

NEOSE TECHNOLOGIES INC
Form 10-Q
November 04, 2004

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2004.

OR

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: 0-27718

NEOSE TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

Delaware

13-3549286

(State or other jurisdiction of incorporation or organization)

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

102 Witmer Road Horsham, Pennsylvania

19044

(Address of principal executive offices)

(Zip Code)

(215) 315-9000

(Registrant's telephone number, including area code)

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 period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

YesNo

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

YesNo

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 24,717,171 shares of common stock, \$.01 par value, were outstanding as of October 25, 2004.

NEOSE TECHNOLOGIES, INC.
(a development-stage company)

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PART I. FINANCIAL INFORMATION**Item 1. Financial Statements**

Neose Technologies, Inc.
(a development-stage company)

Balance Sheets
(unaudited)
(in thousands, except per share amounts)

| | <u>December 31, 2003</u> | <u>September 30, 2004</u> |
|---|------------------------------|-------------------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 48,101 | \$ 55,016 |
| Marketable securities | 4,959 | |
| Restricted funds | 901 | |
| Prepaid expenses and other current assets | 917 | 1,878 |
| | <u>54,878</u> | <u>56,894</u> |
| Total current assets | 54,878 | 56,894 |
| Property and equipment, net | 37,192 | 42,158 |
| Intangible and other assets, net | 2,775 | 2,028 |
| | <u>94,845</u> | <u>101,080</u> |
| Total assets | \$ 94,845 | \$ 101,080 |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Current portion of long-term debt and capital lease obligations | \$ 2,231 | \$ 3,958 |
| Accounts payable | 2,342 | 1,791 |
| Accrued compensation | 2,510 | 1,940 |
| Accrued expenses | 2,433 | 2,533 |
| Deferred revenue | 4,333 | 4,720 |
| | <u>13,849</u> | <u>14,942</u> |
| Total current liabilities | 13,849 | 14,942 |
| Long-term debt and capital lease obligations | 8,370 | 13,767 |
| Other liabilities | 413 | 542 |
| | <u>22,632</u> | <u>29,251</u> |
| Total liabilities | 22,632 | 29,251 |
| Stockholders' equity: | | |
| Preferred stock, par value \$.01 per share, 5,000 shares authorized, none issued | | |
| Common stock, par value \$.01 per share, 30,000 and 50,000 shares authorized; 19,935 and 24,717 shares issued and outstanding | 199 | 247 |
| Additional paid-in capital | 217,849 | 248,027 |
| Deferred compensation | (96) | (53) |
| Deficit accumulated during the development stage | (145,739) | (176,392) |
| | <u>72,213</u> | <u>71,829</u> |
| Total stockholders' equity | 72,213 | 71,829 |
| | <u>\$ 94,845</u> | <u>\$ 101,080</u> |
| Total liabilities and stockholders' equity | \$ 94,845 | \$ 101,080 |

The accompanying notes are an integral part of these financial statements.

Neose Technologies, Inc.
(a development-stage company)

Statements of Operations
(unaudited)
(in thousands, except per share amounts)

| | Three months ended September 30, | | Nine months ended September 30, | | Period from inception (January 17, 1989) to September 30, 2004 |
|--|-------------------------------------|-------------|------------------------------------|-------------|--|
| | 2003 | 2004 | 2003 | 2004 | |
| Revenue from collaborative agreements | \$ 150 | \$ 1,451 | \$ 871 | \$ 3,592 | \$ 22,473 |
| Operating expenses: | | | | | |
| Research and development | 6,747 | 9,305 | 19,031 | 24,971 | 151,470 |
| Marketing, general and administrative | 2,456 | 2,861 | 8,657 | 9,047 | 69,267 |
| Total operating expenses | 9,203 | 12,166 | 27,688 | 34,018 | 220,737 |
| Operating loss | (9,053) | (10,715) | (26,817) | (30,426) | (198,264) |
| Other income | | | | | 7,773 |
| Impairment of equity securities | (1,250) | | (1,250) | | (1,250) |
| Interest income | 103 | 195 | 420 | 431 | 19,773 |
| Interest expense | (138) | (304) | (338) | (658) | (4,424) |
| Net loss | \$ (10,338) | \$ (10,824) | \$ (27,985) | \$ (30,653) | \$ (176,392) |
| Basic and diluted net loss per share | \$ (0.59) | \$ (0.44) | \$ (1.66) | \$ (1.38) | |
| Weighted-average shares outstanding used in computing basic and diluted net loss per share | 17,437 | 24,712 | 16,828 | 22,284 | |

The accompanying notes are an integral part of these financial statements.

Neose Technologies, Inc.
(a development-stage company)

Statements of Cash Flows
(unaudited)
(in thousands)

| | Nine months ended September 30, | | Period from inception (January 17, 1989) to September 30, 2004 |
|---|------------------------------------|-----------------|--|
| | 2003 | 2004 | |
| Cash flows from operating activities: | | | |
| Net loss | \$ (27,985) | \$ (30,653) | \$ (176,392) |
| Adjustments to reconcile net loss to cash used in operating activities: | | | |
| Depreciation and amortization | 3,511 | 4,433 | 22,360 |
| Non-cash compensation | 129 | 93 | 5,010 |
| Loss on disposition of property and equipment | 99 | 5 | 269 |
| Common stock issued for non-cash and other charges | | | 35 |
| Changes in operating assets and liabilities: | | | |
| Prepaid expenses and other current and non-current assets | (370) | (1,008) | (2,239) |
| Accounts payable | (109) | (551) | 1,791 |
| Accrued compensation | 222 | (570) | 1,521 |
| Accrued expenses | (250) | 575 | 2,153 |
| Deferred revenue | (250) | 387 | 4,720 |
| Other liabilities | (220) | 129 | 123 |
| Net cash used in operating activities | (25,223) | (27,160) | (140,649) |
| Cash flows from investing activities: | | | |
| Purchases of property and equipment | (2,137) | (8,942) | (59,505) |
| Proceeds from sale-leaseback of equipment | | | 1,382 |
| Purchases of marketable securities | (38,568) | | (423,307) |
| Proceeds from sales of marketable securities | 8,327 | | 29,686 |
| Proceeds from maturities of and other changes in marketable securities | 25,500 | 5,000 | 394,360 |
| Purchase of acquired technology | | | (4,550) |
| Investment in equity securities | | | (1,250) |
| Impairment of equity securities | 1,250 | | 1,250 |
| Net cash used in investing activities | (5,628) | (3,942) | (61,934) |
| Cash flows from financing activities: | | | |
| Proceeds from issuance of debt | 3,785 | 12,696 | 31,970 |
| Repayments of debt | (2,132) | (5,756) | (16,492) |
| Restricted cash related to debt | 377 | 901 | |
| Proceeds from issuance of preferred stock, net | | | 29,497 |
| Proceeds from issuance of common stock, net | 38,893 | 30,103 | 206,220 |
| Proceeds from exercise of stock options and warrants | 172 | 73 | 6,651 |
| Acquisition of treasury stock | | | (175) |
| Dividends paid | | | (72) |
| Net cash provided by financing activities | 41,095 | 38,017 | 257,599 |
| Net increase in cash and cash equivalents | 10,244 | 6,915 | 55,016 |
| Cash and cash equivalents, beginning of period | 31,088 | 48,101 | |

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| | | | | | | |
|--|----|--------|----|--------|----|--------|
| Cash and cash equivalents, end of period | \$ | 41,332 | \$ | 55,016 | \$ | 55,016 |
|--|----|--------|----|--------|----|--------|

The accompanying notes are an integral part of these financial statements.

