

NEOSE TECHNOLOGIES INC
Form 10-K
March 10, 2008

[QuickLinks](#) -- Click here to rapidly navigate through this document

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

for the fiscal year ended December 31, 2007

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

(State or other jurisdiction
of incorporation or organization)

13-3549286

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

102 Rock Road

Horsham, Pennsylvania

(Address of principal executive offices)

19044

(Zip Code)

Registrant's telephone number, including area code: **(215) 315-9000**

Securities registered pursuant to Section 12(b) of the Act:

Common Stock, par value \$0.01 per share

(Title of each class)

The NASDAQ Stock Market LLC

(Name of each exchange on which registered)

Securities registered pursuant to Section 12(g) of the Act:

None

(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in the definitive proxy statement or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

As of June 30, 2007, the aggregate market value of the registrant's Common Stock held by non-affiliates of the registrant was approximately \$116,082,696 based on the last sale price of the Common Stock on such date as reported by The NASDAQ Stock Market LLC. This calculation excludes 7,280,093 shares held on June 30, 2007 by directors and executive officers.

As of March 7, 2008, there were 54,468,181 shares of the registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2008 Annual Meeting of Stockholders, is incorporated by reference into Part III of this Annual Report on Form 10-K.

TABLE OF CONTENTS

	Page
PART I	1
ITEM 1. BUSINESS	1
ITEM 1A. RISK FACTORS	12
ITEM 1B. UNRESOLVED STAFF COMMENTS	26
ITEM 2. PROPERTIES	26
ITEM 3. LEGAL PROCEEDINGS	26
ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS	26
PART II	27
ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS	27
ITEM 6. SELECTED FINANCIAL DATA	28
ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	31
ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK	44
ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	45
ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	45
ITEM 9A. CONTROLS AND PROCEDURES	45
ITEM 9B. OTHER INFORMATION	47
PART III	48
ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT	48
ITEM 11. EXECUTIVE COMPENSATION	48
ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT	49
ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS	49
ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES	49
PART IV	50
ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES	50
SIGNATURES	54

NEOSE®, GlycoPEGylation®, GlycoAdvance® and GlycoConjugation® are trademarks of Neose Technologies, Inc. This Annual Report on Form 10-K also includes trademarks and trade names of other companies.

PART I

ITEM 1. BUSINESS.

Overview

We are a clinical-stage biopharmaceutical company focused on the development of next-generation therapeutic proteins, which we believe will be competitive with best-in-class protein drugs currently on the market. We have two therapeutic protein candidates in clinical trials: GlycoPEG-GCSF and GlycoPEG-FVIIa; and two therapeutic protein candidates in the research stage: GlycoPEG-FVIII and GlycoPEG-FIX. In 2006, the G-CSF, recombinant Factor VIIa, recombinant Factor VIII, and recombinant Factor IX drug categories had aggregate worldwide sales of approximately \$4.4 billion, \$1 billion, \$2 billion, and \$360 million, respectively.

GlycoPEG-GCSF is a long-acting version of granulocyte colony stimulating factor (G-CSF) that we are co-developing with BioGeneriX AG, a company of the ratiopharm Group. G-CSF is prescribed to stimulate production of neutrophils (a type of white blood cell) and is approved for sale in major markets around the world for treatment of neutropenia associated with myelosuppressive chemotherapy. In November 2007, we reported data from two Phase I clinical trials. That data demonstrated that GlycoPEG-GCSF is a potent stimulator of neutrophils and mobilizer of peripheral blood progenitor cells, and that at comparable doses to Neulasta® (Amgen's marketed, long-acting G-CSF), GlycoPEG-GCSF demonstrates a 60% greater bioavailability, leading to a 30% increase in the generation of neutrophils. We expect BioGeneriX to commence a Phase II study in the first half of 2008.

GlycoPEG-FVIIa is a long-acting form of recombinant Factor VIIa that is being developed by our partner, Novo Nordisk A/S, utilizing our GlycoPEGylation technology. Factor VIIa is used in the treatment of bleeding episodes and for the prevention of bleeding during surgery or invasive procedures in patients with congenital hemophilia with inhibitors to coagulation Factors VIII or IX. In June 2007, Novo Nordisk initiated a Phase I clinical study to assess the safety and pharmacokinetics of GlycoPEG-FVIIa in healthy volunteers. During 2007, poster presentations of preclinical data for GlycoPEG-FVIIa were presented at annual meetings of the International Society on Thrombosis and Haemostasis and the American Society of Hematology. Novo Nordisk is also developing long-acting forms of recombinant Factor VIII and recombinant Factor IX utilizing our GlycoPEGylation technology. Factor VIII products are used in the treatment of Hemophilia A, and Factor IX products are used in the treatment of Hemophilia B.

In January 2008, we announced the discontinuation of further development of GlycoPEG-EPO (NE-180), our product candidate intended for the treatment of anemia in patients with chronic kidney disease and cancer patients receiving chemotherapy. The decision to discontinue development was not due to any safety or efficacy concerns about NE-180, but was based on an evaluation of commercial prospects and the likelihood of entering into a timely collaboration for the compound in the context of increased safety concerns in the erythropoiesis-stimulating agent (ESA) category. In connection with the discontinuation of the NE-180 program, we reduced our workforce by approximately 35%. These actions allowed us to significantly reduce our expected cash expenditures and extend our cash runway by approximately one year. We anticipate paying cash severance benefits of approximately \$0.9 million in connection with the workforce reduction, most of which will be paid in the first quarter of 2008. We do not expect to incur any material contract termination charges or non-cash impairment charges in connection with the program discontinuation.

