Defiante Farmaceutica Unipessoal L.D.A. dated March 15, 2002.
10.18(6)	Warrant between the Company and Defiante Farmaceutica Unipessoal L.D.A. 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.
10.20(14)	Amendment to Employment Agreement between the Company and Charles J. Casamento dated March 21, 2003.
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.

### **Table of Contents**

Exhibit Number	Description
10.23(14)	Letter Agreement dated May 2, 2000 between the Company and Kenneth R. Greathouse.
10.24(14)	Amendment to Letter Agreement dated March 21, 2003 between the Company and Kenneth R. Greathouse.
10.25(14)	Letter Agreement dated August 24, 2001 between the Company and Timothy E. Morris.
10.26(14)	Amendment to Letter Agreement dated November 7, 2001 between the Company and Timothy E. Morris.
10.27(14)	Amendment to Letter Agreement dated March 21, 2003 between the Company and Timothy E. Morris.
10.28*	Letter Agreement dated September 2, 2003 between the Company and R. Jerald Beers.
10.29*	Amendment to Letter Agreement dated November 6, 2003 between the Company and R. Jerald Beers.
10.30*	Supply Agreement dated April 1, 2003 between the Company and BioVectra, dcl.
23.1*	Consent of Ernst & Young LLP, Independent Auditors.
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.

- (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.
- (14) 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, 2002, and incorporated herein by reference.
  - † The Company has requested confidential treatment with respect to portions of this exhibit.

# [QUESTCOR LETTERHEAD]

September 2, 2003

Charles J. Casamento Chairman, President & CEO

R. Jerald Beers 3260 Whipple Road Union City, CA 94587

Re: Offer of Employment

Dear Mr. Beers:

Questcor Pharmaceuticals, Inc. (the "Company") is pleased to offer you the position of Vice President, Marketing, a corporate officer, on the terms described below. Should you accept our offer of employment, your start date will be September 15, 2003.

You will report to Charles J. Casamento, Chief Executive Officer. Your office will be located at our facility in Union City, California. Of course, the Company may change your reporting responsibilities, position, duties, and work location from time to time, as it deems necessary.

Your base compensation will be \$184,000 per annum (\$7,666.66 semi-monthly) less all amounts the Company is required to hold under applicable laws. Effective January 1, 2004, you will be a participant in the annual management incentive program for executives, which has been approved by the Compensation Committee. Your incentive bonus will be based on the attainment of specific milestones during each calendar year. The milestones will be communicated to you in writing by Mr. Casamento following the start of your employment and will be updated annually as part of the performance review process. Your maximum bonus opportunity will be 33% of your base compensation earnings in the calendar year to which it applies. The Company will provide you a relocation allowance of an amount not to exceed \$75,000, to cover all reasonable and customary expenses associated with your relocation to the San Francisco Bay area. Those expenses paid by you which affect your income tax liability will be "grossed-up" accordingly. In addition, as soon as administratively practicable following the start of your employment, the Company will provide you with a change of control agreement commensurate with your position.

You will be eligible to participate in the Company's various benefit plans including medical, dental and vision insurance, as well as life, accidental death and disability insurance. You will receive 16 days of paid vacation per calendar year, in addition to 12 paid regular holidays and two paid floating holidays. You will also be eligible to participate in the Company's 401(k) Plan, Section 529 College Savings Program and Employee Stock Purchase Plan. The eligibility requirements for these plans are explained

in the Company's Employee Handbook, and in the case of the Company's 401(k) Plan, in the 401(k) Plan's summary plan description. A copy of the Employee Handbook and the 401(k) Plan's summary plan description will be provided to you. Please read them carefully. Of course, to the extent the provisions of the various plans are inconsistent with the provisions of the Employee Handbook or summary plan description, the plan provisions will control.

As you no doubt appreciate, as a Company employee, you will be expected to abide by Company rules and regulations, acknowledge in writing that you have read the Company's Employee Handbook, sign and comply with a Proprietary Information and Inventions Agreement which prohibits unauthorized use or disclosure of Company proprietary information and sign the Policy Against Insider Trading.

The Company's management has in effect an employee stock option plan to recognize the talent and skills our employees bring to the Company. Management will recommend to the Board of Directors that, at the time you join the Company, the Company grant to you an option under the stock option plan to purchase 300,000 shares of the Common Stock of the Company at an exercise price equal to 100% of the closing price of the Company's Common Stock on the date prior to approval by the Board of Directors. One-eighth (1/8th) of these options will vest after six (6) months of employment and thereafter the remaining shares will vest at the rate of 1/48th of the total grant on each monthly anniversary of your continued employment with the Company. The option will be subject to the terms and conditions of the Company's stock option plan and your stock option agreement.

The Company will review your performance in accordance with the Employee Handbook, to assess your accomplishment of milestones and goals, which the Company reasonably sets for you. The Company will consider whether and when you should receive increases in your compensation and benefits as described therein based on such accomplishments.

You may terminate your employment with the Company at any time and for any reason whatsoever simply by notifying the Company. Likewise, the Company may terminate your employment at any time and for any reason whatsoever, with or without cause or advance notice. This at-will employment relationship cannot be changed except in writing signed by the Chief Executive Officer or the Chief Financial Officer.

Any and all disputes connected with, relating to or arising from your employment with the Company will be settled by final and binding arbitration in accordance with the rules of the American Arbitration Association as presently in force. The only claims not covered by this Agreement are claims for benefits under the unemployment insurance or workers' compensation laws. Any such arbitration will take place in Alameda County, California. The parties hereby incorporate into this agreement all of the arbitration provisions of Section 1283.05 of the California Code of Civil Procedure. The Company understands and agrees that it will bear the costs of the arbitration filing and hearing fees and the cost of the arbitrator. Each side will bear its own attorneys' fees, and the arbitrator will not have authority to award attorneys' fees unless a statutory section at issue in the dispute authorizes the award of attorneys' fees to the prevailing party, in which case the arbitrator has authority to make such

award as permitted by the statute in question. The arbitration shall be instead of any civil litigation; this means that you are waiving any right to a jury trial, and that the arbitrator's decision shall be final and binding to the fullest extent permitted by law and enforceable by any court having jurisdiction thereof. Judgment upon any award rendered by the arbitrators may be entered in any court having jurisdiction.

The employment terms in this letter supersede any other agreements or promises made to you by anyone, whether oral or written, express or implied. In the event you accept this employment offer, the terms set forth in this letter will comprise our final, complete and exclusive agreement with respect to the subject matter of this letter. Thus, by accepting this employment offer and signing this offer letter, you agree to be bound by its terms and conditions. As required by law, the Company's offer is subject to satisfactory proof of your right to work in the United States no later than three days after your employment begins.

Please sign and date this letter, and return it to me as soon as possible. This offer terminates if it is not signed and delivered to me by September 2, 2003. A facsimile copy will suffice for this purpose, so long as an original signature is delivered when you commence employment. My confidential facsimile number is (510) 400-0710.

We look forward to your favorable reply and to a productive and enjoyable work relationship.

Sincerely,

/s/ Charles J. Casamento

/c/ P larald Roors

Charles J. Casamento Chairman, President and Chief Executive Officer

I hereby acknowledge that I have read the foregoing letter and agree to be bound by all of its terms and conditions:

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R.	Jerald Beers
September	2, 2003
Dat	

[QUESTCOR LETTERHEAD]

Charles J. Casamento Chairman, President & CEO

November 6, 2003

R. Jerald Beers 3260 Whipple Road Union City, CA 94587

Dear Jerry:

Questcor Pharmaceuticals, Inc., a California corporation ("Questcor"), considers it essential to the best interests of its stockholders to foster the continuous employment of key management personnel. In connection with this, Questcor's Board of Directors (the "Board") and the Compensation Committee of the Board (the "Compensation Committee") recognize that, as is the case with many publicly held corporations, the possibility of a change in control of Questcor may exist and that the uncertainty and questions that it may raise among management could result in the departure or distraction of management personnel to the detriment of Questcor and its stockholders.

Accordingly, the Board and the Compensation Committee have decided to reinforce and encourage your continued attention and dedication to your assigned duties without the distraction arising from the possibility of a change in control of Questcor. In order to induce you to remain in the employ of Questcor and its direct and indirect, majority-owned subsidiaries (collectively, the "Company"), Questcor hereby agrees that after this letter agreement (this "Agreement") has been fully executed and delivered by Questcor and you, you shall be entitled to receive the benefits set forth in this Agreement in the event of certain Changes in Control (as defined in this Agreement). Upon the execution and delivery of this Agreement, any prior severance agreement between you and the Company shall terminate and be of no further force or effect.

In the event that a Change in Control occurs, and you are employed by the Company, as a full time employee of the Company at any time during the period commencing 90 days prior to the Change in Control and ending on the Change in Control, all of your stock options under any plan of the Company that are then outstanding shall become vested and exercisable immediately prior to the Change in Control.

Also, in the event that a Change in Control occurs, and your employment with the Company is terminated as a result of Involuntary Termination (as defined below) other than for Cause (as defined below), at any time within the fifteen (15) month period commencing ninety (90) days prior to such Change in Control, and you are a full-time employee of the Company at any time within the thirty (30) days prior to the termination of your employment with the Company, then you will be entitled to receive from Questcor a severance benefit, payable in cash in a lump sum payment, in an amount equal to the sum of: (i) twelve (12) months of base salary, and (ii) your prorated maximum bonus opportunity for the fiscal year of Questcor in which the termination of your employment occurs (the "Termination Fiscal Year"). Such payment will be paid not later than ten (10) days following such termination of employment. For purposes of determining your severance benefit, your monthly rate of base salary will equal your greatest monthly rate of base salary in effect during the thirty (30) days prior to the date of the termination of your employment (or, if greater, your monthly rate of base salary in effect immediately prior to the Change in Control), and your prorated maximum bonus opportunity for the Termination Fiscal Year will equal your maximum bonus opportunity under the Company's bonus and incentive compensation plans for the Termination Fiscal Year, multiplied by a fraction, the numerator of which is the number of days during the Termination Fiscal Year that have elapsed on the date of the termination of your employment, and the denominator of which is the number of days in the Termination Fiscal Year. For purposes of this Agreement, you will be treated as a full-time employee of the Company if you are regularly scheduled to work for the Company for not less than forty (40) hours per week. Furthermore, in the event you are entitled to receive a severance benefit under this paragraph as a result of your termination of employment: (i) if the Board (or the Compensation Committee thereof) has determined the amount of your bonus for the fiscal year of Questcor immediately preceding the Termination Fiscal Year (the "Prior Fiscal Year") prior to the Change in Control, and Questcor has not paid the bonus for the Prior Fiscal Year (if any) to you prior to such termination of employment, Questcor will pay your bonus (as so determined) for the Prior Fiscal Year to you, or (ii) if the Board (or the Compensation Committee thereof) has not determined the amount of your bonus for the Prior Fiscal Year prior to the Change in Control, Questcor will pay to you a bonus for the Prior Fiscal Year in an amount not less than your maximum bonus opportunity for the Prior Fiscal Year. For purposes of this paragraph, any reference to the fiscal year of the Company will include the fiscal year of any successor thereto. Such payment will be paid in cash in a lump sum payment not later than ten (10) days following such termination of employment.

In the event you are entitled to a severance benefit under this Agreement, then in addition to such severance benefit, you will receive such health, term life and disability insurance benefits coverage ("Company-Provided Coverage") as is provided to you (and your dependents, if applicable) immediately prior to the termination of your employment with the Company, for twelve (12) months following the termination of your employment, or until you become covered under another employer's group insurance plan or plans providing health, term life and disability insurance coverage, whichever occurs first. In addition, for fifteen (15) months following the termination of the Company-Provided Coverage, the Company will provide you (and your dependents, if applicable) with such health, term life and disability insurance benefits coverage as is provided to you (and your dependents, if applicable) immediately prior to the termination of your employment with the Company, at your election and expense. The benefits coverage provided under this paragraph will be under such terms and conditions (including benefits, premiums, deductibles and co-payments) as are at least as favorable as those in effect

immediately prior to the date of termination of your employment (or, if more favorable, those in effect immediately prior to the Change in Control); provided, however, that, following the termination of the Company-Provided Coverage, your premiums for such benefits coverage will be based on the full cost of such coverage.

In the event that you are entitled to a severance benefit under this Agreement, then in addition to such severance benefit, you will have the right to require an extension of the exercise period of each of your then outstanding stock options under any plan of the Company (or any options into which any such options have been converted) for a period of two (2) years following the later of: (i) the termination of employment, or (ii) the expiration of a lock-up agreement (if any) imposed on the Company's optionees at the time of your termination of employment; provided, however, that in no event will such extension of such option extend beyond the expiration of the original term of the option.

