NEOSE TECHNOLOGIES INC Form S-3 March 18, 2003

> As filed with the Securities and Exchange Commission on March 17, 2003 Registration No.333-_____ SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 _____ Form S-3 Registration Statement Under The Securities Act of 1933 _____ Neose Technologies, Inc. (Exact name of Registrant as specified in its charter) Delaware 13-3549286 _____ (State or other jurisdiction (I.R.S. Employer of incorporation or organization) Identification No.) 102 Witmer Road Horsham, Pennsylvania 19044 (215) 315-9000 (Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices) Debra J. Poul, Esquire Senior Vice President and General Counsel Neose Technologies, Inc. 102 Witmer Road Horsham, Pennsylvania 19044 (215) 315-9000 (Name, address, including zip code, and telephone number, including area code, of agent for service) COPY TO: Barry M. Abelson, Esquire Pepper Hamilton LLP 3000 Two Logan Square Eighteenth and Arch Streets Philadelphia, PA 19103-2779 (215) 981-4000 Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective. If any of the securities being registered on this Form are to be offered on

1933, check the following box. [X] If this Form is filed to register additional securities for an offering

a delayed or continuous basis pursuant to Rule 415 under the Securities Act of

pursuant to Rule 462(b) under the Securities Act of 1933, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering [_]. _____

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If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act of 1933, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering [_]

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [_]

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. $[_]$

CALCULATION OF REGISTRATION FEE

| Title of Shares to be Registered | Amount to be | Proposed Maximum | Prop |
|---|----------------|------------------------------|-----------|
| | Registered (1) | Offering Price Per Share (2) | Aggregate |
| Common Stock, \$0.01 par value, including preferred stock purchase rights | 2,866,763 | \$ 6.72 | \$1 |

(1) Pursuant to Rule 416, this Registration Statement shall also cover any additional shares of the Registrant's common stock that become issuable by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration that increases the number of the Registrant's outstanding shares of common stock.

(2) The price of \$6.72 per share, which was the averages of the high and low prices of the Common Stock reported on the Nasdaq National Market on March 13, 2003, is set forth solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act of 1933.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the SEC, acting pursuant to said Section 8(a), may determine.

Subject to Completion, dated March 17, 2003

PROSPECTUS

2,866,763 Shares Common Stock

[NEOSE TECHNOLOGIES, INC. LOGO]

This prospectus relates to the resale of 2,866,763 shares of common stock issued to the selling stockholders listed on page 9 under the terms of a stock purchase agreement. We will not receive any proceeds from the sale of the shares by the selling stockholders.

The selling stockholders, or their pledgees, donees, transferees or other successors-in-interest, may offer the common stock from time to time through public or private transactions, at prevailing market prices, at prices related to prevailing market prices, at privately negotiated prices or any other lawful methods.

Our common stock is listed on The Nasdaq National Market under the symbol "NTEC." On March 14, 2003, the reported last sale price of our common stock on The Nasdaq National Market was \$6.90 per share.

Our principal offices are located at 102 Witmer Road, Horsham, Pennsylvania 19044, and our telephone number is (215) 315-9000.

INVESTING IN OUR COMMON STOCK INVOLVES RISKS. YOU SHOULD CAREFULLY CONSIDER THE "RISK FACTORS" BEGINNING ON PAGE 1 OF THIS PROSPECTUS BEFORE YOU DECIDE TO INVEST.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this Prospectus is _____, 2003.

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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus. The selling stockholders are offering to sell, and seeking offers to buy, shares of our

common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of common stock.

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WHO WE ARE

We are a biopharmaceutical company focused on improving glycoprotein therapeutics using our proprietary technologies. We are using our GlycoAdvance(TM), GlycoPEGylation(TM) and GlycoConjugation(TM) technologies to develop improved versions of currently marketed drugs with proven efficacy and to improve therapeutic profiles of glycoproteins in development for our partners. We expect these next generation proteins to offer significant advantages over drugs that are now on the market, including less frequent dosing and improved safety and efficacy. In addition to developing our own products or co-developing products with others, we expect to enter into strategic partnerships for including our technologies into the product design and manufacturing processes of other biotechnology and pharmaceutical companies. While our primary goal is protein drug development, our technologies offer multiple opportunities to participate in the evolving therapeutic protein market by addressing other challenges, such as manufacturing efficiency, manufacturing consistency, and the use of non-mammalian cell expression systems.

