# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

| FORM | 10-Q |
|------|------|
|      |      |

(MARK ONE)

X QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2002,

OR

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

For the transition period from \_\_\_\_\_\_ to \_\_\_\_\_

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, CA 94587-1217 (Address of Principal Executive Offices)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (510) 400-0700

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

At August 12, 2002 there were 38,630,763 shares of the Registrant's common stock, no par value per share, outstanding.

# FORM 10-Q

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# ITEM 1. FINANCIAL STATEMENTS

# QUESTCOR PHARMACEUTICALS, INC.

# CONSOLIDATED BALANCE SHEETS (IN THOUSANDS)

|  |    | June 30,<br>2002 | December 31,<br>2001 |
|--|----|------------------|----------------------|
| ASSETS   | (U | naudited)        | (Note 1)             |
| Current assets:  |    |                  |                      |
| Cash and cash equivalents (which included a compensating balance of \$5,000 at December 31, 2001)                  | \$ | 7,983            | \$ 10,183            |
| Short-term investments   | Ψ  | 304              | 388                  |
| Accounts receivable, net of allowance for doubtful accounts of \$80 at June 30, 2002 and \$78 at December 31, 2001 |    | 1,729            | 672                  |
| Receivable from a related party (see Note 12)  |    | 244              |                      |
| Inventories  |    | 417              | 96                   |
| Prepaid expenses and other current assets  |    | 367              | 265                  |
| Trepute expenses and other current assets  |    | 507              |                      |
| Total current assets   |    | 11,044           | 11,604               |
| Property and equipment, net  |    | 723              | 602                  |
| Purchased technology, net  |    | 673              | 1,159                |
| Goodwill and other intangible assets, net  |    | 479              | 479                  |
| Deposits and other assets  |    | 1,297            | 1,228                |
| 4  | _  |                  |                      |
| Total assets   | \$ | 14,216           | \$ 15,072            |
|  |    |                  |                      |
| LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)   |    |                  |                      |
| Current liabilities:   |    |                  |                      |
| Accounts payable   | \$ | 1,365            | \$ 1,095             |
| Accrued compensation   |    | 578              | 575                  |
| Unissued common stock  |    | _                | 960                  |
| Other accrued liabilities  |    | 1,330            | 1,070                |
| Note payable to bank   |    | _                | 5,000                |
| Current portion of long-term debt  |    | 354              | 368                  |
| Current portion of capital lease obligations   |    | 30               | 57                   |
|  | _  |                  |                      |
| Total current liabilities  |    | 3,657            | 9,125                |
| Convertible debentures, (face amount of \$4,000), net of deemed discount of \$1,319                                |    | 2,681            | _                    |
| Long-term debt   |    | _                | 121                  |
| Other non-current liabilities  |    | 1,062            | 1,045                |
| Commitments  |    |                  |                      |
| Preferred stock, subject to redemption   |    | 5,081            | 5,081                |
| Stockholders' equity (deficit):  |    |                  |                      |
| Common stock   |    | 77,381           | 74,018               |
| Deferred compensation  |    | (13)             | (20)                 |
| Accumulated deficit  |    | (75,618)         | (74,183)             |
| Accumulated other comprehensive income (loss)  |    | (15)             | (115)                |
| Total stockholders' equity (deficit)   |    | 1,735            | (300)                |
| Total liabilities and stockholders' equity (deficit)   | \$ | 14,216           | \$ 15,072            |
| 20th montaco and otocomoracio equity (activity)  | Ψ  | 11,210           | 10,072               |

See accompanying notes.

# CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED) (IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

|  | Three Months Ended |                 |    | Six Months Ended |                  |    |                  |
|--|--------------------|-----------------|----|------------------|------------------|----|------------------|
|  | J                  | une 30,<br>2002 |    | e 30,<br>001     | June 30,<br>2002 |    | June 30,<br>2001 |
| Revenues:  |                    | _               |    | _                |                  |    |                  |
| Net product sales  | \$                 | 3,307           | \$ | 971              | \$ 7,113         | \$ | 1,672            |
| Contract research and grant revenue                                |                    | 81              |    | 57               | 126              |    | 282              |
| Technology revenue   |                    | 250             |    | _                | 250              |    | 90               |
| Royalty revenue  |                    | 3               |    | 5                | 6                |    | 5                |
| Services revenue from a related party (see Note 12)                |                    | 100             |    | _                | 100              |    | _                |
| Total revenues   |                    | 3,741           |    | 1,033            | 7,595            |    | 2,049            |
| Operating costs and expenses:                                      |                    |                 |    |                  |                  |    |                  |
| Cost of product sales  |                    | 579             |    | 276              | 1,155            |    | 637              |
| Sales and marketing ( <i>Note A</i> )                              |                    | 1,652           |    | 834              | 3,028            |    | 1,478            |
| General and administrative ( <i>Note A</i> )                       |                    | 1,216           |    | 1,011            | 2,747            |    | 1,767            |
| Research and development ( <i>Note A</i> )                         |                    | 831             |    | 787              | 1,316            |    | 1,537            |
| Depreciation and amortization                                      |                    | 315             |    | 553              | 659              |    | 1,112            |
| Total operating costs and expenses                                 |                    | 4,593           |    | 3,461            | 8,905            |    | 6,531            |
| Loss from operations   |                    | (852)           |    | (2,428)          | (1,310)          | 1  | (4,482)          |
| Non-cash amortization of deemed discount on convertible debentures |                    | (131)           |    | _                | (175)            | )  | _                |
| Interest income (expense), net                                     |                    | (13)            |    | 32               | 14               |    | 59               |
| Other expense, net   |                    | (181)           |    | (7)              | (110)            | ١  | (7)              |
| Rental income, net   |                    | 74              |    | 406              | 146              |    | 561              |
| Net loss   | \$                 | (1,103)         | \$ | (1,997)          | \$ (1,435)       | \$ | (3,869)          |
| Basic and diluted net loss per common share                        | \$                 | (0.03)          | \$ | (0.07)           | \$ (0.04)        | \$ | (0.14)           |
| Weighted average shares of common stock outstanding                |                    | 38,468          |    | 28,277           | 38,157           |    | 26,832           |
| Note A:  |                    |                 |    |                  |                  |    |                  |
| Includes non-cash charges for stock-based compensation as follows: | \$                 | _               | ¢  | _                | \$ 44            | ¢  |                  |
| Sales and marketing General and administrative                     | Ф                  | 44              | Φ  | 11               | 243              | Ф  | 23               |
|  |                    | 44              |    | 11               | 243              |    | 4                |
| Research and development   |                    | _               |    | 1                | 24               |    | 4                |
| Total  | \$                 | 44              | \$ | 12               | \$ 311           | \$ | 27               |

See accompanying notes.

# CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED) (IN THOUSANDS)

Six Months Ended

|   | Six Months Ended |            | ded           |  |
|---|------------------|------------|---------------|--|
|   | June 30, 2002    |            | June 30, 2001 |  |
| OPERATING ACTIVITIES  |                  |            |               |  |
| Net loss  | \$               | (1,435) \$ | (3,869)       |  |
| Adjustments to reconcile net loss to net cash used in operating activities: |                  |            |               |  |
| Stock-based compensation expense  |                  | 311        | 27            |  |
| Amortization of deemed discount on convertible debentures                   |                  | 175        | _             |  |
| Depreciation and amortization   |                  | 659        | 1,112         |  |
| Other-than-temporary loss on investment                                     |                  | 181        | _             |  |
| Deferred rent expense   |                  | 17         | 32            |  |
| (Gain)/Loss on the sale of equipment  |                  | (2)        | 42            |  |
| Changes in operating assets and liabilities:                                |                  | (4.055)    | (207)         |  |
| Accounts receivable   |                  | (1,057)    | (387)         |  |
| Receivable from a related party   |                  | (244)      |               |  |
| Inventories   |                  | (321)      | (64)          |  |
| Prepaid expenses and other current assets                                   |                  | (102)      | 163           |  |
| Accounts payable  |                  | 270        | 391           |  |
| Accrued compensation  |                  | 3          | 117           |  |
| Accrued development costs   |                  | _          | (541)         |  |
| Other accrued liabilities   |                  | 261        | (130)         |  |
| Net cash flows used in operating activities                                 |                  | (1,284)    | (3,107)       |  |
|   |                  |            |               |  |
| INVESTING ACTIVITIES  |                  |            |               |  |
| Proceeds from the maturity of short-term investments, net                   |                  | _          | 499           |  |
| Purchase of property and equipment  |                  | (309)      | (104)         |  |
| Sale of property and equipment  |                  | 19         | _             |  |
| Decrease in other assets  |                  | 5          | 54            |  |
| Net cash flows (used in) provided by investing activities                   |                  | (285)      | 449           |  |
| FINANCING ACTIVITIES  |                  |            |               |  |
| Issuance of common stock, net   |                  | 532        | 2,088         |  |
| Issuance of convertible debentures  |                  | 4,000      |               |  |
| Short-term borrowings   |                  | 119        | _             |  |
| Repayment of note payable to bank   |                  | (5,000)    | _             |  |
| Repayment of long-term debt   |                  | (254)      | (143)         |  |
| Repayments of capital lease obligations                                     |                  | (28)       | (59)          |  |
| Net cash flows (used in) provided by financing activities                   |                  | (631)      | 1,886         |  |
|   |                  |            |               |  |
| Decrease in cash and cash equivalents                                       |                  | (2,200)    | (772)         |  |
| Cash and cash equivalents at beginning of period                            |                  | 10,183     | 6,818         |  |
| Cash and cash equivalents at end of period                                  | \$               | 7,983 \$   | 6,046         |  |
| SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:                           |                  |            |               |  |
| Cash paid for interest  | \$               | 60 \$      | 213           |  |
|   | -                |            |               |  |

See accompanying notes.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS JUNE 30, 2002 (UNAUDITED)

#### 1. BASIS OF PRESENTATION

Questcor Pharmaceuticals, Inc. (the "Company") was incorporated in California in 1990. The Company is an integrated specialty pharmaceutical company focused on the acquisition and marketing of acute care and critical care hospital/specialty pharmaceutical and related healthcare products. The Company currently markets five products in the U.S.: HP Acthar® Gel ("Acthar"), an injectable drug that is commonly used in treating patients with infantile spasm, or West Syndrome; 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 and Inulin in Sodium Chloride, which are both injectable agents that assess 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 (GI) 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. Additionally, the Company earns royalties from its strategic partner, Sirton Pharmaceuticals S.p.A. ("Sirton"), formerly known as Crinos Industria Farmacobiologica S.p.A., on sales in Italy of Pramidin®, an intranasal form of metoclopramide, a medication used for the treatment of nausea and vomiting, for the treatment of various gastrointestinal disorders.

The accompanying unaudited consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States and applicable Securities and Exchange Commission regulations for interim financial information. These financial statements do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. The unaudited financial statements should be read in conjunction with the audited financial statements and related footnotes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2001, as filed on March 19, 2002 with the Securities and Exchange Commission. In the opinion of the Company's management, all adjustments (consisting of normal recurring adjustments) considered necessary for fair presentation of interim financial information have been included.

Operating results for the interim periods presented are not necessarily indicative of the results that may be expected for the year ending December 31, 2002.

Certain amounts in the prior quarter's financial statements have been reclassified to conform to the current quarter's presentation. The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

#### 2. REVENUE RECOGNITION

Revenues from product sales of Acthar®, Ethamolin®, Glofil™-125, Inulin and VSL#3™ are recognized based upon shipping terms, net of estimated reserves for sales returns and discounts. Revenue is recognized upon shipment of product, provided the title of 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. Revenues from Glofil™-125 unit dose sales are recognized when the product is sold to end-users in accordance with the distribution agreement with the third-party distributor. The Company records estimated sales allowances against product revenues for expected returns, chargebacks and discounts based on historical sales returns, analysis of return merchandise authorization and other known factors such as shelf life of products, as required. The Company continually assesses the historical returns experience and adjusts its allowance as appropriate. The Company's return policy allows customers to return expired product 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 all 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. All returns are subject to quality assurance reviews prior to acceptance. The Company sells product to wholesalers, who in turn sell its products to pharmacies and hospitals. In the case of VSL#3™ we sell direct 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 which 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 obligations exist.

#### 3. CASH AND 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. At June 30, 2002, the Company had cash, cash equivalents and short-term investments of \$8,287,000. Following is a summary of cash equivalents and short-term investments based on quoted market prices for these investments:

|   |    | June 30,<br>2002 | December 31,<br>2001 |
|---|----|------------------|----------------------|
| Money market funds                          | \$ | 7,135            | \$ 4,943             |
| Certificates of deposit                     |    | _                | 5,000                |
| Corporate equity investments                |    | 304              | 388                  |
|   |    |                  |                      |
|   |    | 7,439            | 10,331               |
| Less amounts classified as cash equivalents |    | (7,135)          | (9,943)              |
|   | _  |                  |                      |
| Short-term investments                      | \$ | 304              | \$ 388               |
|   |    |                  |                      |

In September 2000, the Company entered into an agreement with Rigel Pharmaceuticals, Inc. ("Rigel"), to sell exclusive rights to certain proprietary antiviral research technology in exchange for cash and 83,333 shares of Rigel stock. The Company has recorded an other-than-temporary loss of \$181,000 on these shares for the quarter ended June 30, 2002. This write-down is included in Other expense on the Statements of Operations. The recognized loss reduced the cost of the equity investment to the Company's new cost basis of \$319,000. At June 30, 2002, the equity investment had a cost of \$319,000 and an unrealized loss of \$15,000. At December 31, 2001, the equity investment had a cost of \$500,000 and an unrealized loss of \$112,000.

#### 4. INVENTORIES

Inventories are stated at the lower of cost (first-in, first-out method) or market and are comprised of finished goods of \$437,000 and \$152,000, net of an allowance for obsolete inventories of \$20,000 and \$56,000 at June 30, 2002 and December 31, 2001, respectively.

#### 5. PURCHASED TECHNOLOGY AND INTANGIBLE ASSETS

In July 2001, the FASB issued Statement No. 141, "Business Combinations" (SFAS 141) and Statement No. 142, "Goodwill and Other Intangible Assets" (SFAS 142). SFAS 141 establishes new standards for accounting and reporting for business combinations and will require that the purchase method of accounting be used for all business combinations initiated after June 30, 2001 and also specifies the criteria for the recognition of intangible assets separately from goodwill. SFAS 142 establishes new standards for goodwill, including the elimination of goodwill amortization to be replaced with methods of periodically evaluating goodwill for impairment. The Company's adoption of SFAS 142 as of January 1, 2002 did not have a material impact on its financial statements. Goodwill and other indefinite lived intangible assets no longer subject to amortization amounted to \$479,000 at June 30, 2002. The remaining net balance of \$673,000 relates to purchased technology and will be amortized over the estimated sales life of the associated product (seven years).

In accordance with SFAS 141 and 142, the Company discontinued the amortization of goodwill on January 1, 2002, which resulted in a decrease of reported net loss of approximately \$271,000 for the six months ended June 30, 2002, as compared with the accounting prior to the adoption of SFAS 141 and SFAS 142. The Company performed an impairment test of goodwill as of January 1, 2002, which did not result in an impairment charge at transition. The Company will continue to monitor the carrying value of goodwill through the annual impairment tests.

A reconciliation of previously reported net loss and net loss per share to the amounts adjusted for the exclusion of goodwill amortization, follows (in thousands, except per share amounts).

|                                       | <br>Six months ended June 30, |         |  |
|---------------------------------------|-------------------------------|---------|--|
|                                       | <br>2002                      | 2001    |  |
| Reported net loss                     | \$<br>(1,435) \$              | (3,869) |  |
| Add back: Goodwill amortization       | _                             | 271     |  |
| Adjusted net loss                     | \$<br>(1,435) \$              | (3,598) |  |
|                                       |                               |         |  |
| Basic and diluted earnings per share) |                               |         |  |
| Reported net loss                     | \$<br>(0.04) \$               | (0.14)  |  |
|                                       |                               |         |  |
| Add back: Goodwill amortization       | _                             | 0.01    |  |
|                                       |                               |         |  |
| Adjusted net loss                     | \$<br>(0.04) \$               | (0.13)  |  |
|                                       |                               |         |  |

#### 6. NOTE PAYABLE

In December 1998, RiboGene, Inc. ("RiboGene"), a company that Questcor merged with in 1999, borrowed \$5.0 million pursuant to a long-term note payable to a bank. The note required monthly interest only payments at prime plus 1.0%. In November 2000, the \$5.0 million long-term note payable was converted into a \$5.0 million cash secured facility. The minimum \$5.0 million compensatory balance, which was invested in certificates of deposit, is included in cash and cash equivalents at December 31, 2001. The note was paid in full on January 18, 2002.

#### 7. LINE OF CREDIT

In January 2002, the Company entered into a revolving accounts receivable line of credit with an asset based lending division of a bank. Under the Agreement, the Company can borrow up to the lesser of 80% of the 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 line of credit is one year. As of June 30, 2002, there were no borrowings under this line of credit.

#### 8. FABRE KRAMER LICENSE AGREEMENT

In June 2002 the Company signed a definitive License Agreement with Fabre Kramer Pharmaceuticals, Inc., ("Fabre Kramer") for the exclusive worldwide development and commercialization of Hypnostat<sup>TM</sup>, an intranasal form of triazolam to treat patients suffering from insomnia, and for Panistat<sup>TM</sup>, an intranasal form of alprazolam to treat patients suffering from panic disorders. Immediately after the agreement was signed, the Company received a cash payment of \$250,000 for the transfer of all technology related to the products. The Company has no continuing obligations related to the transfer of technology. The Company is entitled to future payments from Fabre Kramer when specific developmental milestones are met. In addition, the Company is entitled to receive royalty payments from worldwide product-related 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 will immediately assume the primary responsibility for the development of Hypnostat<sup>TM</sup> and Panistat<sup>TM</sup>.

## 9. 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. Included in Other accrued liabilities on the Balance Sheet is \$80,000 of accrued interest payable on these debentures. 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 conversion feature and warrant value will be amortized over the term of the debentures.

#### 10. NET LOSS PER SHARE

Under SFAS No. 128, Earnings Per Share, basic and diluted loss per share is based on net loss for the relevant period, divided by the weighted average number of common shares outstanding during the period. Diluted earnings per share gives effect to all potential dilutive common shares outstanding during the period such as options, warrants, convertible preferred stock, and contingently issuable shares. Diluted net loss per share 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 at June 30, 2002, shares used in calculating diluted earnings per share would have included the dilutive effect of an additional 7,971,133 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 4,859,172 warrants.

#### 11. STOCK OPTIONS AND WARRANTS

As permitted by Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"), the Company has elected to account for stock options and purchase rights granted to employees using the intrinsic value method and, accordingly, does not recognize compensation expense for options and purchase rights granted to employees with exercise prices which are not less than the fair value of the underlying common stock.

For equity awards to non-employees, including lenders and lessors, the Company applies the Black-Scholes method to determine the fair value of such instruments. The options and warrants granted to non-employees are re-measured as they vest and the resulting value is recognized as expense over the period of services received or the term of the related financing.

#### 12. RELATED PARTY TRANSACTIONS

In December 2001, the Company entered into a promotion agreement with VSL Pharmaceuticals ("VSL"), a private company owned in part by the major shareholders of Sigma Tau. Sigma Tau beneficially owned approximately 39% of the Company's outstanding stock as of June 30, 2002. 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 for the quarter ending June 30, 2002 was \$88,000 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. The amount of costs incurred by the Company was greater than the amount due to VSL, and as such, VSL owed the Company \$44,000. This amount of reimbursement due to the Company from VSL for the second quarter of 2002 is included as a deduction in the Sales and marketing expense, as VSL has reimbursed the Company for these costs. 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. These amounts due from VSL total to \$244,000 and are included in "Receivable from a related party" on the Balance Sheet as of June 30, 2002. This entire amount has been received subsequent to June 30, 2002. This \$200,000 payment is being recognized over a one-year period and is included in "Services revenue from a related party" on the 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.

