

NEOSE TECHNOLOGIES INC

Form 10-Q

August 08, 2003

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**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

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**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 **June 30, 2003**.

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)

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**Delaware**  
(State or other jurisdiction of incorporation or organization)

**13-3549286**  
(I.R.S. Employer Identification No.)

**102 Witmer Road**

**19044**

**Horsham, Pennsylvania**  
(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.

Yes  No

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

Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 17,250,707 shares of common stock, \$.01 par value, were outstanding as of August 4, 2003.

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**NEOSE TECHNOLOGIES, INC.**

**(a development-stage company)**

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**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****NEOSE TECHNOLOGIES, INC.**

(a development-stage company)

**BALANCE SHEETS**

(unaudited)

(in thousands, except per share amounts)

	<b>December 31, 2002</b>	<b>June 30, 2003</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 31,088	\$ 31,584
Marketable securities	9,952	10,486
Restricted funds	977	379
Prepaid expenses and other current assets	558	1,419
	<hr/>	<hr/>
Total current assets	42,575	43,868
Property and equipment, net	36,508	35,548
Acquired intellectual property, net	2,507	2,209
Other assets	1,502	2,246
	<hr/>	<hr/>
Total assets	\$ 83,092	\$ 83,871
	<hr/>	<hr/>
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Current portion of long-term debt	\$ 1,851	\$ 2,803
Accounts payable	1,127	1,177
Accrued compensation	1,339	1,602
Accrued expenses	1,880	1,639
Deferred revenue	320	70
	<hr/>	<hr/>
Total current liabilities	6,517	7,291
Long-term debt	5,560	6,278
Other liabilities	330	641
	<hr/>	<hr/>
Total liabilities	12,407	14,210
	<hr/>	<hr/>
Stockholders' equity:		
Preferred stock, \$.01 par value, 5,000 shares authorized, none issued		

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Common stock, \$.01 par value, 30,000 shares authorized; 14,330 and 17,248 shares issued; 14,324 and 17,242 shares outstanding	143	172
Additional paid-in capital	178,945	195,506
Treasury stock, 6 shares at cost	(175)	(175)
Deferred compensation	(170)	(137)
Deficit accumulated during the development-stage	(108,058)	(125,705)
	<u>70,685</u>	<u>69,661</u>
Total stockholders' equity		
	<u>\$ 83,092</u>	<u>\$ 83,871</u>
Total liabilities and stockholders' equity		

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

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(a development-stage company)

**STATEMENTS OF OPERATIONS**

(unaudited)

(in thousands, except per share amounts)

	Three months		Six months		Period from
	ended June 30,		ended June 30,		inception
	2002	2003	2002	2003	(January 17, 1989) to
					June 30, 2003
Revenue from collaborative agreements	\$ 1,561	\$ 651	\$ 2,332	\$ 721	\$ 18,167
Operating expenses:					
Research and development	5,139	6,664	10,974	12,284	111,961
Marketing, general and administrative	3,289	3,197	6,209	6,201	55,274
Total operating expenses	8,428	9,861	17,183	18,485	167,235
Operating loss	(6,867)	(9,210)	(14,851)	(17,764)	(149,0680
Other income					7,773
Interest income	419	147	848	317	19,095
Interest expense	(42)	(163)	(82)	(200)	(3,505)
Net loss	\$ (6,490)	\$ (9,226)	\$ (14,085)	\$ (17,647)	\$ (125,705)
Basic and diluted net loss per share	\$ (0.45)	\$ (0.54)	\$ (0.99)	\$ (1.07)	
Weighted-average shares outstanding used in computing basic and diluted net loss per share	14,281	17,229	14,201	16,519	

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

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(a development-stage company)

**STATEMENTS OF CASH FLOWS**

(unaudited)

(in thousands)

