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NEOSE TECHNOLOGIES INC
Form 10-Q
November 14, 2001

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, 2001.

OR

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

For the transition period from _____ to _____

Commission file number: 0-27718

NEOSE TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

Delaware

13-3549286

(State or other jurisdiction of
incorporation or organization)

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

102 Witmer Road
Horsham, Pennsylvania

19044

(Address of principal executive offices)

(Zip Code)

(215) 441-5890

(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

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Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 14,052,214 shares of common stock, \$.01 par value, were outstanding as of October 31, 2001.

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

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PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

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

CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands, except per share amounts)

| | December 31, 2000 | September 30 |
|--|-------------------|--------------|
| | ----- | ----- |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 66,989 | \$ 31,62 |
| Marketable securities | 27,773 | 51,81 |
| Restricted funds | 893 | 62 |
| Prepaid expenses and other current assets | 583 | 58 |
| | ----- | ----- |
| Total current assets | 96,238 | 84,65 |
| Property and equipment, net | 13,577 | 17,19 |
| Other assets | 4,953 | 4,50 |
| | ----- | ----- |
| Total assets | \$ 114,768 | \$ 106,35 |
| | ===== | ===== |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Current portion of long-term debt | \$ 1,100 | \$ 1,10 |
| Accounts payable | 83 | 3 |
| Accrued compensation | 601 | 63 |
| Accrued expenses | 1,527 | 81 |
| Deferred revenue | 389 | 26 |
| | ----- | ----- |
| Total current liabilities | 3,700 | 2,84 |
| Long-term debt | 6,200 | 5,10 |
| | ----- | ----- |
| Total liabilities | 9,900 | 7,94 |
| | ----- | ----- |
| Stockholders' equity: | | |
| Preferred stock, \$.01 par value, 5,000 shares authorized, none issued | - | - |
| Common stock, \$.01 par value, 30,000 shares authorized; 13,992 and 14,052 shares issued and outstanding | 140 | 14 |
| Additional paid-in capital | 173,757 | 174,78 |
| Unrealized gains on investments | - | 5,66 |
| Deferred compensation | (717) | (54) |
| Deficit accumulated during the development-stage | (68,312) | (81,64) |
| | ----- | ----- |
| Total stockholders' equity | 104,868 | 98,40 |
| | ----- | ----- |

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| | | |
|--|---------------------|--------------------|
| Total liabilities and stockholders' equity | \$ 114,768 ===== | \$ 106,35 ===== |
|--|---------------------|--------------------|

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

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

CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except per share amounts)

| | Three months ended September 30, | | Nine months ended September | |
|--|-------------------------------------|---------------------|--------------------------------|----|
| | 2000 | 2001 | 2000 | |
| Revenue from collaborative agreements | \$ 583 | \$ 330 | \$ 4,299 | \$ |
| Operating expenses: | | | | |
| Research and development | 2,987 | 4,010 | 9,644 | |
| Marketing, general and administrative | 1,535 | 1,883 | 4,233 | |
| Total operating expenses | 4,522 | 5,893 | 13,877 | |
| Operating loss | (3,939) | (5,563) | (9,578) | |
| Interest income | 1,578 | 793 | 3,565 | |
| Interest expense | (117) | (54) | (351) | |
| Net loss | \$ (2,478) ===== | \$ (4,824) ===== | \$ (6,364) ===== | \$ |
| Basic and diluted net loss per share | \$ (0.18) ===== | \$ (0.34) ===== | \$ (0.48) ===== | \$ |
| Basic and diluted weighted-average shares outstanding | 13,950 ===== | 14,041 ===== | 13,246 ===== | |

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

CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

| | Nine months ended September 30, | |
|---|------------------------------------|-------------|
| | 2000 | 2001 |
| Cash flows from operating activities: | | |
| Net loss | \$ (6,364) | \$ (13,333) |
| Adjustments to reconcile net loss to cash used in operating activities: | | |
| Depreciation and amortization | 1,470 | 1,766 |
| Non-cash compensation | 1,228 | 493 |
| Common stock issued for non-cash and other charges | - | |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | (1,417) | (1,417) |
| Accounts payable | (97) | (41) |
| Accrued compensation | (9) | 3 |
| Accrued expenses | (136) | (71) |
| Deferred revenue | (374) | (12) |
| Net cash used in operating activities | (5,699) | (11,922) |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | (1,271) | (4,933) |
| Proceeds from sale-leaseback of equipment | - | |
| Purchases of marketable securities | (135,845) | (103,463) |
| Proceeds from sales of marketable securities | - | |
| Proceeds from maturities of and other changes in marketable securities | 66,429 | 85,393 |
| Purchase of acquired technology | (1,000) | |
| Investment in equity securities | (1,250) | (31) |
| Restricted cash related to acquired technology | 1,500 | |
| Net cash used in investing activities | (71,437) | (23,311) |
| Cash flows from financing activities: | | |
| Proceeds from issuance of debt | - | |
| Repayment of debt | (1,000) | (1,100) |
| Restricted cash related to debt | 174 | 26 |

