

NEOSE TECHNOLOGIES INC

Form 10-Q

November 06, 2003

Table of Contents

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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)

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-Q

Delaware
(State or other jurisdiction of
incorporation or organization)

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

102 Witmer Road
Horsham, Pennsylvania
(Address of principal executive offices)

19044
(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: 19,935,215 shares of common stock, \$.01 par value, were outstanding as of October 31, 2003.

Table of Contents

NEOSE TECHNOLOGIES, INC.

(a development-stage company)

INDEX

	<u>Page</u>
PART I.	
	<u>FINANCIAL INFORMATION:</u>
Item 1.	Financial Statements (unaudited)
<u>Balance Sheets at December 31, 2002 and September 30, 2003</u>	3
<u>Statements of Operations for the three and nine months ended September 30, 2002 and 2003, and for the period from inception through September 30, 2003</u>	4
<u>Statements of Cash Flows for the nine months ended September 30, 2002 and 2003, and for the period from inception through September 30, 2003</u>	5
<u>Notes to Financial Statements</u>	6
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
	11
Item 3.	<u>Quantitative and Qualitative Disclosure About Market Risk</u>
	20
Item 4.	<u>Controls and Procedures</u>
	21
PART II.	
	<u>OTHER INFORMATION:</u>
Item 6.	<u>Exhibits and Reports on Form 8-K</u>
	22
<u>SIGNATURES</u>	23

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)

	December 31, 2002	September 30, 2003
	<u> </u>	<u> </u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 31,088	\$ 41,332
Marketable securities	9,952	14,834
Restricted funds	977	600
Prepaid expenses and other current assets	558	953
	<u> </u>	<u> </u>
Total current assets	42,575	57,719
Property and equipment, net	36,508	36,312
Acquired intellectual property, net	2,507	2,059
Other assets	1,502	889
	<u> </u>	<u> </u>
Total assets	<u>\$ 83,092</u>	<u>\$ 96,979</u>
Liabilities and Stockholders Equity		
Current liabilities:		
Current portion of long-term debt and capital lease obligations	\$ 1,851	\$ 3,123
Accounts payable	1,127	1,018
Accrued compensation	1,339	2,024
Accrued expenses	1,880	1,593
Deferred revenue	320	70
	<u> </u>	<u> </u>
Total current liabilities	6,517	7,828
Long-term debt and capital lease obligations	5,560	6,728
Other liabilities	330	529
	<u> </u>	<u> </u>
Total liabilities	12,407	15,085
	<u> </u>	<u> </u>
Stockholders' equity:		
Preferred stock, \$.01 par value, 5,000 shares authorized, none issued		

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-Q

Common stock, \$.01 par value, 30,000 shares authorized; 14,330 and 19,935 shares issued; 14,324 and 19,935 shares outstanding	143	199
Additional paid-in capital	178,945	217,850
Treasury stock, 6 shares at cost	(175)	
Deferred compensation	(170)	(112)
Deficit accumulated during the development-stage	(108,058)	(136,043)
	<u>70,685</u>	<u>81,894</u>
Total stockholders' equity		
	<u>\$ 83,092</u>	<u>\$ 96,979</u>
Total liabilities and stockholders' equity		

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

Table of Contents**NEOSE TECHNOLOGIES, INC.**

(a development-stage company)

STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share amounts)

	Three months ended September 30,		Nine months ended September 30,		Period from inception (January 17, 1989) to September 30, 2003
	2002	2003	2002	2003	
Revenue from collaborative agreements	\$ 2,187	\$ 150	\$ 4,519	\$ 871	\$ 18,317
Operating expenses:					
Research and development	5,285	6,747	16,259	19,031	118,710
Marketing, general and administrative	3,197	2,456	9,405	8,657	57,728
Total operating expenses	8,482	9,203	25,664	27,688	176,438
Operating loss	(6,295)	(9,053)	(21,145)	(26,817)	(158,121)
Other income					7,773
Impairment of equity securities		(1,250)		(1,250)	(1,250)
Interest income	378	103	1,225	420	19,198
Interest expense	(38)	(138)	(120)	(338)	(3,643)
Net loss	\$ (5,955)	\$ (10,338)	\$ (20,040)	\$ (27,985)	\$ (136,043)
Basic and diluted net loss per share	\$ (0.42)	\$ (0.59)	\$ (1.41)	\$ (1.66)	
Weighted-average shares outstanding used in computing basic and diluted net loss per share	14,310	17,437	14,238	16,828	