	Six months ended		Period from inception (January 17, 1989) to June 30, 2003
	June 30,		
	2002	2003	
<b>Cash flows from operating activities:</b>			
Net loss	\$ (14,085)	\$ (17,647)	\$ (125,705)
<b>Adjustments to reconcile net loss to cash used in operating activities:</b>			
Depreciation and amortization	1,382	2,234	15,343
Non-cash compensation	1,162	110	4,883
Common stock issued for non-cash and other charges			35
<b>Changes in operating assets and liabilities:</b>			
Prepaid expenses and other current and non-current assets	(768)	(834)	(1,644)
Accounts payable	1,363	50	1,177
Accrued compensation	588	(199)	1,184
Accrued expenses	(1,264)	(139)	1,639
Deferred revenue	(208)	(250)	70
Other liabilities		(108)	222
<b>Net cash used in operating activities</b>	<b>(11,830)</b>	<b>(16,783)</b>	<b>(102,796)</b>
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(11,533)	(722)	(47,830)
Proceeds from sale-leaseback of equipment			1,382
Purchases of marketable securities	(47,487)	(23,735)	(408,473)
Proceeds from sales of marketable securities		8,328	19,795
Proceeds from maturities of and other changes in marketable securities		15,000	378,860
Purchase of acquired technology			(4,550)
Investment in equity securities			(1,250)
<b>Net cash used in investing activities</b>	<b>(59,020)</b>	<b>(1,129)</b>	<b>(62,066)</b>
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of debt		2,954	17,170
Repayment of debt		(1,657)	(9,809)
Restricted cash related to debt	(556)	598	(308)
Proceeds from issuance of preferred stock, net			29,497
Proceeds from issuance of common stock, net		16,435	153,659
Proceeds from exercise of stock options and warrants	1,778	78	6,484
Acquisition of treasury stock			(175)

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Dividends paid			(72)
Net cash provided by financing activities	1,222	18,408	196,446
Net increase (decrease) in cash and cash equivalents	(69,628)	496	31,584
Cash and cash equivalents, beginning of period	76,245	31,088	
Cash and cash equivalents, end of period	\$ 6,617	\$ 31,584	\$ 31,584

The accompanying notes are an integral part of these financial statements



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**NEOSE TECHNOLOGIES, INC.**

(a development-stage company)

**NOTES TO FINANCIAL STATEMENTS**

(unaudited)

**1. Basis of Presentation**

We have used accounting principles generally accepted in the United States for interim financial information to prepare our unaudited financial statements:

- As of June 30, 2003;
- For the three and six months ended June 30, 2002 and 2003; and
- For the period from inception (January 17, 1989) to June 30, 2003.

Our unaudited financial statements do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In our opinion, 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 2003 solely on our results of operations for the three and six months ended June 30, 2003. 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, 2002.

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 (APB 25), 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 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 123 (in

thousands, except per share data):

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	Three months ended		Six months ended	
	June 30,		June 30,	
	2002	2003	2002	2003
Net loss as reported	\$ (6,490)	\$ (9,226)	\$ (14,085)	\$ (17,647)
Add: Stock-based employee compensation expense included in reported net loss	92	21	120	32
Deduct: Total stock-based employee compensation expense determined under fair value-based method for all awards	(4,157)	(2,380)	(7,049)	(6,250)
Net loss pro forma	\$ (10,555)	\$ (11,585)	\$ (21,014)	\$ (23,865)
Basic and diluted net loss per share as reported	\$ (0.45)	\$ (0.54)	\$ (0.99)	\$ (1.07)
Basic and diluted net loss per share pro forma	\$ (0.74)	\$ (0.67)	\$ (1.48)	\$ (1.44)

**3. Revenue Recognition**

Our revenue from collaborative agreements consists of up-front fees, research and development funding, and milestone payments. We recognize revenues from these agreements consistent with Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements (SAB 101), issued by the Securities and Exchange Commission. Non-refundable up-front fees are deferred and amortized to revenue over the related performance period. We estimate our performance period based on the specific terms of each collaborative agreement, but the actual performance period may vary. We adjust the performance periods based on available facts and circumstances. Periodic payments for research and development activities are recognized over the period that 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 milestone is achieved. Milestones are based on the occurrence of a substantive element specified in the contract or as a measure of substantive progress towards completion under the contract.

In January 2003, the Financial Accounting Standards Board issued Emerging Issues Task Force Issue 00-21, Revenue Arrangements with Multiple Deliverables (EITF 00-21). Our existing revenue recognition policy under SAB 101 of recognizing revenue from the achievement of substantive milestone events when such milestones are met complies with EITF 00-21.