In January 2002, the Company entered into a royalty agreement with Glenridge Pharmaceuticals LLC, ("Glenridge"). Kenneth R. Greathouse, the Company's Vice President of Commercial Operations, is a part owner of Glenridge. This agreement calls for the payment of royalties on a quarterly basis on the net sales of Acthar®. The Company paid Glenridge \$143,000 in May 2002 related to royalties on Acthar® sales for the quarter ended March 31, 2002. The Company has accrued \$108,000 for royalties earned in the quarter ended June 30, 2002, which is included in Other accrued liabilities on the Balance Sheet.

#### ITEM 2. 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 those discussed in our annual report on Form 10-K for the fiscal year ended December 31, 2001, including Item 1 "Business of Questcor," and including without limitation "Risk Factors," as well as factors discussed in any documents incorporated by reference herein or therein.

#### Overview

We are an integrated specialty pharmaceutical company focused on the acquisition and marketing of acute care and critical care hospital/specialty pharmaceutical and related healthcare products. We currently market five products in the United States: HP Acthar<sup>®</sup> Gel ("Acthar"), an injectable drug that is commonly used in treating patients with infantile spasm, or West Syndrome; Ethamolin<sup>®</sup>, 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<sup>TM</sup>-125 and Inulin in Sodium Chloride, which are both injectable agents that assess the kidney function by measuring glomerular filtration rate, or kidney function; and VSL#3<sup>TM</sup>, 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. Additionally, we earn royalties from our strategic partner, Sirton Pharmaceuticals S.p.A. ("Sirton"), formerly known as Crinos Industria Farmacobiologica S.p.A., on sales in Italy of Pramidin<sup>®</sup>, an intranasal form of metoclopramide, a medication used for the treatment of nausea and vomiting, for the treatment of various gastrointestinal disorders.

Since the completion of our merger with RiboGene in late 1999, we have reduced our focus on research and development of non-marketed products and reduced our headcount accordingly. Should we elect to undertake any development work, we expect to fund future clinical trials and additional research and development from our anticipated revenues. Should our revenue projections differ from actual results we would expect our research and development costs to increase or decrease accordingly. For the quarter ended June 30, 2002, our research and development programs included the following products: Emitasol<sup>™</sup> for delayed onset emesis, (the vomiting associated with cancer chemotherapy patients), Hypnostat<sup>™</sup> for the treatment of sleep disorders, Panistat for the treatment of panic disorders and the Glial Excitotoxin Release Inhibitors ("GERI") compounds as cytoprotective agents. Under a License Agreement signed in June 2002, Fabre-Kramer agreed to control the development of Hypnostat<sup>TM</sup> and Panistat<sup>TM</sup>. During the second quarter of 2002, we undertook a thorough review of all of our research and development programs and our patent estate. To assist us in reaching our goal of cash burn breakeven before the end of 2002, we have eliminated certain spending for research and development projects. We have also abandoned certain patents for projects that would not be commercialized in the near term, including Peptide deformylase, EHNA, Phosphosugar, Disulfiram, Aminoglycosides, Polyamine and Polyguanidino and Ceresine. We have also been monitoring a study performed by an independent third party academic institution that involved the use of dichloroacetate for the treatment of congenital lactic acidosis. The preliminary results of this study, which were presented at the Endocrine Society meeting June of 2002, suggested that additional studies would be required in order to allow Ceresine <sup>™</sup> to be commercialized. Given the amount of time and resources that would be necessary, we decided to discontinue the development of Ceresine<sup>™</sup>. The future development of Emitasol<sup>™</sup> and the GERI compounds will be dependent in part on our ability to enter into partnership arrangements or secure additional sources of capital to fund our development efforts. As we rely on current and future strategic partners to develop and fund our remaining 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.

We have sustained an accumulated deficit of \$75.6 million from inception through June 30, 2002. Based on our internal forecast and projections, we believe that our cash on hand and the cash to be generated through the expected sale of our products will be sufficient to fund operations through December 31, 2002. While it is our goal to reach cash burn breakeven before the end of 2002, if we are unable to achieve the revenue forecast for 2002 or if our expenses and costs associated with running our operations exceed our estimates, we may not reach cash burn breakeven before the end of 2002, if ever, and we may incur significant operating losses over the next several years. Results of operations may vary significantly from quarter to quarter depending on, among other factors, the results of our sales efforts, the availability of raw materials and finished goods from our sole-source manufacturers, the timing of certain expenses, the establishment of strategic alliances and corporate partnering and the receipt of milestone payments (See "Liquidity and Capital Resources").

#### **Results of Operations**

#### Three months ended June 30, 2002 compared to the three months ended June 30, 2001:

For the quarter ended June 30, 2002, we incurred a net loss of \$1,103,000 or \$0.03 per share, as compared to a net loss of \$1,997,000, or \$0.07 per share for the quarter ended June 30, 2001, an improvement of \$894,000 or 45%.

For the quarter ended June 30, 2002, net product sales increased \$2,336,000 or 241% to \$3,307,000 from \$971,000 for the quarter ended June 30, 2001. The increase in product revenues was due primarily to sales of Acthar<sup>®</sup>, which was introduced in the third quarter of 2001, and to increased unit sales of Ethamolin®. Effective June 24, 2002, we increased our list price for Ethamolin® and Acthar®. From the date of the notification of the price increase through June 30, 2002, we received \$3,231,000 of Acthar<sup>®</sup> and Ethamolin® orders of which \$777,000 had shipped prior to June 30, 2002. The remaining orders of \$2,454,000 were fulfilled in July 2002. We believe that a portion of the increase in net product sales for the quarter ended June 30, 2002, as compared to the same quarter last year, is attributable to purchases made as a result of the notification of the price increase. Since we do not anticipate a price increase in the near future, we believe that this buying trend will not occur in future periods. Beginning in March of 2002, the remaining on hand inventory of Inulin failed to meet certain specifications under FDA regulations and as such we were unable to ship Inulin to our customers. We have tried to procure additional supply of Inulin from our contract manufacturer but they have been unable to provide us Inulin at this time. As of June 30, 2002, we had a backorder of \$252,000 on our Inulin product. Unless we are able to procure a supply of Inulin in a timely fashion it will be unlikely that we will be able to fulfill any of the backorder requests and recognize the revenue from these backorders. In addition, until a new supply of Inulin is obtained, it appears unlikely that we will be able to sell Inulin in the future.

Contract research and grant revenue increased to \$81,000 for the quarter ended June 30, 2002 from \$57,000 for the quarter ended June 30, 2001. This increase was a result of greater reimbursement as provided under the Small Business Innovation Research ("SBIR") grant due to greater activity taking place with the GERI compound research projects in the quarter ended June 30, 2002.

For the quarter ended June 30, 2002, we recognized \$250,000 in technology revenue, related to the License Agreement with Fabre-Kramer. During the quarter ended June 30, 2001, we did not recognize any technology revenue. Royalty revenue for the quarter ended June 30, 2002 was \$3,000, a slight decrease compared to \$5,000 for the quarter ended June 30, 2001. Royalty revenue represents sales of Pramidin<sup>®</sup> in Italy, under our license agreement with Sirton. Services revenue from a related party was \$100,000 for the quarter ended June 30, 2002. This amount represents the year to date revenue resulting from the \$200,000 payment made by VSL for certain promotional activities we undertook to support the launch of VSL#3<sup>TM</sup>. The remaining balance of \$100,000 will be recognized as revenue ratably through December 2002.

Total revenues for the quarter ended June 30, 2002 increased \$2,708,000 or 262% to \$3,741,000 from total revenues of \$1,033,000 for the comparable quarter ended June 30, 2001.

Cost of product sales increased 110% to \$579,000 during the quarter ended June 30, 2002 from \$276,000 in the comparable quarter ended June 30, 2001. This increase was due to greater overall material costs as a result of the higher product sales for the quarter. However, cost of product sales as a percentage of net product sales decreased to 18% for the quarter ended June 30, 2002 from 28% for the quarter ended June 30, 2001, primarily due to a change in product mix for the quarter ended June 30, 2002 as compared to the quarter ended June 30, 2001.

Sales and marketing expenses for the quarter ended June 30, 2002 were \$1,652,000, which represents an increase of \$818,000 or 98% as compared to \$834,000 for the quarter ended June 30, 2001. This increase is primarily due to salary and other costs associated with the expansion of our sales and marketing departments, and increased marketing costs to support our newer products,  $Acthar^{\text{(B)}}$  and  $VSL\#3^{\text{TM}}$ . A total of five new product specialists and one manager were hired in the second quarter to support the launch of  $VSL\#3^{\text{TM}}$ .

General and administrative expenses for the quarter ended June 30, 2002 were \$1,216,000, which represents an increase of \$205,000 or 20%, compared to \$1,011,000 in the quarter ended June 30, 2001. The increase was primarily related to increased investment banking costs associated with potential product acquisitions, financing opportunities and other general and administrative expenses.

Research and development expenses for the quarter ended June 30, 2002 were \$831,000, which represents an increase of \$44,000 or 6%, as compared to \$787,000 for the quarter ended June 30, 2001. This increase is due to costs and expenses related

to the manufacturing site transfer of Acthar®, offset by decreased internal research and development activities. Under our agreement with Aventis Pharmaceuticals, Inc. ("Aventis"), Aventis will manufacture and supply Acthar® through July 2002. Aventis has manufactured and filled one final lot of Acthar which we expect to receive in August 2002. It is anticipated that this final lot, along with the inventory of Acthar® on hand as of June 30, 2002, will be sufficient to meet expected demand through mid-2003. We have identified a new contract manufacturer of Acthar finished product and have begun to transfer the final fill and labeling process from Aventis to this new manufacturer. As part of the original Asset Purchase Agreement with Aventis, we also acquired a certain amount of active pharmaceutical ingredient, ("API"). This bulk product originally manufactured by Aventis will be transferred to the new final fill manufacturer. It is anticipated that this new contract manufacturer will complete the transfer and begin supplying finished product using the API manufactured by Aventis to us no later than mid-2003. We are also in the process of identifying potential new manufacturers for the API. The manufacturing development costs incurred in the second quarter of 2002 relate primarily to site transfer and validation costs. Once the site transfer to the new final fill manufacturer and the new API manufacturer are complete and they begin to supply Acthar® to us, the cost of the product is expected to increase.

Non-cash amortization of deemed discount on convertible debentures issued March 15, 2002 for the quarter ended June 30, 2002 was \$131,000.

Interest income, net, decreased by \$45,000 to a net interest expense of \$13,000 for the quarter ended June 30, 2002 as compared to net interest income of \$32,000 for the quarter ended June 30, 2001, primarily due to the current quarter's interest expense on the convertible debentures issued March 2002 and lower interest income earned on cash equivalents.

Other expense, net, increased by \$174,000 to \$181,000 for the quarter ended June 30, 2002 as compared to \$7,000 for the quarter ended June 30, 2001, primarily due to the other-than-temporary loss taken on our investment in Rigel common stock in the current quarter. We recorded an other-than-temporary loss of \$181,000 on our Rigel equity securities investment for the quarter ended June 30, 2002.

Rental income, net decreased to \$74,000 for the quarter ended June 30, 2002, from \$406,000 in the comparable quarter ended June 30, 2001, due to a one-time payment for vacating our Hayward facility in May 2001 and the sublease of the entire premises commencing in May 2001.

#### Six months ended June 30, 2002 compared to the six months ended June 30, 2001:

During the six months ended June 30, 2002, we incurred a net loss of \$1,435,000 or \$0.04 per share, as compared to a net loss of \$3,869,000, or \$0.14 per share for the quarter ended June 30, 2001, an improvement of \$2,434,000 or 63%.

For the six months ended June 30, 2002, net product sales increased \$5,441,000 or 325% to \$7,113,000 from \$1,672,000 for the six months ended June 30, 2001. The increase in product revenues was due primarily to increased units sales of Ethamolin® and Acthar®, which was introduced in the third quarter of 2001. The increase of unit sales over the prior period was partially due to a shipment of a backorder in early 2002 and a price increase in June 2002. During the six months ended June 30, 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 \$6,371,000, an increase of \$4,699,000 or 281% over the six months ended June 30, 2001. Effective June 24, 2002, we increased our list price for Ethamolin® and Acthar®. From the date of the notification of the price increase through June 30, 2002, we received \$3,231,000 of Acthar® and Ethamolin® orders of which \$777,000 had shipped prior to June 30, 2002. The remaining orders of \$2,454,000 were fulfilled in July 2002.

Contract research and grant revenue decreased \$156,000 or 55% to \$126,000 for the six months ended June 30, 2002 from \$282,000 for the comparable six months ended June 30, 2001. This decrease was a result of lower reimbursement under the SBIR grant due to less activity taking place with the GERI compound research project in the six months ended June 30, 2002, as compared to the six months ended June 30, 2001.

For the six months ended June 30, 2002, we recognized \$250,000 in technology revenue related to the License Agreement with Fabre-Kramer. During the six months ended June 30, 2001, we recognized \$90,000 in technology revenue related to a one-time payment under our license agreement with Tularik, Inc. for the sale of our antifungal drug discovery program. Royalty revenue for the six months ended June 30, 2002 was \$6,000, a slight increase as compared to \$5,000 for the six months ended June 30, 2001. Royalty revenue represents sales of Pramidin<sup>®</sup> in Italy, under our license agreement with Sirton. Services revenue from a related party was \$100,000 for the six months ended June 30, 2002. This amount represents the recognition of year to date revenue resulting from the \$200,000 payment made by VSL for certain promotional activities we undertook to support VSL#3<sup>TM</sup>. The remaining balance of \$100,000 will be recognized as revenue ratably through December 2002.

Total revenues for the six months ended June 30, 2002 increased \$5,546,000 or 271% to \$7,595,000 from total revenues of \$2,049,000 for the comparable period ended June 30, 2001.

Cost of product sales increased 81% to \$1,155,000 for the six months ended June 30, 2002 from \$637,000 in the six months ended June 30, 2001. This increase was due to greater material costs as a result of higher product sales for the current period. However, cost of product sales as a percentage of net product sales decreased to 16% for the six months ended June 30, 2002 from 38% for the six months ended June 30, 2001, primarily due to a change in product mix.

Sales and marketing expenses for the six months ended June 30, 2002 were \$3,028,000, which represents an increase of \$1,550,000 or 105% as compared to \$1,478,000 for the comparable six months ended June 30, 2001. However, as a percentage of revenue, sales and marketing expenses decreased to 40% for the six months ended June 30, 2002 from 72% for the six months ended June 30, 2001. This increase is primarily due to salary and other costs associated with the expansion of our sales and marketing departments, and increased marketing costs to support our newer products, Acthar<sup>®</sup> and VSL#3<sup>TM</sup>. We had a headcount of 27 individuals to support the commercial sales of our five products as of June 30, 2002, compared to a headcount of 18 individuals to support three products as of June 30, 2001.

General and administrative expenses for the six months ended June 30, 2002 were \$2,747,000, which represents an increase of \$980,000 or 55%, compared to \$1,767,000 in the six months ended June 30, 2001. The increase was primarily related to increased legal fees, investment banking costs associated with potential product acquisitions, financing opportunities and other general and administrative expenses.

Research and development expenses for the six months ended June 30, 2002 were \$1,316,000, which represents a decrease of \$221,000 or 14%, as compared to \$1,537,000 for the six months ended June 30, 2001. Since the completion of our merger with RiboGene in 1999, we have reduced our focus on research and development of non-marketed products and reduced our headcount accordingly. The decrease was due to lower salary and related expenses related to our research and development activities, offset by increased manufacturing costs related to the Acthar<sup>®</sup> site transfer. The manufacturing development costs incurred for the six months ended June 30, 2002, relate primarily to site transfer and validation costs.

Non-cash amortization of deemed discount on convertible debentures for the six months ended June 30, 2002 was \$175,000 due to the current six month's amortization of deemed discount related to the convertible debentures.

Interest income, net, decreased by \$45,000 to \$14,000 for the six months ended June 30, 2002 from \$59,000 for the six months ended June 30, 2001, primarily due to interest expense on the convertible debentures issued March 15, 2002.

Other expense, net, increased by \$103,000 to \$110,000 for the six months ended June 30, 2002 from \$7,000 for the six months ended June 30, 2001, due to the receipt of profits arising from short swing stock trades executed by one of our 10% shareholders, offset by the \$181,000 other-than-temporary loss taken on our Rigel equity securities investment.

Rental income, net decreased to \$146,000 for the six months ended June 30, 2002, from \$561,000 in the comparable six months ended June 30, 2001, due to the receipt of a one-time sublease termination fee of \$130,000 by the former sublessor of our Carlsbad facility and a one-time payment for vacating our Hayward facility in May 2001.

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

We have principally funded our activities to date through various issuances of equity securities, which, through June 30, 2002, have raised total net proceeds of \$46.1 million, and to a lesser extent through product sales.

At June 30, 2002, we had cash, cash equivalents and short-term investments of \$8,287,000 compared to \$10,571,000 at December 31, 2001 (including a compensating balance of \$5,000,000). At June 30, 2002, working capital was \$7,387,000 compared to \$2,479,000 at December 31, 2001. The increase in working capital was principally due to the issuance of \$4,000,000 convertible debentures coupled with increased product sales for the period, and offset by the repayment of the note payable to bank. Currently we use cash earnings/(burn) as a measure of our performance. Cash earnings/(burn) is defined as net loss excluding certain non-cash charges (depreciation and amortization, non-cash amortization of deemed discount on convertible debentures, and non-cash stock based compensation.) Cash burn for the quarter ended June 30, 2002 was \$613,000, an improvement of \$819,000 as compared to cash burn of \$1,432,000 for the quarter ended June 30, 2001. Cash burn for the six months ended June 30, 2002 was \$290,000, an improvement of \$2,440,000, as compared to cash burn of \$2,730,000 for the comparable period in 2001. In the third quarter of 2002, we anticipate that we will still be in a cash burn position.

As a result of the merger with RiboGene, we assumed \$5 million of long-term debt financing with a bank. The note required us to make monthly interest payments, at prime plus 1% (5.75% at December 31, 2001), with the principal payment due at the end of the three-year term (December 2001). The note had a 90-day extension period, and the note's term was extended to March 2002. We paid the note in full on January 18, 2002.

In January, we entered into a revolving accounts receivable line of credit. Under the agreement, we can borrow up to the lesser of 80% of our 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. As of June 30, 2002, we had no borrowings under this line of credit.

We lease four buildings with lease terms expiring between 2004 and 2012. Annual rent payments for all of our facilities in 2002 are estimated to be \$1,449,000. We utilize the Union City facility as our headquarters and the Carlsbad facility as our warehousing and distribution center. Annual rent payments for 2002 for these facilities are \$660,000. We have subleased laboratory space and laboratory equipment in Hayward, California for a term of six years and anticipate that we will receive \$949,000 in 2002 as sublease income to be used to pay the annual rental expense of \$651,000 in 2002. The Lee's Summit facility was closed in May 2001 and this facility is currently available for sublease. Lease payments under the facility in Lee's Summit, Missouri will be \$138,000 for 2002.

We also hold 83,333 shares of Rigel Pharmaceuticals, Inc. (NASD: RIGL) common stock that we received in conjunction with the agreement to sell Rigel exclusive rights to certain of our proprietary antiviral drug research technology. As of June 30, 2002, the shares had a market value of \$3.65 per share, and are classified as a security available-for-sale.

On March 15, 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 our 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 debenture for stock at maturity, provided the total aggregate number of shares of our 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 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).

We 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, we 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 conversion feature and warrant value will be amortized over the term of the debentures.