On February 19, 2008, we received notice from The NASDAQ Stock Market LLC ("NASDAQ") stating that for 30 consecutive business days the bid price for our common stock has closed below the minimum \$1.00 per share required for continued listing on the NASDAQ Global Market. As a result, we no longer meet NASDAQ's continued listing criteria and have 180 calendar days, or until

August 18, 2008, to regain compliance. The notice has no effect on the listing of our common stock at this time, and Neose shares will continue to trade on the NASDAQ Global Market during the 180-day period. We have not yet determined what action, if any, we will take in response to this notice, although we intend to monitor the bid price of our listed securities between now and August 18, 2008, and consider available options if our common stock does not trade at a level necessary to regain compliance with the NASDAQ minimum closing bid price requirement.

We believe that our enzymatic pegylation technology, GlycoPEGylation, can improve the drug properties of therapeutic proteins by building out, and attaching polyethylene glycol (PEG) to, carbohydrate structures at specific sites on the proteins. We are using our technology to develop proprietary versions of protein drugs with proven safety and efficacy and to improve the therapeutic profiles of proteins being developed by our partners. We expect these modified proteins to offer significant advantages, including less frequent dosing and possibly improved efficacy, over the original versions of the drugs now on the market, as well as to meet or exceed the pharmacokinetic profile of next-generation versions of the drugs now on the market. We believe this strategy of targeting drugs with proven safety and efficacy allows us to lower the risk profile of our proprietary development portfolio as compared to *de novo* protein drug development. We intend to continue to focus our research and development resources on therapeutic proteins that we believe have the greatest probability of achieving clinically meaningful therapeutic improvements from our technology and are in commercially attractive categories.

Opportunities in the Therapeutic Protein Market

Worldwide sales of protein drugs in 2006 have been reported at over \$47 billion, and by some estimates are expected to grow to over \$55 billion by 2011. We believe that many of the proteins now on the market will lose the protection of certain patent claims over the next 10 years. In addition, many marketed proteins are facing increased competition from next-generation versions or from other drugs approved for the same disease indications. Although not every protein drug is a candidate for the use of our technology, we believe our technology can be applied to many of these marketed drugs to create products with improved clinical profiles. We are pursuing opportunities in this field through our exploratory research program and our partnering and licensing program. We will continue our efforts to build a portfolio of commercially attractive partnerships in a blend of co-developments and licenses. Where possible, we will seek partnerships that allow us to participate significantly in the commercial success of each of the compounds.

Our Technology

Our GlycoPEGylation technology involves the use of enzymes to attach PEG to carbohydrate structures that we have introduced or modified on proteins. We have developed a special expertise and an extensive intellectual property position in this area. Our technology may permit the development of therapeutic proteins with improved clinical profiles. In some cases, these improvements to therapeutic proteins may also allow us to create new intellectual property relating to our core technology, as well as new compositions of matter. In addition, our technology can be applied to proteins produced in a variety of cell expression systems, including Chinese hamster ovary (CHO) cells, *E. coli*, and insect cells. We continue to make significant investments in research and development and legal services to protect and expand our intellectual property position. We believe our core technology has broad application to protein drug development and can be extended to provide an opportunity for sustainable growth.

Improved Clinical Profiles. Common protein drug delivery problems include poor solubility and stability, proteolysis (rapid degradation), rapid clearance, and immunogenicity. For some proteins, one approach to these problems has been conventional chemical pegylation—the attachment of the large, water-soluble polymer, PEG, directly to the amino acid backbone of the protein. Pegylation may

improve the solubility, stability, half-life and immunogenicity profile of a protein drug. Pegylation has been used in marketed drugs, such as PEG-INTRON®, PEGASYS® and Neulasta®.

For some protein drugs, it has been difficult to achieve the benefits of pegylation by the conventional approach of attaching PEG directly to the protein backbone. A possible explanation is that the sites for the attachment of PEG occur at positions where the bulky PEG molecules block access to the active site on the protein or alter the conformation of the protein. This may diminish or eliminate drug activity.

By employing GlycoPEGylation, we are able to attach PEG selectively and efficiently to the carbohydrate structures on proteins, rather than attaching PEG directly to the protein backbone. By linking PEG to carbohydrate structures that are remote from the protein's active site, GlycoPEGylation may preserve the bioactivity of the drug and extend its half-life. We believe that significant clinical benefits may be achieved through the application of our GlycoPEGylation technology to proteins. By using our GlycoPEGylation technology, we have been able to demonstrate with several drug candidates a prolonged drug effect in animal and human testing, including drug candidates that have not shown biological activity following traditional chemical pegylation.

Enabling Multiple Expression Systems. In addition to attaching PEG to carbohydrate structures, our enzymes also modify or introduce carbohydrates on proteins. We refer to this as our GlycoAdvance technology. Currently, recombinant glycoprotein drugs are often produced in mammalian cell culture expression systems, primarily CHO cells. Generally, carbohydrates are added to proteins during the process of expression. CHO cells, and many other expression systems used for commercial manufacturing of proteins, tend to produce protein molecules with incomplete or inconsistent carbohydrate structures. In the human body, these incompletely glycosylated proteins may be cleared too rapidly, thus compromising the half-life and effectiveness of these proteins.

Our technology addresses these problems by employing enzymes to modify the carbohydrate structures on proteins that have inadequate carbohydrate structures and to introduce carbohydrates on proteins that have none. Proteins may have inadequate carbohydrate structures as a result of the cell expression systems used, or may have no carbohydrate structures in their native state. Our ability to modify or introduce carbohydrate structures allows our GlycoPEGylation technology to be applied to proteins produced in a variety of cell expression systems, including CHO cells, *E. coli*, and insect cells.