**4. Long-term Debt**

During the quarter ended June 30, 2003, we entered into various capital lease obligations for equipment and software with an aggregate book value of \$373,000, which was calculated using an assumed incremental annual borrowing rate of 8.35%. We are required to make monthly payments on each lease. The leases have expiration dates ranging from March 2006 to June 2006.

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In March 2003, we borrowed \$2,954,000 secured by laboratory equipment. We are required to make monthly principal and interest payments at an annual rate of 8.35% through September 2006.

### **5. Stockholders Equity**

In February 2003, we sold 2,866,763 shares of common stock in a private placement to a group of institutional and individual investors at a price of \$6.00 per share, generating net proceeds of \$16,320,000.

In January 2003, employees participating in our employee stock purchase plan purchased 16,724 shares of common stock at a total purchase price of \$115,000.

### **6. Separation Agreement**

In March 2002, we entered into a Separation and Consulting Agreement with our former Chief Executive Officer, Stephen A. Roth. Under this agreement, we agreed to provide medical benefits to Dr. Roth and to pay him \$39,622 per month for 12 months. During the quarter ended March 31, 2002, we recorded severance expense related to this agreement of \$309,000, which represented the present value of his future benefit payments, which has been included in marketing, general and administrative expenses in our statements of operations.

Prior to March 29, 2003, Dr. Roth had the right to extend his non-competition and non-solicitation commitments for two additional years by entering into a separate non-competition agreement. Dr. Roth extended his commitments in March 2003 and, therefore, we will pay him \$39,622 per month for 24 additional months and, should he leave our board of directors during the additional two-year period, we will continue his stock option vesting and exercisability. During the quarter ended March 31, 2003, 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 will be amortized to general and administrative expense in our statements of operations over the two-year term of the agreement.

In January 2002, we entered into a retirement agreement with our Vice President, Research. Under the agreement, he terminated his employment effective June 30, 2002. We have committed to pay a retirement benefit over a five-year period. We will continue to provide Dr. McGuire health insurance benefits through December 31, 2003. During the quarter ended March 31, 2002, we recorded severance expense related to this agreement of \$516,000, which represented the present value of his future retirement benefit. In addition, we extended the period during which he may exercise his stock options and recorded a non-cash severance charge of \$1,608,000 associated with this option modification.

### **7. 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 six months ended June 30, 2002 and 2003, the effects of the exercise of outstanding stock options and warrants to purchase

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3,543,670 and 4,697,235 shares, respectively, were antidilutive; accordingly, they were excluded from the calculation of diluted net loss per share.

**8. Supplemental Disclosure of Cash Flow Information**

The following table contains additional cash flow information for the periods reported.

	<b>Six months ended</b>		<b>Period from inception (January 17, 1989) to June 30, 2003</b>
	<b>June 30,</b>		
	<b>2002</b>	<b>2003</b>	
	<b>_____</b>	<b>_____</b>	<b>_____</b>
<b>Supplemental disclosure of cash flow information:</b>			
Cash paid for interest	\$ 61	\$ 214	\$3,659
	<b>_____</b>	<b>_____</b>	<b>_____</b>
Non-compete agreement	\$	\$ 882	\$ 882
	<b>_____</b>	<b>_____</b>	<b>_____</b>
<b>Non-cash investing activities:</b>			
Increase/(decrease) in accrued property and equipment	\$	\$ (102)	\$
	<b>_____</b>	<b>_____</b>	<b>_____</b>
<b>Non-cash financing activities:</b>			
Issuance of common stock for dividends	\$	\$	\$ 90
	<b>_____</b>	<b>_____</b>	<b>_____</b>
Issuance of common stock to employees in lieu of cash compensation	\$	\$	\$ 44
	<b>_____</b>	<b>_____</b>	<b>_____</b>

**9. New Accounting Pronouncements**

In April 2003, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standard No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities (SFAS No. 149). This Statement amends and clarifies accounting for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities under SFAS No. 133. SFAS No. 149 is effective for contracts entered into or modified after June 30, 2003, for hedging relationships designated after June 30, 2003, and to certain preexisting contracts. We do not expect the adoption of SFAS No. 149 to have a material impact on our financial statements.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity . This Statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and is otherwise effective July 1, 2003. We do not expect the adoption of SFAS No. 150 to have a material impact on our financial statements.