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

Table of Contents**NEOSE TECHNOLOGIES, INC.**

(a development-stage company)

STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Nine months ended September 30,		Period from inception (January 17, 1989) to September 30, 2003
	2002	2003	
Cash flows from operating activities:			
Net loss	\$ (20,040)	\$ (27,985)	\$ (136,043)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	1,687	3,511	16,620
Loss on disposition of property and equipment		99	99
Non-cash compensation	1,139	129	4,902
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	(1,648)	(370)	(1,180)
Accounts payable	501	(109)	1,018
Accrued compensation	840	222	1,605
Accrued expenses	(1,257)	(250)	1,528
Deferred revenue	(1,208)	(250)	70
Other liabilities	45	(220)	110
Net cash used in operating activities	(19,941)	(25,223)	(111,236)
Cash flows from investing activities:			
Purchases of property and equipment	(14,794)	(2,137)	(49,245)
Proceeds from sale-leaseback of equipment			1,382
Purchases of marketable securities	(68,412)	(38,568)	(423,306)
Proceeds from sales of marketable securities		8,327	19,794
Proceeds from maturities of and other changes in marketable securities	31,000	25,500	389,360
Purchase of acquired technology			(4,550)
Investment in equity securities			(1,250)
Impairment of equity securities		1,250	1,250
Net cash used in investing activities	(52,206)	(5,628)	(66,565)
Cash flows from financing activities:			
Proceeds from issuance of debt		3,785	18,001
Repayment of debt	(1,100)	(2,132)	(10,284)
Restricted cash related to debt	227	377	(529)
Proceeds from issuance of preferred stock, net			29,497
Proceeds from issuance of common stock, net		38,893	176,117

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-Q

Proceeds from exercise of stock options and warrants	1,961	172	6,578
Acquisition of treasury stock			(175)
Dividends paid			(72)
	<u> </u>	<u> </u>	<u> </u>
Net cash provided by financing activities	1,088	41,095	219,133
	<u> </u>	<u> </u>	<u> </u>
Net increase (decrease) in cash and cash equivalents	(71,059)	10,244	41,332
Cash and cash equivalents, beginning of period	76,245	31,088	
	<u> </u>	<u> </u>	<u> </u>
Cash and cash equivalents, end of period	\$ 5,186	\$ 41,332	\$ 41,332
	<u> </u>	<u> </u>	<u> </u>

The accompanying notes are an integral part of these financial statements

Table of Contents

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 September 30, 2003;

For the three and nine months ended September 30, 2002 and 2003; and

For the period from inception (January 17, 1989) to September 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 nine months ended September 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

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-Q

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 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):

Table of Contents

	Three months ended September 30,		Nine months ended September 30,	
	2002	2003	2002	2003
Net loss as reported	\$ (5,955)	\$ (10,338)	\$ (20,040)	\$ (27,985)
Add: Stock-based employee compensation expense included in reported net loss	21	72	141	104
Deduct: Total stock-based employee compensation expense determined under fair value-based method for all awards	(4,160)	(3,159)	(11,209)	(9,409)
Net loss pro forma	\$ (10,094)	\$ (13,425)	\$ (31,108)	\$ (37,290)
Basic and diluted net loss per share as reported	\$ (0.42)	\$ (0.59)	\$ (1.41)	\$ (1.66)
Basic and diluted net loss per share pro forma	\$ (0.71)	\$ (0.77)	\$ (2.18)	\$ (2.22)

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.

During the three months ended September 30, 2003, we recognized revenue of \$150,000 under a research and development collaboration. During the three months 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 2002. We also recorded revenue of \$400,000 under a license agreement during the quarter ended June 30, 2003. During the three months ended March 31, 2003, we recognized revenue of \$70,000 under a research and development collaboration.