GlycoPEGylated Products in Development

There are currently four next-generation therapeutic protein candidates in research and development using our GlycoPEGylation technology: GlycoPEG-GCSF, GlycoPEG-FVIIa, GlycoPEG-FVIII, and GlycoPEG-FIX.

GlycoPEG-GCSF. We are developing GlycoPEG-GCSF, a long-acting version of G-CSF, in collaboration with our partner BioGeneriX. In November 2007, we reported data from two Phase I clinical trials. That data demonstrated that GlycoPEG-GCSF is a potent stimulator of neutrophils and mobilizer of peripheral blood progenitor cells, and that at comparable doses to Neulasta® (Amgen's marketed, long-acting G-CSF), GlycoPEG-GCSF demonstrates a 60% greater bioavailability, leading to a 30% increase in the generation of neutrophils. No serious adverse events were reported nor were there any discontinuations for adverse events from that trial. We believe that these data support the initiation of a Phase II study in patients comparing several doses of GlycoPEG-GCSF to the standard fixed dose of Neulasta. We expect BioGeneriX to commence this Phase II study in the first half of 2008.

G-CSF is prescribed to stimulate production of neutrophils (a type of white blood cell), and is approved for sale in major markets around the world for treatment of neutropenia associated with myelosuppressive chemotherapy. Worldwide sales in the G-CSF category in 2006 were approximately

\$4.4 billion. Of these sales, approximately \$3.0 billion were in the U.S. and approximately \$1.4 billion were outside the U.S.

We believe that the expiration of key patents covering G-CSF will provide commercial opportunities in a time frame consistent with our development timeline. We expect that regulatory approval for GlycoPEG-GCSF will be sought both in and outside the U.S. We believe that key patents covering G-CSF have expired in Europe, and will expire in the U.S. in late 2013 and in other jurisdictions between these times. We expect BioGeneriX to pursue regulatory and marketing approval for GlycoPEG-GCSF first in Europe.

GlycoPEG-FVIIa. A long-acting form of recombinant Factor VIIa is being developed by our partner, Novo Nordisk, utilizing our GlycoPEGylation technology. In June 2007, Novo Nordisk initiated a Phase I clinical study for GlycoPEG-Factor VIIa. This trial will assess the safety and pharmacokinetics of GlycoPEG-FVIIa in healthy volunteers. During 2007, poster presentations of preclinical data for GlycoPEG-FVIIa were presented at annual meetings of the International Society on Thrombosis and Haemostasis and the American Society of Hematology. These data indicated that GlycoPEGylation significantly prolonged the active half-life of recombinant Factor VIIa. Factor VIIa is used in the treatment of bleeding episodes and for the prevention of bleeding during surgery or invasive procedures in patients with congenital hemophilia with inhibitors to coagulation Factors VIII or IX. The worldwide market for recombinant Factor VIIa was approximately \$1.2 billion in 2007, with all of the sales being generated by Novo Nordisk. Novo Nordisk is also investigating other applications for Factor VIIa, including its use in hemophilia prophylaxis for patients with inhibitors, trauma, bleeding in emergencies, and spinal and cardiac surgery.

GlycoPEG-FVIII. Novo Nordisk is also developing a long-acting form of recombinant Factor VIII utilizing our GlycoPEGylation technology. This compound is currently in the research stage. In February 2008, we received a milestone payment under our license agreement with Novo Nordisk with respect to this compound. Factor VIII products are used in the treatment of Hemophilia A. People with Hemophilia A do not produce adequate amounts of Factor VIII, which is necessary for the blood to clot effectively. The worldwide market for recombinant Factor VIII products was approximately \$2 billion in 2006.

GlycoPEG-FIX. The third compound being developed by Novo Nordisk utilizing our GlycoPEGylation technology is a long-acting form of recombinant Factor IX. This compound is currently in the research stage, with an anticipated milestone payment in the first half of 2008. Factor IX products are used in the treatment of Hemophilia B. Hemophilia B is caused by a deficiency of a blood plasma protein called Factor IX that affects the clotting property of blood. According to the National Hemophilia Foundation, Hemophilia B is the second most common type of hemophilia, occurring in about one in 25,000 male births. In the United States, Hemophilia B affects about 3,300 individuals. The worldwide market for recombinant Factor IX was approximately \$360 million in 2006.

Partnering and Licensing Program

Currently we have the following collaborations:

BioGeneriX. We are parties to an agreement with BioGeneriX AG to use our proprietary GlycoPEGylation technology to develop a long-acting version of G-CSF. Under the agreement, as amended to date, we and BioGeneriX shared the expenses of preclinical development. BioGeneriX is responsible for supplying the protein and funding the clinical development program and we are responsible for supplying enzyme reagents and sugar nucleotides. As of January 1, 2007, BioGeneriX became responsible for the cost of reagent supply. If we and BioGeneriX proceed to commercialization, we will have commercial rights in the U.S., Canada, Mexico and Japan, and BioGeneriX will have commercial rights in Europe and the rest of the world. Each company has the

ability to search for its own marketing partner for its territories and will receive significant royalties on product sales in the other company's territory. Each party has the right, in various circumstances, to terminate the agreement by giving the required notice to the other party, subject to the other party's right to continue working on the development and commercialization of a long-acting version of G-CSF, as provided in the agreement. In addition, we have immediate termination rights, in which case we will have all rights to the product candidate, including supply of protein from BioGeneriX or its contract manufacturer, in the event BioGeneriX does not meet certain Phase II diligence requirements.