For purposes of this Agreement, "Cause" means: (i) a material and willful violation of any federal or state law by you, (ii) the commission of a fraud by you against the Company, (iii) your repeated unexplained or unjustified absence from the Company, or (iv) your gross negligence or willful misconduct where such gross negligence or willful misconduct has resulted or is likely to result in substantial and material damage to the Company.

Also, for purposes of this Agreement, a "Change in Control" will occur upon any of the following events: (i) upon the acquisition (other than from Questcor) by any person, entity or "group," within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended from time to time (the "Exchange Act") (excluding, for this purpose, Questcor or its affiliates, or any employee benefit plan of Questcor or its affiliates which acquires beneficial ownership of voting securities of Questcor), of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of fifty percent (50%) or more of either the then outstanding shares of common stock, no par value, of Questcor or the combined voting power of Questcor's then outstanding voting securities entitled to vote generally in the election of directors; (ii) at the time individuals who, as of the date hereof, constitute the Board of Directors (the "Board") of Questcor (the "Incumbent Board") cease for any reason to constitute at least a majority of the Board, provided that any person becoming a director subsequent to the date hereof, whose election, or nomination for election by Questcor's stockholders, was approved by a vote of at least a majority of the directors then comprising the Incumbent Board (other than an election or nomination of an individual whose initial assumption of office is in connection with an actual or threatened election contest relating to the election of the directors of Questcor, as such terms are used in Rule 14a-11 of Regulation 14A promulgated under the Exchange Act) shall be, for purposes of this Agreement, considered as though such person were a member of the Incumbent Board; (iii) immediately prior to the consummation by Questcor of a reorganization, merger, consolidation, (in each case, with respect to which persons who were the stockholders of Questcor immediately prior to such reorganization, merger or consolidation do not, immediately thereafter, own more than fifty percent (50%) of the combined voting power entitled to vote generally in the election of directors of the reorganized, merged or consolidated company's then outstanding voting securities) or a liquidation or dissolution of Questcor or the sale of all or substantially all of the assets of Questcor; or (iv) the occurrence of any other event which the Incumbent Board in its sole discretion determines constitutes a Change of Control.

Finally, for purposes of this Agreement, "Involuntary Termination" means the termination of your employment with the Company either: (i) by the Company, or (ii) by you upon 30 days' prior written notice to the Company as a result of any of the following, without your written consent: (A) a material reduction in job responsibilities inconsistent with your position with the Company and your prior responsibilities, (B) a reduction in your annual base compensation or bonus opportunity from the Company, (C) a requirement that you perform services at a principal location that is more than 50 miles from the principal location at which you perform services for the Company, (D) a material reduction in your benefits from the Company, or (E) a reduction of your regularly scheduled work hours for the Company to less than 40 hours per week. The principal location at which you perform services for the Company on the date of this Agreement is the Company's principal offices at 3260 Whipple Road, Union City, California 94587-1217.

Notwithstanding the foregoing, in the event that the Company sells, transfers or otherwise disposes of all or substantially all of the assets or business related to any business unit, division, department or operational unit of the Company, and you are offered employment with the purchaser or other acquiror of such assets or business, or accept employment with such purchaser or acquiror, within 30 days following the termination of your employment with the Company, you will thereupon cease to be eligible for severance benefits and Company-Provided Coverage under this Agreement, unless you reject such offer of employment, and the terms and conditions of employment offered by the purchaser or other acquiror would result in any of the following: (i) a material reduction in job responsibilities inconsistent with your position with the Company and your prior responsibilities, (ii) a reduction in your annual base compensation or bonus opportunity from the Company, (iii) a requirement that you perform services at a principal location that is more than 50 miles from the principal location at which you perform services for the Company, (iv) a material reduction in your benefits, or (v) a reduction of your regularly scheduled work hours to less than 40 hours per week. For purposes of this paragraph, a material reduction in your benefits will occur unless the terms and conditions of employment offered by the purchaser or acquiror would provide for severance benefits to you that are equal to or greater than the benefits to be provided under the terms of this Agreement.

As a condition to receiving your severance benefit under this Agreement, you will waive any and all claims against the Company and its affiliates. Such waiver will be a general release of claims, and will be substantially in the form of the general release attached as Exhibit A hereto (or in such other form of general release as Questcor will, in its sole discretion, determine). The general release will be executed and delivered by you prior to receiving your severance benefit, and your severance benefit will be paid 10 days after you execute and deliver the general release, unless you have revoked the general release.

If any legal action or other proceeding is brought for the enforcement of this Agreement, or because of an alleged dispute, breach or default in connection with any of the provisions of this Agreement, the successful or prevailing party will be entitled to recover attorneys' fees and other expenses and costs incurred in that action or proceeding, in addition to any other relief that may be granted.

Notwithstanding the immediately preceding paragraph, in the case of any legal action or other proceeding by you to enforce a benefit under this Agreement, or an alleged

dispute, breach or default in connection with a benefit under this Agreement, regardless of whether you are successful or prevail: (i) the Company shall bear its attorneys' fees and other expenses and costs, and (ii) the Company shall reimburse you for your reasonable attorneys' fees and other reasonable expenses and costs, to the extent incurred in connection with such enforcement or attempted enforcement or alleged dispute, breach or default as part of the Initial Adjudication (as defined below), in addition to any other relief that may be granted. The Company shall not reimburse you for any attorneys' fees and other expenses and costs incurred in connection with such enforcement or attempted enforcement or alleged dispute, breach or default incurred by you following the Initial Adjudication. Such reimbursements of your attorneys' fees and other expenses and costs shall be made monthly not later than 30 days after the Company has received a copy of the written invoice evidencing such fees, expenses or costs. In the event that a court of competent jurisdiction determines that you have acted in connection with such enforcement or attempted enforcement, or alleged dispute, breach or default, in bad faith, or that your positions, claims or assertions were frivolous or without substantial basis, you shall repay to the Company any attorneys' fees and other expenses and costs paid by the Company to you pursuant to this paragraph. For the purposes of this Agreement, the "Initial Adjudication" shall mean the final order, decree or other adjudication of your claims by a court of competent jurisdiction with regard to such enforcement or attempted enforcement or such alleged dispute, breach or default.

This Agreement shall be construed and enforced in accordance with the laws of the State of California, without giving effect to the principles of conflict of laws thereof.

 $\label{eq:please indicate your acceptance of this Agreement by returning a signed copy of this Agreement.$ 

Sincerely,

/s/ Charles J. Casamento

Charles J. Casamento Chairman, President and CEO Questcor Pharmaceuticals, Inc.

Date: December 1, 2003

Accepted by,

/s/ R. Jerald Beers

- -----

Date: December 14, 2003

### FORM OF GENERAL RELEASE

General Release by Employee. In consideration for certain severance benefits from Questcor Pharmaceuticals, Inc. ("Questcor") under the Change in Control Agreement, dated \_\_\_, \_\_\_\_ (the "Agreement") between Questcor and \_\_\_\_\_ ("Employee") and other valuable consideration, the receipt and adequacy of which are hereby acknowledged, Employee does hereby release and forever discharge the "Company Releasees" herein, consisting of Questcor and each of Questcor's parents, subsidiaries, and affiliates, associates, members, owners, stockholders, predecessors, successors, heirs, assigns, employees, agents, directors, officers, partners, representatives, lawyers, and all persons acting by, through, under, or in concert with them, or any of them, of and from any and all manner of action or actions, causes or causes of action, in law or in equity, suits, debts, liens, contracts, agreements, promises, liabilities, claims, demands, damages, losses, costs or expenses, of any nature whatsoever, known or unknown, fixed or contingent (hereinafter called "Claims"), which they now have or may hereafter have against the Releasees by reason of any and all acts, omissions, events or facts occurring or existing prior to the date hereof, except as expressly provided herein. The Claims released hereunder include, without limitation, any alleged breach of any employment agreement; any alleged breach of any covenant of good faith and fair dealing, express or implied; any alleged torts or other alleged legal restrictions relating to the Employee's employment and the termination thereof; and any alleged violation of any federal, state or local statute or ordinance including, without limitation, Title VII of the Civil Rights Act of 1964, as amended, the Federal Age Discrimination in Employment Act of 1967, as amended, the Americans with Disabilities Act, as amended, the Family and Medical Leave Act, as amended, the Sarbanes-Oxley Act, as amended, the California Fair Employment and Housing Act, as amended, and the California Family Right Act, as amended. This Release shall also not apply to Employee's right to retirement and/or employee welfare benefits that have vested and accrued prior to his separation from employment with Questcor and its parents, subsidiaries and affiliates; or Employee's rights to indemnification under Section 2802 of the California Labor Code.

2. RELEASE OF UNKNOWN CLAIMS. EMPLOYEE ACKNOWLEDGES THAT HE IS FAMILIAR WITH THE PROVISIONS OF CALIFORNIA CIVIL CODE SECTION 1542, WHICH PROVIDES AS FOLLOWS:

"A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH, IF KNOWN BY HIM MUST HAVE MATERIALLY AFFECTED HIS SETTLEMENT WITH THE DEBTOR."

EMPLOYEE BEING AWARE OF SAID CODE SECTION, HEREBY EXPRESSLY WAIVES ANY RIGHTS HE MAY HAVE THEREUNDER, AS WELL AS UNDER ANY OTHER STATUTES OR COMMON LAW PRINCIPLES OF SIMILAR EFFECT.

- 3. Release of Age Discrimination Claims and Rights under the Older Workers' Benefit Protection Act. Employee agrees and expressly acknowledges that this Agreement includes a waiver and release of all claims which Employee has or may have under the Age Discrimination in Employment Act of 1967, as amended, 29 U.S.C. Section 621, et seq. ("ADEA"). The following terms and conditions apply to and are part of the waiver and release of the ADEA claims under this Agreement:
  - (a) That this paragraph, this General Release and the Agreement are written in a manner calculated to be understood by Employee.
  - (b) The waiver and release of claims under the ADEA contained in this General Release do not cover rights or claims that may arise after the date on which Employee signs this General Release.
  - (c) The Agreement provides for consideration in addition to anything of value to which Employee is already entitled.
  - (d) Employee is advised to consult an attorney before signing this General Release.
  - (e) Employee is granted twenty-one (21) days (or forty-five (45) days, if this General Release is in connection with an exit incentive or other employment termination program) after Employee is presented with this General Release to decide whether or not to sign this General Release. If Employee executes this General Release prior to the expiration of such period, Employee does so voluntarily and after having had the opportunity to consult with an attorney.
  - (f) If this General Release is in connection with an exit incentive or other termination program, Employee has received the information required to be disclosed under Section 7(f)(1)(H) of ADEA and the regulations thereunder.
  - (g) Employee will have the right to revoke the waiver and release of claims under the ADEA within seven (7) days of signing this General Release. In the event this General Release is revoked, the General Release executed concurrently herewith will be null and void in their entirety.
  - 4. Manner and Consequences of Revocation of Release
- (a) Manner of Revocation. In the event that Employee elects to revoke this General Release, he or she shall deliver within the time period prescribed above to the Chairperson of the Company's Board of Directors, a writing stating that he or she is revoking this General Release and subscribed by the Employee.
- (b) Consequences of Revocation. In the event that Employee should elect to revoke this General Release as described in the paragraph above, this General Release shall be

null and void in its entirety, and Employee will not receive the benefits provided for under the Agreement.

- 5. No Claims. Employee represents and warrants to the Releasees that there has been no assignment or other transfer of any interest in any Claim which Employee may have against the Releasees, or any of them. Employee agrees to indemnify and hold harmless the Releasees released by him or her from any liability, claims, demands, damages, costs, expenses and attorneys' fees incurred as a result of any person asserting such assignment or transfer of any right or claims under any such assignment or transfer from Employee.
- 6. Indemnification. Employee agrees that if he or she hereafter commence, join in, or in any manner seek relief through any suit arising out of, based upon, or relating to any of the Claims released hereunder or in any manner asserts against the Releasees any of the Claims released hereunder, then Employee will pay to the Releasees against whom such claim(s) is asserted, in addition to any other damages caused thereby, all attorneys' fees incurred by such Releasees in defending or otherwise responding to said suit or Claim; provided, however, that this Section 6 shall not apply to any claim or action to the extent it challenges the validity of this General Release under the ADEA.

The Parties further understand and agree that neither the payment of money nor the execution of this Release shall constitute or be construed as an admission of any liability whatsoever by the Releasees.

QUESTCOR PHARMACEUTICALS, INC.