Table of Contents

During the three and nine months ended September 30, 2002, we recognized \$2,177,000 and \$4,458,000, respectively, under two collaborations with Wyeth. Our collaboration with Wyeth Pharmaceuticals was terminated in September 2002. Of the \$2,177,000 recognized in the third quarter, \$875,000 represented the remaining amortization of a \$1,000,000 up-front fee, which we received from Wyeth in 2001. As required under SAB 101, we deferred the up-front fee and began to amortize this amount as revenue over the expected performance period of the Wyeth agreement. Upon termination of the Wyeth agreement in the third quarter of 2002, the unamortized portion of the up-front fee was recognized as revenue.

4. Long-term Debt and Capital Lease Obligations

In September 2003, we borrowed \$831,000 to finance the purchase of equipment and facility improvements, which are collateralizing the amount borrowed. The terms of the financing require us to pay monthly principal and interest payments over 48 months at an interest rate of 8.35%. During the 12 months ending September 30, 2004, 2005, 2006, and 2007, we will be required to make principal repayments totaling \$190,000, \$224,000, \$243,000, and \$174,000, respectively, under this agreement.

In September 2003, we entered into a capital lease obligation for equipment with a book value of \$354,000, which was calculated using an assumed incremental annual borrowing rate of 7.96%. The terms of the lease required us to make an initial payment of \$90,000 followed by monthly payments through September 2006. During the 12 months ending September 30, 2004, 2005, and 2006, we will be required to make principal repayments totaling \$81,000, \$88,000, and \$95,000, respectively, under this agreement. We also entered into a capital lease obligation during September 2003 for software with a fair value of \$60,000. The terms of the lease require us to make monthly payments through September 2008. During the 12 months ending September 30, 2004, 2005, 2006, 2007, and 2008, we will be required to make principal repayments totaling \$9,000, \$11,000, \$12,000, \$13,000, and \$15,000, respectively, under this agreement.

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 April 2006 to June 2006. During the 12 months ending September 30, 2004, 2005, and 2006, we will be required to make principal repayments totaling \$108,000, \$121,000, and \$77,000, respectively, under these agreements.

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 October 2006. During the 12 months ending September 30, 2004, 2005, 2006, and 2007, we will be required to make principal repayments totaling \$785,000, \$853,000, \$927,000, and \$81,000, respectively, under this agreement.

Table of Contents

5. Stockholders Equity

In September 2003, we sold 2,655,557 shares of common stock in a registered offering to a group of institutional and individual investors at a price of \$9.00 per share, generating net proceeds of \$22,377,000. 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.

During the nine months ended September 30, 2003, options to purchase 62,780 shares of our common stock were exercised at an aggregate exercise price of \$172,000. In addition, during the nine months ended September 30, 2003, employees participating in our employee stock purchase plan purchased 25,836 shares of common stock at a total purchase price of \$196,000. In connection with the employee stock purchases, we reissued 6,000 shares of treasury stock, which were originally acquired in 2001 for \$175,000.

6. Separation and Retirement Agreements

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 marketing, 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. Other Assets

In 2000, we made an investment of \$1,250,000 in Series A convertible preferred stock of Neuronix, Inc., and entered into a research and development collaboration with Neuronix for the discovery and development of drugs for treating Parkinson's disease and other neurological diseases. We recorded the equity investment at cost. In October 2003, Neuronix informed us that they were nearing completion of a Series C equity financing, under which Series C and Series B Neuronix investors would have an

Table of Contents

aggregate liquidation preference that is senior to the Series A liquidation preference and exceeds the assumed post-money valuation of Neuronyx. As a result, we reduced the carrying value of our equity investment to zero as of September 30, 2003 by recording a non-cash charge, which is reflected as an impairment of equity securities in our statements of operations.

8. Net Loss Per Share

Basic and diluted net loss per share are presented in conformity with Statement of Financial Accounting Standards No. 128, Earnings Per Share. Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share reflects the potential dilution from the exercise or conversion of securities into common stock. For the three and nine months ended September 30, 2002 and 2003, the effects of the exercise of outstanding stock options and warrants to purchase 3,713,319 and 4,323,234 shares, respectively, were antidilutive; accordingly, they were excluded from the calculation of diluted net loss per share.