**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:*

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*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*

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*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 and subsequent proprietary drug candidates;*
- *expectations for incurring additional capital expenditures for renovations of our facilities;*
- *expectations for generating revenue;*
- *ability to enter into new or expanded collaboration agreements and the ability of our existing collaboration partners to develop and commercialize 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 develop and commercialize any therapeutic proteins or to commercialize our technologies;*
- *our ability to develop commercial-scale manufacturing processes;*
- *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 compete successfully in an intensely competitive field;*
- *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 Risk Factors of our Registration Statement on Form S-3 dated June 20, 2003. 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*

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*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, 2002, included in our Annual Report on Form 10-K and in our 2002 Annual Report to Stockholders.

## **Overview**

We are a biopharmaceutical company focused on improving protein therapeutics using our proprietary technologies. Most therapeutic proteins in development or on the market today are glycoproteins—proteins with carbohydrate structures attached. These carbohydrates are important to the proper functioning of the proteins. The process by which carbohydrates are attached to proteins is called glycosylation. Manufacturing protein drugs often results in the problem of incomplete glycosylation. We are using our GlycoAdvance, GlycoPEGylation and GlycoConjugation technologies to develop improved versions of currently marketed drugs with proven efficacy, to complete the glycosylation of proteins, and to improve therapeutic profiles of glycoproteins in development for our partners. We expect these next generation proteins to offer significant advantages over drugs that are now on the market, potentially including less frequent dosing and improved safety and efficacy. In addition to developing our own products or co-developing products with others, we expect to enter into strategic partnerships for including our technologies into the product design and manufacturing processes of other biotechnology and pharmaceutical companies. While our primary goal is protein drug development, our technologies offer multiple opportunities to participate in the evolving therapeutic protein market by addressing other challenges, such as manufacturing efficiency, manufacturing consistency, and the use of non-mammalian cell expression systems.

As of June 30, 2003, we had an accumulated deficit of approximately \$125.7 million. We expect additional losses in 2003 and over the next several years as we expand product research and development efforts, increase manufacturing scale-up activities and, potentially, begin sales and marketing activities.

## **Liquidity and Capital Resources**

### *Overview*

We have incurred operating losses each year since our inception. As of June 30, 2003, we had an accumulated deficit of \$125,705,000. We have financed our operations primarily through proceeds from private and public placements of equity securities. We have also funded our operations to a lesser extent from interest earned on investments, proceeds from property and equipment financing, revenues from corporate collaborations and gains from the sale of investments. We had \$42,070,000 in cash, cash equivalents and marketable securities as of June 30, 2003, compared to \$41,040,000 in cash, cash equivalents and marketable securities as of





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December 31, 2002. The increase during 2003 was primarily attributable to the net proceeds from our February 2003 private placement as discussed below, offset by the use of cash to fund our operating loss and capital expenditures.

In February 2003, we sold 2,866,763 shares of common stock in a private placement to a group of institutional and individual investors, generating net proceeds of \$16,320,000. We believe that our existing cash, cash equivalents and marketable securities, expected revenue from collaborations and license arrangements, and interest income should be sufficient to meet our operating and capital requirements at least through the middle of 2004, although changes in our collaborative relationships or our business, whether or not initiated by us, may cause us to deplete our cash and marketable securities sooner than the above estimate. The timing and amount of our future capital requirements and the adequacy of available funds will depend on many factors, including if and when any products manufactured using our technology are commercialized.

During 2002, we focused our business on the development of next generation proprietary protein therapeutics, which we plan to pursue both independently and in collaboration with selected partners. This development and commercialization will require substantial investments by us and our collaborators. Most of our 2002 revenues were derived from agreements that have been terminated or were fully performed early in 2003. As a result, our revenues for the remainder of 2003 are difficult to project and will be largely dependent on entering into new collaborations and on the financial terms of any new collaborations. Other than revenues from any future collaborations, we expect to generate no significant revenues until such time as products incorporating our technologies are commercialized, which is not expected during the next several years. We expect an additional several years to elapse before we can expect to generate sufficient cash flow from operations to fund our operating and capital requirements. Accordingly, we will need to raise substantial additional funds to continue our business activities and fund our operations beyond the middle of 2004.