Based on our internal forecast and projections, we believe that our cash on hand and the cash to be generated through the expected sale of our products will be sufficient to fund operations through December 31, 2002. While it is our goal to reach cash burn breakeven before the end of 2002, if we are unable to achieve the revenue forecast for 2002 or if our expenses and costs associated with running our operations exceed our estimates, we may not reach cash burn breakeven before the end of 2002, if ever, and we may incur significant operating losses over the next several years. Our future funding requirements will depend on many factors, including: the timing and extent of product sales, our ability to receive product timely from our contract manufacturers, any expansion or acceleration of our development programs; the acquisition and licensing of products, technologies or compounds, if any; the results of preclinical studies and clinical trials conducted by our collaborative partners or licensees, if any; our ability to manage growth; competing technological and market developments; costs involved in filling, 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; and other factors.

We may seek additional funds through public or private equity financings or from other sources. Should this occur, there can be no assurance that additional funds can be obtained on desirable terms or at all. We may seek to raise additional capital at any time, even if we do not have an immediate need for additional cash at that time.

#### RISK FACTORS

You should carefully consider the following risk factors. Each of these risks could adversely affect our business, financial condition and results of operations, as well as adversely affect the value of an investment in our common stock.

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

We have a history of consistent operating losses. Our operating losses from inception through June 30, 2002 were \$75.6 million, of which \$8.7 million represented the loss for the year ended December 31, 2001. Further substantial operating losses are expected to continue through the end of 2002. If we are unable to achieve our sales forecast and maintain expenses in a way that allows us to reach cash-burn breakeven by the end of 2002, substantial operating losses will continue to occur. To date, our revenues have been generated principally from sales of Acthar, Ethamolin, Glofil-125, Inulin and VSL#3. During 2001, we discontinued the Neoflo product line. We do not expect Hypnostat, Panistat, or Migrastat, or the GERI compounds to be commercially available for a number of years, if at all. Further, our revenues from the sale of Emitasol will also be dependent on FDA approval and the development of Emitasol in conjunction with a new strategic partner which has not yet been obtained. In December 2001, we acquired the U.S. rights to market VSL#3, a patented probiotic. Our ability to achieve a consistent, profitable level of operations will be dependent in large part upon our ability to:

- finance operations with external capital until positive cash flows are achieved,
- finance and acquire additional marketed products,
- increase sales of current products,
- · finance the future growth of our sales/marketing and customer service organization,
- enter into agreements with corporate partners for the development of Emitasol,
- properly and timely perform the transfer of the manufacturing of our products to new contract manufacturers including receiving the appropriate
  approvals from the FDA and other regulatory authorities, and
- · continue to receive products from our sole-source contract manufacturers on a timely basis and at acceptable costs.

No new product launches are planned. 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.

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

Although we recently completed a \$4.0 million convertible debenture offering with institutional investors, this investment combined with our cash on hand may not be adequate for us to fund operations or reach cash burn breakeven. In addition, 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. In order to conduct our operating activities, we will require substantial additional capital resources in order to acquire new products, increase sales of existing products, and maintain our 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,
- · achieving lower cost of goods sold and better operating efficiencies,
- · obtaining product from our sole-source contract manufacturers and completing the site transfer to new contract manufacturers,
- · acquiring additional product candidates, and
- the status of the equity markets, in general, and investor's tolerance for risk.

Based on our internal forecast and projections, we believe that our cash on hand at June 30, 2002, and the cash to be generated through the expected sales of our products, will be sufficient to fund operations through December 31, 2002. We anticipate obtaining additional financing through corporate partnerships and 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 delay, reduce the scope of, eliminate or divest one or more of our product acquisition or manufacturing efforts. If the time required to generate product revenues and achieve profitability is longer than anticipated, we may not be able to achieve cash burn breakeven by the end of 2002 or fund operations beyond the end of 2002.

# 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 the clinical supplies for Emitasol, our marketed products, Acthar, Ethamolin, Glofil, Inulin and VSL#3, and other products that we may develop or commercialize in the future. Third party manufacturers may not be able to meet our needs with respect to timing, quantity or quality. All of our manufacturers are sole-source manufacturers and no currently qualified alternative suppliers exist. At this time, we have no contract manufacturers in place for clinical supplies of Emitasol.

Aventis Pharmaceuticals Products, Inc. provides the final fill product for Acthar under our Asset Purchase Agreement with them until July 27, 2002. Additionally, we do not have a contract in place for the supply of Acthar's active pharmaceutical ingredient ("API"). We are currently seeking a new vendor to provide the supply of Acthar's API subsequent to July 27, 2002. Aventis has manufactured and filled one final lot of Acthar which we expect to receive in August 2002. It is anticipated that this final lot, along with the inventory of Acthar on hand as of June 30, 2002, will be sufficient to meet expected demand for Acthar through mid-2003. We have identified a new contract manufacturer of Acthar finished product and have begun to transfer the final fill and labeling process from Aventis to this new contract manufacturer. As part of the original asset purchase from Aventis, we also acquired a certain amount of the API. This bulk product originally manufactured by Aventis will be transferred to the new final fill manufacturer. It is anticipated that this new contract manufacturer will complete the transfer and begin supplying finished product using the API manufactured by Aventis to us no later than mid-2003. We are currently identifying potential new manufacturers of the API. The process of manufacturing Acthar is complex and problems associated with the site transfer may be encountered. Once the site transfer to the new final fill manufacturer and the new API manufacturer has been completed and they begin supplying Acthar to us, the cost of the product is expected to increase.

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 and we intend to order inventory on a purchase order basis until a contract is in place. Glofil is manufactured by ISO-Tex Diagnostics, Inc. on a purchase order basis. The API for Inulin is manufactured by Pfanstiehl Laboratories, Inc. under a contract we have with them, and the final fill product for Inulin is manufactured by Ben Venue on a purchase order basis. Beginning in March 2002 the remaining on hand inventory of Inulin failed to meet certain specifications and as such the Company was unable to ship Inulin to its customers. We have tried to procure additional supply of Inulin from our contract manufacturer but they have been unable to provide us Inulin at this time. As of June 30, 2002 we had a backorder of \$252,000 on our Inulin product. Unless we are able to procure a supply of Inulin in a timely fashion it will be unlikely that we will be able to fulfill any of the backorder request and recognize the revenue from these backorders. In addition, until a new supply of Inulin is obtained it appears unlikely that we will be able to sell Inulin. VSL#3 is supplied by VSL Pharmaceuticals, Inc. under a promotion agreement we have with them. VSL Pharmaceuticals, Inc. has the sole responsibility for manufacturing or acquiring the VSL#3 product.

If we are unable to contract for a sufficient supply of our required products and substances on acceptable terms, or if we should encounter delays or difficulties in our relationships with our manufacturers, or if the site transfers 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 and our clinical testing could be delayed, leading to a delay in the submission of products for regulatory approval or the market introduction and subsequent sales of these products. 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. During December of 2001, we were on backorder for Ethamolin and Acthar due to manufacturing constraints at two of our third party contract manufacturers. As of June 30, 2002 we were on backorder for Inulin due to the failure of the product to meet certain specifications. We cannot guarantee that we will not have backorders in the future for Ethamolin and Acthar or any of our current or future 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 revenues from sales of Acthar decline, we may not have sufficient revenues to fund our operations.

We rely heavily on sales of Acthar. For the year ended December 31, 2001, Acthar revenues comprised 41% of our total product revenues. For the quarter ended June 30, 2002, Acthar revenues comprised 64% of our total product revenues. We expect that Acthar will continue to constitute a significant portion of our revenues for 2002. Although our goal is to actively promote Acthar, and we have no reason to believe Acthar will not be successful, we cannot predict whether the strong demand for Acthar will continue in the future or that we will continue to generate significant revenues from sales of Acthar. If the demand for Acthar declines, or if we are forced to reduce the price, our revenues from the sale of Acthar would decline. If the cost to produce Acthar increases, our gross margins on the sale of Acthar would decline. Any delays or problems associated with the site transfer of the manufacturer of Acthar will reduce the amount of the product that will be available for sale. If our revenues from the sale of Acthar decline or our gross margins on the sale of Acthar decline, our total revenues would be harmed and we may not have sufficient revenues to fund our operations.

#### 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 Charles J. Casamento, Chairman, President, and Chief Executive Officer and Kenneth R. Greathouse, Vice President of Commercial Operations. While Mr. Casamento has executed an employment agreement, if we were to lose either Mr. Casamento or Mr. Greathouse 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 some increases in staffing levels are expected during 2002, these future demands are expected to require a substantial increase in management personnel to perform operational work as well as the development of additional expertise by existing management personnel. Accordingly, recruiting and retaining management and operational personnel to perform sales and marketing, business development, regulatory affairs, 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, universities and other research institutions for such personnel. If we are unable to hire necessary skilled personnel in the future, our business could be harmed.

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

Our current development program focuses on Emitasol, an intranasal medication used to treat nausea and vomiting. Emitasol could be developed for two indications: a decreased movement of the stomach region in diabetics causing fullness, bloating and nausea, known as diabetic gastroparesis, and delayed onset emesis, the vomiting associated with cancer chemotherapy patients. The diabetic gastroparesis drug candidate was being developed in collaboration with a subsidiary of Shire Pharmaceutical Group plc in the U.S. and had completed a Phase II clinical trial in the treatment of diabetic gastroparesis. With the expiration in July 2001 of the exclusive option to develop Emitasol held by Shire, development under this collaboration stopped. Further development of Emitasol is on hold pending our entering into an agreement with a future partner to fund the development of Emitasol. We also have intranasal drug candidates, Migrastat, for the treatment of migraine headaches on which pilot trials have been conducted, and Hypnostat for the treatment of insomnia, which has now been licensed to Fabre Kramer. There is no guarantee that any of these drugs will successfully complete Phase III testing. Clinical trial results are frequently susceptible to varying interpretations by scientists, medical personnel, regulatory personnel, statisticians and others, which may delay, limit or prevent further clinical development or regulatory approvals of a product candidate. Also, the length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing can vary by product and by the indicated use of a product. If one or more of these drugs fail to successfully pass Phase III testing, we would be unable to market or sell the product, which could result in lower future revenues as well as a decline in our competitive positioning.

Additionally, 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 any products that we 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 payors, 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.

## We have little experience marketing VSL#3 and may be unsuccessful in doing so.

We currently have limited sales and marketing experience with respect to VSL#3. Also, it is too early to know what the demand for VSL#3 will be. If the demand for VSL#3 is less than we anticipate, or we are unsuccessful in marketing VSL#3, our revenues from the sale of VSL#3 will be less than we are currently anticipating. Additionally, we market VSL#3 as a dietary supplement. Dietary supplements typically are not reimbursable by healthcare providers. If VSL#3 is not reimbursable by healthcare providers, our sales of VSL#3 may be limited and the market acceptance for this product may be reduced.

A large percentage of our common stock is beneficially owned by one shareholder and its affiliates, 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 beneficially own, directly or indirectly, approximately 39% of our outstanding common stock as of June 30, 2002. Accordingly, these shareholders may 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 our large shareholder take control of us and having new management inserted and new objectives adopted.

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

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. A number of companies are pursuing the development of pharmaceuticals and products which target the same diseases and conditions that we will target. For example, there are products on the market that compete with Acthar, Ethamolin, Glofil-125, Inulin, 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 abilities to create and maintain scientifically advanced technology and to develop 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.

Acthar competes with 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. Acthar is currently used in patients suffering from arthritis, multiple sclerosis, and infantile spasm.

Several companies offer sclerotherapy agents (chemicals injected into varicose veins that damage and scar the inside lining of the vein, causing it to close) that compete with Ethamolin. Other competitive agents include Scleromate <sup>™</sup> (an injectable agent used to treat varicose veins and spider veins), Rubber Band Ligation methods (procedures in which bleeding esophageal varices are tied off at their base with rubber bands, cutting off the blood flow) such as the Multi-band Superview manufactured by Boston-Scientific, the Multi-band Six Shooter manufactured by Wilson-Cook, and the Multi-band Ligator manufactured by Bard and Octreotide<sup>®</sup> manufactured by Novartis. The competition to market FDA-approved active bleeding esophageal varices therapies is intense.

A number of companies offer both clinical competition as well as research competition to Glofil-125. The clinical competition includes serum creatinine and creatinine clearance methods (tests used to measure how quickly the kidney is able to clear creatinine, a natural chemical found in blood, from the blood) such as Tc-DTPA, which is manufactured by Mallinckrodt, Inc., as well as Omnipaque<sup>®</sup> (an injectable contrast media agent), which is manufactured by Sanofi, a division of Sanofi-Synthelabo. Research competition includes Conray<sup>®</sup>-iothalamate meglumine (an injectable contrast media agent), which is also manufactured by Mallinckrodt, Inc. and employed through the Mayo Clinic. The competition to market FDA-approved drugs to measure kidney function by evaluating glomerular filtration rate is intense.

We have identified Culturelle<sup>™</sup> by ConAgra, *Probiotica* by Johnson and Johnson, and LiveBac<sup>®</sup> by Nutraceutix as competitors to VSL#3.

Several large companies' products will compete with Emitasol in the delayed onset emesis market, including Zofran<sup>®</sup> (a medication used to prevent and treat chemotherapy induced nausea and vomiting) by Glaxo-Wellcome, Kytril<sup>®</sup> (a medication used to prevent and treat chemotherapy induced nausea and vomiting) by SmithKline Beecham and Reglan<sup>®</sup> (a medication used to prevent and treat chemotherapy induced nausea and vomiting) by A.H. Robins. These competitive products, however, are available in oral and intravenous delivery forms only. The competition to develop FDA-approved drugs for delayed onset emesis and diabetic gastroparesis is intense.

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 partner 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 or marketed products for development and commercialization. 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, our development 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.

If we are unable to settle the dispute surrounding our collaboration agreement with Shire Pharmaceuticals Group plc, we may incur increased legal and/or litigation expenses and lost revenues from delays in the commercialization of Emitasol.

Under a collaboration agreement between Shire (after its acquisition of Roberts Pharmaceuticals) and us, Shire had the option to acquire exclusive North American rights to Emitasol. This option expired in July 2001. Under that collaboration agreement, we were obligated to fund one-half of the clinical development expenses for Emitasol up to an aggregate of \$7 million. Through June 30, 2002, we have made development payments for Emitasol, under the terms of the agreement with Shire, totaling \$4.6 million, which consists of \$4.1 million paid to Shire and approximately \$500,000 paid to other parties for allowable expenses, including patent and trademark costs.

Shire asserts we owe \$348,000 in development expenses incurred by it under the collaboration agreement prior to the expiration of the option. We have requested that Shire return certain items to us, including the manufacturing and clinical data it obtained over the course of the agreement, the transfer of the INDs relating to Emitasol (which is substantially complete) and the assignment of the intellectual property relating to Emitasol generated in the course of the development program. While Shire has returned some of these items, we are still in discussion with them as to the resolution of other open items. The failure to quickly resolve any open items on favorable terms relating to this collaboration could result in difficulties finding a new partner to continue the development of Emitasol. Additionally, Shire holds all of our outstanding 2,155,715 Series A preferred shares which represents a beneficial ownership percentage of approximately 5.31% as of June 30, 2002. If we are unable to settle our disagreements with Shire quickly, we may end up in a protracted contract dispute with this major shareholder which may result in increased legal fees, delayed commercialization of Emitasol and lost revenues from the sale of Emitasol.

### 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 US

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 U.S., including the FDA, and by similar agencies in other countries. Any product that we develop must receive all relevant regulatory approvals or clearances before it may be marketed in a particular country. The regulatory process, which includes extensive preclinical studies and clinical trials of each product to establish its safety and efficacy, is uncertain, can take many years and requires the expenditure of substantial resources. Data obtained from preclinical and clinical activities are susceptible to varying interpretations which 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 has recently revised 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 the 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 will 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 U.S.) and private insurance plans. VSL#3 currently does not qualify for any reimbursements by third party payors. In certain foreign markets, the pricing and profitability of our products generally are subject to government controls. In the U.S., 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. In addition, we believe the increasing emphasis on managed care in the U.S. has and will continue to put pressure on the price and usage of our products, which may 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 U.S., proposals have called for substantial changes in the Medicare and Medicaid programs. If such changes are enacted, they may require significant reductions from currently projected government expenditures for these programs. Driven by budget concerns, Medicaid managed care systems have been under consideration in several states. 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.

Legislation in the US requires us to give rebates to state Medicaid agencies based on each state's reimbursement of pharmaceutical products under the Medicaid program. We also must give discounts or rebates 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, our net sales would decline.

#### We face possible delisting from the American Stock Exchange which would result in a limited public market for our common stock.

We have fallen below certain of the American Stock Exchange's ("Amex") continued listing standards and have therefore become subject to possible delisting. Specifically, on August 9, 2002, we received notification from AMEX that we have fallen below the standards set forth in the AMEX Guide Section 1003(a)(i) by having (1) stockholders' equity of less than \$2,000,000 and losses from continuing operations in the last two fiscal years and (2) stockholders' equity of less than \$4,000,000 and losses from continuing operations in the last three fiscal years. The notification provides that we may submit a plan to AMEX by September 10, 2002 advising it of the measures we intend to take in order to bring us into compliance with AMEX's continuing listing standards. We intend to submit such a plan. If our plan is approved, we will be entitled to an eighteen month grace period to regain compliance with AMEX's continuing listing standards. If our plan is not approved, AMEX may initiate delisting procedures. If we are delisted from AMEX, the public market for our common stock would be limited.

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

The price of our stock, like that of other specialty pharmaceutical companies, is subject to significant volatility. Our stock price has ranged in value from \$0.43 to \$5.25 over the last three 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, results of clinical trials conducted by us, our partners or by our competitors; 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; the resolution of (or failure to resolve) disputes with collaboration partners; corporate restructuring by us; licensing activities by us; and the acquisition or sale by us of products, products in development or businesses.

In connection with our research and development collaborations, from time to time we have received equity securities of our corporate partners. The price of these securities also is subject to significant volatility and may be affected by, among other things, the types of events that affect our stock. Changes in the market price of these securities may impact our profitability.

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. 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 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk at June 30, 2002 has not changed materially from December 31, 2001, and reference is made to the more detailed disclosures of market risk included in our Annual Report on Form 10-K for the year ending December 31, 2001, as filed with the Securities and Exchange Commission on March 19, 2002.

#### PART II. OTHER INFORMATION

#### ITEM 1. LEGAL PROCEEDINGS

Not applicable

#### ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

Not applicable

#### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable

#### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

The Company held its 2002 annual meeting of shareholders on May 17, 2002. The following matters received the votes at the meeting as set forth below:

1. Election of Directors to hold office until the 2003 Annual Meeting of Shareholders.

|                      | Votes For  | Votes Withheld |
|----------------------|------------|----------------|
|                      |            |                |
| Charles J. Casamento | 35,101,014 | 207,879        |
| Robert F. Allnutt    | 35,101,014 | 207,879        |
| Frank J. Sasinowski  | 35,101,014 | 207,879        |
| Jon S. Saxe          | 35,098,514 | 210,379        |
| John T. Spitznagel   | 35,101,014 | 207,879        |
| Roger G. Stoll       | 35,101,014 | 207,879        |
| Virgil Thompson      | 35,101,014 | 207,879        |

2. To amend the Company's 1992 Employee Stock Option Plan (the "1992 Plan") to extend its term through March 1, 2012, and to ratify the Board of Directors' amendment to the 1992 Plan increasing the maximum per employee, per calendar year stock option award limit from 100,000 to 600,000.

| For     | 19,097,936 |
|---------|------------|
| Against | 2,217,363  |
| Abstain | 61,379     |

3. To amend the Company's Bylaws to increase the authorized minimum number of directors from four to five, so that the authorized number of directors will be a range of five to nine.

| For     | 34,599,414 |
|---------|------------|
| Against | 623,887    |
| Abstain | 85,592     |

4. To approve the form of Indemnification Agreement to be entered into by the Company and its officers and directors.

| For     | 33,643,574 |
|---------|------------|
| Against | 1,528,711  |
| Abstain | 136,608    |

To approve the Board of Directors' selection of Ernst & Young LLP as the Company's independent accountants for the fiscal year ending December 31, 2002.

| For     | 35,107,431 |
|---------|------------|
| Against | 45,830     |
| Abstain | 85,632     |

# ITEM 5. OTHER INFORMATION

Not applicable

### ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

# (a) Exhibits

- 10.6 Asset Purchase Agreement dated July 27, 2001 between the Registrant and Aventis Pharmaceuticals Products, Inc.
- 10.7 First Amendment to Asset Purchase Agreement dated January 29, 2002 between the Registrant and Aventis Pharmaceuticals Products, Inc.
- 10.8 Promotion Agreement dated December 1, 2001 between the Registrant and VSL Pharmaceuticals, Inc.
- 10.9 First Amendment to Promotion Agreement dated June 27, 2002 between the Registrant and VSL Pharmaceuticals, Inc.