Novo Nordisk. We are parties to three agreements with Novo Nordisk A/S to use our GlycoPEGylation technology to develop and commercialize next-generation versions of recombinant Factors VIIa, VIII and IX, one of which, Factor VIIa, is currently marketed by Novo Nordisk. We received a \$4.3 million upfront fee under these agreements, and Novo Nordisk funds our research and development activities for these three proteins. We may also receive up to \$52 million in development milestones under these agreements, as amended to date, as well as significant royalties on sales of the licensed products. Under these three agreements, Novo Nordisk's license with respect to each protein continues until the expiration of the last Neose patent covering a licensed product, or until the earlier termination of the applicable agreement. Novo Nordisk has the right to terminate each of the agreements without cause. We have the right to terminate the agreements with respect to Factors VIII and IX if there are no commercial sales of licensed products within a specified period, subject to Novo Nordisk's ability to extend by paying minimum royalties. In February 2008, we received a milestone payment from Novo Nordisk under the Factor VIII license agreement.

Exploratory Research Program

We conduct exploratory research, both independently and with collaborators, on therapeutic candidates, primarily proteins, using our enzymatic technology. Successful therapeutic candidates may be advanced for development through our own drug development program, our partnering and licensing program, or a combination of the two.

Intellectual Property

Our success depends on our ability to protect and use our intellectual property rights in the continued development and application of our technology, to operate without infringing the proprietary rights of others, and to prevent others from infringing on our proprietary rights. In connection with our proprietary protein drug program, we have devoted significant resources to investigating the patent protection for currently marketed proteins. We also devote significant resources to obtaining and maintaining patents, and we expect to aggressively enforce our rights if necessary, although we recognize that the scope and validity of patents is never certain.

Our patent strategy has two main components, the pursuit of a patent portfolio protecting our technology and its anticipated applications, and the evaluation of patent protection for proteins we may target for development.

Patents and Proprietary Rights. We have continued to file patent applications covering new developments in our technology, including compositions and methods for enzymatically introducing and modifying sugar chains on a multitude of proteins to form stable linkages between a sugar attached to a polypeptide and a water soluble polymer, therapeutic compound, targeting agent, or other biologically active molecule.

In addition to developing our own intellectual property, we have obtained and continue to seek complementary intellectual property from others. We have entered into license agreements with various institutions and individuals for certain patent rights, as well as sponsored research and option agreements for the creation and possible license to us of additional intellectual property rights. We are obligated to pay royalties at varying rates based upon, among other things, levels of revenues from the

sale of licensed products under our existing license agreements, and we expect to pay royalties under new license agreements for intellectual property. Generally, these agreements continue for a specified number of years or as long as any licensed patents remain in force, unless the agreements are terminated earlier.

We own 32 issued U.S. patents, and have licensed 86 issued U.S. patents from various institutions. In addition, we own or have licensed over 135 patent applications pending in the U.S. There are also 509 foreign patent applications pending or granted related to our owned and licensed patents. Additionally, we have assigned four issued U.S. patents and seven granted or pending foreign counterparts to Magnolia Nutritionals, our joint venture with McNeil Nutritionals (a subsidiary of Johnson & Johnson).

We recently received eleven U.S. patents and two Notices of Allowance from the U.S. Patent and Trademark Office from and for our patent applications related to our GlycoConjugation and GlycoPEGylation technologies. The granted U.S. claims broadly cover glycosyl-linked polyethylene glycol conjugates of therapeutic peptides, methods of GlycoConjugating therapeutic peptides, and GlycoConjugates comprising more than one peptide. These recently granted U.S. patents and U.S. allowances belong to a series of pending patent applications directed toward our broad GlycoConjugation technology platform and proprietary proteins.

Proprietary Protein Drugs. To pursue our strategy of developing proprietary protein drugs, we must ascertain the nature, scope and expiration of existing patent claims covering the proteins we may target for development, and our methods of improving them, such as adding PEG. The patent coverage on these proteins and methods of making them is complex. These patents must be analyzed on a claim-by-claim basis, and we must make decisions based on our analysis of these varied claims. The patents and their expiration dates often vary from the U.S. to Europe to Japan. It is possible that we are unaware of issued patents or pending patent applications that are relevant to our product candidates, either because our search did not find them or because they are not yet publicly available.

In order to market proprietary versions of currently marketed proteins, it is necessary to determine the expiration dates of existing patent claims that could cover a product candidate by analyzing numerous, complex patent claims and, in some cases, judicial opinions. The analysis of patents is subject to different interpretations and leads to varying legal and business conclusions. For instance, we could analyze the patent coverage of a particular product on the market and determine that our product candidate is eligible for market entry in a jurisdiction prior to our competitors' products, based on the different characteristics or manufacturing processes of those products. If we were to pursue a strategy of early entry into any jurisdiction based on such analysis, others could disagree with our analysis and litigation could result, which would be costly regardless of whether we were successful. Litigation could also result in delays in the launch of a product, even if we ultimately were to prevail in the litigation.

Nature of Protection. The nature of patent protection in the pharmaceutical and biotechnology industry is complex, uncertain and unpredictable, and expensive. The patents we seek may not issue, or may issue with a narrower scope than originally sought, and may not be valid or effectively enforceable. Even if our patents are enforceable, enforcement of our patents could be time-consuming and expensive. If the claims in our pending patent applications are narrowed prior to issuance, others will have greater opportunity to circumvent or design around our patent protection.

We also have proprietary trade secrets and know-how that are not patentable or that we have chosen to maintain as secret rather than filing for patent protection. We seek to protect our secret information by entering into confidentiality agreements with employees, consultants, licensees, and potential collaboration partners. These agreements generally provide that all confidential information developed by us, or made known by us to the other party, during the relationship shall be kept confidential and may not be disclosed to third parties, except in specific circumstances. Our agreements

with employees also provide that inventions made by the employee during the period of employment will be solely owned by us if they are the result of tasks assigned by us or the use of property (including intellectual property) owned or used by us. Our agreements with consultants generally provide that inventions conceived by the consultant while rendering consulting services to us will be our exclusive property.