### *Capital Expenditures*

During the six months ended June 30, 2003, we invested \$722,000 in property, equipment, and building improvements. We anticipate capital expenditures during 2003 of approximately \$5.0 million, which excludes the impact of resuming the facility renovations described below. We may finance some or all of our capital expenditures through the issuance of new debt or equity. If we issue new debt, we may be required 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.

We entered into a lease agreement in 2002 for a 40,000 square foot building, which we intended to convert into laboratory and office space for an expected cost of approximately \$12.0 million. Later in 2002, we suspended work on these renovations and we have not yet made a final decision as to when or if we will resume this project. Our property and equipment at June 30, 2003 includes approximately \$4,030,000 in renovations to this facility. To the extent that we determine the partially completed renovations are of no future use to us, we would be required to recognize an impairment loss in our statement of operations. If we decide to resume the project, we anticipate expending up to an additional \$8.0 million to restart the project and complete the renovations.

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### *Long-term Debt*

#### *Montgomery County (Pennsylvania) IDA Bonds*

In 1997, we issued, through the Montgomery County (Pennsylvania) Industrial Development Authority, \$9,400,000 of taxable and tax-exempt bonds, of which \$3,900,000 remained outstanding as of June 30, 2003. The bonds were issued to finance the purchase of our headquarters building and the construction of a pilot-scale manufacturing facility within our building. The bonds are supported by an AA-rated letter of credit, and a reimbursement agreement between our bank and the letter of credit issuer. The interest rate on the bonds will vary weekly, depending on market rates for AA-rated taxable and tax-exempt obligations, respectively. During the six months ended June 30, 2003, the weighted-average, effective interest rate was 2.0% per year, including letter-of-credit and other fees. The terms of the bond issuance provide for monthly, interest-only payments and a single repayment of principal at the end of the twenty-year life of the bonds. However, under our agreement with our bank, we are making monthly payments to an escrow account to provide for an annual prepayment of principal. As of June 30, 2003, we had restricted funds relating to the bonds of \$379,000, which consisted of our monthly payments to an escrow account plus interest revenue on the balance of the escrow account. During the next 12 months, we will be required to make payments of \$925,000 into the escrow account.

To provide credit support for this arrangement, we have given a first mortgage on the land, building, improvements, and certain machinery and equipment to our bank. We have also agreed to maintain a minimum required cash and short-term investments balance of at least two times the outstanding loan balance. If we fail to comply with this requirement, we are required to deposit with the lender cash collateral up to, but not more than, the unpaid balance of the loan. At June 30, 2003, we were required to maintain \$7,800,000 of cash and short-term investments.

### *Equipment Loans*

In March 2003, we borrowed \$2,954,000 to finance the purchase of equipment, which is collateralizing 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 next 12 months, we will be required to make payments totaling \$976,000 under this agreement.

In December 2002, we borrowed \$2,261,000 to finance the purchase of equipment, which is collateralizing 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 next 12 months, we will be required to make payments totaling \$850,000 under this agreement.

### *Capital Lease Obligations*

In June 2003, we entered into a capital lease to lease \$119,000 of equipment. The terms of the lease required us to make an initial payment of \$31,000 followed by monthly payments through June 2006. During the next 12 months, we will be required to make payments totaling \$28,000 under this agreement.

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In April and May 2003, we entered into capital leases to lease \$254,000 of equipment. The terms of the leases require us to make monthly payments through April 2006. During the next 12 months, we will be required to make payments totaling \$96,000 under these agreements.

In November 2002, we entered into a capital lease to lease \$50,000 of equipment. The terms of the lease require us to make monthly payments through November 2005. During the next 12 months, we will be required to make payments totaling \$19,000 under this agreement.

## **Summary of Contractual Obligations**

A summary of our obligations to make future payments under contracts existing as of December 31, 2002 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, 2002. The Liquidity and Capital Resources section of this Form 10-Q describes additional obligations from contracts entered into during the six months ended June 30, 2003.