9. Supplemental Disclosure of Cash Flow Information

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

	Nine months		Period from inception (January 17, 1989) to September 30, 2003
	ended September 30, 2002	2003	
Supplemental disclosure of cash flow information:			
Cash paid for interest	\$ 86	\$ 352	\$ 3,797
Non-compete agreement	\$	\$ 882	\$ 882
Non-cash investing activities:			
Increase / (decrease) in accrued property and equipment	\$	\$ (37)	\$ 65
Non-cash financing activities:			
Issuance of common stock for dividends	\$	\$	\$ 90
Issuance of common stock to employees in lieu of cash compensation	\$	\$	\$ 44

10. New Accounting Pronouncements

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-Q

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 Statement of Financial Accounting Standard No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity (SFAS No. 150). 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.

Table of Contents

In November 2002, the FASB issued Interpretation No. 45, Guarantor's Accounting and Disclosure Requirement for Guarantees, Including Indirect Guarantees of Indebtedness to Others, an Interpretation of FASB Statements No. 5, 57 and 107 and a Rescission of FASB Interpretation No. 34. This Interpretation elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under guarantees issued. The Interpretation also clarifies that a guarantor is required to recognize, at inception of a guarantee, a liability for the fair value of the obligation undertaken. The initial recognition and measurement provisions of the Interpretation are applicable to guarantees issued or modified after December 31, 2002, and did not have a material effect on our financial statements.

In January 2003, the FASB issued Interpretation No. 46, Consolidation Of Variable Interest Entities, and An Interpretation Of ARB No. 51. This Interpretation addresses the consolidation by business enterprises of variable interest entities as defined in the Interpretation. This Interpretation applies immediately to variable interests in variable interest entities created after January 31, 2003, and in the first fiscal year or interim period ending after December 15, 2003 to variable interests in variable interest entities created prior January 31, 2003. The Company does not believe that it has any variable interest entities.

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;

Table of Contents

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 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 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 achievements. We do not assume responsibility for the accuracy and completeness of the forward-looking statements other than as required by applicable law.

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-Q

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.

Table of Contents

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 or the lack of glycosylation. We are using our GlycoAdvance and GlycoPEGylation technologies to develop improved versions of currently marketed drugs with proven efficacy and to improve the therapeutic profiles of glycoproteins in development. We do this by completing the carbohydrate chains on glycosylated proteins or initiating and extending glycosylation on non-glycosylated proteins. As a final step, we typically attach a sugar molecule linked to polyethylene glycol (PEG). Our goal is to offer next-generation proteins with significant advantages over first-generation drugs that are now on the market, such as 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 utilizing our technologies for the product design and manufacturing processes of other biotechnology and pharmaceutical companies. In addition to 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 September 30, 2003, we had an accumulated deficit of approximately \$136.0 million. We expect additional losses in 2003 and over the next several years as we expand product research and development efforts and increase manufacturing scale-up activities.

Liquidity and Capital Resources

Overview

We have incurred operating losses each year since our inception. As of September 30, 2003, we had an accumulated deficit of \$136,043,000. 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 financings, revenues from corporate collaborations and gains from the sale of investments. We had \$56,166,000 in cash, cash equivalents and marketable securities as of September 30, 2003, compared to \$41,040,000 in cash, cash equivalents and marketable securities as of December 31, 2002. The increase during 2003 was primarily attributable to the net proceeds from our February 2003 and September 2003 equity financings as discussed below, offset by the use of cash to fund our operating losses and capital expenditures.

In September 2003, we sold 2,655,557 shares of common stock in a registered offering to a group of institutional and individual investors, generating net proceeds of \$22,377,000. 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 2004, although changes in our collaborative relationships or our business, whether or not initiated by us, may cause us to deplete our cash

Table of Contents

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 the risks and uncertainties listed and referenced above.

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 2004.