We are aware of numerous pending and issued U.S. and foreign patent rights and other proprietary rights owned by third parties in fields related to our technology. We will continue to expend resources to protect our own technology and seek to avoid infringing the technology of others. Patent protection obtained by others may interfere with our ability to obtain patents, or our ability to effectively employ our technology.

Others may claim that our technology infringes on their patents. Even if successful, the process of defending against such claims could result in substantial costs and delay our ability to commercialize our product candidates that utilize the challenged technology.

Government Regulation

Our research and development activities, the future manufacture of reagents and products incorporating our technology, and the marketing of these products are subject to regulation for safety and efficacy by numerous governmental authorities in the U.S. and other countries.

Regulation of Pharmaceutical Product Candidates. The research and development, clinical testing, manufacture and marketing of products using our technology are subject to regulation by the U.S. Food and Drug Administration (FDA) and by comparable regulatory agencies in other countries. Product development and approval within this regulatory framework take a number of years and involve the expenditure of substantial resources. We anticipate that the development of our next-generation proprietary proteins will involve a traditional development program, including clinical trials.

After laboratory analysis and preclinical testing in animals, a regulatory filing is required to be submitted to the appropriate authorities before human testing may begin. In the U.S., an Investigational New Drug application (IND) filing is made to the FDA. In Europe, a Clinical Trial Application, including an Investigational Medicinal Product Dossier (IMPd) in a country requiring adherence to guidance of the European Agency for the Evaluation of Medicinal Products (EMA), or other country-specific filing, such as is the case in Switzerland, is submitted to the national health authority in each country in which a clinical trial is planned. Typically, a sequential three-phase human clinical testing program is then undertaken, but the phases may overlap or be combined. Certain phases may not be necessary for a particular product. Each clinical study is conducted according to an approved protocol after written approval is obtained from an independent Institutional Review Board (IRB) in the U.S. or Independent Ethics Committee (IEC) in Europe. During Phase I, small clinical trials are conducted to determine the safety of the product in healthy volunteers. During Phase II, clinical trials are expanded in size and are conducted to assess safety, establish an acceptable dose, and gain preliminary evidence of the efficacy of the product in a subset of the target population. During Phase III, clinical trials are further expanded in size and conducted to obtain sufficient data to establish statistically significant proof of safety and efficacy in the target population. The time and expense required to perform this clinical testing vary and can be substantial. The results of the non-clinical and clinical testing of a biological pharmaceutical product are then submitted to the appropriate authority in the form of a Biologics License Application (BLA), or New Drug Application (NDA) in the U.S., or a Marketing Authorization Application (MAA) or equivalent in Europe. If the application contains all pertinent information and data, the appropriate regulatory authority will formally accept the file for review. In responding to this filing, the regulatory authority may grant marketing approval, request additional information, or deny the application.

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

No action may be taken to market any new drug or biologic product in either the U.S. or Europe until an appropriate marketing application has been approved by the responsible regulatory authority. Even after initial regulatory approval is obtained, further clinical trials may be required to provide additional data on safety and efficacy or to gain clearance for the use of a product as a treatment for indications other than those initially approved. Side effects or adverse events that are reported during clinical trials may delay, impede, or prevent marketing approval. Similarly, adverse events that are reported after obtaining marketing approval may result in additional limitations being placed on the use of a product and, potentially, withdrawal of the product from the market.

The regulatory requirements and approval processes of those countries outside the U.S. where some of our Phase II clinical trial sites are located are similar to, but not the same as, those in the U.S. These trials are being performed in a manner consistent with FDA requirements, which would potentially allow the data generated from these trials to be used to support an IND or NDA in the United States.

In addition to regulating and auditing human clinical trials, the FDA regulates and inspects equipment, facilities, and processes used in the manufacture and control of products prior to providing approval to market a product. Among other conditions for marketing approval in the U.S., the prospective manufacturer's quality control and manufacturing procedures must conform on an ongoing basis with current Good Manufacturing Practices (cGMP). Before granting marketing approval, the FDA will perform a pre-licensing inspection of the facility to determine its compliance with cGMP and other rules and regulations. In complying with cGMP, manufacturers must continue to expend time, money and effort in the area of production, training and quality control to ensure full compliance. After approval of a BLA or NDA, manufacturers are subject to periodic inspections by the FDA. If, as a result of FDA inspections relating to our products or reagents, the FDA determines that equipment, facilities, or processes do not comply with applicable FDA regulations or conditions of product approval, the FDA may seek civil, criminal, or administrative sanctions and remedies against us, such as the suspension of manufacturing operations, the seizure of products, and the suspension of sales of our products.

Products manufactured in the U.S. for distribution abroad are subject to FDA regulations regarding export, as well as to the requirements of the country to which they are shipped. Products distributed to European countries that are members of the European Union (EU) are also subject to EU regulations. The requirements of the EU and foreign countries generally cover the conduct of clinical trials, the submission, review and approval of marketing applications, and all aspects of product manufacture and marketing. These requirements may vary significantly from country to country.

We expect to enter into agreements with third parties for the manufacture of bulk protein, enzymes, sugar nucleotides and other reagents that are used in the production of next-generation GlycoPEGylated protein therapeutics using our technology. Any third parties we contract with will be subject to substantially the same regulatory requirements as we are with regard to the items they manufacture for us.

Other Regulations Affecting our Business. We are subject to various other laws and regulations, such as those relating to safe working conditions, employee relations, employee benefits, the environment (including the use and disposal of hazardous or potentially hazardous substances), antitrust and international trade, securities law and taxation. We endeavor to comply with applicable laws and regulations. However, we recognize that this is a complex and expensive process, and that we cannot predict when changes will occur or whether they would have a material adverse effect on our operations.