By:
\_\_\_\_\_\_\_
Title:\_\_\_\_\_

Date:\_\_\_\_\_
"EMPLOYEE"

By:
\_\_\_\_\_\_
Print Name
\_\_\_\_\_\_
Signature

Date:\_\_\_\_\_

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### SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT is as entered into as of this 1st day of April, 2003 ("Effective Date") between Questcor Pharmaceuticals, Inc., a corporation organized under the laws of the State of California and having a place of business at 3260 Whipple Road, Union City, California 94587 U.S.A. ("Questcor") and Diagnostic Chemicals Limited, doing business as BioVectra dcl, a corporation organized under the laws of Prince Edward Island and having a place of business at 16 McCarville Street, Charlottetown, Prince Edward Island, C1E 2A6 Canada ("BioVectra") (each individually a "Party" and collectively the "Parties").

### WITNESSETH:

WHEREAS, Questcor wishes to purchase from BioVectra and BioVectra desires to sell to Questcor the Product (as hereinafter defined); and

WHEREAS, BioVectra represents that it has the technical and scientific experience and expertise necessary to perform manufacturing, packaging, analytical testing and/or quality assurance services for the manufacturing and bulk packaging of such Product, and to handle materials associated with manufacture of such Product in a safe and environmentally sound manner; and

WHEREAS, Questcor desires BioVectra to perform such services as set forth herein and manufacture such Product for Questcor, and BioVectra desires to perform such services and manufacture such Product for supply to Questcor or its designee, all on the terms and conditions set forth in this Agreement;

NOW, THEREFORE, in consideration of the mutual covenants and promises set forth herein, the Parties agree as follows:

### **DEFINITIONS**

The following terms, whether used in the singular or plural, shall have the meanings assigned to them below for purposes of this Agreement:

- 1.1 "Act" shall mean the United States Federal Food, Drug and Cosmetics Act, as amended, and the regulations promulgated under such Act.
- "Affiliate" shall mean any corporation or non-corporate entity 1.2 that controls, is controlled by, or is under common control with a Party. For purposes of this Section 1.2, "control," whether used as a noun or a verb, means the possession, directly or indirectly, of the power to affirmatively direct, or affirmatively cause the direction of, the management and policies of an entity, whether through the ownership of voting securities, by contract, or otherwise.
- 1.3 "Agreement" shall mean this Supply Agreement and any Schedules appended hereto, as may be amended from time to time.
- 1.4 "API" shall mean Active Pharmaceutical Ingredient.
- "Certificate of Compliance" shall mean a document indicating 1.5 that each batch of Product was manufactured in compliance with cGMP, and that all deviations were

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evaluated for impact on Product.

- 1.6 "COA" shall mean Certificate of Analysis.
- 1.7 "Confidential Information" shall mean all proprietary information, data and know-how of each Party, whether disclosed orally or visually or in written, graphic, electronic or other tangible form, which is disclosed by a Party or any of its Affiliates (the "Disclosing Party") to the other Party or any of its Affiliates (the "Receiving Party") or which the Receiving Party obtains in the course of its performance pursuant to this Agreement, and which: (a) if in written, graphic, electronic or other tangible form, is labeled as confidential or proprietary; (b) if disclosed orally or visually, is identified as confidential or proprietary at the time of disclosure and is confirmed to be confidential or proprietary by the Disclosing Party in writing to the Receiving Party within thirty (30) calendar days of such disclosure; or (c) by its nature, should reasonably be considered to be confidential or proprietary. With respect to Questcor, "Confidential Information" shall be deemed to also include (i) the Specifications; (ii) the Questcor Technology; and (iii) all business, financial and technical data of Questcor such as information regarding Questcor's plans, plants, processes, products, costs, equipment, operations, marketing plans, forecasts, customers or suppliers. With respect to BioVectra, "Confidential Information" shall be deemed to also include (i) its manufacturing processes and practices; (ii) the BioVectra technology; and (iii) all business, financial and technical data of BioVectra such as information regarding BioVectra's plans, plants, processes, products, costs, equipment, operations, marketing plans, forecasts, customers or suppliers.
- "Delivery Point" shall mean the Questcor ship-to location specified in the applicable Purchase Order for shipment of the ordered Product.
- 1.9 "FDA" shall mean the United States Food and Drug Administration or any successor entity thereof having or performing substantially the same function.
- 1.10 "Firm Order" shall mean a binding commitment in writing made by Questcor to purchase Product in accordance with Section 5.
- 1.11 "cGMP" shall mean all laws, guidelines and regulations applicable to the manufacture of Product including the current Good Manufacturing Practices as specified in the United States Code of Federal Regulations, as the same may be amended or re-enacted from time to time, and international guidelines and regulations such as ICH Q7A.
- "Non-Process Related Impurities" shall mean any substance that would not be present as a result of the process used to manufacture Product in compliance with cGMP.
- 1.13 "Product" shall mean the chemical substances or the
   formulation(s) thereof thereof listed in Schedule 1, attached
   hereto.
- 1.14 "Product Recall" shall mean any recall, withdrawal, field correction or other action to

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recover possession of quantities of the Product shipped or sold to Third Parties resulting in the event that (i) any government authority or other regulatory agency issues a request, directive or order that any Product or drug products derived from Product be recalled, (ii) a court of competent jurisdiction orders such a recall, (iii) Questcor reasonably determines after consultation with BioVectra that any Products should be recalled because they do not conform to the Specifications or other requirements of this Agreement at the time of shipment by BioVectra or (iv) Questcor reasonably determines that any Products should be recalled for any reason

- "Purchase Order" shall mean a written order for the purchase of Product duly executed by Questcor and transferred to BioVectra via mail, facsimile or electronically, and setting forth the quantity of Product ordered, the required delivery date, the Delivery Point, the price for the Product, the Purchase Order number, the name of the requester, and any special terms and conditions relevant to the particular Purchase Order (special terms and conditions are those that are not preprinted).
- "Quality Assurance" shall mean the total organized arrangements made with the object of ensuring that Product is of the quality required for its intended use and that quality systems are maintained so that all of the provisions set forth in Section 7.1.1 and in Section 9 of this Agreement are met.
- 1.17 "Quarter" shall mean the period of three consecutive calendar
  months ending 31 March, 30 June, 30 September and 31 December.
- 1.18 "Change" or "Deviation" shall mean any planned or unplanned deviation, variance or change.
- "Specifications" shall mean the specifications and quality assurance and other testing for the Product which will be attached hereto as Schedule 2, and made a part hereof, as determined in accordance with the analytical methodology set forth therein, as such Specifications may be amended from time to time in writing by mutual agreement of the Parties.
- 1.20 "Third Party" shall mean any party other than Questcor, BioVectra and their respective Affiliates and agents.
- 1.21 "Section" shall mean a Section of this Agreement.
- "NDA" means a New Drug Application as defined in and contemplated by the Act.
- "DMF" means the Drug Master File pertaining to the manufacture
  of the Product.

## SUPPLY OF PRODUCT

2.1 Supply and Purchase. BioVectra agrees to manufacture for and supply to Questcor or its designee on an exclusive basis such quantities of Product as Questcor may order from BioVectra, and Questcor agrees to purchase such quantities of Product from

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BioVectra, in accordance with the terms and conditions of this Agreement. Questcor shall be obligated to purchase a minimum of One Hundred Eighty (180) kilograms of Product under this Agreement.

- Equipment. Questcor will provide to BioVectra at no cost to BioVectra the equipment required to manufacture Product in accordance with the manufacturing process specified by Questcor, which equipment (and the location thereof) are listed on Schedule 5 attached hereto. BioVectra will be responsible for the costs of installation of the equipment, and providing adequate facilities to house the equipment. BioVectra will receive written authorization from Questcor prior to contracting to purchase additional equipment as may be required to produce Product for Questcor hereunder.
- Applicability and Hierarchy of Terms. The terms and conditions of this Agreement shall apply to any Purchase Order issued by Questcor to BioVectra during the term of this Agreement for the Product that is the subject of this Agreement, whether or not this Agreement or its terms and conditions are expressly referenced in the Purchase Order. In the event of a conflict between the pre-printed terms provided in any Purchase Order and the terms of this Agreement, the terms of this Agreement shall prevail.
- 2.4 Maintenance of Equipment. BioVectra shall be responsible for maintaining Questcor equipment (and any other BioVectra equipment required to manufacture Product) in good working order. Maintenance required of BioVectra includes, but is not limited to, preventative maintenance, calibration and repairs.
- 2.5 Use of Questcor Equipment. Questcor equipment is to be only used to manufacture the Product for Questcor hereunder.

## 3. TERM AND TERMINATION

- 3.1 Term. This Agreement shall commence on the Effective Date and shall continue in effect through December 31, 2007 (the "Initial Term"), unless terminated earlier as provided herein. Questcor, with the prior written approval of BioVectra, may extend this Agreement for successive two (2) year periods (each an "Extension Period") by giving BioVectra written notice of such extension of the Agreement at least ninety (90) calendar days prior to the expiration of the Initial Term or the applicable Extension Period, as the case may be, provided, however, that any refusal by BioVectra shall not be effective unless and until it provides for at least twenty-four (24) months prior written notice to Questcor of BioVectra's intention to end this supply relationship.
- 3.2 Termination Without Cause. Questcor may terminate this Agreement at any time without cause upon twelve (24) months prior written notice to BioVectra. Such termination shall not affect the Parties' obligations with respect to Purchase Orders issued to BioVectra by Questcor, nor relieves Questcor of its obligation to purchase minimum quantities as specified in Section 2.1 prior to the effective date of such

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termination. BioVectra may terminate this Agreement without cause and without liability upon twenty-four (24) months prior written notice to Questcor, during which period Questcor shall endeavor in good faith to locate and qualify a substitute manufacturer for Product, but if such manufacturer cannot be located and/or qualified in such period, this Agreement shall be extended for one six (6) month period to give Questcor additional time to locate and qualify such a manufacturer

- 3.3 Termination for Cause. Without prejudice to any other available legal or equitable rights or remedies, the Parties may terminate this Agreement immediately upon written notice to the other Party as follows:
  - 3.3.1 Material Breach. Either Party may terminate this Agreement in the event of the material breach by the other Party of the terms and conditions hereof ("Default"), through no fault of the non-Defaulting Party, which remains uncured ninety (90) calendar days after the non-Defaulting Party provides written notice of such Default to the Defaulting Party; provided however, that in the event that the Defaulting Party reasonably believes that the Default is incapable of being cured within such ninety (90) day period, then the Defaulting party shall provide written notice to the non-Defaulting Party within seven (7) calendar days from the date of the notice of such Default, specifying that such Default is not capable of being cured within such period and the actions the Defaulting Party is taking to diligently cure such Default, and the non-Defaulting Party may, in its sole discretion, agree in writing to extend the time period for curing such Default for up to an additional thirty (30) calendar days or such time as is reasonably necessary to cure such Default.
  - 3.3.2 Insolvency; Bankruptcy. Either Party may terminate this Agreement in the event that the other Party (a) becomes insolvent; (b) makes an assignment for the benefit of creditors; (c) files or has filed against it a petition in bankruptcy; (d) has a receiver appointed for its assets; or (e) is dissolved or liquidated.
  - 3.3.3 Continued Manufacture. Termination under this Section 3.3 shall not cause Product to be unavailable to persons who are in need thereof. In the event this Section 3.3 becomes applicable, the Parties agree to collaborate in good faith to develop a new source of manufacture thereof so as to keep Product available in the marketplace for the benefit of the users thereof. Questcor agrees to diligently locate and qualify a new manufacturer of the Product and BioVectra agrees that it will not discontinue manufacture of the Product until such new manufacturer is qualified; provided, however, that if BioVectra's inability to manufacture specification conforming Product is the basis for termination under Section 3.3.1 above, then Questcor shall not obligate BioVectra to manufacture further non-conforming Product, but BioVectra agrees that it will, to the best of its ability, correct any deficiencies at its own expense and manufacture specification-conforming Product hereunder after

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any such notice of termination is received until such new manufacturer is qualified.

3.3.4 Transfer of Materials and Equipment. If this
Agreement is terminated under this Section 3.3,
BioVectra shall promptly transfer to Questcor or
Questcor's designee, at Questcor's written request
and expense, all raw materials purchased by Questcor
and supplied to BioVectra and all Questcor equipment.