NEOSE TECHNOLOGIES, INC.
(a development-stage company)

NOTES TO FINANCIAL STATEMENTS
(unaudited)

1. Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the United States for presentation of interim financial statements. Accordingly, the unaudited financial statements do not include all the information and footnotes necessary for a comprehensive presentation of the financial position, results of operations, and cash flows for the periods presented. In our opinion, however, the unaudited financial statements include all the normal recurring adjustments that are necessary for a fair presentation of the financial position, results of operations, and cash flows for the periods presented. You should not base your estimate of our results of operations for 2004 solely on our results of operations for the nine months ended September 30, 2004. You should read these unaudited financial statements in combination with:

The other Notes in this section;

Management's Discussion and Analysis of Financial Condition and Results of Operations appearing in the following section; and

The Financial Statements, including the Notes to the Financial Statements, included in our Annual Report on Form 10-K for the year ended December 31, 2003.

Certain prior year amounts have been reclassified to conform to our current year presentation.

2. Stock-based Compensation

We apply the intrinsic value method of accounting for all stock-based employee compensation in accordance with APB Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations. We record deferred compensation for option grants to employees for the amount, if any, by which the market price per share exceeds the exercise price per share.

We have elected to adopt only the disclosure provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS No. 123), as amended by Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation Transition and Disclosure. The following table illustrates the effect on our net loss and basic and diluted net loss per share if we had recorded compensation expense for the estimated fair value of our stock-based employee compensation, consistent with SFAS No. 123 (in thousands, except per share data):

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| | Three months ended September 30, | | Nine months ended September 30, | |
|---|-------------------------------------|-------------|------------------------------------|-------------|
| | 2003 | 2004 | 2003 | 2004 |
| Net loss as reported | \$ (10,338) | \$ (10,824) | \$ (27,985) | \$ (30,653) |
| Add: Stock-based employee compensation expense included in reported net loss | 72 | 11 | 104 | 89 |
| Deduct: Total stock-based employee compensation expense determined under fair value-based method for all awards | (3,159) | (2,634) | (9,409) | (7,732) |
| Net loss pro forma | \$ (13,425) | \$ (13,447) | \$ (37,290) | \$ (38,296) |
| Basic and diluted net loss per share as reported | \$ (0.59) | \$ (0.44) | \$ (1.66) | \$ (1.38) |
| Basic and diluted net loss per share pro forma | \$ (0.77) | \$ (0.54) | \$ (2.22) | \$ (1.72) |

3. Revenue Recognition

Revenue from collaborative agreements consists of upfront fees, research and development funding, and milestone payments. Non-refundable upfront fees are deferred and amortized to revenue over the related estimated performance period. Periodic payments for research and development activities are recognized over the period in which we perform those activities under the terms of each agreement. Revenue resulting from the achievement of milestone events stipulated in the agreements is recognized when the associated substantive milestone is achieved.

In April 2004, we entered into an agreement with BioGeneriX AG, a company of the ratiopharm Group, to use our proprietary GlycoPEGylation technology to develop a long-acting version of granulocyte colony stimulating factor (G-CSF). Under the agreement, we and BioGeneriX will pursue development and commercialization of a long-acting G-CSF. The parties will share equally preclinical expenses by reconciling quarterly the amounts expended by each party. Because each party is the primary obligor for its research and bears the risk of reimbursement from the other party, we will recognize the reimbursement of our preclinical obligations as revenue and record the obligation to BioGeneriX as research and development expense. The level of spending on preclinical expenses by each party will vary from quarter to quarter; therefore, we will sometimes owe a net reimbursement or be owed a net reimbursement. BioGeneriX will fund the entire clinical development program. If we and BioGeneriX proceed to commercialization, we will have commercial rights in the U.S., Canada, Mexico and Japan. BioGeneriX will have commercial rights in Europe and the rest of the world. Each company will receive royalties on product sales in the other company's territory. In connection with the agreement, we received from BioGeneriX a non-refundable, upfront fee, which is being amortized to revenue over the expected performance period.

4. Significant Customer Concentration

Our revenues from collaborative agreements have been derived from a few major collaborators. Our collaborative agreements have had some or all of the following elements: upfront fees, research and development funding, milestone revenues, and royalties on product sales.

During the three and nine months ended September 30, 2004, one customer accounted for 42% and 76%, respectively, of total revenues. The same customer accounted for 100% and 25% of total revenues during the three and nine months ended September 30, 2003, respectively.

During the three and nine months ended September 30, 2004, a second customer accounted for 58% and 24%, respectively, of total revenues. The same customer did not account for any revenue during the three and nine months ended September 30, 2003, respectively.

5. Long-term Debt and Capital Lease Obligations

In August 2004, we borrowed \$1,255,000 to finance the purchase of equipment and facility improvements, which collateralize the amount borrowed. The terms of the financing require us to pay monthly principal and interest payments over 48 months at an interest rate of 9.0%. During the 12 months ending September 30, 2005, 2006, 2007, and 2008, we will be required to make principal repayments totaling \$313,000, \$343,000, \$375,000, and \$224,000, respectively, under this agreement.

In May 2004, we borrowed \$1,500,000 from the landlord of our leased facility in Horsham, Pennsylvania. The terms of the financing require us to pay monthly principal and interest payments over 48 months at an interest rate of 13%. During the 12 months ending September 30, 2005, 2006, 2007, and 2008, we will be required to make principal repayments totaling \$291,000, \$359,000, \$409,000, and \$343,000, respectively, under this agreement.

In March 2004, we borrowed \$941,000 to finance the purchase of equipment and facility improvements, which collateralize the amount borrowed. The terms of the financing require us to pay monthly principal and interest payments over 48 months at an interest rate of 8.09%. During the 12 months ending September 30, 2005, 2006, 2007, and 2008, we will be required to make principal repayments totaling \$231,000, \$250,000, \$243,000, and \$127,000, respectively, under this agreement.