We contract with third parties for supplies and services that are critical to our business. These third parties are also subject to government regulation. The failure of any of these third parties to

comply with applicable laws and regulations could cause substantial delays to our drug development timelines and have a material adverse effect on our operations.

Third-Party Reimbursement. Our ability and the ability of each of our collaborators to successfully commercialize drug products may depend in part on the extent to which coverage and reimbursement for the cost of such products will be available from government health administration authorities, private health insurers, and other organizations. Uncertainty continues within the pharmaceutical and biotechnology industries as to the reimbursement status of new therapeutic products, and we cannot be sure that third-party reimbursement would be available for any therapeutic products that we or our collaborators may develop. Healthcare reform, especially as it relates to prescription drugs, is an area of increasing attention and a priority of many governmental officials.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly evolving technology and significant competition. Our competitors include pharmaceutical and biotechnology companies. In addition, many specialized biotechnology companies have formed collaborations with large, established companies to support research, development and commercialization of products that may be competitive with our current and future product candidates and technology. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize competitive products or technologies on their own or through collaborations with pharmaceutical and biotechnology companies.

First-Generation G-CSF Products. First-generation G-CSF products are marketed in the U.S. and Europe by Amgen as Neupogen®, in Europe by Sanofi Aventis as Granocyte®, and in Japan by Kirin Brewery (GRAN®), Chugai (Neutrogin®) and Kyowa Hakko Kogyo (Neu-up®). 2006 worldwide sales of these first generation G-CSF products were approximately \$1.7 billion.

Competitive Next-Generation G-CSF Products. Other companies have programs focused on developing next-generation or improved versions of G-CSF, and some are already marketing improved versions of these products.

Amgen currently markets Neulasta®, which is a modified version of its original G-CSF product, Neupogen®. Neulasta is a chemically pegylated compound, with a longer circulating half-life than Neupogen. Amgen launched Neulasta in the first quarter of 2002 and has reported that global sales of Neulasta were approximately \$3.0 billion during 2007.

Other companies are also applying their technologies to develop long-acting competitors to G-CSF. Maxygen's G-CSF product candidate, Maxy-G34, is currently in Phase II clinical development and CoGenesys, which was recently acquired by Teva Pharmaceuticals, also has a G-CSF product candidate (Neugranin) in Phase II clinical development.

First-Generation Blood Factor Products. Several companies market first-generation recombinant blood factor products in the U.S. and Europe. Our collaboration partner, Novo Nordisk, sells NovoSeven®, the only Factor VIIa product presently approved for treatment of hemophilia patients with immunity to Factor VIII or Factor IX. Factor VIII compounds are currently marketed by Baxter Healthcare (Advate® and Recombinate), Bayer Healthcare (Kogenate®) and Wyeth Pharmaceuticals (Refacto®). Wyeth also markets a Factor IX product, BeneFIX®. 2006 worldwide sales of these first generation recombinant products were approximately \$3.4 billion.

Competitive Next-Generation Blood Factor Products. Other companies have early programs focused on developing next-generation or improved versions of Factors VII, VIII and IX.

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

Maxygen and CSL Behring are each developing long-acting versions of Factor VII. Maxygen has announced plans to file an IND for its product candidate, MAXY-VII, in the first half of 2008. Bayer Healthcare is collaborating with Zilip Pharma on a long-acting Factor VIII and Baxter Healthcare has long-acting Factor VIII collaborations with Nektar and Lipoxen. Biogen Idec's subsidiary, Syntonix, is developing a long-acting Factor IX in collaboration with Biovitrum, and Nastech and Inspiration Pharmaceuticals have announced Factor IX research programs.

Next-Generation Protein Development. We are aware that other companies are working on the development of other next-generation protein therapeutics to which we are also applying our technology. Our product candidates will face competition from products already established in the marketplace and new therapies that may be developed by our competitors or may result from advances in biotechnology or other fields.

Follow-on Biologics (Biogenerics). Several companies are pursuing the opportunity to develop and commercialize follow-on versions of currently marketed biologic products. These companies include Novartis (Sandoz), BioGeneriX, Stada (Bioceuticals), BioPartners, Teva Sicor USA and Pliva (which was acquired by Barr Pharmaceuticals). In the U.S. and Japan, a clear development and regulatory path does not currently exist for biologic products that are, or soon will be, off-patent. In Europe, the first guidelines regarding the quality, preclinical and clinical development of follow-on biologics were adopted in September 2005.

Research and Development Services. Although we are focused on the development of proprietary protein drugs, we also use our GlycoPEGylation technology to provide collaborative research services and product improvement opportunities to other pharmaceutical and biotechnology companies. These services may compete with efforts within these companies to improve therapeutic protein profiles and expression, and with services provided by other companies to improve proteins, such as chemical pegylation technology.

Manufacturing

Our partners currently manufacture or otherwise provide the native proteins that are subsequently remodeled using GlycoPEGylation and will incorporate the remodeling processes at their facilities. Our supply chain obligations are therefore confined to the supply of enzyme reagents and sugar nucleotides. We use contract manufacturing organizations (CMOs) for the supply of our enzyme reagents and sugar nucleotides, except those that are available commercially.

Marketing, Distribution, and Sales

We intend to capitalize on the significant experience and resources of our collaborative partners to commercialize proprietary products made using our technology. These partners generally would be responsible for much of the development, regulatory approval, sales, marketing, and distribution activities for products incorporating our technology. However, we intend to retain some commercial rights to some proteins in select territories, as we did in our collaboration with BioGeneriX. If we commercialize any products on our own, we will have to establish or contract for regulatory, sales, marketing, and distribution capabilities, and we may have to supplement our development capabilities. The marketing, advertising, and promotion of any product manufactured using our technology would be subject to regulation by the FDA or other governmental agencies.