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| | | |
|--|----------|----------|
| Proceeds from issuance of preferred stock, net | - | |
| Proceeds from issuance of common stock, net | - | |
| Proceeds from public offerings, net | 68,605 | 70 |
| Proceeds from exercise of stock options and warrants | 2,807 | |
| Dividends paid | - | |
| | ----- | ----- |
| Net cash provided by (used in) financing activities | 70,586 | (12) |
| | ----- | ----- |
| Net increase (decrease) in cash and cash equivalents | (6,550) | (35,36) |
| Cash and cash equivalents, beginning of period | 10,365 | 66,98 |
| | ----- | ----- |
| Cash and cash equivalents, end of period | \$ 3,815 | \$ 31,62 |
| | ===== | ===== |
| Supplemental disclosure of cash flow information: | | |
| Cash paid for interest | \$ 365 | \$ 24 |
| | ===== | ===== |
| Non-cash financing activities: | | |
| Issuance of common stock for dividends | \$ - | \$ |
| | ===== | ===== |
| Issuance of common stock to employees in lieu of cash compensation | \$ - | \$ |
| | ===== | ===== |

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

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

1. Basis of Presentation

We have used generally accepted accounting principles for interim financial information to prepare unaudited consolidated financial statements:

- o As of September 30, 2001;
- o For the three and nine months ended September 30, 2000 and 2001; and
- o For the period from inception (January 17, 1989) to September 30, 2001.

Our consolidated financial statements do not include all of the information and footnotes required by generally accepted accounting principles for complete consolidated financial statements. In our opinion, the unaudited information includes 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 2001 solely on our results of operations for the nine months ended September 30, 2001. You should read these consolidated financial

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statements in combination with:

- o The other Notes in this section;
- o "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing in the following section; and
- o The Consolidated Financial Statements, including the Notes to the Consolidated Financial Statements, included in our Annual Report on Form 10-K for the year ended December 31, 2000.

2. Acquisition of Novazyme Pharmaceutical by Genzyme Corporation

On September 27, 2001, Genzyme Corporation announced it had completed the acquisition of Novazyme Pharmaceuticals. We received shares of Genzyme General, a division of Genzyme Corporation, in exchange for our ownership interest in Novazyme. The value of the Genzyme shares was approximately \$6 million as of September 30, 2001, and was reflected in Marketable Securities on our Balance Sheet. During October 2001 we sold these shares for net proceeds of approximately \$6.4 million, of which \$6.1 million will be reflected as a Gain on Investment on our Statement of Operations for the fourth quarter. In addition, Genzyme acquired Novazyme's obligation to pay us \$1.5 million plus interest in November 2002.

3. Agreement with Bristol-Myers Squibb Amended and Assigned to Progenics

In May 2001, Bristol-Myers Squibb amended and assigned our research and development agreement to Progenics Pharmaceuticals, Inc. Under the amended agreement, Progenics has the right to negotiate with Neose for the supply of two gangliosides for use as the active pharmaceutical ingredients in Progenics' two cancer vaccine candidates. Under the terms of the original agreement, Neose was

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developing proprietary technologies to enable cGMP manufacturing of these gangliosides. On May 15, 2001, Progenics announced the initiation of their second Phase III clinical trial with the most advanced of these vaccine candidates. This second trial is being conducted in Europe, and includes ganglioside manufactured by Neose.

4. 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 loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding for the period. Diluted loss per share reflects the potential dilution from the exercise or conversion of securities into common stock. For the nine months ended September 30, 2000 and 2001, the effects of the exercise of outstanding stock options and warrants were antidilutive; accordingly, they were excluded from the calculation of diluted earnings per share.

5. Comprehensive Loss

Our comprehensive loss for the nine months ended September 30, 2000 and 2001 was approximately \$6.4 million and \$7.7 million, respectively. Comprehensive loss is comprised of net loss and other comprehensive income or loss. Our only source of other comprehensive income or loss is unrealized gain on equity securities held for the nine months ended September 30, 2001.

6. Reclassifications

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

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," "may," "expect," "estimate," 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 Conditions and Results of Operations about our:

- o estimate of the sufficiency of our existing cash and cash equivalents and investments to finance our operating and capital requirements; and
- o expectations for future capital requirements.

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

- o our ability to commercialize any of our products or technologies;
- o our ability to maintain our existing collaborative arrangements and enter into new collaborative arrangements;
- o unanticipated cash requirements to support current operations or research and development;
- o the timing and extent of funding requirements for the activities of our joint venture with McNeil Specialty; and
- o general economic conditions.

