NEOSE TECHNOLOGIES INC Form 10-Q April 28, 2004

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

	_	FORM 10-Q	
(Mark One)			
X	_	ARTERLY REPORT PURSUANT T E SECURITIES EXCHANGE ACT	
	For th	ne quarterly period ended March 31, 2004.	
		OR	
0		ANSITION REPORT PURSUANT T E SECURITIES EXCHANGE ACT	
		to to the transition period from to Commission file number: 0-27718	
	NEOSE T	ECHNOLOGIES,	INC.
	(Exact na	ame of registrant as specified in its charter)	
Delaware	2		13-3549286
(State or other juri incorporation or or			(I.R.S. Employer Identification No.)
102 Witmer 1 Horsham, Penns			19044
(Address of principal ex	ecutive offices)		(Zip Code)
		(215) 315-9000	
	hether the registrant (1) he preceding 12 months (	nt s telephone number, including area code) has filed all reports required to be filed by Sec (or for such shorter period that the registrant wast 90 days.	
		Yes x No o	
Indicate by check mark whether	the registrant is an acce	elerated filer (as defined in Rule 12b-2 of the E	Exchange Act).

Yes x No o

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date: 19,948.921 shares of common stock, \$.01 par value, were outstanding as of April 20, 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)

	December 31, 2003	March 31, 2004
Assets		
Current assets:		
Cash and cash equivalents	\$ 48,101	\$ 39,917
Marketable securities	4,959	4,974
Restricted funds	901	-
Prepaid expenses and other current assets	917	1,906

Total current assets		54,878		46,797
Property and equipment, net		37,192		40,691
Acquired intellectual property, net		1,910		1,760
Other assets		865		845
Total assets	\$	94,845	\$	90,093
Liabilities and Stockholders Equity				
Current liabilities:				
Current portion of long-term debt and capital lease obligations	\$	2,231	\$	2,756
Accounts payable		2,342		1,835
Accrued compensation		2,510		1,218
Accrued expenses		2,433		2,780
Deferred revenue		4,333		4,789
Total current liabilities		13,849		13,378
Long-term debt and capital lease obligations		8,370		13,544
Other liabilities		413		331
Total liabilities		22.622		27.252
Total habilities		22,632		27,253
Stockholders equity:				
Preferred stock, \$.01 par value, 5,000 shares				
authorized, none issued		-		-
Common stock, \$.01 par value, 30,000 shares				
authorized; 19,935 and 19,949 shares issued and outstanding		199		199
Additional paid-in capital		217,849		217,966
Deferred compensation		(96)		(83)
Deficit accumulated during the development-stage		(145,739)		(155,242)
Total stockholders equity		72,213		62,840
Total liabilities and stockholders equity	\$	94,845	<u> </u>	90,093
Total Internaces and stockholders equity	<b>y</b>	77,073	Ψ	70,073
The accompanying notes are an integral na	rt of these financi	al statements		

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

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# NEOSE TECHNOLOGIES, INC.

(a development-stage company)

# STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share amounts)

		Three n	months larch 31,		Period from inception		
	2	003		2004		rch 31, 2004	
Revenue from collaborative agreements	\$	70	\$	1,250	\$	20,131	
	<u> </u>						

Operating expenses:

Research and development		5,619		7,878		134,377
Marketing, general and administrative		3,005		2,862		63,082
Total operating expenses		8,624		10,740		197,459
			-			
Operating loss		(8,554)		(9,490)		(177,328)
Other income		-		-		7,773
Impairment of equity securties		-		-		(1,250)
Interest income		170		105		19,447
Interest expense		(37)		(118)		(3,884)
Net loss	\$	(8,421)	\$	(9,503)	\$	(155,242)
100 1000	Ψ	(0,121)	Ψ	(7,505)	Ψ	(133,212)
Basic and diluted net loss per share	\$	(0.53)	\$	(0.48)		
Wile I I de l'						
Weighted-average shares outstanding used in computing basic and diluted net loss per share		15,801		19,943		

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)

	Three mor Marc	Period from inception			
	2003 2004		(January 17, 1989) to March 31, 2004		
Cash flows from operating activities:					
Net loss	\$ (8,421)	\$	(9,503)	\$	(155,242)
Adjustments to reconcile net loss to cash used in operating activities:					
Depreciation and amortization	1,048		1,347		19,274
Loss on disposition of property and equipment			-		264
Non-cash compensation	-		14		4,931
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	(888)		(1,083)		(2,314)
Accounts payable	(256)		(507)		1,835
Accrued compensation	(612)		(1,292)		799
Accrued expenses	(249)		(98)		1,480
Deferred revenue	-		456		4,789
Other liabilities	 2		(82)		(88)
Net cash used in operating activities	(9,376)		(10,748)	_	(124,237)
Cash flows from investing activities:					
Purchases of property and equipment	(353)		(3,968)		(54,531)
Proceeds from sale-leaseback of equipment	-		-		1,382
Purchases of marketable securities	(18,259)		-		(423,307)