## 4. PRICE AND PAYMENT

- 4.1 Price of Product. The price for Product provided hereunder shall be as set forth in Schedule 3 to this Agreement. Such prices shall be firm through the entire "Initial Term" and through any subsequent contract extensions.
- 4.2 Price Adjustments. The price for Product may only be adjusted as provided in Schedule 3 hereto.
- 4.3 Billing and Payment. BioVectra will submit invoices to Questcor at the address designated in the applicable Purchase Order. Invoices shall include the following information, where applicable: the description and quantity of Product delivered; the date of shipment of Product; the price for the Product; any applicable taxes, transportation charges or other charges provided for in the applicable Purchase Order; and the applicable Purchase Order number. Questcor shall pay all invoices to BioVectra in U.S. dollars within thirty (30) days from when the Product is delivered to or on behalf of Questcor at the Delivery Point, provided that: i) Questcor has received from BioVectra complete and accurate certificates of analysis and any other Process records required to be provided to Questcor pursuant to the provisions of Section 9 for such lot; ii) Questcor or its designee has actually received the applicable lots of Product; and iii) the lot (or partial lot) is not rejected by Questcor or its designee. In the event that any shipment does not contain the entire invoiced quantity of Product, Questcor shall only be obligated to pay for the quantity of Product actually received by or on behalf of Questcor. Payment by Questcor shall not result in a waiver of any of its rights under this Agreement.
- 4.4 Documentation Delays. For each day that such complete and accurate required documentation is delayed, the due and payable date of the related invoice will be delayed by one (1) business day. Questcor will notify BioVectra if payment is to be delayed due to incomplete or inaccurate documentation stating in sufficient detail the reasons therefor. Questcor shall not be obligated to make payment for a lot of Product if Product is rejected. If a lot of rejected Product is subsequently approved by Questcor, Questcor shall pay BioVectra for such lot within thirty (30) calendar days following such approval date.
- 4.5 Disputed Amounts. If Questcor disputes in good faith all or any portion of any invoice submitted by BioVectra, Questcor shall be required to pay that portion of the invoiced amount that is not in dispute. In such event, Questcor shall notify BioVectra in writing of the amount and nature of the dispute within thirty (30) calendar days

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after receipt of the applicable invoice, and the Parties shall promptly attempt in good faith to amicably resolve such dispute. Once the matter is resolved, Questcor shall promptly pay any amount as may be due BioVectra.

Taxes. The Prices stated in this Agreement or a Purchase Order include all taxes except such sales and use taxes that BioVectra is required by law to collect from Questcor. Such taxes, if any, will be separately stated in BioVectra's invoice and will be paid by Questcor to BioVectra unless an exemption is available. BioVectra shall be responsible for the timely payment of all such taxes to the applicable taxing authority, and BioVectra shall pay (without reimbursement by Questcor), and shall hold Questcor harmless against, any penalties, interest or additional taxes that may be levied or assessed as a result of the failure or delay of BioVectra to pay any taxes. Questcor shall be responsible for any duties that result from BioVectra shipping Product to any Questcor designated Delivery Point.

## 5. FORECASTS AND FIRM ORDERS

- Forecasts. Questcor shall provide to BioVectra quarterly 5.1 forecasts of its estimated requirements for Product ("Forecast"). Questcor shall provide such Forecasts to BioVectra at least sixty (60) calendar days before the beginning of each calendar Quarter during the Term of this Agreement (beginning with the first Quarter in which Questcor intends to purchase Product hereunder), and such Forecasts shall provide an estimate of Questcor's requirements for Product for such Quarter and for the next succeeding three (3) Quarters. Such Forecasts shall be estimates for planning purposes only and shall not constitute commitments by Questcor to purchase Product. Questcor shall only be obligated to purchase such quantities of Product as may be ordered by Questcor pursuant to a Purchase Order issued by Questcor to BioVectra, as provided in Section 5.2 below.
- Firm Orders. BioVectra will provide Product to Questcor pursuant to orders placed by Questcor in the form of individual Purchase Orders issued by Questcor to BioVectra. At least forty-five (45) calendar days prior to the beginning of each Quarter during the Term of this Agreement, beginning with the first Quarter in which Questcor intends to purchase Product under this Agreement, Questcor shall issue a Purchase Order for its requirements of Product for such Quarter. Questcor shall ensure that BioVectra has sufficient raw materials therefor in accordance with Section 9.2.1 below.

### 6. DELIVERY; ACCEPTANCE; TITLE; RISK OF LOSS

One Delivery of Product. BioVectra will deliver Product to Questcor FOB, Charlottetown, per UCC Section 2-319(1)(a), at the Delivery Point by the date(s) specified in the applicable Purchase Order (the "Delivery Date"). BioVectra may not deliver Product more than seven (7) calendar days prior to such Delivery Date without the prior written consent of Questcor. Questcor shall not be obligated to accept any untimely, incomplete shipments less than sixty five percent (65%) of the Purchase

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Order amount or excessive shipments greater than one hundred thirty five percent (135%) of the Purchase Order amount, and such shipments, in whole or in part, may, at Questcor's option, be returned to BioVectra or held for disposition at BioVectra's expense and risk.

- 6.2 Timely Delivery. In the event that BioVectra fails to deliver fully conforming Product by the Delivery Date, Questcor, at its option and in addition to any of its other rights or remedies, may: (a) require BioVectra to expedite delivery of Product at BioVectra's own expense; (b) extend the required Delivery Date; or (c) cancel the applicable Purchase Order.
- Transportation. BioVectra will be responsible for routing of all freight, unless Questcor specifies otherwise in writing for a particular Purchase Order. Questcor shall be responsible for all transportation charges on Product shipped from BioVectra to Questcor or its designee, subject to Section 6.2(a) above. BioVectra shall bear the cost of transportation for Product shipped to Questcor or its designee to replace non-conforming or defective Product, and BioVectra shall bear the cost of transportation for Product returned to BioVectra by Questcor due to any defect or non-conformance, whether for the convenience of BioVectra or pursuant to a demand by Questcor as provided herein.
- Title and Risk of Loss. Title to and risk of loss of or damage to the Product sold hereunder shall pass to Questcor upon loading of the Product at BioVectra, Charlottetown. Questcor shall assume the risk of loss of or damage to the Product after such loading of the Product at BioVectra, except to the extent that such loss or damage results from the negligence or willful misconduct of BioVectra or its representatives, for which BioVectra shall retain the risk of loss of or damage to Product.
- Acceptance; Rejection. All Product delivered by BioVectra to Questcor or its designee shall be subject to inspection by or on behalf of Questcor and Final Release (as defined in Section 9 below) by Questcor's Quality Assurance representative. Questcor may, on written notice to BioVectra within sixty (60) calendar days from receipt of delivery, reject any Product that does not fully conform to the requirements of this Agreement and the applicable Purchase Order, and Questcor may return any shipment or any portion of any shipment that does not fully conform. Payment for Product by Questcor shall not constitute acceptance thereof. Questcor may revoke its acceptance of any Product in the event that any non-conformance is discovered after acceptance by Questcor.

### 7. REPRESENTATIONS AND WARRANTIES

- 7.1 Warranties by BioVectra. BioVectra represents and warrants to Questcor that:
  - 7.1.1 Product. All Product provided to Questcor by BioVectra pursuant to this Agreement:

BioVectra

[ ] [ ] Questcor BioVectra

- (a) Will conform in all respects with the Specifications for such Product in effect at the time title to such Product passes from BioVectra to Questcor pursuant to this Agreement;
- (b) Will not be adulterated or misbranded within the meaning of the Act or any similar law of any other jurisdiction; will be free from Non-Process Related Impurities; and will be free of any defects;
- (c) Will not have been manufactured with Deviation(s) unless approved in writing by Questcor prior to release by BioVectra and subsequent delivery of the Product to Questcor or its designee;
- (d) Will conform to and will be manufactured, packaged, labeled, stored and shipped in conformity with FDA regulations, cGMP requirements, the Specifications, the NDA pertaining to the Product, and all applicable national, federal, state, provincial, and local laws, orders, rules and regulations.
- (e) Will be manufactured, packaged and stored in facilities that are approved by the applicable regulatory authorities for the manufacture of Product at the time of such manufacture, packaging and storage, to the extent such approval is required by law or regulation.
- 7.1.2 Title. BioVectra has good title to all Product provided to Questcor pursuant to this Agreement and passes such title to Questcor free and clear of any security interests, liens, or other encumbrances.
- 7.1.3 Debarment. BioVectra represents and warrants that it is not debarred under subsections 306(a) or (b) of the Act and that it has not and will not use in any capacity the services of any person or entity debarred under such law with respect to its performance of this Agreement. BioVectra will immediately notify Questcor in the event that it or any such person or entity is debarred during the term of this Agreement.
- 7.1.4 No Conflict. The execution, delivery and performance of this Agreement by BioVectra does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, and does not violate any law or regulation of any court, governmental body or administrative or other agency having authority over it; BioVectra is not currently a party to, and during the term of this Agreement will not enter into, any agreements, oral or written, that are inconsistent with its obligations under this Agreement.
- 7.1.5 Authority. BioVectra is validly existing and in good standing under the laws of the province of its incorporation and has the corporate power and authority to enter into this Agreement. This Agreement has been duly executed and delivered by BioVectra and constitutes the valid and binding obligation of BioVectra, enforceable against it in accordance with its terms except as

[ ] [ ] Questcor BioVectra enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles. The execution, delivery, and performance of this Agreement have been duly authorized by all necessary action on the part of BioVectra, its officers and directors.

- 7.2 Breach of Warranty by BioVectra. In the event that any Product does not meet any of BioVectra's warranties then, in addition to any other rights or remedies available to Questcor, BioVectra shall, at Questcor 's option, either use its best efforts to replace the non-conforming Product as soon as practicable or promptly refund the payments by Questcor for such non-conforming Product.
- 7.3 Independent Laboratory Testing. If Questcor and BioVectra are unable to agree as to whether any Product conforms to the Specifications for such Product, the Parties shall cooperate to have the Product in dispute analyzed by an independent testing laboratory of recognized repute selected by BioVectra and approved by Questcor, which approval shall not be unreasonably withheld, conditioned or delayed. The results of such laboratory testing shall be final and binding on the Parties on the issue of conformance of the Product to the Specifications. If the Product is determined to so conform, then Questcor shall bear the cost of the independent laboratory testing and pay for the Product in accordance with this Agreement. If the Product is determined not to conform, then BioVectra shall bear the cost of the independent laboratory testing, and BioVectra shall, at Questcor's sole discretion, within thirty (30) calendar days of the date of such determination, either replace the rejected Product at no cost to Questcor or promptly refund to Questcor the price paid for such Product.
- 7.4 Warranties by Questcor. Questcor represents and warrants to BioVectra that:
  - 7.4.1 No Conflict. The execution, delivery and performance of this Agreement by Questcor does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, and does not violate any law or regulation of any court, governmental body or administrative or other agency having authority over it; Questcor is not currently a party to, and during the term of this Agreement will not enter into, any agreements, oral or written, that are inconsistent with its obligations under this Agreement.
  - Authority. Questcor is validly existing and 7.4.2 in good standing under the laws of the state of its incorporation and has the corporate power and authority to enter into this Agreement. This Agreement has been duly executed and delivered by Questcor and constitutes the valid and binding obligation of Questcor, enforceable against it in accordance with its terms except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles. The execution,

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delivery and performance of this Agreement have been duly authorized by all necessary action on the part of Questcor, its officers and directors.

#### 8. PRODUCT RECALLS

- 8.1 Cooperation. In the event of any Product Recall, the Parties shall take all appropriate corrective actions and shall cooperate in the investigations and all necessary activities surrounding the Product Recall.
- 8.2 Consultation. In the event that BioVectra or Questcor determines that Product should be recalled, the Parties shall consult with each other prior to taking any corrective actions. Given that in the marketplace the Product is or will be associated with Questcor, in no event shall BioVectra institute a Product Recall without the prior written approval of an officer of Questcor.
- 8.3 Product Recall Caused by BioVectra. To the extent that any Product Recall results from any cause or event arising from the manufacturing, packaging, labeling, testing, storage, or handling of the recalled Product by BioVectra, by any breach of BioVectra's warranties, by any materials or facilities provided by BioVectra, or otherwise by the acts or omissions of BioVectra or its agents, BioVectra shall be responsible for all expenses of such Product Recall.
- 8.4 Product Recall Caused by Questcor. To the extent that any Product Recall results from any cause or event arising from the Specifications, the raw materials supplied by or on behalf of Questcor, marketing, distribution, shipment, handling (after title passes to Questcor) or sale of the recalled Product by Questcor or its Affiliates or designee at the Delivery Point, or the negligence of Questcor or its Affiliates or designee at the Delivery Point, Questcor shall be responsible for all expenses of such Product Recall, including, without limitation, reasonable and necessary expenses incurred by BioVectra after written notification to Questcor and written approval by Questcor therefor.
- 8.5 Expenses of Product Recall. In the event that a Product Recall is caused by BioVectra, BioVectra shall be liable to reimburse Questcor for all expenses of such Product Recall, including, without limitation, the following: (i) all amounts paid by Questcor to BioVectra for the Product subject to the Product Recall, (ii) all reasonable costs and expenses incurred and not recovered by Questcor directly resulting from such Product Recall (including, without limitation, shipping charges, hours spent coordinating the Product Recall, expenses of notification and destruction or return of the recalled Product, all costs associated with the distribution of replacement Product, and all other costs incurred in connection with such Product Recall). The foregoing remedies shall be in addition to such other rights and remedies as Questcor may have under this Agreement and applicable law.
- 8.6 Disputes Regarding Cause of Product Recall. If the Parties are unable to agree as to which Party's acts or omissions gave rise to a Product Recall, such dispute shall be referred for decision to a mutually agreed upon independent expert of recognized

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repute (acting as an expert and not as an arbitrator, and who may be an attorney knowledgeable in FDA/pharmaceutical product recall law) selected by Questcor and approved by BioVectra, which approval shall not be unreasonably withheld, conditioned or delayed. The results of such independent expert shall be final and binding on the Parties on the issue of which Party's acts or omissions gave rise to the Product Recall. The costs of such independent expert shall be borne by the Party determined to be responsible for the Product Recall.