Capital Expenditures

During the nine months ended September 30, 2003, we invested \$2,137,000 in property, equipment, and building improvements. We anticipate additional capital expenditures during 2003 of approximately \$1.5 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. Later in 2002, we suspended work on these renovations. We are now making plans to resume work on a portion of this space. Our property and equipment at September 30, 2003 included approximately \$4,056,000 in renovations to this facility. If we were to determine that 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 were to resume and fully complete the entire project at this time, the additional cost would be approximately \$8.5 million.

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 September 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 nine months ended September 30, 2003, the weighted-average, effective interest rate was 2.4% per year, including letter-of-credit and other fees. The terms of the bond

Table of Contents

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 September 30, 2003, we had restricted funds relating to the bonds of \$600,000, 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 \$650,000 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 September 30, 2003, we were required to maintain \$7,800,000 of cash and short-term investments.

Equipment Loans

In September 2003, we borrowed \$831,000 to finance the purchase of equipment and facility improvements, which are collateralizing the amount borrowed. The terms of the financing require us to pay monthly principal and interest payments over 48 months at an interest rate of 8.35%. During the 12 months ending September 30, 2004, 2005, 2006, and 2007, we will be required to make principal and interest payments totaling \$214,000, \$269,000, \$269,000, and \$182,000, respectively, under this agreement.

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 12 months ending September 30, 2004, 2005, and 2006, we will be required to make principal and interest payments totaling \$976,000, \$976,000, \$976,000, and \$81,000, respectively, 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 12 months ending September 30, 2004, 2005, and 2006, we will be required to make principal and interest payments totaling \$850,000, \$850,000, and \$283,000, 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 during each of the 12 months ending September 30, 2004, 2005, and 2006. We also entered into a capital lease obligation during September 2003 for \$60,000 of software. The terms of the lease require us to make monthly payments through September 2008. Under this agreement, we will be required to make lease payments totaling \$16,000 during each of the 12 months ending September 30, 2004, 2005, 2006, 2007, and 2008.

Table of Contents

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. During the 12 months ending September 30, 2004, 2005, and 2006, we will be required to make lease payments totaling \$34,000, \$37,000, and \$28,000, respectively, under this agreement.

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. During the 12 months ending September 30, 2004, 2005, and 2006, we will be required to make lease payments totaling \$96,000, \$96,000, and \$51,000, respectively, under these agreements.

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 through November 2005. During the 12 months ending September 30, 2004, 2005, and 2006, we will be required to make lease payments totaling \$19,000, \$19,000, and \$5,000, respectively, 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 nine months ended September 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. There have not been any changes or additions to our significant accounting policies during the nine months ended September 30, 2003.

Results of Operations

Our net loss for the three and nine months ended September 30, 2003 was \$10,338,000 and \$27,985,000, respectively, compared to \$5,955,000 and \$20,040,000 for the corresponding periods in 2002. The following section explains the changes between the reporting periods in each component of net loss.

Table of Contents

Revenue from Collaborative Agreements

Revenues from collaborative agreements for the three and nine months ended September 30, 2003 were \$150,000 and \$871,000, respectively, compared to \$2,187,000 and \$4,519,000 for the corresponding periods in 2002.

During the three months ended September 30, 2003, we recognized revenue of \$150,000 under a research and development collaboration. During the three months 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 received in October 2002. During the quarter ended June 30, 2003, we also recognized revenue of \$400,000 under a license agreement. During the three months ended March 31, 2003, we recognized revenue of \$70,000 under a research and development collaboration.

During the three and nine months ended September 30, 2002, we recognized \$2,177,000 and \$4,458,000, respectively, under two collaborations with Wyeth. Our collaboration with Wyeth Pharmaceuticals was terminated in September 2002. Of the \$2,177,000 recognized in the third quarter, \$875,000 represented the remaining amortization of a \$1,000,000 up-front fee received from Wyeth in 2001. As required under SAB 101, we deferred the up-front fee and began to amortize this amount as revenue over the expected performance period of the Wyeth agreement. Upon termination of the Wyeth agreement in the third quarter of 2002, the unamortized portion of the up-front fee was recognized as revenue.

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. We are planning to conduct various preclinical development activities during 2003 and the first half of 2004, with the goal of submitting an investigational new drug application during the third quarter of 2004.