Proceeds from sales of marketable securities		-	- 29,686
Proceeds from maturities of and other changes in marketable			
securities	10,00	0	- 389,360
Purchase of acquired technology		-	- (4,550)
Investment in equity securities		-	- (1,250)
Impairment of equity securities			1,250
		_	
Net cash used in investing activities	(8,61	2) (3,	968) (61,960)
			<u> </u>
Cash flows from financing activities:			
Proceeds from issuance of debt	2,95	4 9,	941 29,215
Repayment of debt	(11	5) (4,	426) (15,162)
Restricted cash related to debt	(30		901 -
Proceeds from issuance of preferred stock, net		-	- 29,497
Proceeds from issuance of common stock, net	16,43	5	86 176,203
Proceeds from exercise of stock options and warrants		-	30 6,608
Acquisition of treasury stock		-	- (175)
Dividends paid		-	- (72)
		_	
Net cash provided by financing activities	18,97	2 6,	532 226,114
. , ,		_	<u> </u>
Net increase (decrease) in cash and cash equivalents	98	4 (8,	184) 39,917
Cash and cash equivalents, beginning of period	31,08		
, , , , , , , , , , , , , , , , , , , ,			
Cash and cash equivalents, end of period	\$ 32,07	2 \$ 39,	917 \$ 39,917
cash and cash equivalents, the of period	÷ 32,07	-	, , , , , , , , , , , , , , , , , , ,

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 March 31, 2004;

For the three months ended March 31, 2003 and 2004; and

For the period from inception (January 17, 1989) to March 31, 2004.

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 2004 solely on our results of operations for the three months ended March 31, 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. 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 milestone is achieved.

During the three months ended March 31, 2004, we recognized revenue of \$1,250,000, all of which related to our collaboration agreements with Novo Nordisk A/S. Approximately \$215,000 of the revenue recognized during the quarter ended March 31, 2004 represented the amortization of the non-refundable, upfront fee received from Novo Nordisk upon execution of the agreements in November 2003. The remaining revenue of \$1,035,000 was recognized in connection with our research and development activities conducted under the agreements during the quarter ended March 31, 2004.

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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, next-generation version of granulocyte colony stimulating factor (G-CSF). Under the agreement, we and BioGeneriX will pursue development and commercialization of a next-generation G-CSF. The parties will share equally preclinical expenses, and 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 rest of 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 will be amortized to revenue over the expected period in which we perform activities under the agreement.

#### 3. Long-term Debt and Capital Lease Obligation

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 March 31, 2005, 2006, 2007, 2008, and 2009 we will be required to make principal repayments totaling \$204,000, \$240,000, \$261,000, \$218,000, and \$18,000, 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 \$31,000, \$34,000, \$37,000, \$40,000, and \$40,000 during the 12 months ending March 31, 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 outstanding of our 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, PA.

The interest rate on the bond and bank debt will vary quarterly, depending on LIBOR rates. We will have the option each quarter to incur interest on the outstanding principal at a LIBOR-based variable interest rate or a fixed rate offered by our bank.

For the \$1,000,000 of tax-exempt debt, 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. For the remaining \$8,000,000 borrowed, 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.

To provide credit support for these borrowings, we granted a mortgage to our 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, we

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.

# 4. Stockholders Equity

During the three months ended March 31, 2004, participating employees purchased 8,456 shares of common stock pursuant to our employee stock purchase plan, resulting in net proceeds of \$86,000. In addition, during the first quarter of 2004, we received proceeds of \$30,000 upon the exercise of options to purchase 5,250 shares of common stock.

#### 5. Separation Agreement

During the quarter ended March 31, 2003, we entered into a non-competition agreement with our former Chief Executive Officer, Stephen A. Roth. Under this agreement, we agreed 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 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 will be amortized to marketing, general and administrative expense on our statements of operations over the two-year term of the agreement. As of March 31, 2004, the present value of remaining minimum payments under this agreement was \$419,000.