8.7 Notification Regarding Product Recall. Subject to Section 8.2 above, in the event that any Product Recall is required because Product violates applicable laws, regulations, agreed upon Specifications, the NDA pertaining to the Product, or is deemed unacceptable for some other reason, whether or not such action is requested by any governmental agency, the initiating Party shall notify the Quality Assurance Representative of the other Party as soon as possible, but not later than the end of the next business day following the decision to implement such action.

### 9. QUALITY ASSURANCE

9.1 Change Control. BioVectra will utilize a documented system of procedures for the control of changes to raw materials, packaging materials, suppliers, equipment, manufacturing methods, Product, intermediates and raw materials specifications, sampling, test methods, and release requirements, consistent with cGMPs, all applicable laws, rules and regulations, including the NDA pertaining to the Product, and industry standards. BioVectra shall not implement any Change without the express prior written approval of Questcor. BioVectra will submit any proposed Change to Questcor in writing for its review, using the Deviation/Change Form attached hereto as Schedule 4. The Parties will provide written responses to requests from the other pursuant to this Section 9.1 as soon as commercially possible but in no event more than twenty (20) business days from receipt of the request from the other Party hereto. All updates to BioVectra's DMF (and any other of BioVectra's regulatory documents) related to the Product (or manufacture of the Product) are the responsibility of BioVectra. Updates to regulatory applications such as the NDA pertaining to the Product are the responsibility of Questcor

## 9.2 Raw Materials.

9.2.1 Procurement of Raw Materials. BioVectra will utilize a documented system of procedures to evaluate, qualify and approve raw materials and suppliers.

BioVectra is responsible for procuring suitable raw materials (other than pituitary gland starting material and oxycellulose gauze) from the approved and qualified sources.

Questcor, at Questcor's expense, shall provide pituitary gland starting material and oxycellulose gauze to BioVectra in amounts required for BioVectra to

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fulfill its supply obligations to Questcor hereunder. In this regard, Questcor will provide sufficient quantity of appropriate quality pituitary gland starting material and oxycellulose gauze necessary to fulfill Questcor's obligation to purchase minimum quantities of Product as set forth in Section 2.1 above.

9.2.2 Inspection and Testing of Raw Materials. BioVectra must utilize documented material inspection plans and testing procedures. The results of this inspection and testing must be in accordance with BioVectra established specifications and the NDA pertaining to the Product.

BioVectra shall inspect all containers of raw materials (including the pituitary gland starting material) promptly upon receipt by BioVectra. BioVectra will inspect and/or test all raw materials on a batch-by-batch basis. BioVectra may accept and release certain starting materials utilizing the COA with abbreviated or no additional testing. However, a minimum of an identification test is required unless the material is too hazardous or reactive to sample.

9.2.3 Storage and Handling of Raw Materials. BioVectra agrees to store and handle the materials under appropriate conditions, consistent with cGMPs, all applicable laws, rules and regulations, including the NDA pertaining to the Product, and industry standards.

BioVectra agrees to store Product labeling materials under appropriate controlled and secured conditions, consistent with cGMPs, all applicable laws, rules and regulations, including the NDA pertaining to the Product, and industry standards.

BioVectra shall have all necessary and appropriate controls in place to prevent cross-contamination of the raw materials and intermediates used in the manufacture of Product from other chemicals stored, used, or manufactured by BioVectra, including but not limited to potent hormones, cytotoxic compounds, beta-lactams, highly potent drugs, biological preparations or non-pharmaceutical chemicals.

9.2.4 Transmissible Spongiform Encephalopathies (TSE)
Compliance. Upon request by Questcor, BioVectra will
promptly provide a written TSE declaration that all
materials (except porcine pituitary glands and
porcine gelatin supplied by or on behalf of Questcor)
used by BioVectra to manufacture Product are free
from animal derived material. BioVectra shall obtain
such written TSE declarations from each supplier of
raw material used in the manufacturing of Product and
shall maintain such TSE declarations for inspection
by Questcor upon its request.

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If BioVectra is unable to provide the above mentioned declaration(s), BioVectra must comply with applicable TSE laws and regulations and must supply all associated TSE documentation, as requested by Questcor, during the Term. Such documentation may include, but is not limited to, an application for a TSE Certificate of Suitability in accordance with European Directive 75/318/EEC as amended by directive 1999/82/EEC, the note for guidance EMEA/410/01 rev1, as amended and AP-CSP (99)4, Appendix 2, as amended.

- 9.2.5 Certificate of Compliance for Animal Derived Components. BioVectra is to issue a Certificate of Compliance (signed by BioVectra's Head of Quality Assurance) that states that the only animal derived components used in the manufacture of Product are porcine pituitary glands and porcine gelatin. This Certificate of Compliance is to be included in each lot batch record. The format of a Certificate of Compliance approved by Questcor is attached hereto as Schedule 6.
- 9.3 Product Specifications. BioVectra will manufacture, package, label and handle all Product in conformance with, and in order for the Product to be in conformance with, the Specifications and the NDA pertaining to the Product.
- 9.4 Manufacturing and Packaging of Product. BioVectra shall manufacture, package, and label all Product in accordance with specific procedures and instructions consistent with cGMPs, all applicable laws, rules and regulations, and the NDA pertaining to the Product, and industry standards.

BioVectra will prepare all appropriate and required manufacturing and packaging batch documentation for each batch of Product manufactured pursuant to this Agreement. BioVectra shall retain such batch documentation in accordance with any document retention schedules provided by Questcor and as required in order to comply with applicable regulatory requirements. BioVectra will make any such batch documentation available for review and inspection by Questcor and/or any regulatory personnel, and BioVectra shall provide to Questcor all such batch documentation upon the expiration or termination of this Agreement or upon request by Questcor.

BioVectra shall have all necessary and appropriate controls in place to prevent cross-contamination of Product and intermediates used in the manufacture of Product from other chemicals stored, used, or manufactured by BioVectra, including but not limited to potent hormones, cytotoxic compounds, highly potent drugs, biological preparations or non-pharmaceutical chemicals. Beta-lactam and cephalosporin antibiotics must be handled in facilities separate from those in which Product is manufactured and packaged.

BioVectra shall assure that materials in its possession containing any potentially hazardous component are sufficiently isolated and segregated from the Product

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manufactured for Questcor. BioVectra shall make Questcor aware of the presence of any potentially hazardous products and will adhere to all reasonable requests of Questcor with respect to the storage of such materials. BioVectra will adhere to any regulatory requirements or restrictions with respect to the storage of raw materials, intermediates, or Product.

BioVectra will destroy any waste material or labeling materials in a secure and legal manner, in order to prevent unauthorized use and/or environmental problems.

9.5 Inspection and Testing of Product. BioVectra will perform the inspection and testing of Product as provided in Schedule 2 to this Agreement. Questcor reserves the right to inspect and/or test all batches of the Product delivered to Questcor or any Questcor designee.

BioVectra will provide to Questcor a complete copy of the entire batch record that shall include but not be limited to (i) COA, (ii) executed batch record, (ii) all testing results conducted by BioVectra and/or independent testing labs contracted by BioVectra, (iii) Certificate of Compliance concerning animal derived components (per Section 9.2.5 above), (iv) Deviation final reports that have been approved by Questcor, and (v) any other associated documentation mutually agreed to by both Parties for each batch of Product delivered. BioVectra will deliver the complete batch record and associated documents with each batch no later than the time of delivery of the batch by BioVectra to Questcor or its designee.

- 9.6 Notification and Approval of Deviations. BioVectra will have a documented system for handling Deviations, Deviation investigations, and corrective actions. All Deviations will be investigated and fully documented by BioVectra. BioVectra is to notify Questcor within five (5) business days from the time that BioVectra discovers the Deviation. All Deviations (including the final report which outlines the Deviation, investigation and corrective actions taken) must be reviewed and approved by Questcor. BioVectra will retain such documentation as part of the batch documentation for the batch affected. Shipment of a lot shall not occur until Questcor has approved all Deviations.
- 9.7 Release and Shipment of Product. BioVectra has the responsibility to release the Product for shipment to Questcor or its designee, provided, however, that if Product does not meet the Specifications in all respects, without any deviations not approved by Questcor, the Product can be released only with the prior written consent of Questcor.

BioVectra will not ship any Product to any Delivery Point, as identified by Questcor, until the Product is released.

9.8 Retained Samples of Product. BioVectra shall retain samples of all Product batches in accordance with the retention schedule mutually agreed upon but for no less than seven (7) years. The amount of such retained samples shall be of sufficient quantity to conduct at least full Specification analyses in duplicate. BioVectra shall store the

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retained samples under appropriate Product label storage conditions in a secure area and in a suitable storage facility, consistent with cGMPs, all applicable laws, rules and regulations, and industry standards. All such samples shall be available for inspection by Questcor during any audit by Questcor of BioVectra's facilities or upon reasonable notice to BioVectra by Questcor.

- 9.9 Storage of Product. BioVectra agrees to store the Product under appropriate Product storage conditions and in a secure area, consistent with cGMPs, all applicable laws, rules and regulations, and the NDA pertaining to the Product, and industry standards.
- 9.10 Annual Product Quality Review(s). BioVectra will prepare and provide to Questcor a Product Quality Review Report ("PQRR") on an annual basis, consisting of a systems review to confirm 1) processing, 2) that Product consistently meets the Specifications and limits, 3) identification of any significant trends (data or nonconformance) and 4) continued support for established retest dating. Such PQRR shall be provided by BioVectra to Questcor within thirty (30) calendar days from each one-year anniversary of the Effective Date of this Agreement or such other times as may be mutually agreed upon by the Parties.
- 9.11 In addition, Questcor and BioVectra will meet as necessary to review quality issues related to the obligations and responsibilities as described in this Agreement. During this review, quality issues related to the past production by BioVectra of Product will be reviewed. The information presented and discussed during this review meeting will be documented by BioVectra and submitted to Questcor for its review and approval.
- 9.12 Complaints about the Product. BioVectra will have a documented system to receive, communicate with Questcor, investigate, and resolve all complaints related to Product. BioVectra will investigate the complaints as requested by Questcor and provide a written report on the results of the investigation to Questcor within thirty (30) calendar days. If necessary, Questcor will communicate with the customers and/or the regulatory authorities the results of the complaint investigation.
- 9.13 Returned Goods. BioVectra will have a documented system for handling returned goods, consistent with cGMPs, all applicable laws, rules and regulations, and industry standards.
- 9.14 Audits and Inspections of Facilities and Product. BioVectra will notify Questcor of any inspections of BioVectra's facilities used in the manufacture or storage of Product, or other actions that could potentially impact Product, by any regulatory agencies or other enforcement entities. BioVectra will provide Questcor with a written summary describing all results of inspections within thirty (30) days after the visit or inquiry. If any inspection is specifically related to the Product, BioVectra shall promptly inform Questcor and give Questcor representatives the opportunity to participate, at Questcor's expense, in the inspection.

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Questcor reserves the right to audit BioVectra's facilities, systems, and documentation as they relate to the manufacture and control of Product, and to assure compliance with this Agreement, including but not limited to Product manufacturing, storage, quality control, environmental compliance and health and safety compliance. These audits may be performed on a periodic basis at times mutually agreed upon by both Parties. The right to audit will also cover any subcontractors (e.g. a contract laboratory) if utilized by BioVectra. Questcor also reserves the right to be present at BioVectra's facility during the manufacture of Product.