In February 2004, we entered into a capital lease obligation for equipment with a book value of \$184,000, which was calculated using an assumed incremental annual borrowing rate of 8.66%. The terms of the lease require us to make monthly payments through February 2009. Under this agreement, we will be required to make principal repayments totaling \$32,000, \$35,000, \$39,000, \$42,000, and \$19,000 during the 12 months ending September 30, 2005, 2006, 2007, 2008, and 2009, respectively.

During the three months ended March 31, 2004, we and a bank entered into agreements under which the bank acquired and reissued the \$1,000,000 of our outstanding tax-exempt Industrial Development Authority bonds. In addition, we borrowed \$8,000,000 from the bank, of which \$1,800,000 was combined with \$1,100,000 of our restricted cash for the purpose of paying in full the \$2,900,000 outstanding of our taxable Industrial Development Authority bonds. The

remaining \$6,200,000 borrowed funded improvements to our leased facility in Horsham, Pennsylvania, which we occupied in April 2004.

For the \$8,000,000 term loan, we will make quarterly, interest-only payments through March 31, 2005. Commencing on March 31, 2005, we will make quarterly principal payments of \$222,000 plus interest over the remaining nine years of the ten-year loan period. The bank debt bears interest at a rate equal to the 90-day LIBOR plus 3.0%. We will have the option each quarter to incur interest on the outstanding principal at the LIBOR-based variable interest rate or a fixed rate offered by the bank.

For the \$1,000,000 tax-exempt Industrial Development Authority Bond, we will make quarterly, interest-only payments for ten years followed by a single repayment of principal at the end of the ten-year loan period. If the 90-day LIBOR at the beginning of any calendar quarter is less than 4.0%, as it is currently, the bond will bear interest at a rate equal to the 90-day LIBOR plus 1.5%. If the 90-day LIBOR at the beginning of any calendar quarter is between 4.0% and 6.0%, the bond will bear interest at a rate equal to the 90-day LIBOR plus 1.25%. If the 90-day LIBOR at the beginning of any calendar quarter exceeds 6.0%, the bond will bear interest at a rate equal to the 90-day LIBOR plus 1.0%. We will have the option each quarter to incur interest on the outstanding principal at the LIBOR-based variable interest rate or a fixed rate offered by the bank.

To provide credit support for these borrowings, we granted a mortgage to the bank on the land and building where our present headquarters are located, as well as on improvements, certain equipment, and other tangible personal property. Under our agreements with the bank, if the bank determines a material adverse change has occurred in our business, financial condition, results of operations, or business prospects, the bank, in its sole discretion, may declare at any time an event of default, of which one potential outcome could be the accelerated repayment of the loan balance, which was \$9,000,000 as of September 30, 2004. Under our agreements with the bank, we agreed to limit our total outstanding debt to \$22,000,000. As of September 30, 2004, our total outstanding debt was \$17,725,000. At any time after the fourth year of the loan period, or if we fail to maintain a minimum required cash and short-term investments balance of at least \$22,000,000, our bank has the option to require additional collateral from us in the form of a security interest in certain cash and short-term investments, or in the form of a letter of credit, which may have the effect of requiring us to repay the outstanding loan balance to the bank. The agreements with our bank also contain covenants that, among other things, require us to obtain consent from the bank prior to paying dividends, making certain investments, changing the nature of our business, assuming or guaranteeing the indebtedness of another entity or individual, selling or otherwise disposing of a substantial portion of our assets, and merging or consolidating with another entity.

6. Stockholders Equity

In May 2004, we sold 4,733,476 shares of common stock in a registered direct offering to a number of institutional and individual investors, including 812,408 shares sold to officers and an investment fund affiliated with a director, at a price of \$6.77 per share, generating net proceeds of \$29,928,000.

During the nine months ended September 30, 2004, participating employees purchased 23,564 shares of common stock pursuant to our employee stock purchase plan, resulting in net

proceeds of \$175,000. In addition, during the nine months ended September 30, 2004, we received proceeds of \$73,000 upon the exercise of options to purchase 24,766 shares of common stock.

7. Separation and Non-competition Agreements

In September 2004, we entered into a separation agreement with our Chief Financial Officer in connection with his retirement in January 2005. Under the agreement, we are required to pay him \$10,781 per month (or one-half of his current monthly base salary) and provide medical benefits over a 12-month period commencing on his retirement date. We have also committed to pay any bonus earned by him for 2004, as determined using the same criteria as if he were employed as of the time of payment. We estimate the present value of these benefits as of the anticipated retirement date will be approximately \$240,000, which we will accrue through the anticipated retirement date. In addition, we extended for twelve months the period during which he may exercise his stock options that were vested and outstanding as of his retirement date. Because the stock options had no intrinsic value as of the modification date, there was no charge associated with the option modification.

In March 2003, our former Chief Executive Officer exercised the right under his separation agreement to enter into a non-competition agreement with us. Under the non-competition agreement, we are required to pay him \$39,622 per month for 24 months and, should he leave our board of directors during such two-year period, continue his stock option vesting and exercisability. Upon entering into the non-competition agreement, we recorded a liability of \$882,000, which represented the present value of the future payments, and a corresponding asset for the value of the non-competition commitment. The asset is being amortized on a straight-line basis to marketing, general and administrative expense on our statements of operations over the two-year term of the agreement. As of September 30, 2004, the present value of remaining minimum payments under the non-competition agreement was \$194,000.

8. Impairment of Equity Securities

In 2000, we made an investment of \$1,250,000 in Series A convertible preferred stock of Neuronix, Inc., and entered into a research and development collaboration with Neuronix for the discovery and development of drugs for treating Parkinson's disease and other neurological diseases. We recorded the equity investment at cost. In October 2003, Neuronix informed us that they were nearing completion of a Series C equity financing, under which Series C and Series B Neuronix investors would have an aggregate liquidation preference that was senior to the Series A liquidation preference and exceeded the assumed post-money valuation of Neuronix. As a result, we reduced the carrying value of our equity investment to zero as of September 30, 2003 by recording a non-cash charge, which was reflected as an impairment of equity securities in our statements of operations.

9. Net Loss Per Share

Basic and diluted net loss per share are presented in conformity with Statement of Financial Accounting Standards No. 128, Earnings Per Share. Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share reflects the potential dilution from the exercise or conversion of securities into common stock. For the three and nine months ended September 30, 2003 and 2004,

the effects of the exercise of outstanding stock options and warrants to purchase 4,323,234 and 5,166,254 shares, respectively, were antidilutive; accordingly, they were excluded from the calculation of diluted net loss per share.