# 6. 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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	111100	months ended arch 31,
	2003	2004
Net loss as reported	\$ (8,42	1) \$ (9,503)
Add: Stock-based employee compensation expense included in reported net loss	1	1 11
Deduct: Total stock-based employee compensation expense determined under fair value-based method for all awards	(3,87)	0) (2,280)
Net loss pro forma	\$ (12,28	0) \$ (11,772)
Basic and diluted net loss per share as reported	\$ (0.5)	3) \$ (0.48)
Basic and diluted net loss per share pro forma  Net Loss Per Share	\$ (0.7	8) \$ (0.59)

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 months ended March 31, 2003 and 2004, the effects of the exercise of outstanding stock options and warrants to purchase 4,650,376 and 5,116,228 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 (in thousands).

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	Three months ended March 31,  2003 2004		Period from inception (January 17, 1989)			
			2	2004	to Mar	rch 31, 2004
Supplemental disclosure of cash flow information:						
Cash paid for interest	\$	52	\$	209	\$	4,119
Non- compete agreement	\$	882	\$	-	\$	882
					_	
Non-cash investing activities:						
Increase (decrease) in accrued property and equipment	\$	(41)	\$	445	\$	1,300
Assets acquired under capital leases and tenant improvement loan	\$	-	\$	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

# 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

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 renovate our facilities as required 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 meet forecasted project timelines;
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 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

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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 March 31, 2004, we had an accumulated deficit of approximately \$155.2 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, potentially, begin sales and marketing activities. 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, cash equivalents, and marketable securities, expected revenue from collaborations and license arrangements, proceeds under the agreements with a bank we entered into during the three months ended March 31, 2004, and interest income should be sufficient to meet our operating and capital requirements into 2005, although changes in our collaborative relationships or our business, whether or not initiated by us, may cause us to deplete our cash, cash equivalents, and marketable securities sooner than the above estimate.

Under our agreements with a bank we entered into during the three months ended March 31, 2004, we have agreed to limit our total outstanding debt to \$22.0 million. As of March 31, 2004, our total outstanding debt was approximately \$16.3 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 Long-term Debt Proceeds from 2004 Arrangements 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 \$44,891,000 in cash, cash equivalents, and marketable securities as of March 31, 2004, compared to \$53,060,000 as of December 31, 2003. The decrease for 2004 was primarily attributable to the use of cash to fund our operating activities, capital expenditures, and debt repayments. These uses of cash were partially offset by proceeds from debt financings and cash inflows from our collaborative agreements.

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. Because our 2004 revenues could be substantially affected by entering into new collaborations and on the financial terms of any new collaborations, we cannot estimate our 2004 revenues. Other than revenues from our collaborations with Novo Nordisk and BioGeneriX, and any future collaborations with others, 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

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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 2004.

Significant 2004 Cash Flows

During the three months ended March 31, 2004, our operating activities consumed \$10,749,000. In addition, we invested \$3,968,000 in capital expenditures, and made debt principal repayments of \$4,426,000. Partially offsetting these expenditures were \$9,941,000 in proceeds from debt financings and \$901,000 from the use of restricted cash to make debt repayments. We also entered into a capital lease obligation during the three months ended March 31, 2004 for equipment with an aggregate book value of \$184,000. During the three months ended March 31, 2004, participating employees purchased 8,456 shares of common stock pursuant to our employee stock purchase plan, resulting in net proceeds of \$86,000. In addition, during the first quarter of 2004, we received proceeds of \$30,000 upon the exercise of options to purchase 5,250 shares of common stock.

Long-term Debt Proceeds from 2004 Arrangements

In this section, we describe the material features of our new issuances of debt, and capital lease obligations entered into, during 2004. In the following section, Long-term Debt Other Arrangements, we describe the material features of long-term debt arrangements entered into in prior years.

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 outstanding of our 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, PA.

Initially, the interest rate on the bond and bank debt will vary quarterly, depending on LIBOR rates. We will have the option each quarter to incur interest on the outstanding principal at a LIBOR-based variable interest rate or a fixed rate offered by our bank.

For the \$1,000,000 of tax-exempt debt, we will make quarterly, interest-only payments on the related \$1,000,000 debt for ten years followed by a single repayment of principal at the end of the ten-year loan period. For the remaining \$8,000,000 borrowed, 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 payments over the remaining nine years of the ten-year loan period.

To provide credit support for these borrowings, we granted a mortgage to our 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, we agreed to limit our total outstanding debt to \$22,000,000. As of March 31, 2004, our total

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outstanding debt was \$16,300,000. 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.