# (b) Reports on Form 8-K

None

# **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

|                       | QUESTCOR PHARMACEUTICALS, INC. |   |
|-----------------------|--------------------------------|---|
| Date: August 14, 2002 | Ву:                            | /s/ Charles J. Casamento                          |
|                       |                                | Charles J. Casamento<br>Chairman, President & CEO |
| Date: August 14, 2002 | Ву:                            | /s/ TIMOTHY E. MORRIS                             |

Timothy E. Morris
Vice President, Finance & Administration
And Chief Financial Officer (Principal
Financial and Accounting Officer)

#### Exhibit Index

- 10.6 Asset Purchase Agreement dated July 27, 2001 between the Registrant and Aventis Pharmaceuticals Products, Inc.
- 10.7 First Amendment to Asset Purchase Agreement dated January 29, 2002 between the Registrant and Aventis Pharmaceuticals Products, Inc.
- 10.8 Promotion Agreement dated December 1, 2001 between the Registrant and VSL Pharmaceuticals, Inc.
- 10.9 First Amendment to Promotion Agreement dated June 27, 2002 between the Registrant and VSL Pharmaceuticals, Inc.

\* Certain information in this exhibit has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

#### ASSET PURCHASE AGREEMENT

THIS ASSET PURCHASE AGREEMENT (the "Agreement"), dated as of July 27, 2001 (the "Effective Date"), is made and entered into by and between AVENTIS PHARMACEUTICALS PRODUCTS INC., a Delaware corporation ("Seller"), and QUESTCOR PHARMACEUTICALS, INC., a California corporation ("Purchaser"). Capitalized terms used in this Agreement shall have the meanings ascribed to them in Article I hereof or as otherwise set forth herein.

#### RECITALS

**WHEREAS,** Seller is engaged in the business of manufacturing and selling the Product (as defined herein), with such Product being sold under the Trademarks (as defined herein); and

**WHEREAS,** Seller desires to sell, transfer and assign to Purchaser, and Purchaser desires to purchase and acquire from Seller, any and all rights in, to and under the Product and related Assets (as defined herein), and in connection therewith, Purchaser has agreed to assume certain liabilities of Seller relating to the Product and such Assets, all on the terms and conditions set forth herein.

**Now, THEREFORE,** in consideration of the mutual covenants and agreements set forth in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto hereby agree as follows:

#### ARTICLE 1

#### **DEFINITIONS**

The following terms shall have the meanings set forth below. Unless the context indicates otherwise, the singular shall include the plural and the plural shall include the singular.

- **1.1** "Affiliate" shall mean any entity that directly, or indirectly through one or more intermediaries, controls or is controlled by or is under common control with the party specified. For the purposes of this Section 1.1 only, "control" will refer to (a) the possession, directly or indirectly, of the power to direct the management or policies of a person or entity, whether through the ownership of voting securities, by contract or otherwise, or (b) the ownership, directly or indirectly, of at least fifty percent (50%) (or, if less, the maximum ownership interest permitted by law) of the voting securities or other ownership interest of an entity.
  - **1.2** "Agreement" shall have the meaning set forth in the preamble.
  - **1.3** "Assets" shall have the meaning set forth in Section 2.1 herein.
  - **1.4** "Assumed Liabilities" shall have the meaning set forth in Section 2.2(a) herein.
- **1.5 "Athena Agreement"** shall mean any and all agreements, written or oral, between Seller or any of its Affiliates and Athena Rx Home Pharmacy, a division of Elan Pharmaceuticals, Inc.

- 1.6 "Business Day" or "business day" shall mean a day other than Saturday, Sunday or any day on which banks located in the State of Delaware are authorized or obligated to close. Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days (or business days) are specified.
  - **1.7 "Effective Date"** shall have the meaning set forth in the preamble.
  - **1.8 "Equipment"** shall have the meaning set forth in Section 2.1(d) herein.
  - **1.9 "FDA"** shall mean the United States Food and Drug Administration or any successor entity thereto.
  - **1.10** "FDA Meeting" shall mean the February 7, 2001 meeting between representatives of the FDA, Seller and Purchaser.
  - **1.11 "Finished Product Inventory"** shall have the meaning set forth in Section 2.3(b).
- **1.12 "Governmental or Regulatory Authority"** shall mean any court, tribunal, arbitrator, authority, agency, commission, official or other instrumentality of the United States or any state, county, city or other political subdivision within the United States.
  - **1.13 "Indemnitee"** shall have the meaning set forth in Section 5.2 herein.
  - **1.14 "Indemnitor"** shall have the meaning set forth in Section 5.2(a) herein.
  - **1.15** "**Inventory**" shall have the meaning set forth in Section 2.1(e) herein.
- **1.16** "Knowledge" or "knowledge"shall mean actual knowledge after reasonable investigation by any executive officer of those things which a reasonably diligent inquiry and exercise of means of information at hand would have disclosed.
  - **1.17 "Labeling Material"** shall have the meaning set forth in Section 6.3 herein.
- **1.18** "Laws" shall mean all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of the United States or any state, county, city or other political subdivision within the United States or of any Governmental or Regulatory Authority.
- **1.19** "Losses" shall mean any and all liabilities, debts, obligations, damages, fines, penalties, deficiencies, losses and expenses (including, without limitation, interest, court costs, amounts paid in settlement, reasonable fees of attorneys, accountants and other experts or other reasonable expenses of litigation or other proceedings or of any claim, default or assessment).
  - **1.20** "NDA" shall mean the New Drug Application filed with the FDA under application number 8-372.
- 1.21 "Net Sales" shall mean total gross invoiced sales of the Product, including any sales of the Product under any trademark other than the Trademark, by Purchaser, its Affiliates

and/or their respective assignees, licensees or distributors to a Third Party end user, less the following deductions to the extent included in such gross invoiced sales price for the Product, or otherwise directly paid or incurred by Purchaser, its Affiliates, sublicensees and/or their respective assignees, licensees or distributors with respect to the sale of the Product to non-Affiliates:

- (a) any rebates, quantity, trade and cash discounts, retroactive price reductions, and other usual and customary discounts to customers accrued and subsequently paid, in the ordinary course of business;
  - (b) returns;
  - (c) freight, transportation, postage and insurance to the extent included in the invoice price; and
- (d) sales taxes, tariffs, duties and other governmental charges (including value added tax) actually paid in connection with the sale (but excluding income taxes).
- **1.22 "NORD Agreement"** shall mean any and all agreements, written or oral, between Seller or any of its Affiliates and the National Organization for Rare Disorders, Inc.
- **1.23 "Product"** shall mean any and all dosage forms of the finished product that have corticotropin as such product's active ingredient that Seller has rights to.
  - **1.24 "Proprietary Rights"** shall have the meaning set forth in Section 2.1(c) herein.
  - **1.25** "Purchase Price" shall have the meaning set forth in Section 2.3 herein.
  - **1.26 "Purchaser"** shall have the meaning set forth in the preamble.
  - **1.27 "Regulatory Documents"** shall have the meaning set forth in Section 2.1(b) herein.
  - **1.28 "Remaining Inventory"** shall have the meaning set forth in Section 2.3(b) herein.
  - **1.29 "Retained Liabilities"** shall have the meaning set forth in Section 2.2(b) herein.
  - **1.30 "Royalty Payment"** shall have the meaning set forth in Section 2.3(c) herein.
  - **1.31 "Seller"** shall have the meaning set forth in the preamble.
  - 1.32 "Third Party" shall mean a person or entity other than Seller, Purchaser or Affiliates of either.
  - 1.33 "Trademarks" shall mean ACTHAR and ACTHAR GEL.

#### ARTICLE 2

#### SALE OF ASSETS, LICENSE GRANT, CLOSING AND CERTAIN POST-CLOSING OBLIGATIONS

- **2.1 Sale of Assets.** As of the Effective Date, and subject to the terms and conditions of this Agreement, Seller hereby sells, assigns, conveys, transfers, and delivers to Purchaser, and Purchaser purchases and accepts from Seller, the following assets related to the Product (collectively, the "Assets"):
- (a) any and all of Seller's and its Affiliates' rights, title, and interests in, to and under the Trademarks in any country of the world, together with the goodwill of the business symbolized by the Trademarks, including but not limited to, common law rights and the registrations listed in **Schedule 2.1(a)** attached hereto;
- **(b)** any and all of Seller's and its Affiliates' rights, title, and interest in, to and under the NDA and all related regulatory filings, and any regulatory filings of Seller for the Product outside the United States (if any), and including, without limitation, all documents related to the safety database and medical information files for the Product (collectively, the "Regulatory Documents");
- (c) any and all of Seller's and its Affiliates' rights, title and interest in, to and under any and all know-how and other proprietary rights owned and/or controlled by Seller or its Affiliates and used in the manufacture and/or testing of the Product, including, without limitation, records, processes and procedures used in the extraction process, biological assay testing and manufacturing of the Product (collectively, the "Proprietary Rights");
  - (d) the equipment set forth on **Schedule 2.1(d)** attached hereto (the "Equipment"); and
- **(e)** the Product inventory set forth on **Schedule 2.1(e)** attached hereto delivered to Purchaser in accordance with the terms and conditions of this Agreement, consisting of finished Product, work-in-progress, raw materials (active ingredients and excipients), packaging materials and other supplies and materials on hand, to the extent used exclusively in the production of the Product (collectively, the "Inventory"). Inventory held pursuant to the terms of the Athena Agreement at Athena Rx Home Pharmacy's place of business is expressly excluded from the Assets.

#### 2.2 Liabilities.

- (a) Assumed Liabilities. On the Effective Date, and subject to the terms and conditions of this Agreement, Purchaser assumes and agrees to pay, perform and discharge when due the following liabilities and obligations arising in connection with the Assets (the "Assumed Liabilities"):
- **(i) Obligations under the Trademarks and Regulatory Documents.** All liabilities and obligations under the Trademarks and the Regulatory Documents arising and to be performed on or after the Effective Date.

#### (ii) Medicaid/Medicare Rebates; Chargebacks; Credits.

- (1) State and federal Medicaid/Medicare rebates in connection with the Product sold by Purchaser after the Effective Date;
- (2) Chargeback rebates and similar payments to wholesalers and other distributors in connection with the Product in the Territory beginning one month after the Effective Date; and
- (3) Credits, utilization based rebates, reimbursements, and similar payments to buying groups, insurers and other institutions in connection with the Product sold by Purchaser after the Effective Date.
- (iii) Recalls. From and after the Effective Date, all liabilities, obligations and responsibilities relating to voluntary and involuntary recalls of units of the Product sold by Purchaser after the Effective Date.
- (iv) Products Liability. From and after the Effective Date, all liabilities, obligations and responsibilities relating to product liability claims or threatened claims relating to units of the Product sold by Purchaser after the Effective Date; provided, however, that liability for such claims or threatened claims shall not be assumed by Purchaser solely to the extent such claims arise from: (i) the manufacturing, storage or handling of Finished Product Inventory by Seller or its Affiliates before shipment of such Finished Product Inventory to Purchaser; and (ii) the storage or handling of the Remaining Inventory by Seller or its Affiliates after the Effective Date.
- **(v) Returns.** From and after the Effective Date, all liabilities and obligations with respect to return of units of Product, provided that Seller shall reimburse Purchaser for the actual cost of credits given to the trade for returned Product with respect to returns received at any time regarding units of Product sold by Seller prior to the Effective Date. Purchaser shall provide Seller with reasonably detailed documentation for any costs to be reimbursed by Seller hereunder and Seller shall have the right to audit such documentation pursuant to the procedures set forth in Section 2.6(d) herein.
- **(b) Retained Liabilities.** Except for the Assumed Liabilities and as set forth in this Agreement, Purchaser shall not assume by virtue of this Agreement or the transactions contemplated hereby, and shall have no liability for, any Losses of Seller of any kind, character or description whatsoever or wheresoever, including, but not limited to, any obligations or Losses with respect to the NORD Agreement, the Athena Agreement or distribution of Product by Seller pursuant to such Agreements (the "Retained Liabilities").
- **2.3 Purchase Price.** Subject to the terms and conditions of this Agreement, Purchaser shall pay to Seller as full and fair consideration for the Assets the following consideration (the "Purchase Price"):
- (a) Upon the later to occur of (i) the date of the first commercial shipment of Product by Purchaser to a Third Party or (ii) the date that is ninety (90) days after the Effective

Date, Purchaser shall pay to Seller \* by wire transfer to an account designated by Seller; and

- (b) Upon the later to occur of (i) the date of the first commercial shipment of Product by Purchaser to a Third Party or (ii) the date that is ninety (90) days after the Effective Date, Purchaser shall pay Seller \* per vial as the total purchase price for all of the filled and labeled vials of finished Product in the Inventory and available for sale to Purchaser as of the Effective Date (the "Finished Product Inventory"), an estimate of which is set forth on **Schedule 2.1(e)** attached hereto. In addition, in accordance with the provisions of Section 2.5 herein, Purchaser shall pay Seller for any of the Inventory described on **Schedule 2.1(e)** other than the Finished Product Inventory purchased as described in the first sentence of this Section 2.3(b), including any of the frozen mini-bombs of active raw ingredient, that is used by Purchaser to produce product to be sold by Purchaser to the trade, (the "Remaining Inventory"), such Inventory to be sold to Purchaser by Seller at a purchase price equal to Seller's standard costs for such Inventory, the standard costs for which are set forth on **Schedule 2.1(e)**, and payment shall be due and payable upon receipt of such Inventory delivered in accordance with Section 2.5; and provided, however, that Purchaser shall not be obligated to purchase any more than one hundred twenty five percent (125%) of the estimate set forth on **Schedule 2.1(e)**; and
- (c) for so long as Purchaser, any of its Affiliates or any of its licensees, or any of their respective successors or assigns, sells the Product, Purchaser shall pay to Seller an annual royalty equal to \* in any given calendar year (the "Royalty Payment"), pursuant to the terms and conditions of Section 2.6 herein.
- **2.4 Grant of Security Interest.** Purchaser hereby grants to Seller a purchase money security interest in and to the Assets, as security solely for the performance by Purchaser of its payment obligations only for the portion of the Purchase Price set forth in Sections 2.3(a) and 2.3(b), together with the right of Seller to repossess the Assets with reasonable advance written notice in the event such obligations are not paid in full within thirty (30) days after becoming due and payable (the "Security Interest"). Purchaser agrees to execute all documents, including without limitation, an UCC-1 Financing Statement or its equivalent, reasonably necessary for Seller to perfect the Security Interest. The Security Interest shall terminate automatically upon receipt by Seller of the payments set forth in Sections 2.3(a) and 2.3(b). Promptly upon receipt of such payments, Seller shall execute all documents reasonably necessary to remove and eliminate the Security Interest, including, without limitation, any liens arising therefrom.

#### 2.5 Inventory.

- (a) Finished Product Inventory. Promptly after the Finished Product Inventory has been relabeled as provided in Section 6.3, Seller shall ship to Purchaser, FOB Seller's distribution facility on a carrier designated by Purchaser, all of such relabeled Finished Product Inventory. Payment for such Finished Product Inventory shall be made by Purchaser as described in Section 2.3(b) hereof.
- \* Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

- **(b)** Remaining Inventory. Seller shall retain the Remaining Inventory in Seller's possession and control after the Effective Date and until: (i) such Remaining Inventory is used by Seller to manufacture filled and labeled vials of finished Product from all or any part of such Remaining Inventory pursuant to Section 6.1(a); and/or (ii) Seller ships all or any part of such Remaining Inventory to Purchaser or to a Third Party designated by Purchaser. Notwithstanding the other provisions of this Section 2.5(b), Seller shall have no obligation to retain or maintain such Remaining Inventory longer than one (1) year after the Effective Date and Purchaser expressly acknowledges that Remaining Inventory may be used in manufacturing under the Supply Agreement and may be unavailable or available in different quantities thereafter as set forth herein. Payment for such Remaining Inventory shall be made by Purchaser as described in Section 2.3(b) hereof. During the period after the Effective Date that Seller remains in possession and control of the Remaining Inventory, Seller shall use reasonable commercial efforts to maintain such Remaining Inventory in accordance with the specifications therefor.
- **(c) Shipping.** All shipments hereunder shall be FOB Seller's distribution facility and the risk of loss for such shipments shall pass to Purchaser upon the transfer of the Inventory to the carrier designated by Purchaser for each such shipment. Seller shall, at its sole cost and expense, package and label Finished Product Inventory and Remaining Inventory (to the extent purchased by Purchaser) for shipping to Purchaser using reasonable commercial diligence to prevent breakage, spoilage or damage to such Finished Product Inventory and Remaining Inventory.

#### 2.6 Royalty Payments.

- (a) Annual Report and Payment. Within thirty (30) days after the end of each calendar year following the Effective Date during which Purchaser records any Net Sales, Purchaser shall provide to Seller a written report setting forth in reasonable detail, including, without limitation, the deductions taken in computing Net Sales, the total amount of Net Sales for such calendar year and the amount of any Royalty Payment due to Seller based on (i) the Net Sales for such calendar year and (ii) the Royalty Payment terms and conditions set forth in Section 2.3(c) herein. Each such annual report shall include payment in the amount of any Royalty Payment due to Seller for the calendar year to which the annual report relates.
- **(b) Taxes.** Any tax required to be withheld by Purchaser on Royalty Payments due Seller hereunder shall be deducted from the amount of Royalty Payments otherwise due, and Purchaser shall supply Seller with appropriate evidence of such tax and payment thereof.
- **(c) Books and Records.** Purchaser shall, and shall require its licensees or distributors to, maintain full and complete books and records of all information necessary for the computation of Net Sales and the royalties payable hereunder for a period of three (3) years after the end of the fiscal year to which they relate. All such books and records shall be maintained in accordance with generally accepted accounting principles consistently applied.
- (d) Audit Rights. Upon reasonable prior written notice to Purchaser, Seller shall have the right at any time (but no more often than once yearly and in any event within three

- (3) years after the close of the year to which the audit relates) to have an audit performed of the books of account and other records of Purchaser during normal business hours for the sole purpose of verifying the Royalty Payments made hereunder. The fees and expenses of any such audit shall be borne by Seller, except in the event that the audit reveals an underpayment of more than five percent (5%) of the actual amount determined to be due, whereupon such fees and expenses shall be borne by Purchaser. Purchaser shall within sixty (60) days of the results of such audit provide for payment of amounts which are underpaid, unless a bona fide dispute exists as to the results of such audit.
- **2.7 Delivery of Documentation.** Within twenty (20) days after the Effective Date, Seller shall, at its sole cost and expense, deliver to Purchaser, at the address set forth in Section 7.3 herein, originals of the materials comprising the Regulatory Documents (provided that Seller shall have the right to retain one copy of such Regulatory Documents solely for its archival purposes); provided, however, that if, Purchaser receives an inquiry from the FDA or an equivalent foreign regulatory agency relating to the Product, then Seller shall use its best efforts to deliver to Questcor such documentation within ten (10) days of the Effective Date or allow Questor to have access to such documentation at its current location so that Questcor may respond as necessary to such inquiry.
- **2.8 Taxes.** Purchaser shall be responsible for and shall promptly pay all federal, state, and local transfer, sales, and other taxes, if any, levied or imposed as a result of the transactions contemplated by this Agreement, excluding any tax payable on any income or gain of Seller.
- **2.9 Further Actions by the Parties.** Each of the parties shall use its reasonable commercial efforts to take all actions and to do all things necessary, proper, or advisable in order to consummate and make effective the transactions contemplated by this Agreement.