#### 10. CONFIDENTIALITY

- 10.1 Restrictions. Except as otherwise provided in this Section 10, during the Term of this Agreement, including any renewals thereof, and for a period of ten (10) years thereafter: (i) each Party will hold the Confidential Information of the other Party in strict confidence and will protect such Confidential Information with at least the same degree of care that it exercises with respect to its own Confidential Information, which shall be no less than a reasonable degree of care; (ii) neither Party will disclose the Confidential Information of the other without in each instance obtaining the prior written consent of the Disclosing Party; (iii) each Party will use the Confidential Information of the other only as is necessary to fulfill its obligations under this Agreement and for achieving the purposes of this Agreement and not for any other purpose; and (iv) each Party will limit internal disclosure of the other Party's Confidential Information to its and its Affiliates' officers, employees or agents on a need-to-know basis for purposes of fulfilling its obligations under this Agreement and achieving the purposes of this Agreement, provided, however, that each of these officers, employees and agents shall have been advised of the confidential nature of the Confidential Information, are bound by these restrictions, and have been directed to treat such information confidentially and otherwise comply with this Agreement. In any event, the Receiving Party shall be responsible for any breach of the terms of this Agreement by any of its or its Affiliates' officers, employees or agents.
- 10.2 Exceptions. Notwithstanding the provisions of Section 10.1 above, neither Party shall have any obligations with respect to information which the Receiving Party can demonstrate: (i) is or becomes generally available to the public other than through the Receiving Party's disclosure; (ii) was in the Receiving Party's possession prior to it being furnished by or on behalf of the Disclosing Party, provided that the Receiving Party's source had the legal right to disclose such information; (iii) becomes available to the Receiving Party on a non-confidential basis from a source other than the Disclosing Party, provided that the Receiving Party's source had the legal right to disclose such information; (iv) is or becomes independently developed by an employee of the Receiving Party without access to the Confidential Information and without violating any of the Receiving Party's obligations under this Agreement; (v) is required to be disclosed to any governmental agency for purposes of obtaining patents or approvals to test or market the Product; or (vi) is required to be disclosed by order of any court of competent jurisdiction or other governmental authority, provided, however, that the Receiving Party shall provide to the Disclosing Party

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prompt written notice (but in no event less than fourteen (14) calendar days) prior to such disclosure so that the Disclosing Party may attempt by appropriate legal means to limit such disclosure at its cost and expense, and the Receiving Party shall endeavor in good faith to limit the disclosure and maintain the confidentiality of such Confidential Information to the maximum extent possible, provided, however, that nothing in this Agreement shall be deemed to require the Receiving Party to violate and law or judicial order.

10 3 Return of Confidential Information. Each Party agrees to promptly return all Confidential Information and all copies thereof to the Disclosing Party, and to destroy all information created by Receiving Party that contains Confidential Information furnished by Disclosing Party, at the expiration or termination of this Agreement, or at any time prior to the expiration or termination of this Agreement upon the Disclosing Party's written request (provided, however, that the Receiving Party shall not be required to return such Confidential Information to the Disclosing Party prior to the expiration or termination or this Agreement that the Receiving Party reasonably requires in order to perform its obligations under this Agreement). Upon request of the Disclosing Party, the Receiving Party shall provide written certification of such return or destruction. Notwithstanding the foregoing, the Receiving Party may retain one (1) copy of such Confidential Information in its legal archive files solely for purposes of identifying such Party's obligations under this Agreement or complying with other legal requirements, including under the Act. Notwithstanding the Receiving Party's return and destruction of the Confidential Information, Receiving Party will continue to be bound by its obligation of confidentiality as otherwise provided herein.

## 11. INDEMNIFICATION

Indemnification by Questcor. Except as otherwise specifically 11.1 provided in Section 11.2 below, Questcor shall indemnify, defend and hold harmless BioVectra, its Affiliates, and its and their respective directors, officers, employees, agents, successors and assigns from and against any and all claims, demands, losses, damages, judgments, settlement amounts, suits, actions, liabilities, costs and expenses (including, but not limited to, court costs and reasonable attorneys' fees) arising out of or resulting from: (i) any negligence or willful misconduct of Questcor, its employees or agents in the use, handling (after title has passed to Questcor), shipment, distribution, marketing or sale of any Product; (ii) any injury or death to persons or theft of or damage to property resulting from the use, handling (after title has passed to Questcor), shipment, distribution, marketing or sale of any Product unless caused by defective or non-conforming Product; (iii) the material default by Questcor in the performance of any obligation hereunder or Questcor 's breach of any of its warranties or representations hereunder; (iv) any labeling of any Product to the extent that such labeling has been supplied by or at the direction of Questcor and applied in accordance with instructions from Questcor; and/or (v) any proceeding instituted by or on behalf of a Third Party based upon a claim that the manufacture, use or sale of the Product infringes any intellectual property right, including any patent, trademark

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or trade secret of such Third Party.

- 11.2 Indemnification by BioVectra. Except as otherwise specifically provided in Section 11.1 above, BioVectra shall indemnify, defend and hold harmless Questcor, its Affiliates, and its and their respective directors, officers, employees, agents, successors and assigns from and against any and all claims, demands, losses, damages, judgments, settlement amounts, suits, actions, liabilities, costs and expenses (including, but not limited to, court costs and reasonable attorneys' fees) arising out of or resulting from: (i) any injury or death to persons or theft of or damage to property caused directly or indirectly by defective or non-conforming Product or by the negligence or willful misconduct of BioVectra, its employees or agents; (ii) the material default by BioVectra in the performance of any obligation hereunder or BioVectra's breach of any of its warranties or representations hereunder; (iii) BioVectra's negligent acts or omissions or willful misconduct in the manufacture, labeling, packaging, storage, or handling of Product; and/or (iv) BioVectra's failure to comply with the provisions of any applicable law or regulation, including, but not limited to, the NDA pertaining  $% \left( 1\right) =\left( 1\right) \left( 1\right$ to the Product, those of the Act and those relating to the environment and health and safety.
- A Party (the "Indemnitee") which intends to claim 11.3 indemnification under this Section 11 shall promptly notify the other Party (the "Indemnitor") in writing of any action, claim or other matter in respect of which the Indemnitee or any of its Affiliates, or any of their respective directors, officers, employees or agents, or any Third Party entitled to indemnification under Sections 11.1 or 11.2 above, intend to claim such indemnification; provided, however, the failure to provide such notice within a reasonable period of time shall not relieve the Indemnitor of any of its obligations hereunder except to the extent the Indemnitor is prejudiced by such failure. The Indemnitee shall permit, and shall cause its Affiliates, and their respective directors, officers, employees and agents to permit, the Indemnitor, at its discretion, to settle any such action, claim or other matter and the Indemnitee agrees to the complete control of such defense or settlement by the Indemnitor; provided that such settlement does not adversely affect the Indemnitee's rights hereunder or impose any obligations on the Indemnitee in addition to those set forth herein in order for it to exercise such rights. No such action, claim or other matter shall be settled without the prior written consent of the Indemnitee, and the Indemnitee shall not be responsible for any attorneys' fees or other costs incurred other than as provided herein. The Indemnitee, its Affiliates, and their respective directors, officers, employees and agents shall reasonably cooperate with the Indemnitor and its legal representatives in the investigation and defense of any action, claim or other matter covered by this indemnification. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and at its own expense.
- 11.4 The provisions of this Section 11 shall survive the expiration or termination of this Agreement.

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### 12. LIMITATIONS ON LIABILITY

In no event shall either Party be liable to the other Party for any indirect, incidental, special, consequential, punitive or exemplary damages (including, but not limited to, damages based upon lost profits, business interruption, lost business, or lost savings) for any acts or failure to act under this Agreement, even if it has been advised of their possible existence. Notwithstanding the foregoing, there shall be no limitation on a Party's liability for claims: a) arising out of a breach of its confidentiality obligations under this Agreement; or b) arising out of its indemnification obligations under this Agreement.

BioVectra shall reimburse Questcor for loss or damage to (i) raw materials purchased by Questcor, supplied to BioVectra and stored at BioVectra and (ii) Questcor equipment. Reimbursement of raw materials and equipment shall be at replacement value.

### 13. INSURANCE

Each Party shall obtain and maintain at its expense during the term of this Agreement and for a period of at least one (1) year after the expiration or termination of this Agreement, all insurance coverage required by law as well as appropriate insurance coverage to protect against any and all claims or liabilities that may arise directly or indirectly as a result of its performance under this Agreement. In this regard, each Party shall maintain at least three million dollars (\$3,000,000) of product liability insurance for the duration of this Agreement and for five (5) years thereafter.

### 14. MISCELLANEOUS

- Independent Contractors. The relationship between Questcor and 14.1 BioVectra is that of independent contractors and nothing contained in this Agreement shall be deemed to constitute or create any other relationship, including employment, partnership, agency or joint venture, between Questcor and BioVectra. Neither Party shall have any express or implied right or authority to employ any person as agent or employee for or on behalf of the other, or to bind or attempt to bind the other Party to any obligation with any Third Party. BioVectra has and retains full control and supervision over the performance of its obligations hereunder and over the employment, direction, compensation and discharge of all employees, agents and subcontractors it utilizes in the performance of such obligations. BioVectra is responsible for its acts and omissions and those of its employees, agents and subcontractors.
- Assignment and Subcontracting. BioVectra shall not assign any of its rights nor delegate or subcontract any of its duties under this Agreement without the prior written consent of Questcor. Any such attempted assignment of rights or delegation or subcontracting of duties without the prior written consent of Questcor shall be void and ineffective. Any such assignment, delegation or subcontracting consented to by

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Questcor shall not relieve BioVectra of its responsibilities and liabilities hereunder, and BioVectra shall remain liable to Questcor for the conduct and performance of each permitted delegate and subcontractor hereunder. Questcor shall have the right to assign this Agreement, in whole or in part, to any Third Party, provided, however, that such Third Party assumes in writing the rights, duties and obligations of Questcor as set forth in this Agreement that are being assumed by such Third Party and guarantees such in writing to BioVectra.

- Advertising and Publicity. BioVectra shall not use the name or any trademark, trade name, logo or symbol of Questcor or any Questcor Affiliates, or disclose any matters relating to this Agreement, in any advertising, promotion, press/publicity release, written articles or other form of public written disclosure without the prior written consent of Questcor. Questcor shall not disclose and matters relating to this Agreement nor issue any press/publicity release referring to BioVectra without the prior written permission of BioVectra, which shall not be unreasonably withheld, conditioned or delayed. It is understood by BioVectra that Questcor, as the holder of the Product NDA, will have to make certain disclosures and regulatory filings indicating that BioVectra is manufacturing the Product for Questcor.
- Force Majeure. Neither Party shall be liable for delays in 14.4 performance or nonperformance in whole or in part due to any causes that are beyond its reasonable control and not due to its acts or omissions, such as acts of God, fire, strikes, embargo, war, acts of terrorism, acts of the government, or any other similar causes, but not acts which could be anticipated, such as raw material price increases, shortages of raw materials, or an increase in demand for Product. In such event, the Party delayed shall promptly give notice to the other Party, and shall endeavor in good faith to eliminate, cure or overcome any such causes and to resume performance of its obligations as soon as possible. The Party affected by the other Party's delay may elect to: (a) suspend performance and extend the time for performance for the duration of the event, or (b) cancel all or part of any part of the unperformed part of this Agreement or any individual Purchase Order(s) hereunder.

Questcor shall have the right, but not the obligation, to terminate this Agreement under this Section 14.4 upon not less than ninety (90) days written notice to BioVectra if BioVectra cannot, or appears unable in Questcor's good faith opinion, to supply Product hereunder to Questcor to meet Questcor's needs therefor due to a condition of Force Majeure.

Notices. Any notice, communication, or statement required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given when delivered to the person(s) listed below in any of the following manners: (i) in person; (ii) by registered or certified mail, postage pre-paid, return receipt requested; (iii) by a nationally-recognized courier service guaranteeing next-day delivery, charges prepaid; or (iv) by facsimile with the original promptly sent by any of the foregoing manners. Notice or receipt of a particular communication shall

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be considered given or received when actually received. Either Party may, by notice to the other, change the names and addresses given below for receipt of notices. 14.6 If to BioVectra:

BioVectra dcl

Attn: Chief Executive Officer

16 McCarville Street

Charlottetown, Prince Edward Island

C1E2A6 Canada

Facsimile No.: (902) 628-2045

With a copy to:

BioVectra dcl Attn: VP, Finance 16 McCarville Street

Charlottetown, Prince Edward Island

C1E2A6 Canada

Facsimile No.: (902) 628-2045

If to Questcor:

Questcor Pharmaceuticals, Inc.

3260 Whipple Road

Union City, California 94587 Attn: Chief Executive Officer Facsimile No. (510) 400 -0715

With a copy to:

Questcor Pharmaceuticals, Inc.