10. Supplemental Disclosure of Cash Flow Information

The following table contains additional cash flow information for the periods reported (in thousands).

| | Nine months ended September 30, | | Period from inception (January 17, 1989) to September 30, 2004 |
|--|------------------------------------|----------|--|
| | 2003 | 2004 | |
| Supplemental disclosure of cash flow information: | | | |
| Cash paid for interest | \$ 352 | \$ 533 | \$ 4,443 |
| Non-compete agreement | \$ 882 | \$ | \$ 882 |
| Non-cash investing activities: | | | |
| Increase (decrease) in accrued property and equipment | \$ (37) | \$ (475) | \$ 380 |
| Assets acquired under capital leases | \$ | \$ 184 | \$ 1,525 |
| Non-cash financing activities: | | | |
| Conversion of debt into common stock | \$ | \$ | \$ 660 |
| Issuance of common stock for dividends | \$ | \$ | \$ 90 |
| Issuance of common stock to employees in lieu of cash compensation | \$ | \$ | \$ 44 |

11. Comprehensive Loss

Our comprehensive loss for the three and nine months ended September 30, 2004 was comprised only of our net loss, and was \$10,824,000 and \$30,653,000, respectively. Our comprehensive loss for the three and nine months ended September 30, 2003 was comprised only of our net loss, and was \$10,338,000 and \$27,985,000, respectively. Our cumulative comprehensive loss from inception (January 17, 1989) through September 30, 2004 was comprised only of our net loss, and was \$176,392,000.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

CAUTIONARY STATEMENT PURSUANT TO SAFE HARBOR PROVISIONS OF THE PRIVATE SECURITIES LITIGATION ACT OF 1995:

This report and the documents incorporated by reference herein contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. When used in

this report and the documents incorporated herein by reference, the words anticipate, believe, estimate, may, expect, intend, and similar expressions are generally intended to identify forward-looking statements. These forward-looking statements include, among others, the statements in Management's Discussion and Analysis of Financial Condition and Results of Operations about our:

estimate of the length of time that our existing cash, cash equivalents and marketable securities, expected revenue, and interest income will be adequate to finance our operating and capital requirements;
expected losses;
expectations for future capital requirements;
expectations for increases in operating expenses;
expectations for increases in research and development, and marketing, general and administrative expenses in order to develop products, manufacture commercial quantities of reagents and products, and commercialize our technology;
expectations for the development of an improved EPO, G-CSF, and subsequent proprietary drug candidates;
expectations for incurring additional capital expenditures for renovations of our facilities;
expectations for generating revenue; and
expectations regarding the timing and character of new or expanded collaborations and for the performance of our existing collaboration partners in connection with the development and commercialization of products incorporating our technologies.

Our actual results could differ materially from the results expressed in, or implied by, these forward-looking statements. Potential risks and uncertainties that could affect our actual results include the following:

our ability to obtain the funds necessary for our operations;
our ability to meet forecasted project timelines;
our ability to develop commercial-scale manufacturing processes for our products and reagents, either independently or in collaboration with others;
our ability to enter into and maintain collaborative arrangements;
our ability to obtain adequate sources of proteins and reagents;
our ability to expand and protect our intellectual property and to operate without infringing the rights of others;
our ability to develop and commercialize therapeutic proteins and to commercialize our technologies;
our ability to compete successfully in an intensely competitive field;
our ability to renovate our facilities as required for our operations;
our ability to attract and retain key personnel; and
general economic conditions

These and other risks and uncertainties that could affect our actual results are discussed in this report and in our other filings with the Securities and Exchange Commission, particularly the section entitled Factors Affecting The Company's Prospects of our Annual Report on

Form 10-K filed February 17, 2004. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance, or achievements. We do not assume responsibility for the accuracy and completeness of the forward-looking statements other than as required by applicable law.

We do not undertake any duty to update after the date of this report any of the forward-looking statements in this report to conform them to actual results.

You should read this section in combination with the Management's Discussion and Analysis of Financial Condition and Results of Operations for the year ended December 31, 2003, included in our Annual Report on Form 10-K and in our 2003 Annual Report to Stockholders.

Overview

We are a biopharmaceutical company focused on improving protein therapeutics using our proprietary technologies. Our core technologies, GlycoAdvance and GlycoPEGylation, enable us to manipulate, enzymatically, the carbohydrate structures of glycoproteins, and thereby pursue the objective of improving the therapeutic profiles of proteins that have already been marketed or substantially developed. Our business strategy is to use our technologies to improve proteins for which there exists a substantial body of data demonstrating safety and efficacy. We intend to apply this strategy to next-generation products that we are developing on our own or in collaboration with others. We also expect to use our technologies, through strategic partners, to improve products of other parties.

We have incurred operating losses each year since our inception. As of September 30, 2004, we had an accumulated deficit of approximately \$176.4 million. We expect additional losses in 2004 and over the next several years as we expand product research and development efforts, increase manufacturing scale-up activities and expand our intellectual property portfolio. We have financed our operations through private and public offerings of equity securities, proceeds from debt financings, and revenues from our collaborative agreements.

We believe that our existing cash and cash equivalents, expected revenue from our existing collaborations and license arrangements, and interest income should be sufficient to meet our operating and capital requirements through 2005, although changes in our collaborative relationships or our business, whether or not initiated by us, may affect the rate at which we deplete our cash and cash equivalents.

Under agreements we entered into with a bank during the three months ended March 31, 2004, we have agreed to limit our total outstanding debt to \$22.0 million. As of September 30, 2004, our total outstanding debt was approximately \$17.7 million. At any time after the fourth year of the ten-year loan period, or if we fail to maintain a minimum required cash and short-term investments balance of at least \$22.0 million, the bank has the option to require additional collateral from us in the form of a security interest in certain cash and short-term investments, or in the form of a letter of credit, which may have the effect of requiring us to repay the outstanding loan balance to the bank. See Financing Activities Debt Financing Activities Credit Agreement in the Liquidity and Capital Resources section of this Form 10-Q for a description of the material features of this borrowing.

Liquidity and Capital Resources

Overview

We had \$55,016,000 in cash and cash equivalents as of September 30, 2004, compared to \$53,060,000 in cash, cash equivalents, and marketable securities as of December 31, 2003. The increase for 2004 was primarily attributable to net proceeds from our May 2004 equity financing, proceeds from debt financings, and cash inflows from our collaborative agreements. These sources of cash were partially offset by the use of cash to fund our operating activities, capital expenditures, and debt repayments.

The development of next-generation proprietary protein therapeutics, which we are pursuing both independently and in collaboration with selected partners, will require substantial expenditures by us and our collaborators. To finance those expenditures, we plan to continue financing our operations through private and public offerings of equity securities, proceeds from debt financings, and revenues from existing and future collaborative agreements. Our future revenues could be substantially affected by entering into new collaborations and on the financial terms of any new collaborations. Because we do not know the timing or terms of any new collaborations we may enter into, we cannot estimate our future revenues. Other than revenues from our existing collaborations, and any future collaborations with others, we do not expect to generate significant revenues until such time as products incorporating our technologies are commercialized. We expect an additional several years to elapse before we will be able to generate sufficient cash flow from operations to fund our operating and investing requirements. Accordingly, we will need to raise substantial additional funds to continue our business activities and fund our operations beyond 2005.