#### **ARTICLE 3**

#### REGULATORY MATTERS

- 3.1 Filings with Governmental or Regulatory Authorities Regarding Transfer of the NDA and Foreign Equivalents.
- (a) On or promptly after the Effective Date, but not later than ten (10) days after the Effective Date, the parties shall each file with the FDA a letter containing any information required pursuant to 21 C.F.R. § 314.72, or any successor regulation thereto, regarding the transfer of ownership of the NDA from Seller to Purchaser (the "Notification Letters"). In their respective Notification Letters, Seller shall file the information required of a former owner of the NDA, and Purchaser shall file the information required of a new owner of the NDA. The parties shall file such Notification Letters in a form similar to the sample letters set forth in **Schedule 3.1**. The parties also agree to use their best efforts to take any and all other actions required by the FDA, or other necessary Governmental or Regulatory Authorities, if any, to effect the transfer of the NDA from Seller to Purchaser. Seller may retain an archival copy of the NDA, including supplements and records that are required to be kept under 21 C.F.R. § 314.81.

**(b)** Seller shall transfer to Purchaser, at Purchaser's request and sole expense, any Regulatory Documents relating to filings equivalent to the NDA made outside the United States. In addition, Seller will use its best efforts, at Purchaser's request and sole cost and expense, to cause its Affiliates to transfer any regulatory filings of Seller's Affiliates for the Product outside the United States (if any).

### 3.2 Responsibility for the Assets and the Product.

- (a) Subject to Section 6.1(b), on the date of receipt by the FDA of the Notification Letter of Seller, Purchaser shall assume all regulatory responsibilities permitted by applicable laws and regulations to be assumed by Purchaser, reporting and otherwise, in connection with the Assets and the Product including, but not limited to, responsibility for reporting any adverse drug events in connection with the Product, and responsibility for compliance with the Prescription Drug Marketing Act of 1987, as the same may be amended from time to time; provided however, that from the Effective Date until the date that the FDA is notified of such transfer, Purchasers shall only be obligated to assume such responsibilities to the extent permitted by law, and the parties shall work together to assure that such obligations are met during such period.
- **(b)** The parties will agree upon procedures to ensure a smooth transition from Seller to Purchaser of the activities required to be undertaken by the holder of the NDA.
- (c) Upon the Effective Date, Purchaser shall assume all responsibility for any and all fee obligations for holders or owners of approved new drug applications and approved, marketed prescription drug products relating to the Assets and Product, including, but not limited to, those defined under the Prescription Drug User Fee Act of 1992, as the same may be amended from time to time.
- **(d)** Promptly after the Effective Date, Purchaser and Seller shall take all actions necessary or required under applicable Laws to reflect that the Assets are owned by Purchaser and that Purchaser has responsibility therefor.

### **ARTICLE 4**

### REPRESENTATIONS AND WARRANTIES

- **4.1 Representations and Warranties of Seller.** Seller represents and warrants to Purchaser as follows:
- (a) Organization and Standing. Seller is a corporation, duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation.
- **(b) Power and Authority.** Seller has all requisite corporate or limited liability company power and authority to execute, deliver, and perform this Agreement and the other agreements and instruments to be executed and delivered by it pursuant hereto and to consummate the transactions contemplated herein and therein. The execution, delivery, and performance of this Agreement by Seller does not, and the consummation of the transactions contemplated hereby will not, violate any provisions of Seller's organizational documents,

bylaws, any law or regulation applicable to Seller, or any agreement, mortgage, lease, instrument, order, judgment, or decree to which Seller is a party or by which Seller is bound or result in the creation or acceleration of any lien charge, security interest, or other encumbrance on the Assets.

- **(c) Corporate Action; Binding Effect.** Seller has duly and properly taken all action required by law, its organizational documents, or otherwise, to authorize the execution, delivery, and performance of this Agreement and the other instruments to be executed and delivered by it pursuant hereto and the consummation of transactions contemplated hereby and thereby. This Agreement has been duly executed and delivered by Seller and constitutes, and the other instruments contemplated hereby when duly executed and delivered by Seller will constitute, legal, valid, and binding obligations of Seller enforceable against it in accordance with their respective terms, except as enforcement may be affected by bankruptcy, insolvency, or other similar laws and by general principles of equity as applied by a court of competent jurisdiction.
- **(d) Consents.** No consent or approval of, or filing with or notice to, any Governmental or Regulatory Authority or any other person not a party to this Agreement is required or necessary to be obtained by Seller or on its behalf in connection with the execution, delivery, and performance of this Agreement or to consummate the transactions contemplated hereby, except as contemplated by Section 3.1 hereof.
- **(e) Ownership of Assets; Condition of Assets.** Seller is the sole owner of the Assets and the Assets are free and clear of all liens, claims, charges, or encumbrances.
- **(f) Finished Product Inventory Warranty.** The Finished Product Inventory delivered hereunder shall conform to the specifications therefor, and shall have been manufactured in accordance with cGMP and the manufacturing process as approved by the FDA at the time of manufacture.
- **(g) Litigation or Disputes.** There is no claim, outstanding commitment to any governmental regulatory agency, action, suit, proceeding, investigation, or arbitration pending or, to Seller's knowledge, threatened against Seller relating to the Assets, and Seller is not in violation of or in default with respect to any applicable law, rule, regulation, judgment, order, writ, injunction, award, or decree of any arbitrator, court, or administrative body, the result of any of which, either individually or cumulatively, would have a materially adverse effect on the Assets or Seller's compliance with and performance under the terms of this Agreement.

# (h) Patents, Trademarks and Proprietary Rights.

(i) Seller is not aware of any unexpired patent that claims or covers any of the Assets owned by Seller (the "Patent"). To the extent that a Patent or patent application exists as of the Effective Date of this Agreement, Seller covenants not to sue Purchaser under such Patent or any other patent issuing from a patent application that claims priority to the patent application that issued into such Patent.

- (ii) There is no claim, action, suit, or proceeding, pending or, to Seller's Knowledge, threatened alleging that the use by Seller or its Affiliates of the Trademarks or the Proprietary Rights infringes any intellectual property rights of third parties.
- (iii) Seller has not executed or granted to any Affiliate or any Third Party any license, sublicense, or contract covering the Trademarks or the Proprietary Rights.
- (i) Equipment. The equipment listed on Schedule 2.1(d) is all the equipment solely dedicated to the extraction process of the manufacture (but not the filling process) and testing of the Product in Seller's Kankakee, IL, plant.
  - **4.2 Representations and Warranties of Purchaser.** Purchaser represents and warrants to Seller as follows:
- (a) Organization and Standing. Purchaser is a corporation duly organized, validly existing and in good standing under the laws of the State of California.
- **(b) Power and Authority.** Purchaser has all requisite corporate power and authority to execute, deliver, and perform this Agreement, and the other agreements and instruments to be executed and delivered by it pursuant hereto and to consummate the transactions contemplated herein and therein. The execution, delivery, and performance of this Agreement by Purchaser do not, and the consummation of the transactions contemplated hereby will not, violate any provision of Purchaser's articles of incorporation, bylaws, any law or regulation applicable to Purchaser, or any agreement, mortgage, lease, instrument, order, judgment, or decree to which Purchaser is a party or by which Purchaser is bound.
- **(c) Corporate Action; Binding Effect.** Purchaser has duly and properly taken all action required by law, its articles of incorporation, its bylaws, or otherwise, to authorize the execution, delivery, and performance by it of this Agreement and the other instruments to be executed by it pursuant hereto and the consummation of the transactions contemplated hereby and thereby. This Agreement has been duly executed and delivered by Purchaser and constitutes, and the other instruments contemplated hereby when duly executed and delivered by Purchaser will constitute, legal, valid, and binding obligations of Purchaser enforceable against it in accordance with their respective terms, except as enforcement may be affected by bankruptcy, insolvency, or other similar laws and by general principles of equity as applied by a court of competent jurisdiction.
- **(d) Consents.** No consent or approval of, or filing with or notice to, any federal, state, or local governmental or regulatory authority, agency, or department or any other person not a party to this Agreement is required or necessary to be obtained by Purchaser or on its behalf in connection with the execution, delivery, and performance of this Agreement or to consummate the transactions contemplated hereby, except as contemplated by Section 3.1 hereof.
- **4.3 Survival of Representations/Warranties.** The representations and warranties contained in this Article IV, and that portion of the indemnification with respect thereto pursuant to Article V, shall survive the Effective Date and continue in effect for a period of one (1) year

thereafter, except for the representation set forth in Section 4.1(f) which shall survive beyond such one (1) year period.

- **4.4 Brokers.** Each party hereby represents that all negotiations relative to this Agreement and the transactions contemplated hereby have been carried out by each such party directly with the other party without the intervention of any Third Party on behalf of either party in such manner as to give rise to any valid claim by any Third Party against either party for a finder's fee, brokerage commission or similar payment.
- 4.5 Manufacturing Process. Purchaser hereby acknowledges and agrees that the Assets and Product are being sold hereunder on an 'as is' compliance basis with respect to the manufacture of the Product in accordance with the FDA's position at the FDA Meeting and that Seller makes no representation or warranty or in any way guarantees that the FDA will issue minutes of the FDA Meeting that reflect the FDA's consent to allow the manufacture of the Product as it is being manufactured by Seller as of the Effective Date, or that the FDA will continue to allow the manufacture in such manner in the future, regardless of the FDA's position in the minutes of the FDA Meeting. Purchaser acknowledges that the FDA has not approved or issued minutes of the FDA Meeting documenting the FDA's consent to manufacture in the manner set forth at the FDA Meeting, and Purchaser accepts any risk associated therewith. Accordingly, Purchaser accepts any and all risks of Losses associated with any change of the FDA's position from that set forth at the FDA Meeting regarding the manufacture of the Product.
- **4.6 Disclaimer of Warranties.** EXCEPT AS EXPRESSLY PROVIDED HEREIN, SELLER DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH REGARD TO THE ASSETS AND THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, THE WARRANTY OF MERCHANTABILITY AND THE WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.
- **4.7 As-Is Acknowledgement.** Except as expressly set forth herein, Purchaser acknowledges that the Assets are being sold hereunder on an as-is basis, the Assets are being sold with no representations made by Seller as to condition of the Assets.
- **4.8 Patent Acknowledgement.** Purchaser acknowledges that other parties, including without limitation American Medical Technologies, may have filed patent applications claiming or covering products that have corticotropin as an active ingredient, and that Seller has done no investigation with respect to such patent applications.

#### **ARTICLE 5**

### INDEMNIFICATION

### 5.1 Indemnification.

(a) Subject to Section 5.1(c) and Section 5.2, Seller shall indemnify Purchaser and its officers, directors, employees, agents and Affiliates in respect of, and hold each of them harmless from and against, any and all Losses suffered, incurred or sustained by any of them or to which any of them becomes subject, resulting from, arising out of, or relating to,:

- (i) The Retained Liabilities; and
- (ii) For the term set forth in Section 4.3, misrepresentation or breach of any warranty or covenant by Seller made or contained in this Agreement; and
- (iii) Litigation or other claims arising from acts, failures to act or events relating to the Assets or the Product which occurred prior to the Effective Date; and
  - (iv) The use, storage or transportation of the Products before the Effective Date; and
  - (v) The testing performed by Seller pursuant to Section 6.1(b).

Notwithstanding any provision herein to the contrary, the parties agree that in no event will Seller be liable to Purchaser for special, consequential, indirect, punitive or similar damages; provided however, that indemnification claims for Losses arising solely out of third party claims shall not be so limited.

- **(b)** Subject to Section 5.1(c) and Section 5.2, Purchaser shall indemnify Seller and its officers, directors, employees, agents and Affiliates in respect of, and hold each of them harmless from and against, any and all Losses suffered, incurred or sustained by any of them or to which any of them becomes subject, resulting from, arising out of or relating to:
  - (i) The Assumed Liabilities; and
- (ii) For the term set forth in Section 4.3, misrepresentation or breach of any warranty or covenant by the Purchaser made or contained in this Agreement; and
- (iii) Litigation or other claims arising from acts, failures to act or events relating to the Assets or the Product that occur on or after the Effective Date; except for claims arising from: (1) the manufacturing, storage or handling of Finished Product Inventory by Seller or its Affiliates before shipment of such Finished Product Inventory to Purchaser; and (2) the storage or handling of the Remaining Inventory by Seller or its Affiliates after the Effective Date.
  - (iv) The use of the Assets on or after the Effective Date, except those Assets that remain within Seller's exclusive control.
  - (v) The manufacture or testing of the Assets or the Products by Purchaser or a Third Party appointed by Purchaser; and
  - (vi) Any cartons, package inserts, labels or any other supplies provided by Purchaser.

Notwithstanding any provision herein to the contrary, the parties agree that in no event will Purchaser be liable to Seller for special, consequential, indirect, punitive or similar damages.

- **(c)** Notwithstanding anything to the contrary contained in this Agreement, no amounts of indemnity shall be payable as a result of any claim in respect of any Losses arising under paragraph (a) or (b) of Section 5.1:
- (i) unless, until and then only to the extent that the Indemnified Parties thereunder have suffered, incurred, sustained or become subject to Losses referred to in such paragraphs in excess of Twenty-Five Thousand Dollars (\$25,000) in the aggregate;
- (ii) with respect to any Losses, to the extent that the party seeking indemnification had a reasonable opportunity, but failed, in good faith to mitigate such Losses, including, but not limited to, the failure to use commercially reasonable efforts to recover under such party's policy of insurance or under a contractual right of set-off or indemnity; or
- (iii) with respect to any Losses, to the extent that such Losses are caused by (a) any inaccuracy of a representation or breach of a warranty made by the party seeking indemnification in the Agreement or (b) the gross negligence or intentional misconduct of such party or any of its officers, directors, employees, agents or Affiliates.
  - **5.2 Method of Asserting Claims.** A party (the "Indemnitee") that intends to claim indemnification under this Article V shall:
- (a) notify the other party (the "Indemnitor") in writing of any Losses with respect to which the Indemnitee intends to claim indemnification as soon as practicable after the Indemnitee becomes aware of any such Losses;
  - (b) permit the Indemnitor to assume the defense thereof with counsel mutually satisfactory to the parties; and
  - (c) cooperate with the Indemnitor, at the Indemnitor's expense, in the defense thereof.

With respect to any matter for which the Indemnitor has an obligation to indemnify the Indemnitee under this Agreement, the Indemnitee shall have the right to participate and be represented (at the Indemnitor's expense) by legal counsel of the Indemnitee's choice in all proceedings and negotiations, if representation by counsel retained by Indemnitor would be inappropriate due to actual or potential differing interests between the Indemnitee and any other party represented by such counsel in such proceedings. The indemnity agreement in this Article V shall not apply to amounts paid in settlement of any Losses if such settlement is effected without the consent of the Indemnitor, which consent shall not be unreasonably withheld. Failure of the Indemnitee to deliver notice to the Indemnitor within a reasonable time after becoming aware of potential Losses shall not relieve the Indemnitor of any liability to the Indemnitee pursuant to this Article V, except to the extent such delay prejudices the Indemnitor's ability to defend such action. The Indemnitor shall not settle or compromise any claim or Losses in any manner that admits fault on the part of the Indemnitee without the express prior written consent of the Indemnitee, which consent may be withheld for any reason or no reason.

#### ARTICLE 6

#### TRANSITION SERVICES

### 6.1 Product Supply and Testing.

- (a) Supply. If needed by Purchaser and only until the earlier to occur of (i) such time as manufacturing of the Product can be transferred to Purchaser or its designated Third Party supplier or (ii) twelve (12) months following the Effective Date, Seller shall, at Purchaser's written request, manufacture, and fill and label vials of, finished Product from existing mini-bombs of raw active ingredient in the Remaining Inventory pursuant to terms and conditions of a supply agreement to be negotiated and agreed upon in good faith by and between the parties; provided that the price shall be \* per vial of filled and labeled finished Product and the other terms and conditions of such manufacture shall be consistent with Seller's previous manufacture of filled and labeled vials of Product for its own use.
- **(b) Testing.** Seller will perform, at its sole cost and expense, any and all testing of all batches of the Finished Product Inventory and related tasks that Seller has, as of the Effective Date, committed to the FDA to perform on the Finished Product Inventory produced by Seller prior to the Effective Date, such testing commitments consisting solely of stability testing on lots of Finished Product Inventory manufactured by Seller until the second anniversary of the manufacture of such lots. For purposes of clarity, this obligation relates solely to Finished Product Inventory manufactured before the date hereof. Any testing related to Products produced pursuant to Section 6.1(a) will be set forth in the supply agreement, which is described in Section 6.1(a).

### 6.2 Transfer of Product Manufacturing and Testing.

- (a) Site Identification; Timetable. Subject to Section 6.1(a), Purchaser shall identify sites for the manufacture of the active ingredient for, and finished dosage forms of, the Product, and for the testing of the Product and the active ingredient, components and intermediates that is required by the FDA or similar regulatory agency. Seller shall transfer the manufacturing and testing of the active ingredient, components and intermediates and the finished Product to such sites as set forth on **Schedule 6.2** in accordance with the provisions of Section 6.2(b) herein.
- **(b) Seller's Obligations.** Seller will provide Purchaser with reasonable assistance in transferring the manufacturing and testing of the Product and the active ingredient, components and intermediates to Purchaser or its designated Third Party suppliers, including the shipment of the Equipment to, and reinstallation of the Equipment at, the applicable transferee site and the training of employees of Purchaser or its designated Third Party suppliers on the manufacturing and testing processes. **Schedule 6.2** sets forth the project team and a projected timeline for the transfers. The costs and expenses of preparing and shipping the Equipment to the Third Party sites and any Seller costs or expenses related to such training and/or consultation services provided by Seller or its Affiliates at the Kankakee, Illinois manufacturing site shall be at Seller's sole cost and expense. Purchaser shall reimburse Seller for all costs and expenses related to assistance with re-installing Equipment at the Third Party sites and any training and/or
- \* Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

consulting services performed by Seller or its Affiliate at locations outside of the Kankakee, Illinois manufacturing site at a rate of One Thousand Dollars (\$1,000) per person per day plus reasonable travel expenses.

- **(c) Payment.** Purchaser shall pay Seller for the costs and expenses to be reimbursed by Purchaser to Seller pursuant to Section 6.2(b) herein within thirty (30) days after Purchaser's receipt of each invoice from Seller for such costs and expenses. Each Seller invoice shall include reasonable details and documentation regarding the costs and expenses being invoiced by Seller for services rendered pursuant to Section 6.2(b) herein.
- **6.3 Relabeling.** Seller shall relabel such amount of the Finished Product Inventory as Purchaser shall request (which amount shall allow a reasonable number of vials to not be relabeled and remain available to Athena for use in administration of the NORD program until such program is terminated by Seller) using such materials ("Labeling Materials") as Purchaser shall make available to Seller. Seller shall use commercially reasonable efforts to complete such relabeling no later than 8 weeks after receipt of the last to be received Labeling Materials. Such relabeling shall be performed in accordance with Seller's standard procedures for such relabeling. The cost for such relabeling shall be \* per vial.