We were incorporated in Delaware in May 1991. Our executive offices and research facility are located at 102 Witmer Road, Horsham, PA 19044, our telephone number is 215-315-9000 and our website is at http://www.neose.com. Information contained on our website is not incorporated into this registration statement.

RISK FACTORS

You should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones facing our company. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations.

Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment.

This prospectus also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us described below and elsewhere in this prospectus.

Risks Related to Development Stage Company

If we fail to obtain necessary funds for our operations, we will be unable to maintain and improve our technology position and we will be unable to develop and commercialize our therapeutic proteins.

To date, we have funded our operations primarily through proceeds from the public and private placements of debt and equity securities, revenues from corporate collaborations, capital equipment and leasehold financing proceeds, gains from the sale of investments, and interest earned on investments. We believe that our existing cash and short-term investments, expected revenue from

collaborations and license arrangements, anticipated financing of capital expenditures, and interest income should be sufficient to meet our operating and capital requirements at least through the middle of 2004. Our present and future capital requirements depend on many factors, including:

- . the level of research and development investment required to develop our therapeutic proteins and improve our technology position;
- . the progress of preclinical and clinical testing;
- . the time and cost involved in obtaining regulatory approvals;
- our ability to enter into new agreements with collaborators and to extend our existing collaborations, and the terms of these agreements;
- . our success rate or that of our collaborators in discovery efforts associated with milestones and royalties;

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- . the timing, willingness, and ability of our collaborators to commercialize products incorporating our technologies;
- . costs of recruiting and retaining qualified personnel;
- . costs of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights;
- . our need or decision to acquire or license complementary technologies or new drug targets; and
- . changes in product candidate development plans needed to address any difficulties in clinical studies or in commercialization.

We will require significant amounts of additional capital in the future, and we do not have any assurance that funding will be available when we need it on terms that we find favorable, if at all. We may seek to raise these funds through public or private equity offerings, debt financings, credit facilities, or through corporate collaborations and licensing arrangements.

If we raise additional capital by issuing equity securities, our existing stockholders' percentage ownership would be reduced and they may experience substantial dilution. We may also issue equity securities that provide for rights, preferences, or privileges senior to those of our common stock. If we raise additional funds by issuing debt securities, these debt securities would have rights, preferences, and privileges senior to those of our common stock, and the terms of the debt securities issued could impose significant restrictions on our operations. If we enter into a credit facility, the agreement may require us to maintain compliance with financial covenants and restrict our ability to incur additional debt, pay dividends, make redemptions or repurchases of capital stock, make loans, investments or capital expenditures, or engage in other activities. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technologies or drug candidates, or to grant licenses on terms that are not favorable to us. If adequate funds are not available or are not available on acceptable terms, our ability to fund our operations, take advantage of opportunities, develop products or technologies, or otherwise respond to competitive pressures could be significantly delayed or limited, and we may need to downsize or halt our operations.

We have a history of losses, and we may incur continued losses for some time.

We have incurred losses each year, including net losses of approximately \$8.5 million for the year ended December 31, 2000, approximately

\$13.3 million for the year ended December 31, 2001, and approximately \$26.4 million for the year ended December 31, 2002. Given our planned level of operating expenses, we expect to continue incurring losses for some time. As of December 31, 2002, we had an accumulated deficit of approximately \$108 million. To date, we have derived substantially all of our revenue from corporate collaborations, license agreements, and investments. We expect that substantially all of our revenue for the foreseeable future will result from these sources and from the licensing of our technologies. We also expect to spend significant amounts to expand our research and development on our proprietary drug candidates and technologies, maintain and expand our intellectual property position, expand our manufacturing scale-up activities, and expand our business development and commercialization efforts. We may continue to incur substantial losses even if our revenues increase.