## **Off-Balance Sheet Arrangements**

We do not have 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**

A discussion of our critical accounting policies 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, 2002.

## **Results of Operations**

Our net loss for the three and six months ended June 30, 2003 was \$9,226,000 and \$17,647,000, respectively, compared to \$6,490,000 and \$14,085,000 for the corresponding periods in 2002. The following section explains the changes between the reporting periods in each component of net loss.

### *Revenue from Collaborative Agreements*

Revenues from collaborative agreements for the three and six months ended June 30, 2003 were \$651,000 and \$721,000, respectively, compared to \$1,561,000 and \$2,332,000 for the corresponding periods in 2002.

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During the quarter ended June 30, 2003, we completed activities related to our research and development collaboration with Wyeth Nutrition, and recorded as revenue the last scheduled payment for research and development funding of \$250,000, which we had received in October

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2002. During the quarter ended June 30, 2003, we recognized revenue of \$400,000 under a license agreement.

Revenues for the 2002 periods were primarily related to our agreements with Wyeth Pharmaceuticals and Wyeth Nutrition. The Wyeth Pharmaceuticals agreement was terminated in September 2002, and we expect to receive no further revenues under this agreement.

*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 preliminary laboratory data and animal studies, we believe it is feasible to develop a longer-acting EPO through GlycoPEGylation. We are planning to conduct various preclinical activities during 2003 and the first half of 2004, with the goal of initiating clinical trials in the second half of 2004.

We are continuing to generate internal data on other potential proprietary drug candidates, and we expect to announce additional drug development projects at appropriate times in the future based on emerging data and market conditions. Concurrently, we are continuing to invest in the development of our core technologies, particularly new applications of our GlycoPEGylation and GlycoConjugation technologies.

Our current research and development projects are divided among two categories: (i) GlycoAdvance and GlycoPEGylation, and (ii) Other Glycotechnology Programs, which includes projects investigating other applications of our intellectual property. We are exploring the most cost-effective means of continuing some of the projects classified as Other Glycotechnology Programs. The following chart sets forth our projects in each of these categories and the stage to which each has been developed:

	<u>Development Stage</u>	<u>Status</u>
<b><u>GlycoAdvance, GlycoPEGylation and GlycoConjugation</u></b>		
Improved erythropoietin	Preclinical	Active
Other protein projects	Research	Active
<b><u>Other Glycotechnology Programs</u></b>		
Non-protein therapeutic applications	Research	Active
Nutritional applications	N/A	Evaluating Outlicensing Opportunities

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, consulting and preclinical development costs. Indirect expenses include the costs of operating and maintaining our facilities, property, and equipment, to the extent used for



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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 \$6,664,000 and \$12,284,000 for the three and six months ended June 30, 2003, respectively, and \$5,139,000 and \$10,974,000 for the comparable 2002 periods. The following table illustrates research and development expenses incurred in each period for our significant groups of research and development projects (in thousands).

	Three months ended		Six months ended	
	June 30,		June 30,	
	2002	2003	2002	2003
GlycoAdvance, GlycoPEGylation and GlycoConjugation	\$ 1,843	\$ 2,483	\$ 3,080	\$ 4,319
Other Glycotechnology Programs	549	250	1,021	384
Indirect expenses	2,747	3,931	6,873	7,581
	\$ 5,139	\$ 6,664	\$ 10,974	\$ 12,284

*GlycoAdvance, GlycoPEGylation and GlycoConjugation*

Our GlycoAdvance, GlycoPEGylation and GlycoConjugation research and development expenses increased during the 2003 periods, compared to 2002, primarily due to increased purchases of proteins, hiring of employees, and the reallocation of resources from our Other Glycotechnology Programs.

*Other Glycotechnology Programs*

Research and development expenses related to our Other Glycotechnology Programs decreased during the 2003 periods, compared to 2002, consistent with our decision during 2002 to focus our resources on our GlycoAdvance, GlycoPEGylation and GlycoConjugation programs.