### **ARTICLE 7**

#### GENERAL PROVISIONS

- **7.1 Payment of Transaction Expenses.** All legal fees and other expenses incurred on behalf of Seller in connection with the negotiation of this Agreement and the consummation of the transactions contemplated herein will be borne by Seller; and all legal fees and other expenses incurred on behalf of Purchaser in connection with the negotiation of this Agreement and the consummation of the transactions contemplated herein will be borne by Purchaser.
- 7.2 No Other Representations. Except as expressly set forth in this Agreement, neither Seller nor Purchaser are making any representation or warranty whatsoever, express or implied, including, but not limited to, any implied representation or warranty as to condition, merchantability or suitability as to any of the Assets. In particular, Seller does not make any representation or warranty to Purchaser with respect to (i) the information set forth in the offering materials provided to Purchaser by Seller or (ii) any financial projection or forecast relating to the business prospects for the Product. With respect to any projection or forecast delivered by or on behalf of Seller to Purchaser, Purchaser acknowledges that (i) there are uncertainties inherent in attempting to make such projections and forecasts, (ii) it is familiar with such uncertainties, (iii) it is taking full responsibility for making its own evaluation of the adequacy and accuracy of all such projections and forecasts furnished to it and (iv) it shall have no claim against Seller with respect to such projections and forecasts prepared in good faith by Seller.

#### 7.3 Notices.

- (a) Except as otherwise specifically provided herein, any notice or other documents to be given under this Agreement shall be in writing and shall be deemed to have
- \* Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

been duly given if sent by registered post, nationally recognized overnight courier or facsimile transmission to a party or delivered in person to a party at the address or facsimile number set out below for such party or such other address as the party may from time to time designate by written notice to the other:

If to Purchaser, to:

Questcor Pharmaceuticals, Inc. 3260 Whipple Road Union City, California 94587 Attn: Vice President, Sales & Marketing

Facsimile: 510-400-0719

### If to Seller, to:

Aventis Pharmaceuticals Products Inc. 300 Somerset Corporate Center Bridgewater, New Jersey 08807-2854 Attn: Vice President, Business Development

Facsimile: 908-243-7219

### with a copy to:

Aventis Pharmaceuticals Products Inc. 300 Somerset Corporate Center Bridgewater, New Jersey 08807-2854 Attn: General Counsel North America

Facsimile: 908-243-7220

- **(b)** Any such notice or other document shall be deemed to have been received by the addressee three (3) business days following the date of dispatch of the notice or other document by post or, where the notice or other document is sent by overnight courier, by hand or is given by facsimile, simultaneously with the transmission or delivery. To prove the giving of a notice or other document it shall be sufficient to show that it was dispatched.
- **7.4 Late Payments.** Any payments due to Seller hereunder that are not received within thirty (30) days of the date on which such payment is due shall accrue interest on any amount overdue, at the lesser of (i) the prime rate as reported by the Morgan Guaranty Bank and Trust, New York, New York (the "Prime Rate") on the date such payment is due, plus an additional three percent (3%) or (ii) the maximum rate permitted by law, such interest to begin accruing on a daily basis from the date of invoice or the date the payment is due hereunder, as the case may be, and shall accrue both before and after any judgment rendered with respect thereto by a court of competent jurisdiction.

### 7.5 Entire Agreement; Amendment.

(a) This Agreement, together with the Schedules attached hereto, embodies and sets forth the entire agreement and understanding of the parties with respect to the subject

matter herein and there are no promises, terms, conditions or obligations, oral or written, expressed or implied, other than those contained herein. The terms of this Agreement shall supersede all previous and contemporaneous oral or written agreements which may exist or have existed between the parties relating to the subject matter of this Agreement. No party shall be entitled to rely on any agreement, understanding or arrangement which is not expressly set forth in this Agreement. Any other terms and conditions are hereby expressly excluded.

- **(b)** This Agreement shall not be amended, modified, varied or supplemented except in writing signed by duly authorized representatives of the parties.
- **7.6 Assignment.** No party shall be entitled to assign its rights and obligations hereunder without the prior written consent of the other party; provided, however, a party shall be entitled, without the prior written consent of the other party, to assign its rights and obligations hereunder to an Affiliate, but such assignment to an Affiliate shall not relieve the assigning party of its obligations hereunder. No permitted assignment hereunder shall be deemed effective until the assignee shall have executed and delivered an instrument in writing reasonably satisfactory in form and substance to the other parties pursuant to which the assignee assumes all of the obligations of the assigning party hereunder. Any purported assignment of this Agreement in violation of this Section 7.6 shall be void. This Agreement shall be binding upon the successors and permitted assigns of the parties and the name of a party appearing herein shall be deemed to include the names of its successors and assigns.
- **7.7 Headings, Interpretation.** The headings used in this Agreement are for convenience only and are not a part of this Agreement nor affect the interpretation of any of its provisions.
  - **7.8 Attachments.** All Schedules referenced herein are hereby made a part of this Agreement.
- **7.9 Independent Parties.** This Agreement shall not be deemed to create any partnership, joint venture, amalgamation or agency relationship between the parties. Each party shall act hereunder as an independent contractor.
- **7.10 Governing Law.** This Agreement shall be governed by and construed under the laws of the State of Delaware, without giving effect to the choice of law provisions thereof.
- **7.11 Dispute Resolution.** If a dispute or claim relating to or arising from this Agreement cannot be resolved by representatives of the parties in the ordinary course of business, then such dispute or claim shall be referred in writing and by referencing this Section 7.11 to the President of Seller and the Chief Executive Officer of Purchaser, respectively. If such officers are unable to resolve such dispute or claim presented to them under the preceding sentence within thirty (30) days of referral, then either party may take whatever action is available to it under law and equity.
- **7.12 No Waiver.** Neither the failure nor delay on the part of either party to require the strict performance of any term, covenant or condition of this Agreement or to exercise any right or remedy available on a breach thereof shall constitute a waiver of any such breach or of any such term or condition. The consent to, or the waiver of, any breach, or the failure to require on

any single occasion the performance or timely performance of any term, covenant, or condition of this Agreement shall not be construed as authorizing any subsequent or additional breach and shall not prevent a subsequent enforcement of such term, covenant, or condition.

- **7.13 Severability.** In the event that any provision of this Agreement or the application thereof to any party or circumstance shall be finally determined by a court of proper jurisdiction to be invalid or unenforceable to any extent, then (i) a suitable and equitable provision shall be agreed to by the Parties in writing and substituted for the invalid or unenforceable provision in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid and unenforceable provision and (ii) the remainder of this Agreement and the application of such provision to the parties or circumstances other than those to which it is held invalid or unenforceable shall not be affected thereby.
- **7.14 Interpretation.** The parties hereto acknowledge and agree that (i) each party and its representatives has reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision, (ii) the rule of construction to the effect that any ambiguities are resolved against the drafting party shall not be employed in the interpretation of this Agreement and (iii) the terms and provisions of this Agreement shall be construed fairly as to each party hereto and not in favor of or against either party regardless of which party was generally responsible for the preparation of this Agreement.
- **7.15 Counterparts.** This Agreement may be executed simultaneously in two or more counterparts, each of which shall be deemed an original, but both of which together shall constitute a single agreement.
- **7.16 Third Party Beneficiaries.** This Agreement is not intended to confer upon any Third Party rights or remedies hereunder, except as may be received or created as part of a valid assignment.
- **7.17 Further Assurances.** Each party shall execute and deliver such additional instruments and other documents and use all commercially reasonable efforts to take or cause to be taken, all actions and to do, or cause to be done, all things necessary under applicable law to consummate the transactions expressly set forth in this Agreement.
- **7.18 Terms of this Agreement.** The parties agree not to disclose any terms or conditions of this Agreement to any Third Party without the prior written consent of the other party, except to advisors, investors, lenders and others on a need-to-know basis under conditions which reasonably ensure the confidentiality thereof or for disclosures only of the existence and general subject matter of this Agreement, or to the extent required by applicable Laws; provided, however, prior to any such required disclosure the non-disclosing party shall be allowed to review the proposed disclosure, and the disclosing party agrees to consider in good faith any proposed revisions thereof provided to the disclosing party within two (2) business days of the non-disclosing party's receipt of the proposed disclosure and the disclosing party shall seek confidential treatment for such disclosure as permitted by applicable Laws.

| IN WITNESS WHEREOF, the parties hereto have each caused this Agreement to be duly executed as of the date first above written. |                                       |   |  |
|--|---------------------------------------|---|--|
|  | Seller:                               |   |  |
|  | AVENTIS PHARMACEUTICALS PRODUCTS INC. |   |  |
| Date: July 27, 2001  | By:                                   | /s/ JOHN R. LEONE                                 |  |
|  |                                       | John R. Leone<br>Sr. Vice President               |  |
|  | PURCHASER:                            |   |  |
|  | QUESTCOR PHARMA                       | ACEUTICALS, INC.                                  |  |
|  |                                       |   |  |
| Date: July 27, 2001  | By:                                   | /s/ CHARLES J. CASAMENTO                          |  |
|  |                                       | Charles J. Casamento<br>Chairman, President & CEO |  |
|  |                                       |   |  |
|  |                                       |   |  |

# SCHEDULE 2.1(a)

# TRADEMARKS

| Country        | Trademark  | Registration Number | Registration Date  |
|----------------|------------|---------------------|--------------------|
|                |            |                     |                    |
| United States  | ACTHAR GEL | 2,255,322           | June 22, 1999      |
| Canada         | ACTHAR     | 36927               | October 26, 1980   |
| Finland        | ACTHAR     | 26021               | November 8, 1992   |
| Hong Kong      | ACTHAR     | 902/1952            | June 12, 1994      |
| India          | ACTHAR     | 212482              | November 27, 1983  |
| Ireland        | ACTHAR     | 70434               | August 2, 1987     |
| Lebanon        | ACTHAR     | 49876               | January 14, 1987   |
| United Kingdom | ACTHAR     | 693384              | October 27, 1985   |
| Uruguay        | ACTHAR     | 280287              | September 19, 1985 |
| Venezuela      | ACTHAR     | 136836              | February 17, 1989  |

# SCHEDULE 2.1(d)

# LIST OF EQUIPMENT

| PART NUMBER | SAP NUMBER | DESCRIPTION               |
|-------------|------------|---------------------------|
| L-1629      | 10004508   | MOD I DRUM ROLLER         |
| L-2154      | 10004516   | NORTH CENTRIFUGE          |
| L-2397      | 10004520   | GELATIN BULK CAN          |
| L-2399      | N/A        | GELATIN BULK CAN          |
| L-2400      | N/A        | GELATIN BULK CAN          |
| L-2401      | N/A        | GELATIN BULK CAN          |
| NC-2847     | 10004919   | MOD I RESIN COLUMN        |
| NC-2848     | 10004920   | MOD IC GEL BOMB           |
| NC-2849     | 10004921   | PHENOL HOOD               |
| LM-4029     | N/A        | MOD IC POTENTIATION TK    |
| L-4066      | 10004535   | AAAP OVEN AND TRAYS       |
| L-4092      | 10004536   | SOUTH CENTRIFUGE          |
| L-4244      | 10004550   | MOD I RECON POT           |
| K-4490      | N/A        | MILLIPORE CART. HOUSING   |
| L-5750      | 10004599   | TWIN SHELL V BLENDER      |
| L-5912      | 10004604   | WILEY MILL                |
| L-6125      | 10004612   | FITZMILL COMMINUTOR       |
| L-6211      | N/A        | MOD I DRUM                |
| L-6370      | 10009065   | 32% GEL TANK              |
| L-6511      | 10006334   | 18" BUCHNER FUNNEL        |
| L-6780      | 10006335   | AAAP G/L BLOW TANK        |
| L-6782      | 10004057   | AAAP 80 GAL. G/L POT      |
| K-7650      | 10004490   | AAAP EXTRACTION TANK      |
| K-7652      | 10004492   | AAAP PRECIPITATION TANK   |
| L-8224      | 10006558   | 100 GAL SS POT            |
| L-8269      | N/A        | SS POT                    |
| N/A         | N/A        | MOD IC RECON AGITATOR (2) |
| N/A         | N/A        | MOD IC RECON VESSEL       |
| N/A         | N/A        | MOD IC GLASS FILTER #1    |
| N/A         | N/A        | MOD IC GLASS FILTER #2    |
| N/A         | N/A        | MISC. EQUIPMENT           |
| L-911C      | N/A        | UTENSIL CART              |
| N/A         | N/A        | MOD 1 BOMB HEADER         |
| N/A         | N/A        | AIR/NITROGEN FILTER       |
| NC-5262     | N/A        | ORION 310 PH METER        |
| L-4143      | N/A        | BOMB FREEZER              |
| N/A         | N/A        | BOWL STAND FOR CENTRIFUGE |
| NC-5735     | N/A        | PUMP                      |
| NC-3344     | 10004932   | PUMP                      |
| L-9119 D    | N/A        | POT                       |

# SCHEDULE 2.1(d) (CONT.)

| PART NUMBER | SAP NUMBER | DESCRIPTION       |
|-------------|------------|-------------------|
| L-9119 E    | N/A        | POT               |
| L-9119 F    | N/A        | POT               |
| L-9119 (3)  | N/A        | POT               |
| L-6965      | 10004669   | SCALE 0-200KG     |
| NC-3366     | N/A        | SCALE             |
| N/A         | N/A        | TABLE             |
| N/A         | N/A        | 2 GLASS BOTTLES   |
| N/A         | N/A        | 2 SS POTS         |
| N/A         | N/A        | 2 BUCHNER SHIELDS |

# MATERIALS USED IN ACTHAR ASSAY

- 1) Rotary Mixer
- 2) Homogenizer, 2 Speed with Rehostat, Foot Pedal, Teflon Pestle (Glas-Col)
- 3) Volustat Dispenser
- 4) Balance for weighing Adrenal Glands
- 5) Thermomax Microtiter Plate reader with Printer

# MATERIALS USED IN HP ACTHAR MOD 1CL PILOT PREP

- 1) 1-Millipore 600 mL pressure system
- 2) 1-Millipore Swinnex 47 filter press
- 3) 1-Millipore AP 25 prefilter
- 4) 1-MF Millipore SS 3.0 m membrane
- 5) 1-MF Millipore RA 1.2 m membrane
- 6) 1-MF Millipore AA 0.8 m membrane
- 7) 1-MF Millipore DA 0.65 m membrane
- 8) 1-MF Millipore PH 0.30 m membrane
- 9) 1-MF Millipore GS 0.22 m membrane
- 10) 10 Millipore mesh spacers

# SCHEDULE 2.1(e)

# LIST OF INVENTORY

# As of 06/14/01

| Part #  | Description                              | Unit of<br>Measure | RM or<br>WIP | Total<br>Quantity | Price Per<br>Unit | Total Value |
|---------|--|--------------------|--------------|-------------------|-------------------|-------------|
| 277     | GAUZE<br>OXYCELLULOSE                    | G                  | RM           | *                 | *                 | *           |
| 280     | GELATIN                                  | KG                 | RM           | *                 | *                 | *           |
| 367     | PORK PIT GLANDS                          | KG                 | RM           | *                 | *                 | *           |
| 374     | AAAP PWD MOD I                           | G                  | WIP          | *                 | *                 | *           |
| 679     | GELATIN, 32%<br>SOLUTION W/1.0<br>PHENOL | KG                 | WIP          | *                 | *                 | *           |
| 948     | CYS L FREE BASE                          | G                  | RM           | *                 | *                 | *           |
| 1979    | HP ACTH MOD I POOL                       | G                  | WIP          | *                 | *                 | *           |
| 3175    | HPAG MOD ICL                             | KG                 | WIP          | *                 | *                 | *           |
| 3879    | LIQUIFIED PHENOL,<br>USP                 | L                  | RM           | *                 | *                 | *           |
| 17500   | LABEL, ACTHAR GEL<br>80U 5ML             | EA                 | RM           | *                 | *                 | *           |
| 17565   | CARTON HP ACTHAR<br>GEL 80U 5ML          | EA                 | RM           | *                 | *                 | *           |
| 17620   | INSERT, HP ACTHAR<br>GEL                 | EA                 | RM           | *                 | *                 | *           |
| 63760   | BAG POLYETHYLENE<br>DRUM LINER           | EA                 | RM           | *                 | *                 | *           |
| 65795   | STR 13MM RED                             | EA                 | RM           | *                 | *                 | *           |
| 67195   | SEAL YELLOW 13MM                         | EA                 | RM           | *                 | *                 | *           |
| 1350-01 | HPAG 80U 5ML                             | EA                 | FIN          | *                 | *                 | *           |
| TOTAL   |  |                    |              |                   |                   | *           |

<sup>\*</sup> Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

### **SCHEDULE 3.1**

### FORM OF NOTIFICATION LETTERS

[Questcor Pharmaceuticals, Inc. Letterhead]

| July | _, 2001 |
|------|---------|
|------|---------|

# [Address to FDA Contact Person for this NDA]

Re: NDA # 08-372, H.P. Acthar Gel (corticotropin)

## Dear [name of FDA contact person]:

Reference is made to NDA 08-372 for H.P. Acthar Gel (corticotropin). In accordance with 21 C.F.R. § 314.72, the purpose of this letter is to inform the Food and Drug Administration that ownership of, and all rights and responsibilities for, the referenced NDA have been transferred to Questcor Pharmaceuticals, Inc. (Questcor) from Aventis Pharmaceuticals, Inc. (Aventis), effective July \_\_\_\_\_, 2001.

Questcor is committed to complying with all agreements, promises and conditions made by Aventis, as the former owner, and contained in the NDA. Aventis has provided Questcor with a complete copy of the NDA.

If you have any questions, please contact me at [phone].

Sincerely,

[Name]

Director of Scientific and Regulatory Affairs

### SCHEDULE 3.1 (CONT.)

[Aventis Pharmaceuticals, Inc. Letterhead]

| July | , | 2001 |
|------|---|------|
|      |   |      |

# [Address to FDA Contact Person for this NDA]

Re: NDA # 08-372, H.P. Acthar Gel (corticotropin)

# Dear [name of FDA contact person]:

Reference is made to NDA 08-372 for H.P. Acthar Gel (corticotropin). In accordance with 21 C.F.R. § 314.72, the purpose of this letter is to inform the Food and Drug Administration that Aventis Pharmaceuticals, Inc. has transferred all rights to the referenced NDA to Questcor Pharmaceuticals, Inc. effective July \_\_\_\_\_, 2001.

Please contact me at (816) 966-7104 if you have any questions.

Sincerely,

Dhiren N. Shah, Ph.D. Director, CMC-US Drug Regulatory Affairs

### cc: [Name]

Director of Regulatory Affairs, Questcor Pharmaceuticals, Inc.

### SCHEDULE 6.2

### MANUFACTURING AND TESTING TRANSFER TIMETABLE AND PROJECT TEAM

July 20, 2001

Steve Gould Senior Director, Business Development Aventis Behring 1020 1st Ave

### **KING OF PRUSSIA, PA 19406-0901**

Dear Steve,

You had asked last week for a statement of intent from us regarding the site transfer plan for Acthar Gel. The sequence of events, as contemplated at this time, are as follows:

- 1. Immediately following the signing of the definitive agreement, QSC will request a meeting with the FDA to discuss the proposed site transfer plan for Acthar Gel.
- 2. Unless modified following the FDA meeting, QSC will first negotiate and sign the contract manufacturer agreement with the vial filler, the raw material manufacturer, and the assay testing laboratory.
- 3. Following the signing of the contract manufacturing agreements, it is our intention to proceed initially with the assay transfer to the new contract testing lab.
- 4. Concurrently with the assay transfer, we intend to begin the process development work at the new vial filler.
- 5. The raw material extraction vendor will come to Kankakee and observe the set-up of the current process, become familiar with all aspects of the extraction procedures, and then Kankakee will be able to dismantle the dedicated equipment and ready it for shipment.

Steve, this site transfer process may be modified at a future point depending on agreements between QSC and the FDA, or upon further discussion with Aventis personnel. However, this represents our best description of the site transfer process at this time.

Let me know if you need anything further.

Sincerely,

/s/ Kenneth R. Greathouse

Kenneth R. Greathouse Vice President, Sales and Marketing

cc:

KG/cs

THIS FIRST AMENDMENT TO ASSET PURCHASE AGREEMENT (this "Agreement"), is dated and effective as of January 29, 2002, by and among AVENTIS PHARMACEUTICALS INC., a Delaware corporation f/k/a AVENTIS PHARMACEUTICALS PRODUCTS INC. ("Seller"), and QUESTCOR PHARMACEUTICALS, INC., a California corporation ("Purchaser").