3260 Whipple Road

Union City, California 94587 Attn: VP Manufacturing Facsimile No. (510) 400 -0715

- 14.7 Non-Waiver. The failure of either Party to strictly enforce any of the terms or conditions of this Agreement shall not be considered as a waiver of any right hereunder nor shall it deprive that Party of the right at some other time to insist upon strict adherence to that term or condition or to any other terms or conditions.
- 14.8 Severability. If any section, subsection, sentence or clause of this Agreement shall be adjudged illegal, invalid or unenforceable, such illegality, invalidity or unenforceability shall not affect the legality, validity or enforceability of this Agreement as a whole or of any section, subsection, sentence or clause hereof not so adjudged, and the remaining terms and provisions of this Agreement shall remain unimpaired and in full force and effect.
- 14.9 Paragraph Headings. All paragraph headings in this Agreement are for convenience of reference only and shall not be construed as a limitation of the scope of the

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particular sections to which they refer.

- 14.10 Governing Law and Arbitration. This Agreement will be governed by the laws of the State of California U.S.A., without regard to its, or any other jurisdictions, conflicts of laws provisions or rulings. Any dispute, claim or controversy that may arise under, out of, in connection with or relating to this Agreement or any breach or default in the performance of the terms and conditions thereof, which cannot be settled by the Parties, shall be settled by final and binding arbitration in the English language in New York, New York, U.S.A. in accordance with the then-existing Rules of Commercial Arbitration (the "Rules") promulgated by the American Arbitration Association (the "AAA"). The arbitrator(s) shall apply the governing law as set forth above in this Section 14.10 and judgment upon the award of the arbitrator(s) may be entered in any court having appropriate jurisdiction.
- 14.11 Successors and Assigns. This Agreement shall apply to, inure to the benefit of and be binding upon the Parties hereto and upon their respective successors and permitted assigns. The Parties agree that this Agreement is not intended by either Party to give any benefits, rights, privileges, actions or remedies to any person, partnership, firm or corporation as a third party beneficiary or otherwise under any theory of law, except as expressly set forth herein.
- 14.12 Survival of Obligations. The termination or expiration of this Agreement shall not affect the survival and continuing validity of the Sections entitled "Representations and Warranties; "Product Recalls", "Confidentiality", "Indemnification" and "Limitations on Liability" nor of any other provision that is expressly or by implication intended to continue in force after such termination or expiration. Termination or expiration of this Agreement shall not relieve either Party from full performance of any obligations incurred prior to the Effective Date of such termination or expiration.
- 14.13 Schedules. All schedules referred to herein form an integral part of this Agreement and are incorporated into this Agreement by such reference.
- 14.14 Review by Legal Counsel. Each of the Parties agrees that it has had the opportunity to review this Agreement with its legal counsel. Accordingly, the rule of construction that any ambiguity in this Agreement is to be construed against the drafting Party shall not apply.
- Amendments. No modification, alteration or amendment of this Agreement or any Purchase Order(s) hereunder shall be binding upon the Parties unless contained in a writing signed and delivered by a duly authorized representative of each respective Party and specifically referring hereto or thereto, as the case may be.
- 14.16 Counterparts. This Agreement and any amendment or supplement hereto may be executed in any number of counterparts, each of which when executed and delivered shall be deemed to be an original and all of which counterparts taken together shall constitute but one and the same instrument. The execution of this Agreement and any

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such amendment or supplement by any Party hereto will not become effective until counterparts hereof have been executed (i.e., signed and delivered) by both Parties hereto.

14.17 Entire Agreement. This Agreement, together with any documents attached hereto, constitutes the entire agreement of the Parties with respect to its subject matter and merges and supersedes all prior discussions and writings with respect thereto. No modification to this Agreement shall be affected by the acknowledgment or acceptance of any purchase order or shipping instruction forms or similar documents containing terms or conditions at variance with or in addition to those set forth herein.

Notwithstanding the above, the Mutual Nondisclosure Agreement dated August 15, 2002 (a signed copy of which is attached hereto as Schedule 7) and the Equipment & Materials Transfer Agreement (a signed copy of which is attached hereto as Schedule 8) shall remain in full force and effect for the Initial Term, any Extension Period and the period of Confidentiality as set forth in Section 10.1 above, except for the provisions of the Equipment & Materials Transfer Agreement entitled: "Term; "Termination", "Development and Supply Agreement" and "Non-Binding Term Sheet", which shall be superseded hereby. In the event of any direct conflict of the terms and conditions of the Mutual Nondisclosure Agreement and the Equipment & Materials Transfer Agreement with the terms and conditions of this Agreement, the terms and conditions of this Agreement shall control. The period of confidentiality of the Mutual Nondisclosure Agreement shall be as set forth in Section 10.1 hereof.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized representatives to be effective as of the Effective Date set forth above.

QUESTCOR PHARMACEUTICALS, INC. DIAGNOSTIC CHEMICALS LIMITED

(doing business as BioVectra dcl)

Signature: /s/ David Medeiros Signature: /s/ Gordon Rogers

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Name: David Medeiros Name: Gordon Rogers

Title: VP, Manufacturing Title: VP, Finance & Corporate Systems

Date: October 22, 2003 Date: October 28, 2003

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PRODUCT

ACTHAR BULK CONCENTRATE (API)

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To the April 1, 2003 Supply Agreement between QUESTCOR and BIOVECTRA DCL.

## **SPECIFICATIONS**

ALL SPECIFICATIONS AND INSPECTION AND TESTING METHODS WILL BE CONSISTENT WITH THE DMF AND OTHER REGULATORY FILINGS FOR THE PRODUCT AND SUBSEQUENT UPDATES TO THE DMF AND OTHER REGULATORY FILINGS FOR THE PRODUCT INCLUDING:

STARTING MATERIALS,

API REGISTRATION SPECIFICATIONS,

API CONTROL TARGETS, AND

INSPECTION AND TESTING METHODS.

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To the April 1, 2003 Supply Agreement between Questcor and BioVectra dcl.

## PRICE

The price for ACTHar Gel shall be Nine Thousand Five Hundred Fifty-Five Dollars United States (\$9,555 USD) per kilogram for the first One Hundred Eighty (180) kilograms of Product purchased by Questcor hereunder. The price for subsequent Product purchased by Questcor hereunder shall be Seven Thousand Six Hundred Seventy-five Dollars United States (\$7,675 USD) per kilogram of Product. Documented raw material increases greater than three percent (3%) will be added to the price per kilogram on an actual cost basis, with documentation of the increase provided to Questcor in advance of any such adjustment being made.

BioVectra

[ ] [ ] Questcor BioVectra

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To the April 1, 2003 Supply Agreement between QUESTCOR and BIOVECTRA DCL.

## DEVIATION/CHANGE FORM

CP0006-0

## BIOVECTRA

STANDARD OPERATING PROCEDURE FOR WRITING AND MANAGING SOPS

ATTACHMENT 1: DOCUMENT CREAT	TION/CHANGE CONTROL	FORM		
SOP Title:				
SOP Form ID:		Date:		
Change Type: [ ] Major [ ] Minor				
Check One: [ ] Annual Review [ ] Revision [ ] New Issue				
SUMMARY OF CHANGES AND JUST: (Attach additional pages as				
Comments:				
-	Signature		Date	
BioVectra				[ ] BioVectra
		_		

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Reviewed by	
Approved by	
QA/RA Approval	
DOCUMENT CONTROL	
[ ] Revision History Ledger updated	Date
[ ] Training Requirements Completed	Date
[ ] Read and Understood	
[ ] Additional Training Required (Explain)	
PERFORMED E FORM ID TITLE REVISION # COMMENTS (INITIAL AND D	ATE)
BioVectra	[ ] [ ] Questcor BioVectra

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FORM ID CP0006 WRITTEN BY REVISION NO. Zero (0) APPROVED BY

QA APPROVAL

EFFECTIVE DATE

BioVectra

[ ] [ ] Questcor BioVectra

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To the April 1, 2003 Supply Agreement between QUESTCOR and BIOVECTRA DCL.

QUESTCOR PROVIDED EQUIPMENT AND LOCATION THEREOF

BioVectra

[ ] [ ] Questcor BioVectra

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40	NC-2847	MOD I Resin Column
41(new)	N/A	Berg - 12 Ton chiller
42(new)	Not Assigned Yet	Amsco 3033 Autoclave
43(new)	Not Assigned Yet	Reitschlie VC-100 Vacuum Pump
44(new)	Not Assigned Yet	Welch 1374M-01 High Vacuum Pump
45 (new)	N/A	Culligan Mixed Bed DI Water System
		[ ][ ]
BioVectra		Questcor BioVectra

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To the April 1, 2003 Supply Agreement between QUESTCOR and BIOVECTRA DCL.

FORMAT OF AN APPROVED CERTIFICATE OF COMPLIANCE

To the April 1, 2003 Supply Agreement between Questcor and BioVectra dcl

(as referred to in Section 9.2.5 of that Agreement)

## CERTIFICATE OF COMPLIANCE

The only animal-sourced materials used in the production of Acthar Bulk Concentrate, Lot YYYY, were porcine pituitary glands and porcine gelatin.

BIOVECTE	RA DCL		
Ву:			
	Signature		
	Date		
	Print name and title		
BioVectr	-a	[ ] Questcor	[ ] BioVectra

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To the April 1, 2003 Supply Agreement between QUESTCOR and BIOVECTRA DCL.

MUTUAL NONDISCLOSURE AGREEMENT (dated August 15, 2002)

THIS AGREEMENT is made on Aug 15, 2002, by and between Questcor Pharmaceuticals, Inc., a California Corporation located at 3260 Whipple Road, Union City, CA 94587 ("Questcor") and BioVectra, dcl LLC located at ("BioVectra").

- 1. Purpose. Questcor and BioVectra wish to evaluate the possibility of, establishing a business relationship. For this purpose, either party may disclose information it regards as confidential to the other.
- 2. Definition. "Confidential Information" means any information, technical data, or know-how, including, but not limited to, that which relates to research, development, products, biological materials, chemical compounds, processes, test data, animal studies, clinical trials, markets, inventions, marketing or finances, which Confidential Information is designated in writing to be confidential or proprietary, or if given orally, is confirmed promptly in writing as having been disclosed as confidential or proprietary. Confidential Information does not include information, technical data or knowhow which (i) is in the possession of the receiving party at the time of disclosure as shown by the receiving party's files and records immediately prior to the time of disclosure; or (ii) prior to or after the time of disclosure becomes part of the public knowledge or literature, not as a result of any action or inaction of the receiving party; or (iii) is approved for release by the disclosing party, or (iv) is at any time disclosed to the receiving party by a third party without, to the knowledge of the receiving party, violation of any obligation of confidentiality.
- 3. Non-Disclosure of Confidential Information. Questcor and BioVectra each agree not to use the Confidential Information disclosed to it by the other party for its own use or for any purpose except as specified in paragraph 1. Neither will disclose the Confidential Information of the other to third parties or to its own employees and advisors except those employees and advisors who are required to have the information in order to evaluate it. Each agrees to advise such employees and advisors of the confidential nature of the information they are receiving, and to take all other reasonable steps to protect the secrecy of and avoid disclosure or use of Confidential Information of the other in order to prevent it from falling into the public domain or the possession of unauthorized persons. Each agrees to notify the other in writing of any misuse or misappropriation of such Confidential Information of the other which may come to its attention.
- 4. Return of Material. Upon request, any materials or documents which have been furnished by one party to the other will be returned, accompanied by all copies of such documentation. Except that one copy may be retained for legal archival purposes.
- 5. Patent or Copyright Infringement. Nothing in this Agreement is intended to grant any rights under any patent or copyright of either party, nor shall this Agreement grant either party any rights in or to the others party's Confidential Information, except the limited right to review such Confidential Information solely for the purpose specified in

[ ] [ ] Questcor BioVectra

### paragraph 1.

- 6. Term. The foregoing commitments in this Agreement shall terminate on the later of five (5) years following the date of this Agreement, or five (5) years following the termination of any business relationship between the parties.
- 7. Q~ Neither this letter agreement nor any action taken in connection with this letter agreement will give rise to any obligation on the part of either party to (i) engage in any discussions or negotiations with the other party with regard. to a possible transaction, or (ii) pursue or enter into any transaction of any nature with the other party.
- 8. Miscellaneous. This Agreement shall be binding upon and for the benefit of the undersigned parties, their successors and assigns, provided that Confidential Information may not be assigned without consent of the disclosing party. Failure to enforce any provision of this Agreement shall not constitute a waiver of any term hereof.
- 9. Governing Law and Jurisdiction. This Agreement shall be governed by and construed under the laws of the State of California. The federal and state courts within the State of California shall have exclusive jurisdiction to adjudicate any dispute arising out of this Agreement.
- 10. Remedies. Each party agrees that its obligations hereunder are necessary and reasonable in order to protect the other party and the other party's business. Accordingly, each party agrees and acknowledges that any such violation or threatened violation may cause irreparable injury to the other party and that, in addition to any other remedies that may be available, in law, in equity or otherwise, the other party shall be entitled to obtain injunctive relief against the threatened breach of this Agreement or the continuation of any such breach.