Equipment Loan

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 March 31, 2005, 2006, 2007, 2008, and 2009 we will be required to make principal and interest payments totaling \$267,000, \$291,000, \$291,000, \$292,000, and \$19,000, respectively, under this agreement.

2004 Capital Lease Obligation

In February 2004, we entered in to 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 \$42,000 during the 12 months ending March 31, 2005, 2006, 2007, 2008, and 2009, respectively.

Long-term Debt Other Arrangements

In this section, we describe the material features of our debt arrangements that did not involve new borrowings during 2004. In the previous section, Long-term Debt Proceeds from 2004 Arrangements, we describe the material features of long-term debt arrangements entered into during 2004.

**Equipment Loans** 

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 March 31, 2005, 2006, 2007, and 2008, we will be required to make principal and interest payments totaling \$366,000, \$366,000, \$359,000, and \$269,000, 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 March 31, 2005, 2006, 2007, and 2008, we will be required to make principal and interest payments totaling \$269,000, \$269,000, \$224,000, and \$93,000, 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

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principal and interest payments over 42 months at an interest rate of 8.35%. During the 12 months ending March 31, 2005, 2006, and 2007, we will be required to make principal and interest payments totaling \$976,000, \$976,000, and \$570,000, respectively, under this agreement.

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 March 31, 2005 and 2006, we will be required to make principal and interest payments totaling \$850,000 and \$708,000, respectively, under this agreement.

#### Capital Lease Obligations

In September 2003, we entered into a capital lease for \$354,000 of equipment. The terms of the lease required 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, \$99,000, and \$50,000 during the 12 months ending March 31, 2005, 2006, and 2007, 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, \$16,000, \$16,000, and \$8,000 during the 12 months ending March 31, 2005, 2006, 2007, 2008, and 2009, respectively.

In June 2003, we entered into a capital lease for \$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. Under this agreement, we will be required to make lease payments totaling \$37,000, \$37,000, and \$9,000 during the 12 months ending March 31, 2005, 2006, and 2007, 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, \$96,000, and \$4,000 during the 12 months ending March 31, 2005, 2006, and 2007, 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 \$14,000 during the 12 months ending March 31, 2005 and 2006, respectively.

#### Capital Expenditures

During the three months ended March 31, 2004, we invested \$3,968,000 in property, equipment, and building improvements. Of this amount, \$3,430,000 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. We anticipate additional capital expenditures during 2004 of approximately \$6.0 million, of which \$1.3 million was accrued at March 31, 2004 for 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.

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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. Later in 2002, we suspended plans to complete these renovations. In November 2003, we reinitiated renovation activities at an expected additional cost of \$6,300,000, which was incremental to \$4,081,000 previously invested in these renovations, on approximately 25,000 square feet of the facility, leaving approximately 15,000 square feet available for future expansion. Our construction-in-progress at March 31, 2004 included \$9,101,000 in renovations to this facility. During the three months ended March 31, 2004, we entered into agreements with a bank for the purpose of funding these improvements. See Long-term Debt Proceeds from 2004 Arrangements Credit Agreement in the Liquidity and Capital Resources section of this Form 10-Q for a description of the material features of this borrowing.

#### **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. The Liquidity and Capital Resources section of this Form 10-Q describes additional obligations from contracts entered into during the three months ended March 31, 2004.

## **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 three months ended March 31, 2004.

#### **Results of Operations**

Our net loss for the three months ended March 31, 2003 and 2004 was \$8,421,000 and \$9,503,000, respectively. 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 months ended March 31, 2003 and 2004 were \$70,000 and \$1,250,000, respectively. Our revenues from collaborative agreements have historically been derived from a few major collaborators. Our collaborative agreements provide for some or all of the following elements: upfront fees, research and development funding, milestone revenues, and royalties on product sales.

All of the revenues recognized during the three months ended March 31, 2004 related to

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our collaboration agreements with Novo Nordisk A/S. Approximately \$215,000 of the revenue recognized during the quarter ended March 31, 2004 represented the amortization of the non-refundable, upfront fee received from Novo Nordisk upon execution of the agreements in November 2003. The remaining revenue of \$1,035,000 was recognized in connection with our research and development activities conducted under the agreements during the quarter ended March 31, 2004. During the three months ended March 31, 2003, we recognized revenue of \$70,000 under a research and development collaboration.

Because our 2004 revenues could be substantially affected by entering into new collaborations and on the financial terms of any new collaborations, we cannot estimate our 2004 revenues.