#### WITNESSETH

WHEREAS, Purchaser and Seller entered into an Asset Purchase Agreement, dated as of July 27, 2001 (the "Asset Purchase Agreement").

**WHEREAS**, Purchaser and Seller wish the amend certain provisions thereof to correct the Asset Purchase Agreement to reflect the understanding of the parties, and correct certain scrivener's errors;

NOW, THEREFORE, in mutual covenants, the parties hereto agree as follows:

Section 1. Section 4.1(f) is hereby is hereby amended and restated in its entirety as follow:

"Finished Product Inventory Warranty. The Finished Product Inventory delivered hereunder shall conform to the specifications therefor, and shall have been formulated, filled, tested, labeled and packaged in accordance with manufacturing procedures in effect as of the Effective Date, copies of which have been provided to Questcor.

Section 2. The parties hereto acknowledge that Seller reserved the rights necessary and Purchaser agrees that it has licensed and granted Seller such rights, to sell the Product to Athena Rx Pharmacy for the Limited Access Programs, as well as to other customers, in both cases for orders that need to be filled on or prior to the date that Purchaser has received relabeled Product, and for the period of any termination phase of the Agreement with Athena Rx Pharmacy. The parties acknowledge that Seller has billed and shipped such Products under the terms and conditions that were specified in the agreement between Seller and Athena Rx Pharmacy, and to other customers in accordance with past practice. Sales of such quantities of Product have been booked by Seller and Purchaser shall not have any claim to the revenues or profits from this commercial activity. The parties also acknowledge that any future claim arising from the sales of Product by Seller made under this Section 2 shall be borne fully by Seller, consistent with the provisions of the Asset Purchase Agreement that relate to sales of the Product prior to the execution date thereof.

Section 3. Seller and Purchaser acknowledge that notwithstanding anything in Sections 2.1(e), 2.3(b) and 2.5(b) the Asset Purchase Agreement to the contrary, Purchaser has the option, but not the obligation, to purchase any Remaining Inventory remaining at the termination of the Supply and License Agreement described in Section 1 hereof. Seller and Purchaser further acknowledge that the terms of the sale of such.

Remaining Inventory elected to be purchased by Purchaser shall be governed by Sections 2.3(b) and 2.5(b) of the Asset Purchase Agreement. Purchaser shall notify Seller in writing of its election to purchase some or all of the Remaining Inventory at least 30 days prior to the first anniversary of the Effective Date of the Asset Purchase Agreement. Purchaser acknowledges that Seller has no responsibility to retain or maintain such Remaining Inventory after the first anniversary of the Effective Date.

In all other respects, the Asset Purchase Agreement remains unamended.

*IN WITNESS WHEREOF*, the parties have caused this First Amendment to be executed by their duly authorized representatives effective as of the date first above written.

### AVENTIS PHARMACEUTICALS PRODUCTS INC.

By: /s/ John R. Leone

Name: John R. Leone
Title: Senior Vice President and
COO, U.S. Commercial Operations

QUESTCOR PHARMACEUTICALS, INC.

By: /s/ Kenneth R. Greathouse

Name: Kenneth R. Greathouse
Title: Vice President, Commercial Operations

Certain information in this exhibit has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to
omitted portions.

### PROMOTION AGREEMENT

This PROMOTION AGREEMENT is made as of December 1, 2001, by and between QUESTCOR PHARMACEUTICALS. INC. a California corporation ("Questcor") and VSL PHARMACEUTICALS, INC., a Delaware corporation ("VSL").

### RECITALS

- A. WHEREAS, VSL produces, markets and distributes a probiotic preparation of live freeze-dried lactic acid bacteria, developed specifically to provide the optimal concentration and types of healthy bacteria for the gastrointestinal tract and to be used in various gastrointestinal disorders under the trademark "VSL#3  $\hat{O}$ "; and
  - B. WHEREAS, Questcor is engaged in the business, among other things, of marketing pharmaceutical products; and
- C. WHEREAS, VSL wishes to expand the promotion of VSL#3Ô, and Questcor desires to have the right to promote and sell VSL#3Ô, upon the terms specified herein.

### **AGREEMENT**

NOW, THEREFORE, in consideration of the mutual covenants herein set forth, and intending to be legally bound hereby, the parties hereto agree as follows:

### 1. Definitions.

For purposes of this Agreement, the following terms shall have the corresponding meanings set forth below.

"Affiliate" means, with respect to any Person, any other Person which directly or indirectly controls, is controlled by, or is under common control with, such Person. A Person shall be regarded as in control of another Person if it/he/she owns, or directly or indirectly controls, more than fifty percent (50%) of the voting securities (or comparable equity interests) or other ownership interests of the other Person, or if it/he/she directly or indirectly possesses the power to direct or cause the direction of the management of the other Person, whether through the ownership of voting securities, by contract or any other means whatsoever.

"<u>Agreement</u>" means this agreement, together with all appendices, exhibits and schedules hereto, and as the same may be amended or supplemented from time to time hereafter by a written agreement duly executed by authorized representatives of each party hereto.

"<u>Agreement Quarter</u>" means each three-month period commencing on the first day of January, April, July or October, as the ease may be during the Term. The first Agreement Quarter shall commence on the Effective Date and end on March 31,2002.

- "Agreement Year" means each 12-months period commencing on January 1, 2002 and each anniversary thereof during the Term.
- "Confidential or Proprietary Information" has the meaning set forth in Section 10 hereof.
- "Direct Customer Support" has the meaning set forth in Section 2(g) hereof.
- "Effective Date" of this Agreement means January 1, 2002.
- "Initial Product Purchase" has the meaning set forth in Section 2(e) hereof.
- "Laws" has the meaning set forth in Section 3(f) hereof.
- "<u>Net Sales</u>" means for the applicable period the gross amount invoiced for the Product sold in the Territory to Third Parties, less the following amounts to the extent deducted on such invoice or absorbed by Questcor or any other invoicing party:
- (i) trade, quantity and cash discounts or rebates actually and lawfully allowed and taken and any other adjustments on account of price adjustments, billing errors, rejected good, and damaged goods;
- (ii) price reductions, credits, rebates, product returns, charge-back and prime vendor rebates, fees, reimbursements or similar payments or adjustments actually granted or given to wholesalers and other distributors, buying groups, health care insurance carriers, pharmacy benefit management companies, health maintenance organizations or other institutions or health care organizations;
- (iii) any sales or use tax, customs duties, excise or other duties or other governmental charge (other than an income tax) levied and actually paid on the sale, transportation or delivery of the Product in the Territory;
- (iv) price reductions, credits, rebates, charge-back and prime vendor rebates, fees, reimbursements or similar payments or adjustments actually granted or given in connection with sales of the Product in the Territory to any governmental or regulatory authority in respect to any state or federal Medicare, Medicaid or similar programs; and
- (v) costs of transportation and insurance, as well as amounts to be paid to credit card processing companies and/or entrusted banks in connection with the sales in question.

Notwithstanding the foregoing. it is understood that Net Sales shall not include bad debt expense.

"*Person*" shall mean, an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority, or any other form of entity nor specifically listed herein.

- "Prepaid Reimbursement" has the meaning specified in Section 4(d) hereof.
- "Product" means the VSL#3Ô product.
- "Quarterly Net Sales Commission" has the meaning specified in Section 4(b) hereof.
- "Quarterly Net Sales Payment" has the meaning specified in Section 4(a) hereof.
- "Quarterly Reimbursement" has the meaning specified in Section 4(c) hereof.
- "Sales/Marketing Committee" has the meaning specified in Section 2(h) hereof.
- "*Term*" has the meaning specified in Section 6(a) hereof.
- "<u>Territory</u>" means the fifty states of the United States of America and all its territories and possessions, including without limitation, the Commonwealth of Puerto Rico.
  - "Third Party" means any Person other than (i) VSL and any of its Affiliates and (ii) Questcor and any of its Affiliates.

### 2. Obligations of VSL and Questcor

- (a) VSL herby engages Questcor to promote and sell the Product in the Territory during the Term on an exclusive basis (except that VSL and Sigma Tau Pharmaceuticals, Inc. retain the right to promote and sell the Product in the Territory), upon the terms and conditions set forth in this Agreement; provided, however, VSL may request a meeting with Questcor from time to time throughout the Term to discuss whether additional opportunities exist for the promotion of the Product that would not adversely affect Questcor's Net Sales of the Product, which may include a good faith discussion of whether additional parties should be permitted to promote the Product in the Territory. Questcor agrees to employ reasonable good faith efforts in connection with the activities contemplated within this Agreement.
- (b) As between VSL and Questcor, VSL shall have the sole responsibility, at its cost and expense, for manufacturing or acquiring the Product, as the case may be, in final dosage form and package, for all future Product development, for obtaining and maintaining proper insurance and regulatory approvals and compliance related to the Product, for conducting all future clinical trials of the Product, and for obtaining and maintaining all necessary authorizations with the United States Food and Drug Administration ("FDA"), if any, to market the Product in the Territory.
- (c) Subject to the reimbursement provision contained in Section 4(c) of this Agreement and the other terms and conditions of this Agreement, with respect to Product sold by Questcor in the Territory, Questcor shall have the sole responsibility, at its cost and expense for the shipping, distribution, and warehousing of the Product, for the preparation and distribution of promotional material for the product for the invoicing and billing of purchases of the Product for paying credit card fees for order confirmation (if any) in accordance with Questcor customary practices for the collection of receivables resulting from Net Sales, for booking all

sales of the Product sold by Questcor and its Affiliates and for handling all returns of the Product.

- (d) Subject to the terms and conditions of this Agreement, Questcor shall be responsible for the costs and expenses of establishing and maintaining its sales force, controlling its sales force directing the activities of its sales force and for carrying out through its sales force the detailed marketing and promotional plan for the Product in the Territory, as agreed to by the Sales/Marketing Committee.
- (e) Prior to or about the Effective Date, Questcor shall order and VSL shall deliver up to \* boxes of the Product at a purchase price of \* point of manufacture in the Territory (the "Initial Product Purchase"). Questcor shall submit payment to VSL for the Initial Product Purchase within one hundred twenty (120) days of receipt of the Initial Product Purchase; provided, however, Questcor shall not be obligated to submit payment to VSL for the Initial Product Purchase until all of the Product in the Initial Product Purchase has been sold by Questcor. Upon request by Questcor, VSL shall deliver to Questcor any subsequent orders (the frequency and quantity of such orders to be determined by Questcor after taking into account the marketing strategies and promotional plans as discussed by the Sales/Marketing Committee) of the Product at a purchase price of \* point of manufacture in the Territory. Questcor shall submit payment to VSL for any subsequent orders of the Product within sixty (60) days of receipt of such order.
  - (f) VSL shall establish and maintain a commercially reasonable and competitive price for the Product in the Territory.
- (g) Subject to the reimbursement provisions contained in Section 4(c) of this Agreement and the other terms and conditions of this Agreement, with respect to Product sold by Questcor in the Teritory, Questcor shall provide the Direct Customer Support. "Direct Customer Support" means that Questcor shall respond to all calls, communications, complaints and inquiries relating to Product sold by Questcor in the Territory, including, but not limited to pre- and post-sale inquiries concerning the efficacy, side effects, and benefits of the Product. In fulfilling the foregoing duties, Questcor shall conform to the guidelines agreed upon by VSL and Questcor as expressed by the Sales/Marketing Committee. Questcor shall inform the Sales/Marketing Committee quarterly of how it resolved all inquiries relating to the Product.
- (h) Questcor and VSL shall establish a marketing committee after execution of this Agreement (such committee being referred to herein as the "Sales/Marketing committee"). The Sales/Marketing Committee shall meet not less than once in each Agreement Quarter during the Term or as otherwise agreed by the parties in writing, at such locations as are designated by each party alternatively. Each party shall name two members to the Sales/Marketing Committee and shall bear the costs and expenses of its designated members that are incurred in connection with the Sales/Marketing Committee meetings. The activities of the Sales/Marketing Committee related to the development and coordination of the marketing strategy and promotional plans for Product sold by Questcor in the Territory shall include, inter alia:
- \* Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

- (i) developing and revising existing and new promotional materials for the Product for in-person promotion to the event that the same relate specifically to the marketing of the Product in the Territory.
  - (ii) developing promotional programs and materials for the Product:
- (iii) establishing, based on Questcor's proposal, the number and type of detailing to be performed by Questcor sales representative in connection with the promotion of the Product in the Territory;
  - (iv) establishing appropriate sampling scheduling for the Product;
- (v) establishing appropriate guidelines that Questcor must confirm to in responding to calls, communications, complaints and inquires relating to the Product, including but not limited to pre- and post-sales inquiries concerning the efficacy, side effects and benefits of the Product;
  - (vi) updating the customer list; and
  - (vii) establishing a policy for minimizing bad debt expense and pursuing the collection of bad debts.
- (i) Subject to the terms and conditions of this Agreement, VSL herby grants to Questcor the right to use the trademark VSL#3Ô during the Term in connection with the promotion and sale of the Product in the Territory.

### 3. Certain Regulatory Matters

- (a) As between VSL and Questcor, all regulatory matters regarding the Product shall remain under the exclusive control of VSL, subject to the participation by Questcor in matters related to the marketing and sale of the Product by Questcor in the Territory.
- (b) VSL shall furnish Questcor with all efficacy and safety information reasonably requested by Questcor to assist it in promoting and selling the Product in the Territory. Such information shall be treated as confidential information of VSL, and shall not be disclosed to Third Parties without VSL's period written approval, unless required by law.
- (c) Beginning as of the Effective Date of this Agreement, each party shall immediately notify the other party of any significant event(s) that affect the marketing of the Product in the Territory, including, but not limited to, adverse drug reactions and governmental inquiries. VSL shall have the responsibility for evaluating such events and reporting such events to applicable regulatory health authorities, if required.
- (d) Beginning as of the Effective Date of this Agreement, each party shall immediately notify the other party in writing of any order request or directive of a court or other governmental authority to recall or withdraw the Product in any jurisdiction. Each party shall be responsible of the costs associated with a recall or recalls resulting from that area of responsibility associated with such party as described in this Agreement (e.g. if the Product is

recalled as a result of a problem associated with the manufacturing of the Product, then VSL shall be responsible for such costs, however, if the Product is recalled due to a problem with the shipping or handling of the Product by Questcor. then Questcor shall be responsible for such costs).

- (e) Subject to the reimbursement provisions contained in Section 4 (c) of this Agreement, and the other terms and conditions of this Agreement, with respect to Product sold by Questcor in the Territory, Questcor shall be responsible, at its sole cost and expense, for handling all medical inquiries concerning the Product, including without limitation responding to questions concerning permitted and off-label uses of the Product, requests for journal articles, the administration of and response to medical inquiries concerning the Product by consumers, physicians, pharmacists and other health care professionals, including those forwarded by sales representatives and field force personnel promoting the Product in the Territory.
- (f) Each party shall maintain in full force and effect all necessary licenses, permits and other authorizations required by law to carry out its duties and obligations under this Agreement. Each party shall comply with all laws, ordinances, guidelines, rules and regulations (collectively, "Laws") applicable to its activities under this Agreement, including without limitation, any requirements of any product license applicable to the Product, if any; provided however, that Questcor shall be solely responsible for compliance with those Laws pertaining to the activities conducted by it hereunder (including, without limitation, those Laws that apply to documentation and records retention pertaining to the distribution and use of samples of the Product by it under this Agreement), notwithstanding that the FDA may, as a matter of law, be entitled to hold VSL accountable or responsible (whether primarily or secondarily) for failure of Questcor to comply with such Laws. The parties will reasonably cooperate with one another with the goal of ensuring full compliance with Laws. VSL shall be responsible for all labeling changes to the Product.

### 4. Compensation and Reimbursement.

- (a) Subject to the provisions contained in Paragraphs (b), (c) and (d) of this Section 4 and the other terms and conditions of this Agreement, within thirty (30) days after the end of each Agreement Quarter, Questcor shall submit payment to VSL for the Net Sales of the Product sold by Questcor in the Territory for such Agreement Quarter (the "Quarterly Net Sales Payment").
- (b) Questcor shall deduct a quarterly commission (the "Quarterly Net Sales Commission") from the Quarterly Net Sales Payment. The Quarterly Net Sales Commission shall be calculated in accordance with the following schedule:
  - \* of Net Sales in an Agreement Year for Net Sales up to \*.
  - \* of Net Sales in an Agreement Year for Net Sales between \* and \*.
- \* Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

- \* of Net Sales in an Agreement Year for Net Sales between \* and \*
- \* of Net Sales in an Agreement Year for Net Sales between \* and \*
- \* of Net Sales in an Agreement Year for Net Sales between \* and \*
- \* of Net Sales in an Agreement Year for Net Sales between \* and \*
- In the event Net Sales in an Agreement Year exceed \*, VSL and Questcor shall discuss in good faith the commission that VSL shall pay to Questcor. In no event shall such commission be less than \* or higher than \*.
- (c) Questcor shall also deduct a quarterly reimbursement fee (the "Quarterly Reimbursement") from the Quarterly Net Sales Payment. The Quarterly Reimbursement shall be based on Questcor's fully burdened cost of engaging in all of the activities and obligations described in Sections 2(c), 2(g), and 3(e) of this Agreement, including, but not limited to, all documented out-of-pocket costs and expenses and all documented fully burdened costs and expenses of all personnel and facilities used in connection with such activities and obligations. Such Quarterly Reimbursement shall also include Questcor's cost of purchasing the Product (that is to say the actual amount paid by Questcor and already received by VSL for the purchasing of the Product) and shipping the Product, as applicable, as described in Section 2(e).
- (d) VSL and Questcor shall agree on an up-front reimbursement payment, to be paid by VSL to Questcor, to cover the initial fully burdened costs described in Section 4(c) (the "Prepaid Reimbursement"). To this end, Questcor shall submit an estimate of the Prepaid Reimbursement to VSL. Questcor shall supply a statement of the actual costs at the end of the first Agreement Quarter and the estimated Prepaid Reimbursement shall be reconciled against these actual costs.

## 5. Payments and Reporting.

- (a) Questcor shall furnish VSL, within 30 days after the end of each Agreement Quarter (within 60 days at the end of each Agreement Year), a report setting forth in reasonable details the calculation of Net Sales for the Agreement Quarter and the calculation of the Quarterly Net Sales Payment, the Quarterly Net Sales Commission, and the Quarterly Reimbursement with respect to such period (and, in addition to a report for the fourth Agreement Quarter, with respect to the entire Agreement Year).
- (b) All payments to a party under this Agreement shall be made by wire transfer in immediately available funds in legal currency of the United States and shall be delivered to the account of such party as designated by it in writing from time to time.
- \* Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

(c) During the Term and for two (2) years following any expiration or termination of the Term, the parties will maintain complete and accurate books and records in sufficient detail to enable verification of the Net Sales and charged costs. Either party may demand an audit of the other party's relevant books and records in order to verify the other's reports on the aforesaid matter upon reasonable prior notice to the party to be audited. Such access shall be available during normal business hours not more than twice each calendar year during the Term and two years after the relevant period in question. The party requesting the audit shall bear the full cost of the performance of any such audit except as hereinafter set forth. If, as a result of any inspection of the books and records of either party, it is shown that such party's payments or declaration of costs to the other under this Agreement were less than the amount which should have been paid or charged, then the audited party shall make all payments required to be made to eliminate any discrepancy revealed by said inspection within seven (7) days after the other party's demand therefore. Any such late payments or any other late payments under this Agreement shall bear interest at a rate of 1.5% per month, 18% per annum, until paid. Furthermore, if the payments were less than the amount which should have been paid by an amount in excess of five percent (5%) of the payments actually made during the period in question (or the costs charged were more than the costs which should have been charged), the party responsible for the discrepancy shall also reimburse the auditing party for its out-of-pocket costs of such inspection.