In October 2003, we announced the selection of an improved granulocyte colony stimulating factor (G-CSF) as the target for our second proprietary drug development project. G-CSF is prescribed to stimulate production of white blood cells, 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. We are planning to conduct various preclinical development activities during 2003 and 2004, with the goal of submitting an investigational new drug application during the middle of 2005.

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.

Table of Contents

Our current research and development projects are divided between two categories: (i) GlycoAdvance, GlycoPEGylation, and GlycoConjugation 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>
<u>GlycoAdvance, GlycoPEGylation and GlycoConjugation</u>		
Improved erythropoietin	Preclinical	Active
Improved granulocyte colony stimulating factor	Preclinical	Active
Other protein projects	Research	Active
<u>Other Glycotechnology Programs</u>		
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 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 \$6,747,000 and \$19,031,000 for the three and nine months ended September 30, 2003, respectively, and \$5,285,000 and \$16,259,000 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		Nine months ended	
	September 30,		September 30,	
	2002	2003	2002	2003
GlycoAdvance, GlycoPEGylation and GlycoConjugation	\$ 2,013	\$ 2,535	\$ 5,093	\$ 6,854
Other Glycotechnology Programs	608	84	1,629	468
Indirect expenses	2,664	4,128	9,537	11,709
	\$ 5,285	\$ 6,747	\$ 16,259	\$ 19,031

Table of Contents

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 supplies and outside services, including preclinical studies, 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, additional personnel, and the purchase of more supplies and outside services. Substantially offsetting the increases during the comparable nine-month period 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 our former executive officers.

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 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 effort 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

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-Q

Marketing, general and administrative expenses for the three and nine months ended September 30, 2003 were \$2,456,000 and \$8,657,000, respectively, compared to \$3,197,000 and \$9,405,000 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

Table of Contents

agreement entered into with one of our former executive officers. The 2002 periods also included 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 and higher insurance premiums than in the 2002 periods.

Impairment of Equity Securities, Interest Income and Interest Expense

Impairment of equity securities for the three and nine months ended September 30, 2003 was \$1,250,000, and consists of a non-cash impairment charge relating to our investment in Series A convertible preferred stock of Neuronix, Inc. We recorded the equity investment, which was made in 2000, at cost. In October 2003, Neuronix informed us that they were nearing completion of a Series C equity financing, under which Series C and Series B Neuronix investors would have an aggregate liquidation preference that is senior to the Series A liquidation preference and exceeds the assumed post-money valuation of Neuronix. As a result, we reduced the carrying value of our equity investment to zero as of September 30, 2003 by recording the non-cash impairment charge.

Interest income for the three and nine months ended September 30, 2003 was \$103,000 and \$420,000, respectively, compared to \$378,000 and \$1,225,000 for the corresponding periods in 2002. The decreases during the 2003 periods were due to lower average cash, cash equivalents and marketable securities balances as well as lower interest rates.

Interest expense for the three and nine months ended September 30, 2003 was \$138,000 and \$338,000, respectively, compared to \$38,000 and \$120,000 for the corresponding periods in 2002. The increases in the 2003 periods were due to higher average debt balances and a reduction in capitalized interest due to the completion of improvements to our cGMP facility. 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. Since we completed construction of the improvements to our cGMP facility in December 2002, we have not capitalized 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 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 September 30, 2003, we held \$14.8 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 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 September 30, 2003 was \$56.1 million. The annualized weighted-average interest rate for the nine months ended September 30, 2003 was approximately 1.3%.

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

Table of Contents

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 nine months ended September 30, 2003, the annualized weighted-average, effective interest rate was approximately 2.4%.

Item 4. Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act), for financial reporting as of September 30, 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 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.

Table of Contents

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 September 17, 2003.

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 August 7, 2003, we filed a Current Report on Form 8-K announcing our second quarter financial results.

On September 22 and 23, 2003, we filed Current Reports on Form 8-K announcing our agreement to sell registered shares of the Company's Common Stock for approximately \$23 million.

Table of Contents

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: November 5, 2003

By:

/s/ Robert I. Kriebel

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

Signatory)