## 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 proof-of-concept data, we believe it is feasible to develop a long acting EPO through GlycoPEGylation. During 2004, we are planning to continue various preclinical development activities.

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 proof-of-concept data, we believe it is feasible to develop a long acting G-CSF through GlycoPEGylation. During 2004, we are planning to continue various preclinical development activities.

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, next-generation version of G-CSF. Under the agreement, we and BioGeneriX will pursue development and commercialization of a next-generation G-CSF. The parties will share equally preclinical expenses, and 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 rest of 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 will be amortized to revenue over the expected period in which we perform activities under the agreement.

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.

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

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partnering and licensing program. 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. 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:

	Development Stage	Status
GlycoAdvance and GlycoPEGylation		
Improved erythropoietin	Preclinical	Active
Improved granulocyte colony stimulating factor	Preclinical	Active
Other protein projects	Research	Active
Other Glycotechnology Programs		
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 and manufacturing, consulting, and preclinical 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 \$5,619,000 and \$7,878,000 for the three months ended March 31, 2003 and 2004, respectively. We expect our research and development expenses to be significantly greater in 2004 than they were in 2003, as a result of the development and preclinical activities we plan to conduct during the year. 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).

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	Т	hree months	ended Ma	rch 31,
		2003		2004
GlycoAdvance and GlycoPEGylation	\$	1,836	\$	3,542
Other Glycotechnology Programs		133		66
Indirect expenses		3,650		4,270
		-		
	\$	5,619	\$	7,878
	_			

GlycoAdvance and GlycoPEGylation

Our GlycoAdvance and GlycoPEGylation research and development expenses increased during the 2004 periods, compared to 2003, primarily due to hiring of additional employees and increased purchases of supplies and outside services, including preclinical studies, associated with our proprietary drug development programs and our agreements with Novo Nordisk.

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 and GlycoPEGylation 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 and depreciation of capital expenditures.

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 and non-clinical outcomes that are inherent in drug 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

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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 months ended March 31, 2003 and 2004 were \$3,005,000 and \$2,862,000, respectively. This decrease is consistent with a slightly lower general and administrative headcount in 2004, as well as some savings in consulting and travel. During 2004, we expect our marketing, general and administrative expenses to increase by less than 10% over 2003.

Interest Income and Expense

Interest income for the three months ended March 31, 2003 and 2004 was \$170,000 and \$105,000, respectively. The decrease during the 2004 period is due to lower average cash, cash equivalents and marketable securities balances as well as lower interest rates.

Interest expense for the three months ended March 31, 2003 and 2004 was \$37,000 and \$118,000, respectively. The increase in the 2004 period is due to higher average debt balances. We expect our interest expense during 2004 to increase due to our entering into an agreement in January 2004 to borrow \$9,000,000, all of which was borrowed during the first quarter of 2004. See Long-term Debt Proceeds from 2004 Arrangements Credit Agreement in the Liquidity and Capital Resources section of this Form 10-Q for a description of the material features of this debt financing.

## 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 assuredness of the safety of principal and market liquidity by investing in fixed income rated 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 March 31, 2004, we held \$4.9 million in an obligation of a U.S. government agency with an original maturity of 347 days. The balance of our investment portfolio was held in money market securities. The approximate principal amount of our investment portfolio as of March 31, 2004 was \$44.9 million. The annualized weighted-average interest rate for the three months ended March 31, 2004 was approximately 0.8%.

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 LIBOR rates. During the three months ended March 31, 2004, the annualized weighted-average, interest rate was approximately 4.0%.

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#### 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 March 31, 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 and Reports on Form 8-K.

(a) List of Exhibits:

10.1 Promissory Note of the Company to General Electric Capital Corporation, dated March 30, 2004.

- 10.2 Financing Agreement by and among Montgomery County Industrial Development Authority, the Company and Brown Brothers Harriman & Co., dated February 23, 2004.
- 0.3 General Security Agreement by the Company to Brown Brothers Harriman & Co., dated February 23, 2004.

- 10.4 Open-end Mortgage and Security Agreement by and between the Company and Brown Brothers Harriman & Co., dated February 23, 2004.
- 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.
- (b) Reports on Form 8-K:

On February 12, 2004, we filed a Current Report on Form 8-K announcing our fourth quarter and year end financial results for 2003.

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## **SIGNATURES**

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

NEOSE TECHNOLOGIES, INC.

Date: April 28, 2004 By: /s/ Robert I. Kriebel

Robert I. Kriebel Senior Vice President and Chief Financial Officer (Principal Financial Officer and Duly Authorized Signatory)