Operating Activities

Cash used in operating activities was \$27,160,000 and \$25,223,000 for the nine months ending September 30, 2004 and 2003, respectively. The net cash used in operating activities is substantially the result of our operating loss. The increase in depreciation and amortization expense over the prior year resulted primarily from the commencement of amortization of leasehold improvements that were placed in service in April 2004.

During the nine months ended September 30, 2004, we used cash of \$1,038,000 to fund changes in operating assets and liabilities, primarily due to decreases in accrued compensation and accounts payable and an increase in prepaid expenses and other current and non-current assets. The reduction in accrued compensation during the nine months ended September 30, 2004 resulted from the payment of bonuses attributable to employee service in 2003. During the nine months ended September 30, 2004, prepaid expenses and other current and non-current assets increased by \$1,008,000, primarily due to an increase in our receivables from collaborative partners and the annual payment of insurance premiums and maintenance agreements. Prepaid expenses fluctuate period-to-period depending on the timing of payment of significant annual expenditures, such as insurance premiums and maintenance contracts. In addition, we are often required to prepay contract research organizations for services prior to the initiation of work performed.

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Our uses of cash during the nine months ended September 30, 2004 were offset in part by an increase of \$387,000 in deferred revenue. This increase was primarily due to the receipt from BioGeneriX of an upfront fee under our collaborative agreement. Fluctuations in operating items vary period-to-period due to, among other factors, the timing of research and development activities, such as the preparation and initiation of preclinical trials.

Investing Activities

During the nine months ended September 30, 2004, we invested \$8,942,000 in property, equipment, and building improvements. Of this amount, \$5,075,000 was invested in leasehold improvements that are described below. In addition, we entered into capital lease obligations for equipment with an aggregate book value of \$184,000, and we had accrued property and equipment of \$380,000 as of September 30, 2004. We anticipate additional capital expenditures during the remainder of 2004 of approximately \$1.0 million. We may finance some or all of our capital expenditures through the issuance of new debt or equity. We would prefer to finance capital expenditures through the issuance of new debt, to the extent that we are allowed to do so under our existing bank covenants. The terms of new debt could require us to maintain a minimum cash and investments balance, or to transfer cash into an escrow account to collateralize some portion of the debt, or both.

In April 2004, we occupied our leased facility in Horsham, Pennsylvania and began amortizing the costs of constructing 25,000 square feet of laboratory and office space within the facility, which totals 40,000 square feet. As of September 30, 2004, we had expended \$10,165,000 and accrued \$101,000 of costs related to improving the facility. During the first quarter of 2004, we entered into agreements with a bank for the purpose of funding these improvements. See *Financing Activities Debt Financing Activities Credit Agreement* in the *Liquidity and Capital Resources* section of this Form 10-Q for a description of the material features of this borrowing.

Financing Activities

Equity Financing Activities

In May 2004, we sold 4,733,476 shares of common stock in a registered direct offering to a number of institutional and individual investors, including 812,408 shares sold to officers and an investment fund affiliated with a director, at a price of \$6.77 per share, generating net proceeds of \$29,928,000.

During the nine months ended September 30, 2004, participating employees purchased 23,564 shares of common stock pursuant to our employee stock purchase plan, resulting in net proceeds of \$175,000. In addition, during the nine months ended September 30, 2004, we received proceeds of \$73,000 upon the exercise of options to purchase 24,766 shares of common stock.

Debt Financing Activities

Our total debt increased by \$7,124,000 to \$17,725,000 at September 30, 2004, compared to \$10,601,000 at December 31, 2003. This increase primarily resulted from \$12,696,000 in proceeds from the issuance of debt during the nine months ended September 30, 2004. Partially

offsetting the debt proceeds were \$5,756,000 of debt principal repayments during the nine months ended September 30, 2004. In addition, we entered into a capital lease obligation during the nine months ended September 30, 2004 for equipment with an aggregate book value of \$184,000.

Term Loan

In May 2004, we borrowed \$1,500,000 from the landlord of our leased facility in Horsham, Pennsylvania. The terms of the financing require us to pay monthly principal and interest payments over 48 months at an interest rate of 13%. During the 12 months ending September 30, 2005, 2006, 2007, and 2008, we will be required to make principal and interest payments totaling \$443,000, \$483,000, \$483,000, and \$362,000, respectively, under this agreement.

Credit Agreement

During the three months ended March 31, 2004, we and a bank entered into agreements under which the bank acquired and reissued the \$1,000,000 of our outstanding tax-exempt Industrial Development Authority bonds. In addition, we borrowed \$8,000,000 from the bank, of which \$1,800,000 was combined with \$1,100,000 of our restricted cash for the purpose of paying in full the \$2,900,000 outstanding of our taxable Industrial Development Authority bonds. The remaining \$6,200,000 borrowed funded improvements to our leased facility, which we occupied in April 2004, in Horsham, Pennsylvania.

For the \$8,000,000 term loan, we will make quarterly, interest-only payments through March 31, 2005. Commencing on March 31, 2005, we will make quarterly principal payments of \$222,000 plus interest over the remaining nine years of the ten-year loan period. The bank debt bears interest at a rate equal to the 90-day LIBOR plus 3.0%. We will have the option each quarter to incur interest on the outstanding principal at the LIBOR-based variable interest rate or a fixed rate offered by our bank.

For the \$1,000,000 tax-exempt Industrial Development Authority Bond, we will make quarterly, interest-only payments for ten years followed by a single repayment of principal at the end of the ten-year loan period. If the 90-day LIBOR at the beginning of any calendar quarter is less than 4.0%, as it is currently, the bond will bear interest at a rate equal to the 90-day LIBOR plus 1.5%. If the 90-day LIBOR at the beginning of any calendar quarter is between 4.0% and 6.0%, the bond will bear interest at a rate equal to the 90-day LIBOR plus 1.25%. If the 90-day LIBOR at the beginning of any calendar quarter exceeds 6.0%, the bond will bear interest at a rate equal to the 90-day LIBOR plus 1.0%. We will have the option each quarter to incur interest on the outstanding principal at the LIBOR-based variable interest rate or a fixed rate offered by our bank.