Employees

As of December 31, 2007, we employed 50 individuals, consisting of 34 employees engaged in research and development activities, and 16 employees devoted to corporate and administrative activities. Following the January 2008 restructuring discussed below, we anticipate this number will be

reduced to approximately 30 individuals, consisting of 20 employees engaged in research and development activities, and 10 employees devoted to corporate and administrative activities. None of our employees is covered by collective bargaining agreements. We believe we have good relations with our employees, including those impacted by the most recent restructuring.

Restructurings and Employee Severance Costs

In January 2008, we discontinued further development of NE-180, our product candidate intended for the treatment of anemia in patients with chronic kidney disease and cancer patients receiving chemotherapy. The decision to discontinue development was not due to any safety or efficacy concerns about NE-180, but was based on an evaluation of commercial prospects and the likelihood of entering into a timely collaboration for the compound in the context of increased safety concerns in the ESA category. We concluded that the safety concerns expressed in recent quarters about marketed ESAs not only impacted the market potential for new ESAs, but also made it unlikely that a collaborative relationship could be formed for the future development of NE-180 in a reasonable time frame. This decision allows us to forego \$60 to \$80 million of incremental spending over the next two years. In connection with the discontinuation of the NE-180 program, we implemented a workforce reduction of approximately 35%. We anticipate paying cash severance benefits of approximately \$0.9 million in connection with the workforce reduction, most of which will be paid in the first quarter of 2008. We do not expect to incur any material contract termination charges or non-cash impairment charges in connection with the program discontinuation.

In March 2007, we implemented a restructuring of operations designed to allow for significantly higher clinical development costs for NE-180. The restructuring included a workforce reduction of approximately 40%. The employee severance costs incurred for this restructuring were payable pursuant to an employee severance plan established in August 2005. Our net loss for the year ended December 31, 2007 included \$0.6 million of employee severance costs related to this restructuring, of which \$0.5 million was included in research and development expenses and \$0.1 million was included in general and administrative expenses. All employee severance costs related to this restructuring were paid by December 31, 2007.

In September 2006, we implemented a restructuring of operations in connection with the sale of our former Witmer Road pilot manufacturing facility (Witmer Road Facility). The employee severance costs incurred for this restructuring were payable pursuant to an employee severance plan established in August 2005. Therefore, these costs did not meet the definition for classification as a restructuring charge on our Statements of Operations. Our net loss for the year ended December 31, 2006 included \$0.7 million of employee severance costs related to this restructuring, of which \$0.6 million was included in research and development expenses and \$0.1 million was included in general and administrative expenses.

Internet Address and Securities Exchange Act Filings

Our internet address is www.neose.com. We make available free of charge through our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended. We make these reports and amendments available on our website as soon as practicable after filing them electronically with, or furnishing them to, the Securities and Exchange Commission (SEC).

ITEM 1A. RISK FACTORS.

Financial Risks

We require additional capital to fund our operations. Any additional financing could result in equity dilution.

To date, we have funded our operations primarily through proceeds from the public and private placements of equity securities. We have also funded our operations to a lesser extent from proceeds from the sale of the Witmer Road Facility, property and equipment financing, interest earned on investments, corporate collaborations, and the sale of investments. In March 2007, we sold 21.4 million shares of our common stock and warrants to purchase 9.6 million shares of common stock through a private placement at a price of \$2.02 per unit, generating net proceeds of approximately \$40.5 million. The warrants have a five-year term and an exercise price of \$1.96 per share. We believe that our existing cash and cash equivalents, expected proceeds from collaborations and license arrangements, and interest income should be sufficient to meet our operating and capital requirements into the third quarter of 2009, although changes in our collaborative relationships or our business, whether or not initiated by us, may affect the rate at which we deplete our cash and cash equivalents. Our present and future capital requirements, and our ability to raise additional capital, depend on many factors, including:

level of research and development investment required to develop our therapeutic proteins, and maintain and improve our technology position;

the costs of process development and scale-up of proteins and reagents for research, development and at commercial scale;

the results of non-clinical and clinical testing, which can be unpredictable in drug development, including any failure of a product candidate in clinical development;

the time and costs involved in obtaining regulatory approvals, or the failure to obtain any necessary regulatory approvals;

changes in product candidate development plans needed to address any difficulties that may arise in process development, scale-up, manufacturing, non-clinical activities, clinical studies or commercialization;

our ability to enter into new agreements with collaborators and to extend or maintain our existing collaborations, and the terms of these agreements;

the timing of milestone and royalty payments from our collaborators;

the costs and impact of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights, and the costs of investigating patents that might block us from developing potential drug candidates;

disruptions and expenses resulting from our workforce reductions, and the continuing costs of recruiting and retaining qualified personnel;

the timing, willingness, and ability of our collaborators to commercialize products incorporating our technology;

our need or decision to acquire or license complementary technologies or new product candidate targets; and

the evolution of the competitive landscape.

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

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 corporate collaborations and licensing arrangements. In addition, the investors in our March 2007 financing have the right to participate in future capital raising transactions by us until June 2008. The existence of this participation right may reduce or diminish our ability to establish terms with respect to, or enter into, any capital raising transaction with parties other than those investors until this participation right expires in June 2008.