These and other risks and uncertainties that could affect our actual results are discussed in greater detail in this report and in our other filings with the Securities and Exchange Commission. 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.

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, 2000, included in our Annual Report on Form 10-K and in our 2000 Annual Report to Stockholders.

Overview

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Neose develops proprietary technologies for the synthesis and manufacture of complex carbohydrates, which are chains of simple sugar molecules that can be joined together in many different combinations. Our enzymatic glycosylation technology platform makes feasible the synthesis of a wide range of complex carbohydrates for pharmaceutical, biotechnology, nutritional, and consumer product applications. Our GlycoAdvance(TM) program uses our technologies to enable the completion and correction of glycosylation in recombinant glycoprotein discovery, development, and manufacture. Our GlycoTherapeutics(TM) program uses our technologies to develop and produce novel carbohydrate-based therapeutics, and our GlycoActives(TM) program uses our technologies to develop and produce novel carbohydrate-based food ingredients. We have incurred operating losses each year. As of September 30, 2001, we had an accumulated deficit of approximately \$81.6 million. We expect additional losses for some time as we expand research and development efforts, manufacturing scale-up activities, and marketing activities.

Results of Operations

Revenues

Revenues from collaborative agreements for the three and nine months ended September 30, 2001 were \$330,000 and \$934,000, respectively, compared to \$583,000 and \$4,299,000, respectively, for the corresponding period in 2000. Payments under our Bristol-Myers agreement, which has subsequently been assigned to Progenics Pharmaceuticals, accounted for approximately \$3.3 million of our collaborative revenues in the nine months ended September 30, 2000. We do not expect any future payments under this agreement unless we negotiate new terms with Progenics.

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Operating Expenses

Research and development expenses for the three and nine months ended September 30, 2001, were \$4,010,000 and \$11,111,000, respectively, compared to \$2,987,000 and \$9,644,000, respectively, for the corresponding periods in 2000. The increases were primarily attributable to increased personnel and related costs.

General and administrative expenses for the three and nine months ended September 30, 2001, were \$1,883,000 and \$6,080,000, respectively, compared to \$1,535,000 and \$4,233,000, respectively, for the corresponding periods in 2000. The increases were primarily attributable to the hiring of additional business development and administrative personnel, marketing and promotional expenses as we have accelerated our commitment to the commercialization of GlycoAdvance, and increased legal and patent expenses as we continue to expand our intellectual property position.

Interest Income and Expense

Interest income for the three and nine months ended September 30, 2001 was \$793,000 and \$3,145,000, respectively, compared to \$1,578,000 and \$3,565,000, respectively, for the corresponding periods in 2000. The changes were primarily due to lower interest rates during the 2001 periods.

Interest expense for the three and nine months ended September 30, 2001 was \$54,000 and \$221,000, respectively, compared to \$117,000 and \$351,000, respectively, for the corresponding periods in 2000. The changes were due to lower average interest rates and lower average loan balances outstanding during the 2001 periods.

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Net Loss

We incurred net losses of \$4,824,000 and \$13,333,000, or \$0.34 and \$0.95 per share, for the three and nine months ended September 30, 2001, respectively, compared to \$2,478,000 and \$6,364,000, or \$0.18 and \$0.48 per share, respectively, for the corresponding periods in 2000.

Liquidity and Capital Resources

We have incurred operating losses each year since our inception. As of September 30, 2001, we had an accumulated deficit of approximately \$81.6 million. We have financed our operations through private and public offerings of our securities, and revenues from our collaborative agreements. We had \$83.4 million in cash and marketable securities as of September 30, 2001, compared to \$94.8 million in cash and marketable securities as of December 31, 2000.

As of September 30, 2001, our marketable securities included Genzyme stock valued at approximately \$6 million which we received in exchange for our ownership interest in Novazyme Pharmaceuticals. During October 2001, we sold these shares for net proceeds of approximately \$6.4 million.

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During the nine months ended September 30, 2001, we invested approximately \$4.9 million in property, equipment, and building improvements. We anticipate capital expenditures during 2001 and 2002 of approximately \$16 million, of which \$3.3 million was recorded as of September 30, 2001, to provide additional cGMP manufacturing capacity in our Horsham, Pennsylvania facility to support the initial requirements of our anticipated GlycoAdvance customers. Even if we make these capital expenditures, we may not be able to enter into collaborations with potential GlycoAdvance customers. In addition, we anticipate in the next 12 months we will obtain, either through lease or purchase, another facility, which we will renovate at a cost of approximately \$8 million. We plan to relocate our non-cGMP research laboratories and corporate office space from our current facility in Horsham, Pennsylvania into the new facility, leaving our current facility available for future expansion of our cGMP manufacturing capacity. The cost of these capital projects will be financed by a combination of state economic development programs, private debt financing, and cash from our balance sheet.