To provide credit support for these borrowings, we granted a mortgage to the bank on the land and building where our present headquarters are located, as well as on improvements, certain equipment, and other tangible personal property. Under our agreements with the bank, if the bank determines a material adverse change has occurred in our business, financial condition, results of operations, or business prospects, the bank, in its sole discretion, may declare at any time an event of default, of which one potential outcome could be the accelerated repayment of the loan balance, which was \$9,000,000 as of September 30, 2004. Under our agreements with

the bank, we agreed to limit our total outstanding debt to \$22,000,000. As of September 30, 2004, our total outstanding debt was \$17,725,000. At any time after the fourth year of the loan period, or if we fail to maintain a minimum required cash and short-term investments balance of at least \$22,000,000, our bank has the option to require additional collateral from us in the form of a security interest in certain cash and short-term investments, or in the form of a letter of credit, which may have the effect of requiring us to repay the outstanding loan balance to the bank. The agreements with our bank also contain covenants that, among other things, require us to obtain consent from the bank prior to paying dividends, making certain investments, changing the nature of our business, assuming or guaranteeing the indebtedness of another entity or individual, selling or otherwise disposing of a substantial portion of our assets, and merging or consolidating with another entity.

Equipment Loans

In August 2004, we borrowed \$1,255,000 to finance the purchase of equipment and facility improvements, which collateralize the amount borrowed. The terms of the financing require us to pay monthly principal and interest payments over 48 months at an interest rate of 9.0%. During the 12 months ending September 30, 2005, 2006, 2007, and 2008 we will be required to make principal and interest payments totaling \$417,000, \$414,000, \$414,000, and \$235,000, respectively, under this agreement.

In March 2004, we borrowed \$941,000 to finance the purchase of equipment and facility improvements, which collateralize the amount borrowed. The terms of the financing require us to pay monthly principal and interest payments over 48 months at an interest rate of 8.09%. During the 12 months ending September 30, 2005, 2006, 2007, and 2008, we will be required to make principal and interest payments totaling \$291,000, \$291,000, \$263,000, and \$130,000, respectively, under this agreement.

In December 2003, we borrowed \$1,201,000 to finance the purchase of equipment and facility improvements, which collateralize the amount borrowed. The terms of the financing require us to pay monthly principal and interest payments over 48 months at an interest rate of 8.66%. During the 12 months ending September 30, 2005, 2006, 2007, and 2008, we will be required to make principal and interest payments totaling \$366,000, \$366,000, \$337,000, and \$108,000, respectively, under this agreement.

In September 2003, we borrowed \$831,000 to finance the purchase of equipment and facility improvements, which collateralize the amount borrowed. The terms of the financing require us to pay monthly principal and interest payments over 48 months at an interest rate of 8.35%. During the 12 months ending September 30, 2005, 2006, 2007, and 2008, we will be required to make principal and interest payments totaling \$269,000, \$269,000, \$169,000, and \$13,000, respectively, under this agreement.

In March 2003, we borrowed \$2,954,000 to finance the purchase of equipment, which collateralize the amount borrowed. The terms of the financing require us to pay monthly principal and interest payments over 42 months at an interest rate of 8.35%. During the 12 months ending September 30, 2005, 2006, and 2007, we will be required to make principal and interest payments totaling \$976,000, \$976,000, and \$81,000, respectively, under this agreement.

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In December 2002, we borrowed \$2,261,000 to finance the purchase of equipment, which collateralize the amount borrowed. The terms of the financing require us to pay monthly principal and interest payments over 36 months at an interest rate of 8.0%. During the 12 months ending September 30, 2005 and 2006, we will be required to make principal and interest payments totaling \$850,000 and \$283,000, respectively, under this agreement.

Capital Lease Obligations

In February 2004, we entered into a capital lease obligation for equipment with a book value of \$184,000, which was calculated using an assumed incremental annual borrowing rate of 8.66%. The terms of the lease require us to make monthly payments through February 2009. Under this agreement, we will be required to make lease payments totaling \$46,000, \$46,000, \$46,000, \$46,000, and \$19,000 during the 12 months ending September 30, 2005, 2006, 2007, 2008, and 2009, respectively.

In September 2003, we entered into a capital lease for \$354,000 of equipment. The terms of the lease require us to make an initial payment of \$90,000 followed by monthly payments through September 2006. Under this agreement, we will be required to make lease payments totaling \$99,000 during each of the 12 months ending September 30, 2005 and 2006, respectively. We also entered into a capital lease obligation during September 2003 for \$60,000 of software. The terms of the lease require us to make monthly payments through September 2008. Under this agreement, we will be required to make lease payments totaling \$16,000 during each of the 12 months ending September 30, 2005, 2006, 2007, and 2008, respectively.

In June 2003, we entered into a capital lease for \$119,000 of equipment. The terms of the lease require us to make an initial payment of \$31,000 followed by monthly payments through June 2006. Under this agreement, we will be required to make lease payments totaling \$37,000 and \$28,000 during the 12 months ending September 30, 2005 and 2006, respectively.

In April and May 2003, we entered into capital leases for \$254,000 of equipment. The terms of the leases require us to make monthly payments through April 2006. Under these agreements, we will be required to make lease payments totaling \$96,000 and \$52,000 during the 12 months ending September 30, 2005 and 2006, respectively.

In November 2002, we entered into a capital lease for \$50,000 of equipment. The terms of the lease require us to make monthly payments over 36 months. Under this agreement, we will be required to make lease payments totaling \$19,000 and \$5,000 during the 12 months ending September 30, 2005 and 2006, respectively.

Summary of Contractual Obligations

A summary of our obligations to make future payments under contracts existing as of December 31, 2003 is included in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, of our Annual Report on Form 10-K for the year ended December 31, 2003. Other than the two agreements described below, the Liquidity and Capital Resources section of this Form 10-Q describes obligations from contracts entered into during the nine months ended September 30, 2004.

In September 2004, we entered into a separation agreement with our Chief Financial Officer in connection with his retirement in January 2005. Under the agreement, we are required to pay him \$10,781 per month (or one-half of his current monthly base salary) and provide medical benefits over a 12-month period commencing on his retirement date. We have also committed to pay any bonus earned by him for 2004, as determined using the same criteria as if he were employed as of the time of payment. We estimate the present value of these benefits as of the anticipated retirement date will be approximately \$240,000, which we will accrue through the anticipated retirement date. In addition, we extended through the twelve months, the period during which he may exercise his stock options that were vested and outstanding as of his retirement date. Because the stock options had no intrinsic value as of the modification date, there was no charge associated with the option modification.

We also entered into an amendment of an operating lease in September 2004 for our existing warehouse and office space located in Horsham, Pennsylvania. The lease amendment extended our scheduled lease termination date from December 31, 2004 to April 30, 2007. Under the amended lease, we will be required to make payments totaling \$47,500, \$48,750, and \$16,250 in the years ended December 31, 2005, 2006, and 2007, respectively.

Off-Balance Sheet Arrangements

We are not involved in any off-balance sheet arrangements that have or are reasonably likely to have a material future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources.

Critical Accounting Policies and Estimates

A discussion of our critical accounting policies and estimates is included in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, of our Annual Report on Form 10-K for the year ended December 31, 2003. There have not been any changes or additions to our critical accounting policies during the nine months ended September 30, 2004.