*Indirect expenses*

Our indirect research and development expenses increased during the 2003 periods, compared to 2002, primarily due to increases related to depreciation of our recently completed pilot manufacturing facility, which was placed in service in January 2003, additional personnel since the second quarter of 2002, and the purchase of more supplies and outside services than in the first half of 2002. Substantially offsetting the increases during the comparable six-month periods was a reduction in severance expense of \$2,124,000, of which \$1,608,000 was a non-cash charge, related to an agreement entered into during the first quarter of 2002 with one of the our former executive officers.



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The process of bringing drugs from the preclinical research and development stage through Phase I, Phase II, and Phase III clinical trials and FDA approval is a time consuming and expensive process. Because our announced product candidates are currently in the preclinical stage and there are a variety of potential intermediate clinical outcomes that are inherent in drug

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development, we cannot reasonably estimate the timing and costs we will incur to complete these research and development projects. In addition, the timing and costs to complete our research and development projects will be affected by the timing and nature of any collaboration agreements we may enter into with a third party, neither of which we can currently estimate.

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 level of efforts committed and made by our collaborative partners. Even if we achieve technical success in developing drug candidates, our collaborative partners may not devote the resources necessary to complete development and commence marketing of these products or they may not successfully market potential products.

### *Marketing, General and Administrative Expense*

Marketing, general and administrative expenses for the three and six months ended June 30, 2003 were \$3,197,000 and \$6,201,000, respectively, compared to \$3,289,000 and \$6,209,000 for the corresponding periods in 2002. The 2002 periods included expenses associated with recruiting and relocating executives, as well as severance expense related to an agreement entered into with one of our former executive officers. The 2002 periods also included extensive consulting costs incurred in the development of the Company's strategic plan. Offsetting the decrease in those expenses in the 2003 periods were increased salary expense related to additional executive personnel, higher insurance premiums, and higher patent-related legal expenses than in the 2002 periods.

### *Interest Income and Expense*

Interest income for the three and six months ended June 30, 2003 was \$147,000 and \$317,000, respectively, compared to \$419,000 and \$848,000 for the corresponding periods in 2002. The decrease was due to lower average cash, cash equivalents and marketable securities balances during the 2003 period as well as lower interest rates during the 2003 period.

Interest expense for the three and six months ended June 30, 2003 was \$163,000 and \$200,000, respectively, compared to \$42,000 and \$82,000 for the corresponding periods in 2002. During the 2002 period, our investment in improvements to our cGMP facility and other facility improvements, as discussed in the Liquidity and Capital Resources section, was significant enough to require the capitalization of related interest costs. Because we completed construction of the improvements to our cGMP facility in December 2002, we are no longer capitalizing any interest expense.

### **Item 3. Quantitative and Qualitative Disclosure About Market Risk**

Our holdings of financial instruments are comprised primarily of government agency securities. All such instruments are classified as securities held to maturity. We seek reasonable



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assuredness of the safety of principal and market liquidity by investing in rated fixed income securities, while at the same time seeking to achieve a favorable rate of return. Our market risk exposure consists 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 June 30, 2003, we held \$10.5 million in obligations of U.S. government agencies with original maturities ranging from 132 to 139 days. The balance of our investment portfolio was held in money market securities and in obligations of U.S. government agencies with original maturities of three months or less. The approximate principal amount of our investment portfolio as of June 30, 2003 was \$42.0 million. The annualized weighted-average interest rate for the six months ended June 30, 2003 was approximately 1.5%.

We have exposure to changing interest rates on our taxable and tax-exempt bonds, and we are currently not engaged in hedging activities. Interest on approximately \$3.9 million of outstanding indebtedness is at an interest rate that varies weekly, depending on the market rates for AA-rated taxable and tax-exempt obligations. During the six months ended June 30, 2003, the annualized weighted-average, effective interest rate was approximately 2.0%.

### **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 June 30, 2003. 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 the Company in reports that it files or submits under the Exchange Act, is recorded, processed, summarized and reported as specified in Securities and Exchange Commission rules and forms. There were no significant changes in these controls or procedures, or in other factors that could significantly affect these controls or procedures, during the most recent fiscal quarter.

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

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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.

**PART II. OTHER INFORMATION**

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

- A. Our Annual Meeting of Stockholders was held on May 13, 2003.
  
- B. The motions before stockholders were:
  - 1. To elect nine Directors.