We have a joint venture with McNeil Nutritionals, a subsidiary of Johnson & Johnson. The joint venture has incurred losses since its inception, and we expect that the joint venture will incur additional losses for some time while it explores opportunities to continue the development of this technology.

We have not yet commercialized any products or technologies, and we may never become profitable.

We have not yet developed any products or commercialized any products or technologies, and we may never be able to do so. Since we began operations in 1990, we have not generated any revenues, except for interest income and revenues from collaborative agreements and investments. We do not know when or if we will complete any of our product development efforts, receive regulatory approval of any of our product candidates, or successfully commercialize any approved products. Even if we should be successful in developing products that are approved for marketing, we will not be successful unless our products, and products incorporating our technologies, gain market acceptance. The degree of market acceptance of these products will depend on a number of factors, including:

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. the receipt of regulatory approvals for the uses we seek;

- . the establishment and demonstration in the medical community of the safety and clinical efficacy of our products and their potential advantages over existing therapeutic products; and
- pricing and reimbursement policies of government and third-party payors, such as insurance companies, health maintenance organizations and other plan administrators.

Physicians, patients, payors or the medical community in general may be unwilling to accept, utilize or recommend any of our products or products incorporating our technologies. As a result, we are unable to predict the extent of future losses or the time required to achieve profitability, if at all. Even if we or our collaborators successfully develop one or more products that incorporate our technologies, we may not become profitable.

Risks Related to Development of Products and Technologies

We have limited product development and commercial manufacturing capability and experience, and we may be unable to develop therapeutic proteins and commercialize our technologies.

Until recently, we have not focused on the development of our own proprietary products. We are now seeking to use our GlycoAdvance, GlycoPEGylation and GlycoConjugation technologies to develop proprietary next

generation proteins, generally in collaboration with a partner. Our technologies may not result in the successful remodeling, optimization or development of proteins that are safe or efficacious. Because the development of new pharmaceutical products is highly uncertain, our technologies may not produce any commercially successful proteins. If we fail to validate our technologies through the successful remodeling of the proteins we select for development, we will not be able to license our next generation drug candidates, and our customers will not be able to develop drug candidates incorporating our technologies.

To date, we have manufactured only smaller, noncommercial quantities of our enzymes, sugar nucleotides, and complex carbohydrates. We intend to manufacture enzymes and sugar nucleotides for use in our proprietary product development programs and for use by our customers. Our success depends on our ability to manufacture these compounds on a commercial scale and in accordance with current Good Manufacturing Practices, or cGMP, prescribed by the U.S. Food and Drug Administration, or FDA. We may not be able to manufacture sufficient quantities of the products we develop, even to meet our needs for pre-clinical or clinical development, and we may have problems complying, or maintaining compliance, with cGMP.

In addition to the normal scale-up risks associated with any manufacturing process, we may face unanticipated problems unique to the manufacture of enzymes, sugar nucleotides, or complex carbohydrates. If we are unable to develop commercial-scale manufacturing capacity, we would seek collaborators, licensees, or contract manufacturers to manufacture the compounds necessary to commercialize our technologies. We may not be able to find parties willing to manufacture these compounds at acceptable prices.

Any manufacturing facility must adhere to the FDA's evolving regulations on cGMP, which are enforced by the FDA through its facilities inspection program. The manufacture of products at these facilities will be subject to strict quality control, testing, and record keeping requirements, and continuing obligations regarding the submission of safety reports and other post-market information. Ultimately, we or our contract manufacturers may not meet these requirements.

If we encounter delays or difficulties in connection with manufacturing, commercialization of our products and technologies could be delayed, or we could breach our obligations under our collaborative agreements.

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Our success depends on collaborative relationships, and our failure to enter into new collaborations, or to successfully manage our existing and future collaborations and license arrangements, could prevent us from commercializing our product candidates and technologies.

We rely to a large extent on collaborative partners to co-develop our products and