Results of Operations

Our net loss for the three and nine months ended September 30, 2004 was \$10,824,000 and \$30,653,000, respectively, compared to \$10,338,000 and \$27,985,000 for the corresponding periods in 2003. The following section explains the changes between the reporting periods in each component of net loss.

Revenue from Collaborative Agreements

Our revenues from collaborative agreements have historically been derived from a few major collaborators. Our collaborative agreements have had some or all of the following elements: upfront fees, research and development funding, milestone revenues, and royalties on product sales. Revenues from collaborative agreements for the three and nine months ended September 30, 2004 were \$1,451,000 and \$3,592,000, respectively, compared to \$150,000 and \$871,000 for the corresponding periods in 2003. These increases were primarily due to research and development funding under our collaboration with Novo Nordisk A/S and BioGeneriX AG.

We are working in collaboration with Novo Nordisk to incorporate our technology in three next-generation versions of marketed proteins, one of which is currently marketed by Novo Nordisk. Under our agreements with Novo Nordisk, we received a \$4,300,000 upfront fee in the fourth quarter of 2003, and Novo Nordisk is funding our research and development activities for these three proteins.

In April 2004, we entered into an agreement with BioGeneriX, a company of the ratiopharm Group, to use our proprietary GlycoPEGylation technology to develop a long-acting version of G-CSF. Under the agreement, we will pursue with BioGeneriX the development and commercialization of a long-acting G-CSF. The parties will share equally all preclinical expenses by reconciling quarterly the amounts expended by each party. Because each party is the primary obligor for its research and bears the risk of reimbursement from the other party, we will recognize the reimbursement of our preclinical obligations as revenue and record the obligation to BioGeneriX as research and development expense. The level of spending on preclinical expenses by each party will vary from quarter to quarter; therefore, we will sometimes owe a net reimbursement or be owed a net reimbursement. BioGeneriX will fund the entire clinical development program. If we and BioGeneriX proceed to commercialization, we will have commercial rights in the U.S., Canada, Mexico and Japan. BioGeneriX will have commercial rights in Europe and the rest of the world. Each company will receive royalties on product sales in the other company's territory. In connection with the agreement, we received from BioGeneriX a non-refundable, upfront fee, which is being amortized to revenue over the expected performance period.

Because our future revenues could be substantially affected by entering into new collaborations and on the financial terms of any new collaborations, we cannot estimate our future revenues. Material cash inflows from proprietary drug development projects are highly uncertain, and we cannot reasonably estimate the period in which we will begin to receive material net cash inflows from our major research and development projects. Cash inflows from development-stage products are dependent on several factors, including entering into collaborative agreements, the achievement of certain milestones, and regulatory approvals. We may not receive milestone payments from any existing or future collaborations if a development-stage product fails to meet technical or performance targets or fails to obtain the required regulatory approvals. Further, our revenues from collaborations will be affected by the levels of effort committed and made by our collaborative partners. Even if we achieve technical success in developing drug candidates, our collaborative partners may discontinue development, may not devote the resources necessary to complete development and commence marketing of these products, or they may not successfully market potential products.

Research and Development Expense

In January 2003, we announced the selection of an improved erythropoietin (EPO) as the target for our first proprietary drug development project. EPO is prescribed to stimulate production of red blood cells, and is approved for sale in major markets around the world for the treatment of anemia associated with oncology chemotherapy, end stage renal disease, and chronic renal insufficiency. Based on our current preclinical data, we believe it is feasible to develop a long-acting EPO through GlycoPEGylation. We are planning to continue various preclinical development activities during the remainder of 2004.

In October 2003, we announced the selection of an improved granulocyte colony stimulating factor (G-CSF) as the target for our second proprietary drug development project. G-CSF is prescribed to stimulate production of neutrophils (a type of white blood cell), and is approved for sale in major markets around the world for treatment of neutropenia associated with

oncology chemotherapy. Based on our current preclinical data, we believe it is feasible to develop a long-acting G-CSF through GlycoPEGylation. We are planning to continue various preclinical development activities with our partner, BioGeneriX, during the remainder of 2004.

We are also conducting exploratory research, both independently and with collaborators, to identify proteins that are likely candidates for development using our technologies, which may be advanced for development through our own proprietary drug program or through our partnering and licensing program. In addition, we are continuing some work on the development of our other programs, including new applications of our GlycoPEGylation and GlycoConjugation technologies.

Our current research and development projects are divided between two categories: (i) GlycoAdvance and GlycoPEGylation and (ii) Other Glycotechnology Programs, which includes projects investigating other applications of our intellectual property. The following chart sets forth our projects in each of these categories and the stage to which each has been developed:

| | <i>Development Stage</i> | <i>Status</i> |
|--|------------------------------|---------------|
| GlycoAdvance and GlycoPEGylation | | |
| Improved erythropoietin | Preclinical | Active |
| Improved granulocyte colony stimulating factor | Preclinical | Active |
| Other protein projects | Research/ Preclinical | Active |
| Other Glycotechnology Programs | | |
| Non-protein therapeutic applications | Research | Active |
| Nutritional applications | N/A | Inactive |

The process of bringing drugs from the preclinical research and development stage through Phase I, Phase II, and Phase III clinical trials to FDA approval is time consuming and expensive. Because our announced product candidates are currently in the preclinical stage and there are a variety of intermediate clinical and non-clinical outcomes that can occur in drug development, we cannot reasonably estimate either the timing or costs we will incur to complete these research and development projects. In addition, the timing and costs to complete our proprietary research and development projects will be affected by the timing and nature of any collaboration agreements we may enter into with any third parties, none of which we can currently estimate.

For each of our research and development projects, we incur both direct and indirect expenses. Direct expenses include salaries and other costs of personnel, raw materials, and supplies for each project. We may also incur third-party costs related to these projects, such as contract research and manufacturing, consulting, preclinical and clinical development costs. Indirect expenses include depreciation expense and the costs of operating and maintaining our facilities, property, and equipment, to the extent used for our research and development projects, as well as the costs of general management of our research and development projects.