### 6. Term and Termination.

- (a) The Term shall be for three (3) years and shall begin on the Effective Date and shall end on the three year anniversary of the Effective Date, unless terminated earlier or unless extended by the parties' mutual agreement in accordance with this section 6 (the "Term").
- (b) The Term may be terminated upon the mutual agreement of the parties, it being understood that neither party shall be under any obligation, express or implied, to do so, except that VSL is entitled to unilaterally terminate the Term according to the provisions of Section 6(g). In order to be binding upon either party, any mutually agreed termination, and the terms governing such termination, must be evidenced by a written agreement executed by duly authorized representatives of both parties.
- (c) (i) In the event that either party shall materially breach any of the terms, conditions and agreements contained in this Agreement, the other party may terminate this Agreement, an all rights granted hereunder by giving the party who committed the breach thirty (30) days notice in writing, particularly specifying the breach, unless the notified party within such thirty (30) day period shall have rectified the breach. Termination under this Section 6(c)(i) shall be without prejudice to any of the terminating party's other legal and equitable rights and remedies.
- (ii) Either party to this Agreement may terminate this Agreement upon receipt of notice that the other party has become insolvent or has suspended business in all material respects hereof, or has consented to an involuntary petition purporting to be pursuant to any reorganization or insolvency law of any jurisdiction, or has made an assignment for the benefit or creditors or has applied for or consented to the appointment of a receiver or trustee for

a substantial part of its property, by giving written notice to the other party, and termination of this Agreement will be effective upon receipt of such notice.

- (d) The Term may be extended upon the mutual agreement of the parties, it being understood that neither party shall be under any obligation, express or implied, to do so. In order to be binding upon either party, any such extension, and the terms governing such extension, must be evidenced by a written agreement executed by duly authorized representatives of both parties.
- (e) Neither the termination nor expiration of the Term shall release or operate to discharge either party from any liability or obligation that may have accrued prior to such termination or expiration.
- (f) If the Term is terminated prior to the completion of an Agreement Quarter. Questcor shall be entitled to receive a pro rata portion of the Quarterly Net Sales Commission and Quarterly Reimbursement which it would have been entitled to receive under Section 4 had the Term been in effect for the entire Agreement Quarter (based on the number of days that Questcor was responsible for marketing the Product in the Territory during such Agreement Quarter).
- (g) Notwithstanding the provisions in the Section 6, VSL is entitled to terminate the Term by providing a written notice to Questcor to that effect after the one year anniversary of the Effective Date and prior to the expiration of the Term. In the event of this unilateral termination by VSL, VSL shall pay to Questcor both (i) a first residual payment, to be paid immediately, equal to the total Quarterly Net Sales Commissions and Quarterly Reimbursements due to Questcor under this Agreement for the twelve (12) months immediately prior to such termination and (ii) a second residual payment, to be paid on the one year anniversary of such termination, equal to one half of the total Quarterly Net Sales Commissions due to Questcor under this Agreement for the twelve (12) months immediately prior to such termination.
- (h) Upon the termination or expiration of the Term, Questcor shall (i) promptly cease all of its promotion activities pursuant to this Agreement, (ii). discontinue any use of the trademark VSL#3<sup>TM</sup> as well as any other tradename, mark, or tradedress relating to the Product, (iii) return to VSL all sales training, promotional, marketing material, call lists, customer lists and computer files, and (iv) return to VSL any remaining inventory of the Product, including samples, in marketable condition (i.e., not already distributed or destroyed with destruction certified by Questcor) that may have been supplied to Questcor by VSL under this Agreement; provided, however, VSL shall reimburse Questcor for Questcor's cost of purchasing any remaining inventory of the Product not previously reimbursed by VSL in accordance with Section 4(c).
- (i) Notwithstanding the expiration or termination of the Term, any provision which extends beyond the Term will survive such expiration or termination of the Term.
- (j) During the Term and for two (2) years following the termination of the Term by VSL pursuant to Section 6(f) or for one (1) year following the expiration or termination

of the Term for any other reason, Questcor shall not, directly or by or through any Affiliate or Third Party, market, sell or promote in the Territory any product which competes with the Product.

### 7. Representations, Warranties and Covenants.

- (a) VSL represents and warrants to Questcor that as of the Effective Date, (i) the execution, delivery and performance of this Agreement by VSL does not conflict with, or constitute a breach of or under, any order, judgment, agreement or instrument to which VSL is a party; (ii) the execution, delivery and performance of this Agreement by VSL does not require the consent of any person or the authorization of (by notice or otherwise) any governmental or regulatory authority; (iii) the rights granted by VSL to Questcor hereunder do not conflict with any rights granted by VSL to any Third Party; and (iv) VSL owns the development rights for the Product.
- (b) VSL represents, warrants and agrees that as of the Effective Date, VSL has not received any valid notice of any claim of infringement or any other claim or proceeding relating to any patent, trademark, trade name, service mark, copyright or trade secret relating to the Product. VSL also represents and warrants that, as of the Effective Date, to the best of its knowledge the manner in which VSL conducts its business does not constitute an infringement of any patent or other intellectual property right, or a misappropriation of any trade secret. During the Term VSL will advise Questcor within fifteen (15) days of receiving any valid notice of any claim of infringement of any other claim or proceeding relating to any patent, trademark, trade name, service mark, copyright or trade secret relating to the Product that would have an adverse affect upon its ability to perform its obligations under this Agreement.
- (c) Questcor represents and warrants to VSL that as of the Effective Date, (i) the execution, delivery and performance of this Agreement by Questcor does not conflict with, or constitute a breach of or under, any order, judgment, agreement or instrument to which Questcor is a party; (ii) the execution, delivery and performance of this Agreement by Questcor does not require the consent of any person or the authorization of (by notice or otherwise) any governmental or regulatory authority, and (iii) Questcor is not now selling nor promoting nor will it sell or promote during the Term of this Agreement any product which directly competes with the Product.
- (d) A party that has knowledge that the Product fails to comply with any applicable safety rules or standards of any government agency or which contains a defect that could present a substantial risk to the public health or the environment shall notify the other party to telephone, followed by written confirmation, within five (5) business days, of obtaining such knowledge.

### 8. <u>Indemnification</u>.

(a) VSL shall defend, indemnify and hold Questcor and its employees, agents, officers, directors and Affiliates (each an "*Questcor Party*") harmless from an against any and all losses, liabilities, obligations, claims, fees (including, without limitation, attorneys fees). expenses incurred by a Questcor Party that are claimed by any Third Party and that result from or

arise in connection with (i) the breach of any covenant representation or warranty of VSL contained in this Agreement. (ii) any claim of infringement of any patent trademark or other intellectual property right related to the Product, (iii) any product liability claim related to the Product, (iv) any contamination of or defect in the Product, and (v) breach by VSL of its obligations under Section 10 hereof. Notwithstanding anything in this Section 8(a), VSL shall not be obligated to indemnify a Questcor Party for any liability related to the Product for which Questcor has assumed an indemnification obligation under Section 8(b) helow.

(b) Questcor shall defend, indemnify and hold VSL and its employees, agents, officers, directors and Affiliates (each a "VSL Party") harmless from and against any and all losses, liabilities, obligations, claims, fees (including, without limitation, attorneys' fees), expenses and lawsuits brought against or incurred by a VSL Party or by a Third Party resulting from or arising in connection with (i) the breach by Questcor of any covenant, representation or warranty of Questcor contained in this Agreement, (ii) any contamination or adulteration of the Product while such Product is under the control of Questcor, (iii) the promotion or distribution of the Product performed by Questcor as provided in this Agreement, and (iv) breach by Questcor of its obligations under Section 10 hereof.

### 9. <u>Limitations of Liability</u>

(a) NEITHER PARTY SHALL BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, INDIRECT OR PUNITIVE DAMAGES (INCLUDING LOST REVENUES OR PROFITS) OF ANY KIND DUE TO ANY CAUSE, REGARDLESS OF WHETHER SUCH PARTY HAS BEEN ADVISED OR IS AWARE OF THE POSSIBILITY OF SUCH DAMAGES.

## 10. Confidentiality

- (a) Each party acknowledges that it may receive confidential or proprietary information of the other party in the performance of this Agreement. Each party shall hold confidential and shall not, directly or indirectly, disclose, publish or use for the benefit of any Third Party or itself, except in carrying out its duties hereunder, any confidential or proprietary information of the other party, without first having obtained the furnishing party's written consent to the such disclosure or use. "Confidential or proprietary information" shall include, inter alia, know-how, scientific information, clinical data, efficacy and safety data, protocols, adverse event information, formulas, methods and processes, specifications, pricing information (including discounts, rebates and other price adjustments) and other terms and conditions of sales, customer informations, business plans, patent applications and all other intellectual property. This restriction shall not apply to any information within the following categories:
- (i) information that is known to the receiving party or its Affiliates prior to the time of disclosure to it, to the extent evidenced by written records or other competent proof;
- (ii) information that is independently developed by employees, agents, or independent contractors of the receiving party or its Affiliates without reference to or reliance

upon the information furnished by the disclosing party as evidenced by written records or other competent proof.

- (iii) information disclosed to the receiving party or its Affiliates by a Third Party that has a right to make such disclosure:
- (iv) information that is contained in any written promotional material prepared by Questcor or VSL for use in connection with the promotion of the Product and actually distributed to the public; or
  - (v) any other information that becomes part of the public domain through no fault or negligence of the receiving party.

The receiving party shall also be entitled to disclose the other party's Confidential Information that is required to be disclosed in compliance with applicable laws or regulations (including without limitation, to comply with SEC, Nasdaq or stock exchange disclosure requirements), or by order of any governmental body or a court of competent jurisdiction; <u>provided</u> that the party required to disclose such information shall use all reasonable efforts to obtain confidential treatment of such information by the agency or court.

- (b) This obligation shall survive the termination or expiration of this Agreement for five (5) years.
- (c) It is expressly understood and agreed that Questcor may disclose confidential information to members of its board of directors who are not employees of Questcor (and to consultants who have received VSL's prior written approval), <u>provided</u> that Questcor shall ensure that such directors and consultants are bound by a written obligation of confidentiality to Questcor as regards confidential information hereunder that is disclosed to them that is reasonably satisfactory to VSL.
- 11. <u>Notices</u>. Unless otherwise explicitly set forth herein, any notice required or permitted to be given hereunder shall be in writing and shall be delivered personally by hand, or sent by reputable overnight courier, signature required, to the addresses of each party set forth below or to such other address or addresses as shall be designated in writing in the same matter:
  - (a) If to VSL:

VSL Pharmaceuticals. Inc. 500 E, Broward Blvd., Suite 1800 Ft. Lauderdale, FL 33394 Attention: CEO

(b) If to Questcor:

Questcor Pharmaceuticals. Inc. 3260 Whipple Road Union City, CA 94587 Attention: President & CEO All notices shall be deemed given when received by the addressee.

#### 12. Miscellaneous Provisions.

- (a) <u>Assignment</u>. Questcor is not entitled to assign or otherwise transfer this Agreement, or any of its rights or obligations under this Agreement, without the prior written consent of VSL, except that such prior written consent shall not be unreasonably withheld in case of assignment by Questcor to an Affiliate. Upon written notice to Questcor, VSL shall be entitled to transfer or assign, without the consent of Questcor, this Agreement to any Affiliate or Third Party.
- (b) <u>Non-Waiver</u>. Any failure on the part of a party to enforce at any time or for any period of time any of the provisions of this Agreement shall not be deemed or construed to be a waiver of such provisions or of any right of such party thereafter to enforce each and every such provision on any succeeding occasion or breach thereof.
- (c) Entirety of Agreement. This Agreement contains the entire understanding of the parties with respect to the subject matter hereof and thereof and supersedes all previous and contemporaneous verbal and written agreements, representations and warrantees with respect to such subject matter. This Agreement (or any provision or term hereof) may be released, waived, changed or supplemented only by a written agreement signed by an officer or other authorized representative of the party against whom enforcement of any release, waiver, change or supplement is sought. This Agreement shall not be strictly construed against either party hereto.
- (d) <u>Public Announcements</u>. The form and content of any public announcement to be made by one party regarding this Agreement, or the subject matter contained herein, shall be subject to the prior written consent of the other party (which consent may not be unreasonably withheld), except as may be required by applicable law (including, without limitation, disclosure requirements of the SEC, the American Stock Exchange, Nasdaq, or any other stock exchange) in which event the other party shall endeavor to give the other party reasonable advance notice and review of any such disclosure.
- (e) <u>Governing Law</u>. This Agreement shall be governed by and construed under the laws of the State of New York without reference to its conflicts of law principles. The parties expressly consent to personal jurisdiction in the State of New York for any litigation arising out of or related to this Agreement.
- (f) Relationship of the Parties. In making and performing this Agreement, the parties are acting, and intend to be treated, as independent entities and nothing contained in this Agreement shall be construed or implied to create an agency, partnership, joint venture, or employer and employee relationship between VSL and Questcor. Except as otherwise provided herein. neither party may make any representation. warranty or commitment. whether express or implied. on behalf of or incur any charges or expenses for or in the name of the other party. No party shall be liable for the act of any other party unless such act is expressly authorized in writing by both parties hereto.

- (g) <u>Counterparts</u>. This Agreement shall become binding when any one or more counterparts hereof. individually or taken together. shall bear the signatures of each of the parties hereto. This Agreement may be executed in any number of counterparts. each of which shall be deemed an original as against the party whose signature appears thereon. but all of which taken together shall constitute but one and the same instrument.
- (h) <u>Force Majeure</u>. Neither party shall be liable to the other party for any failure to perform as required by this Agreement if the failure to perform is due to circumstances reasonably beyond such party's control, including, without limitation, acts of God, civil disorders or commotions, acts of aggression, fire, explosions, floods, drought, war, sabotage, embargo, unexpected safety or efficacy results obtained with a Product, utility failures, supplier failures. material. labor, or energy shortages, labor disturbances, a national health emergency, or appropriations of property. A party whose performance is affected by a force majeure event shall take prompt action using its reasonable best efforts to remedy the effects of the force majeure event.
- (i) No Implied Rights. Nothing in this Agreement is intended to create or imply any right or license in the other Party under any patent rights, copyrights, trademarks or other intellectual property rights owned or controlled by a Party, except as expressly set forth herein.

[Signature Page Follows]

IN WITNESS WHEREOF. the parties hereto have duly executed this Agreement in multiple counterparts through their duly authorized representatives as of the date first above written.

QUESTCOR PHARMACEUTICALS, INC.

VSL PHARMACEUTICALS, INC.

By: /s/ CHARLES J. CASAMENTO

By: /s/ CLAUDIO DE SIMONE

Name: Charles J. Casamento Title: Chairman, President & CEO Name: Claudio De Simone

Title: CEO

\* Certain information in this exhibit has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to omitted portions.

#### FIRST AMENDMENT TO PROMOTION AGREEMENT

This FIRST AMENDMENT TO PROMOTION AGREEMENT (the "Amendment") is made as of June 27, 2002, by and between **QUESTCOR PHARMACEUTICALS, INC.,** a California Corporation ("Questcor"), and **VSL PHARMACEUTICALS, INC.,** a Delaware corporation ("VSL").

#### RECITALS

- A. WHEREAS, Questcor and VSL have entered into that certain Promotion Agreement dated as of December 1, 2001(the "Agreement"); and
- B. WHEREAS, the parties desire to modify the Agreement in certain respects and to clarify certain of their obligations thereunder and have agreed to enter into the following Amendment to the Agreement.

### **AGREEMENT**

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth herein and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

- A. <u>Definitions</u>. Capitalized terms used in this Amendment but not otherwise defined shall have the meanings specified in the Agreement, unless the context requires otherwise.
- **B.** <u>Certain Amendments</u>. The Agreement is hereby amended, supplemented or modified, as the case may be, as indicated below:
  - (a) The definition of "<u>Incremental Expense Forecast</u>" is hereby added to Section 1 and shall read, "has the meaning set forth in Section 5(a) hereof."
  - (b) The definition of "*Incremental Expenses*" is hereby added to Section 1 and shall read, "has the meaning set forth in Section 4(c) hereof."
  - (c) The definition of "*Prepaid Reimbursement*" is hereby deleted in its entirety.
  - (d) Section 4(c) is amended in its entirety and shall read, "(i) In addition to the Quarterly Net Sales Commission, Questcor shall also deduct a quarterly reimbursement fee (the "Quarterly Reimbursement") from the Quarterly Net Sales Payment. The Quarterly Reimbursement shall be calculated in accordance with the following schedule:
    - \* of Net Sales for Net Sales up to \*
- \* Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

- \* of Net Sales for Net Sales between \* and \*; and
- \* of Net Sales for Net Sales over \*.
- (ii) Notwithstanding the foregoing, in no event shall the Quarterly Reimbursement be less than Questcor's documented incremental cost of engaging in all of the activities and obligations described in Sections2(c), 2(g), and 3(e) of this Agreement, including, but not limited to, all documented incremental costs and expenses of all personnel and facilities used in connection with such activities and obligations (the "*Incremental Expenses*"), provided, however, that the Incremental Expenses shall be agreed upon in advance in accordance with Section 5(a) (iii) of this Agreement. The Incremental Expenses shall also include Questcor's cost of purchasing the product (that is to say the actual amount paid by Questcor and already received by VSL for the purchasing of the Product) and shipping the Product, as applicable, as described in Section 2(e). In the event that the Quarterly Reimbursement is less than the Incremental Expenses for any Agreement Quarter, then VSL shall submit payment to Questcor in an amount equal to the difference between the Quarterly Reimbursement and the Incremental Expenses (such Incremental Expenses to be agreed upon in advance in accordance with Section 5(a)(iii) of this Agreement) on a monthly basis through September 30, 2002, and after such date, within 30 days of the end of each Agreement Quarter."
- (e) Section 4(d) is amended in its entirety and shall read, "VSL shall pay Questcor a one-time up-front reimbursement payment in the amount of \* not later than July 31, 2002."
- (f) Section 5(a) is amended in its entirety and shall read, "Questcor shall furnish VSL, within 30 days after the end of each Agreement Quarter (within 60 days after the end of each Agreement Year), a report setting forth in reasonable detail the following (in each case with respect to each Agreement Quarter and, in addition to a report for the fourth Agreement Quarter, with respect to the entire Agreement Year): (i) the calculation of Net Sales for the Agreement Quarter, (ii) the calculation of the Quarterly Net Sales Payment, the Quarterly Net Sales Commission and the Quarterly Reimbursement, and (iii) a description of Questcor's yearly forecast of the Incremental Expenses updated quarterly (the "Incremental Expense Forecast") to be mutually agreed upon in good faith by Questcor and VSL. With respect to clause (iii) of the preceding sentence, Questcor and VSL shall meet not later than July 31, 2002 to establish a specific process for reaching mutual agreement on the Incremental Expenses and for resolving any disputes regarding Incremental Expenses. Questcor and VSL acknowledge that for the period of March 1, 2002 through June 30, 2002, the Incremental Expenses for such period are at least \* with additional
- \* Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

disputed Incremental Expenses for such period in the amount of \* to be mutually agreed upon in good faith by Questcor and VSL"

- **C.** <u>No Further Modification</u>. Except as expressly provided in this Amendment, the Agreement remains unmodified and in full force and effect in accordance with its terms.
- **D.** <u>Counterparts; Governing Law.</u> This Amendment may be executed in one or more counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same instrument; and this Amendment shall be governed by the laws of the State of New York.
- \* Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

IN WITNESS WHEREOF, Questcor and VSL have executed this Amendment as of the day and year first above written.

| QUESTCOR PHARMACEUTICALS, INC., a California corporation |                                       | VSL PHARMACEUTICALS, INC., a Delaware corporation |                |
|--|---------------------------------------|---|----------------|
| By:  | /s/ KENNETH R. GREATHOUSE             | By:   | /s/ MAURO BOVE |
| Name:  | Kenneth R. Greathouse                 | Name:   | Mauro Bove     |
| Title:   | Vice President, Commercial Operations | Title:  |                |