BioVectra

[ ] [ ] Questcor BioVectra

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To the April 1, 2003 Supply Agreement between QUESTCOR and BIOVECTRA DCL.

EQUIPMENT & MATERIALS TRANSFER AGREEMENT

BioVectra [ ] [ ] Questcor BioVectra

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### TERM SHEET

### **EQUIPMENT & MATERIALS TRANSFER AGREEMENT**

**PARTTES** 

Questcor Pharmaceuticals, Inc. ("Questcor")
Diagnostic Chemicals Limited, doing business as
BioVectra ("BIO")

MATERIAL AND EQUIPMENT TRANSFER

Upon reasonable prior notice to BIO, Questcor will cause to be delivered, and BIO will accept for delivery, the certain manufacturing equipment (the "Equipment") and the raw materials (the "Materials") described and listed on Exhibit A as associated with the commercial production of Acthar bulk concentrate (corticotropin in a concentrated gel matrix) (the "Concentrate"). Questcor will be responsible for all costs associated with the delivery of the Materials and Equipment to the Storage Location (defined below), including applicable import/export costs actually and reasonably incurred by BIO. BIO will reasonably assist Questcor to arrange for the delivery and receipt of the Materials and Equipment.

HANDLING AND STORAGE

BIO will (i) handle, store, maintain and deliver the Materials and Equipment in accordance with the terms and conditions of this Term Sheet and applicable laws and regulations and (ii) take such action as reasonably requested by Questcor in respect of the handling, storage, maintenance or delivery of such Materials and Equipment. BIO will store and maintain the Equipment and the Materials in a secure location within the premises located at BioVectra DCL, Charlottetown Airport Business Park, 328 Brackley Point Road, Charlottetown, PE C1E 2E6 (the "Storage Location") and in a manner that preserves the operation and effectiveness of the Materials and Equipment, but in no event in a manner less than the specifications described on Exhibit A. Except as directed in writing by Questcor, BIO will not remove the Equipment from its original shipping packaging or otherwise tamper with, remove or relocate the Equipment or Materials from the Storage Location. BIO will provide Questcor or its designee access to the Equipment and/or Materials in the Storage Location, upon reasonable prior notice. BIO shall immediately notify Questcor at the address provided below of any breach of this Term Sheet or any theft of and/or damage or unauthorized access to the Equipment and/or Materials.

OWNERSHIP

Questcor will retain ownership over all rights in and to the Equipment and Materials delivered to BIO. BIO shall not use, retain for itself or grant to any third party any access or rights in or to the Materials or Equipment, including, without limitation, the imposition of any levy, lien or encumbrance of any nature whatsoever.

INSURANCE; DAMAGE

Questcor will maintain general commercial liability and property insurance covering the Equipment and Materials during the Term in reasonable and customary amounts as it may determine. BIO will be responsible

BioVectra

l J [ ] Questcor BioVectra Questcor for any loss, damage or destruction of the Equipment and Materials or any claim by any third party with respect to personal injury relating to the Equipment or Materials, in each case to the extent arising out of BIO's negligence or willful misconduct.

TERM; TERMINATION

This Term Sheet will be in effect from the date last written below until the earlier of (a) the execution by the parties of a definitive Development and Supply Agreement or (b) June 30, 2003, unless otherwise earlier terminated by either party in accordance with this Term Sheet or extended in writing by the mutual agreement of the parties (the "Term").

Either party may terminate this Term Sheet upon 60 days prior written notice to the other for any reason or within 30 days upon the uncured material breach by either party; provided however, that Questcor may at any time request the return and delivery of the Materials and/or Equipment to itself or its designee as described below.

**RETURN & DELIVERY** 

Promptly upon the request of Questcor (but in no event later than five business days), BIO will prepare the Equipment and Materials for shipment and make them available for transfer to Questcor or its designee at the Storage Location. Questcor will reimburse BIO with respect to its reasonable and actual costs incurred in connection with the foregoing and will bear the costs of transporting the Equipment and/or Materials from the Storage Location.

**FEES** 

BIO will handle and store the Equipment and Materials in consideration for the negotiation by the parties of a Development and Supply Agreement as described herein and no additional fees or charges will apply.

QUALITY AUDIT

At a time as mutually agreed by the parties, BIO will permit Questcor, at no cost to Questcor, access to its facilities, records and personnel necessary for Questcor to conduct a Quality System Audit. Questcor will bear the costs of conducting such audit.

DEVELOPMENT AND SUPPLY AGREEMENT

Subject to the successful completion of the Quality Audit described above, the parties will use their good faith, commercially reasonable efforts to negotiate a definitive Development and Supply Agreement pursuant to which BIO will provide the Concentrate for Questcor's commercial requirements.

The definitive Development and Supply Agreement will contain the following batch pricing by BIO to Questcor: (a) US\$9,555/kg for each of the first three 60 kg qualification batches; and (b) US\$7,675/kg for any subsequent qualification and/or production batches. Under the terms of such definitive Development and Supply Agreement, Questcor will agree to purchase at least three (3) batches of approximately 60 kg each prior to December 31, 2006. The definitive Development and Supply Agreement

BioVectra

[ ] [ ] Questcor BioVectra

will contain other usual and customary terms for agreements of this type.

**GOVERNING LAW** 

This Term Sheet and the terms of the definitive agreement will be governed by the laws of the State of California, United States, without regard to its conflicts of laws.

CONFIDENTIALITY

The parties agree that the contents of this Term Sheet and any and all information provided by one party to the other pursuant to this Term Sheet shall be "Confidential Information" subject to the terms of that certain Mutual Nondisclosure Agreement between Questcor and BIO dated as of August 15, 2002.

NON-BINDING TERM SHEET

The terms provided in the paragraph entitled "Supply Agreement" are for discussion purposes only, and such terms shall not constitute a binding agreement, an offer to enter into a binding agreement or an amendment to or termination of the certain terms and conditions provided to Questcor by BIO in a letter dated March 18, 2003 (the "Non-Binding Terms"). The Non-Binding Terms and any proposals contained herein are subject to additional due diligence, the negotiation of a definitive agreement, the terms and conditions provided to Questcor by BIO in a letter dated march 18, 2003, and approval by the parties' respective Board of Directors.

Notwithstanding the foregoing, the parties agree and acknowledge that all provisions other than the Non-Binding Terms will constitute a binding agreement between the parties as of the date last written below. It is the intention of BIO and Questcor to promptly and in good faith negotiate and finalize a definitive agreement regarding the terms and conditions set forth herein and other usual and customary terms for transactions of this type. In the event that the parties fail to reach a definitive agreement on or before June 30, 2003 or otherwise extend the term hereof by mutual agreement in writing, this Term Sheet shall terminate as of June 30, 2003 and be of no further force and effect, except for provisions regarding confidentiality. In such event, BIO shall promptly return the Materials and Equipment to Questcor in accordance with the paragraph entitled "Return & Delivery".

QUESTCOR PHARMACEUTICALS, INC. DIAGNOSTIC CHEMICALS LIMITED

By: /s/ Kenneth R. Greathouse By: /s/ Gordon Rogers

Name: Kenneth R. Greathouse Name: Gordon Rogers

Systems

Date: March 28, 2003 Date: April 1, 2003

Address: 3260 Whipple Rd. Address: 16 McCarville Street

Charlottetown, Prince Edward Island Canada, C1E 2A6

Canada, CIL ZAO

[ ] [ ] Questcor BioVectra

BioVectra

Union City, CA 94587

EXHIBIT A

EQUIPMENT DESCRIPTION AND INVENTORY:

(see attached list)

MATERIALS DESCRIPTION AND INVENTORY:

600 lbs. of frozen porcine pituitaries

ENVIRONMENTAL AND OTHER STORAGE REQUIREMENTS:

Equipment: clean, dry, secure at normal room temperature

Materials: cGMP storage at -20 degrees Celsius

BioVectra [ ] [ ] Questcor BioVectra

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## EQUIPMENT FOR HP ACTHAR GEL TRUCK 1

## TRUCK 1

SKID	PART NUMBER	DESCRIPTION
1 2 3 3 4 5 6 7 8 9 10 10 10 10 10 10 10 10	L-8269 NC-5735 L-4244 NC-3344 L-8224 LM-4029 NC-2849 NC-2849 L-5750 L-6125 N/A N/A N/A N/A N/A N/A N/A N/A	SS POT PUMP/VENT LM-4029 MOD 1 RECON POT PUMP 100 GAL SS POT MOD IC POTENTIATION TK PHENOL HOOD PHENOL HOOD TWIN SHELL V BLENDER FITZMILL COMMINUTOR MOD IC RECON AGITATOR (2) MOD IC RECON VESSEL MOD IC GLASS FILTER #1 MOD IC GLASS FILTER #2 AIR/NITROGEN FILTER ORION 310 PH METER 2 GLASS BOTTLES AAAP G/L BLOW TANK 18" BUCHNER FUNNEL
13 13 13 13 13 14 14 15 16	K-4490 L-9119 D L-9119 E L-9119 F L-9119 (2) L-4066 L-5912 L-6965 N/A L-6782	MILLIPORE CART, HOUSING POT POT POT
19 19	L-6370 L-1629 L-6211 L-4143	PIPING FOR GEL TANK MOD 1 DRUM ROLLER MOD 1 DRUM BOMB FREEZER

# EQUIPMENT FOR HP ACTHAR GEL TRUCK 2

## TRUCK 2

SKID	PART NUMBER	DESCRIPTION
1	K-7652 N/A	AAP PRECIPITATION TANK MISC. EOUIPMENT
2	NC-3366	SCALE
2	N/A	2 STAINLESS STEEL POTS

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2	N/A	2 BUCHNER SHIELDS
3	K-7650	AAAP EXTRACTION TANK
4	L-6370	32% GEL TANK
5	L-2154	NORTH CENTRIFUGE
5	L-4092	SOUTH CENTRIFUGE
6	NC-2848	MOD IC GEL BOMB
6	N/A	9 STAINLESS STEEL BOMBS
6	N/A	MOD 1 BOMB HEADER
6	N/A	MISC. PIPING
7	L-9119 C	UTENSIL CART
8	NC-2847	MOD 1 RESIN COLUMN

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[ ] [ ] Questcor BioVectra

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## CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-102988, 333-85160, 333-61866, 333-25661, 333-32159, 333-23085, 333-17501, 333-03507 and 33-107755) and the Registration Statements Form S-8 (Nos. 333-30558, 333-46990, 333-81243, 333-105694 and 333-105693), pertaining to the 1992 Stock Option Plan, the 1993 Non-Employee Directors' Equity Incentive Plan and the 2000 Employee Stock Purchase Plan of Questcor Pharmaceuticals, Inc. of our report dated February 12, 2004, with respect to the financial statements and schedules of Questcor Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2003.

/s/ Ernst & Young LLP

Palo Alto, California March 29, 2004

## CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

- I, Charles J. Casamento, certify that:
- I have reviewed this annual report on Form 10-K of Questcor Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
- a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2004

/s/ Charles J. Casamento

## CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

- I, Timothy E. Morris, certify that:
- I have reviewed this annual report on Form 10-K of Questcor Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2004

/s/ Timothy E. Morris

TIMOTHY E. MORRIS CHIEF FINANCIAL OFFICER

## CERTIFICATIONS PURSUANT TO SECTION 906 OF THE PUBLIC COMPANY ACCOUNTING REFORM AND INVESTOR PROTECTION ACT OF 2002

On March 30, 2004, Questcor Pharmaceuticals, Inc. filed its Annual Report on Form 10-K for the year ended December 31, 2003 (the "Form 10-K") with the Securities and Exchange Commission. Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the following certifications are being made to accompany the Form 10-K:

## CERTIFICATION OF CHIEF EXECUTIVE OFFICER

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Questcor Pharmaceuticals, Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

- (i) the Annual Report on Form 10-K of the Company for the year ended December 31, 2003 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 30, 2004 /s/ Charles J. Casamento

Charles J. Casamento Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

## CERTIFICATION OF CHIEF FINANCIAL OFFICER

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Questcor Pharmaceuticals, Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

- (i) the Annual Report on Form 10-K of the Company for the year ended December 31, 2003 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 30, 2004 /s/ Timothy E. Morris

Timothy E. Morris Chief Financial Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.