We may be required to make additional investments in our joint venture with McNeil Specialty to fund capital expenditures. If the joint venture builds additional production facilities, and we wish to maintain our 50% ownership interest in the joint venture, we are required to invest up to \$8.85 million to fund half of such expenditures. However, we may elect to fund as little as \$1.85 million of the cost of the facilities, so long as our aggregate investments in the joint venture are at least 15% of the joint venture's aggregate capital expenditures. In this case, McNeil Specialty will fund the remainder of our half of the joint venture's capital expenditures, and our ownership percentage will be proportionately reduced. We have an option, expiring in September 2006, to return to 50% ownership of the joint venture by reimbursing McNeil Specialty for this amount.

In 1997, we issued, through the Montgomery County (Pennsylvania) Industrial Development Authority, \$9.4 million of taxable and tax-exempt bonds, the current balance of which is \$6.2 million. The bonds were issued to finance the purchase of our previously leased building and the construction of a pilot-scale manufacturing facility within our building. The bonds are supported

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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. As of September 30, 2001, the weighted-average, effective interest rate was 4.6% per year, including letter-of-credit and other fees. The terms of the bond issuance provide for monthly, interest-only payments and a single repayment of principal at the end of the twenty-year life of the bonds. However, under our agreement with our bank, we are making monthly payments to an escrow account to provide for an annual prepayment of principal. As of September 30, 2001, we had restricted funds relating to the bonds of \$626,000, which consisted of our monthly payments to an escrow account plus interest revenue on the balance of 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 a covenant to maintain a minimum required cash and short-term investments balance of at least two times the current loan balance. At September 30, 2001, we were required to maintain a cash and short-term investments balance of \$12.4 million. If we fail to comply with this covenant, we are required to deposit with the lender cash collateral up to, but not more than, the loan's unpaid balance, which was \$6.2 million as of September 30, 2001.

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We expect that our existing cash and short-term investments will be adequate to fund our operations through at least 2002, although changes in our collaborative relationships or our business, whether or not initiated by us, may cause us to deplete our cash and short-term investments sooner than the above estimate. The timing and amount of our future capital requirements and the adequacy of available funds will depend on many factors, including if or when any products manufactured using our technology are commercialized.

Joint Venture with McNeil Specialty

Our joint venture with McNeil Specialty is owned equally by Neose and McNeil Specialty. Each of Neose and McNeil Specialty contributed various intellectual property to the joint venture. In addition, McNeil Specialty contributed to the joint venture the pilot commercial manufacturing facility, for which 50% of the cost will be reimbursed by the joint venture. We account for our investment in the joint venture under the equity method, under which we recognize our share of the income and losses of the joint venture. In 1999, we reduced the carrying value of our initial investment in the joint venture of approximately \$350,000 to zero to reflect our share of the joint venture's losses. We recorded this amount as research and development expense in our Consolidated Statements of Operations. We will record our share of post-1999 losses of the joint venture, however, only to the extent of our actual or committed investment in the joint venture.

If the joint venture becomes profitable, we will recognize our share of the joint venture's profits only after the amount of our capital contributions to the joint venture is equivalent to our share of the joint venture's accumulated losses. As of September 30, 2001, the joint venture had an accumulated loss since inception of approximately \$6 million, of which our 50% share is approximately \$3 million. Until the joint venture is profitable, McNeil Specialty is required to fund, as a non-recourse, no-interest loan, all of the joint venture's aggregate capital expenditures in excess of an agreed-upon amount, and all of the joint venture's operating losses. The loan balance would be repayable by the joint venture to McNeil Specialty over a seven-year period commencing on the earlier of September 30, 2006 or the date on which Neose

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attains a 50% ownership interest in the joint venture after having had a lesser ownership interest. In the event of any dissolution of the joint venture, the loan balance would be payable to McNeil Specialty before any distribution of assets to us. As of September 30, 2001, the joint venture owed McNeil Specialty approximately \$8 million.

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. The approximate principal amount and weighted-average interest rate of our investment portfolio at September 30, 2001 was \$79.3 million and 3.5%, respectively.

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At September 30, 2001, we also held stock worth approximately \$6 million of Genzyme General, a division of Genzyme Corporation. During October 2001, we sold these shares for net proceeds of approximately \$6.4 million.

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 \$6.2 million of outstanding indebtedness is at an interest rate that varies weekly, depending on the market rates for AA-rated taxable and tax-exempt obligations. As of September 30, 2001, the weighted-average, effective interest rate was approximately 4.6% per year.

Item 6. Exhibits and Reports on Form 8-K.

(a) Reports on Form 8-K.

None.

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SIGNATURES

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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 14, 2001

By: /s/ A. Brian Davis

A. Brian Davis
Principal Financial and Accounting
Officer