Our research and development expenses were \$9,305,000 and \$24,971,000 for the three and nine months ended September 30, 2004, respectively, and \$6,747,000 and \$19,031,000 for the comparable 2003 periods. We expect our research and development expenses to continue to

be significantly greater in 2004 than they were in 2003 primarily due to development and preclinical activities we plan to conduct during the year, including process development and pilot plant activities associated with our proprietary drug development programs. The following table illustrates research and development expenses incurred during 2003 and 2004 in each period for our significant groups of research and development projects (in thousands).

| | Three months ended September 30, | | Nine months ended September 30, | |
|--|-------------------------------------|-----------------|------------------------------------|------------------|
| | 2003 | 2004 | 2003 | 2004 |
| GlycoAdvance, GlycoPEGylation and GlycoConjugation | \$ 2,535 | \$ 4,386 | \$ 6,854 | \$ 11,254 |
| Other Glycotechnology Programs | 84 | 19 | 468 | 141 |
| Indirect expenses | 4,128 | 4,900 | 11,709 | 13,576 |
| | <u>\$ 6,747</u> | <u>\$ 9,305</u> | <u>\$ 19,031</u> | <u>\$ 24,971</u> |

GlycoAdvance, GlycoPEGylation, and GlycoConjugation

Our GlycoAdvance, GlycoPEGylation and GlycoConjugation expenses result primarily from the development and preclinical activities, including process development and pilot plant activities, associated with our proprietary drug development programs. These expenses increased during the 2004 periods, compared to 2003, primarily due to hiring of additional employees and increased purchases of outside services and supplies associated with our proprietary drug development programs.

Other Glycotechnology Programs

Research and development expenses related to our Other Glycotechnology Programs decreased during the 2004 periods, compared to 2003, consistent with our decision to focus our resources on our GlycoAdvance, GlycoPEGylation, and GlycoConjugation programs.

Indirect expenses

Our indirect research and development expenses increased during the 2004 periods, compared to 2003, primarily due to increases related to additional personnel, depreciation of capital expenditures, and operating an additional facility.

Marketing, General and Administrative Expense

Marketing, general and administrative expenses for the three and nine months ended September 30, 2004 were \$2,861,000 and \$9,047,000, respectively, compared to \$2,456,000 and \$8,657,000 for the corresponding periods in 2003. The increase for the three and nine months ended September 30, 2004 was primarily due to higher patent legal expenses. These costs were partially offset by savings in salary and other personnel-related costs as well as lower marketing costs. During 2004, we expect our marketing, general and administrative expenses to increase by less than 10% over 2003.

Impairment of Equity Securities

In 2000, we made an investment of \$1,250,000 in Series A convertible preferred stock of Neuronix, Inc., and entered into a research and development collaboration with Neuronix for the discovery and development of drugs for treating Parkinson's disease and other neurological diseases. We recorded the equity investment at cost. In October 2003, Neuronix informed us that they were nearing completion of a Series C equity financing, under which Series C and Series B Neuronix investors would have an aggregate liquidation preference that was senior to the Series A liquidation preference and exceeded the assumed post-money valuation of Neuronix. As a result, we reduced the carrying value of our equity investment to zero as of September 30, 2003 by recording a non-cash charge, which was reflected as an impairment of equity securities in our statements of operations.

Interest Income and Interest Expense

Interest income for the three and nine months ended September 30, 2004 was \$195,000 and \$431,000, respectively, compared to \$103,000 and \$420,000 for the corresponding periods in 2003. The increases during the 2004 periods resulted primarily from slightly higher cash, cash equivalents, and marketable securities balances due to our May 2004 equity offering, partially offset by lower interest rates.

Interest expense for the three and nine months ended September 30, 2004 was \$304,000 and \$658,000, respectively, compared to \$138,000 and \$338,000 for the corresponding periods in 2003. The increases in the 2004 periods were due to higher average debt balances. Partially offsetting the increases during the nine months ended September 30, 2004 was \$131,000 of interest that was capitalized during the construction of improvements to our leased facility in Horsham, Pennsylvania. See *Investing Activities* in the *Liquidity and Capital Resources* section of this Form 10-Q for a description of those improvements. During the nine months ended September 30, 2003, we capitalized interest of \$15,000. We expect our interest expense during 2004 to increase compared to 2003 primarily due to the issuance of new debt. See *Financing Activities* *Debt Financing Activities* in the *Liquidity and Capital Resources* section of this Form 10-Q for a description of the material features of our debt financings.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

As of September 30, 2004, our holdings of financial instruments are comprised solely of money market securities. To date, our market risk exposure has consisted principally of exposure to changes in interest rates. Our holdings are also exposed to the risks of changes in the credit quality of issuers. We typically invest in the shorter-end of the maturity spectrum. As of September 30, 2004, we were not invested in any marketable securities. The approximate principal amount of our investment portfolio as of September 30, 2004 was \$55.0 million. The annualized weighted-average interest rate earned on our portfolio during the nine months ended September 30, 2004 was approximately 1.0%.

We have exposure to changing interest rates on our tax-exempt bonds and variable rate bank debt, and we are currently not engaged in hedging activities. Interest on approximately \$9.0 million of outstanding indebtedness is at an interest rate that varies quarterly, depending on

changes in the 90-day LIBOR. During the nine months ended September 30, 2004, the annualized weighted-average, interest rate on this debt was approximately 4.0%.

Item 4. Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act), for financial reporting as of September 30, 2004. Based on that evaluation, our principal executive officer and principal financial officer concluded that these controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported as specified in Securities and Exchange Commission rules and forms. There were no changes in these controls or procedures identified in connection with the evaluation of such controls or procedures that occurred during our last fiscal quarter, or in other factors that have materially affected, or are reasonably likely to materially affect, these controls or procedures.

Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the Securities and Exchange Commission. These disclosure controls and procedures include, among other things, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Our internal controls and procedures for financial reporting are designed to provide reasonable assurance, and management believes that they provide such reasonable assurance, that our transactions are properly authorized, our assets are safeguarded against unauthorized or improper use, and our transactions are properly recorded and reported, in order to permit the preparation of our financial statements in conformity with generally accepted accounting principles.

Our management group, including our principal executive officer and principal financial officer, does not expect that our disclosure controls and internal controls and related procedures will prevent all error and all fraud. A control system, no matter how well designed and implemented, can provide only reasonable assurance that the objectives of the control system are met. In addition, the design and implementation of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered in relation to their costs. The design of any system of controls is based, in part, upon certain assumptions about the likelihood of future events, which may prove to be incorrect. Due to the limitations of all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within an organization have been detected or prevented.

PART II. OTHER INFORMATION

Item 6. Exhibits

- 10.10 Separation Agreement between the Company and Robert I. Kriebel dated September 23, 2004.(1)
- 10.11 Promissory Note of the Company to General Electric Capital Corporation dated August 20, 2004.*
- 10.12 Form of Incentive Stock Option Award Agreement under the Company s 2004 Equity Incentive Plan.*
- 10.13 Form of Non-Qualified Stock Option Award Agreement under the Company s 2004 Equity Incentive Plan.*
- 10.14 Form of Annual Director Grant Agreement under the Company s 2004 Equity Incentive Plan.*
- 10.15 Form of Director Fee Option Grant Agreement under the Company s 2004 Equity Incentive Plan.*
- 31.1 Certification by Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
- 31.2 Certification by Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
- 32.1 Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
- 32.2 Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*

* Filed herewith.

(1) Filed as Exhibit 10.10 to our Current Report on Form 8-K filed with the SEC on September 24, 2004 and incorporated herein by reference.