If we raise additional capital by issuing equity securities, our existing stockholders' percentage ownership will be reduced and they may experience substantial dilution. We may also issue equity securities that provide for rights, preference and 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 raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technology 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 and technologies, and 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 of our existence, including net losses of \$28.5 million for the year ended December 31, 2007, \$27.1 million for the year ended December 31, 2006, and \$51.8 million for the year ended December 31, 2005. Given our planned level of operating expenses, we expect to continue incurring losses for some time. As of December 31, 2007, we had an accumulated deficit of \$294.8 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 technology. We also expect to spend significant amounts to continue research and development on our proprietary drug candidates and technology, maintain and expand our intellectual property position, and expand our business development and commercialization efforts. Our level of operating expenditures will vary depending upon the stage of development of our proprietary proteins and the number and nature of our collaborations. We may continue to incur substantial losses even if our revenues increase.

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

We have not yet 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 from corporate collaborations, license agreements, and investments. We do not know when or if we will complete any of our product development efforts, obtain regulatory approval for any product candidates incorporating our technology, or successfully commercialize any approved products. Even if we are successful in developing products that are approved for marketing, we will not be successful unless these products gain market acceptance. The degree of market acceptance of these products will depend on a number of factors, including:

the timing of regulatory approvals in the countries, and for the uses, we seek;

the competitive environment;

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;

the adequacy and success of distribution, sales and marketing efforts; and

the 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 technology. 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 technology, we may not become profitable.

If the estimates we make and the assumptions on which we rely in preparing our financial statements prove inaccurate, our actual results may vary significantly.

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges taken by us and related disclosure. Such estimates and judgments include the carrying value of our property, equipment and intangible assets, revenue recognition and the value of certain liabilities. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. However, these estimates and judgments, or the assumptions underlying them, may change over time, which could require us to restate some of our previously reported financial information. A restatement of previously reported financial information could cause our stock price to decline and could subject us to securities litigation. For a further discussion of the estimates and judgments that we make and the critical accounting policies that affect these estimates and judgments, see "Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates" elsewhere in this annual report on Form 10-K.

Risks Related to Development of Products and Technologies

We may be unable to develop next-generation therapeutic proteins.

We are seeking to use our enzymatic technology to develop proprietary next-generation proteins, generally in collaboration with a partner. The development of protein drugs involves a range of special challenges at various stages of the process.

In the preclinical phase of product development, we and our partners will face several potential problems, including producing or obtaining supplies of the protein on commercially reasonable terms, successfully modifying the protein using our enzymatic technology, and achieving adequate yields of the next-generation protein. Even if a protein development program appears to be proceeding well in the early phases, a product candidate may fail in clinical trials for several reasons, such as results indicating that the product candidate is less effective than desired (e.g., the trial failed to meet its primary objectives) or that it has harmful or problematic side effects. If clinical trials are successful, it is possible that problems may arise later during commercialization, such as the subsequent discovery of adverse side effects or the increase in product category safety concerns after marketing authorization. Before and even after a product is approved for marketing, problems may arise that can negatively affect the market potential and increase the costs of our product development.

Our failure to solve any of these problems could delay or prevent the commercialization of products incorporating our technology and could negatively impact our business by, among other things, reducing our ability to obtain necessary capital funds or causing us to scale back operations through the discontinuation of research or development activities and/or the reduction of our workforce.

Our long-term success depends upon our ability to develop, receive regulatory approval for and commercialize drug product candidates.

All of our product candidates are in the development stage and have not received regulatory approval, an important requirement to the commercialization of any product candidate. If we or our collaboration partners fail to complete the development, receive regulatory approvals for and/or commercialize our product candidates, we will not be able to generate revenues from the sale of products resulting from our product candidates. As we or our collaboration partners continue our product development, there is a significant risk that testing will demonstrate that our product candidates are not suitable for commercialization, either because they are unsafe, inefficient, or too costly to manufacture, or because third party competitors market a more clinically effective, safer, or more cost-effective product.

Moreover, even if we believe that the clinical data demonstrates the safety and efficacy of a product candidate, regulators may disagree with us, and we could be delayed, limited or prevented from obtaining the required regulatory approval of such product candidate. In addition, regulatory approval may take longer than we expected. The FDA or foreign regulators could at any point forbid us or our collaborators to initiate or continue testing of our product candidates in human clinical trials. There is also the risk that one of our product candidates is later discovered to cause adverse effects that prevent widespread use, require withdrawal from the market, or serve as the basis for product liability claims.

If we or our collaboration partners are unable to successfully develop and commercialize our product candidates, we will not have a sufficient source of revenue. Moreover, the failure of one or more of our product candidates in clinical development could harm our ability to raise additional capital.

Our ability to enter into new collaborations and to achieve success under existing collaborations is uncertain.

A material component of our business strategy is to establish and maintain collaborative arrangements with third parties to co-develop our products and to commercialize products made using our technology. We also intend to establish collaborative relationships to obtain domestic or international sales, marketing and distribution capabilities for product candidates receiving regulatory approval. We currently have active collaborative agreements with Novo Nordisk and BioGeneriX. We anticipate that substantially all of our revenues during the next several years will continue to be generated from collaboration or license agreements.

The process of establishing collaborative relationships is difficult, time-consuming and involves significant uncertainty. Our partnering strategy entails many risks, including:

we may be unsuccessful in entering into or maintaining collaborative agreements for the co-development of our products or the commercialization of products incorporating our technology;

we may not be successful in applying our technology to or otherwise satisfying the needs of our collaborative partners;

our collaborators may not be successful in, or may not remain committed to, co-developing our products or commercializing products incorporating our technology;

our collaborators may seek to develop other proprietary alternatives to our products or technology;

our collaborators may not commit sufficient resources to incorporating our technology into their products;

our collaborators are not obligated to market or commercialize our products or products incorporating our technology, and they are not required to achieve any specific commercialization schedule;

our collaborative agreements may be terminated by our partners on short notice; and

continued consolidation in our target markets may limit our ability to enter into collaboration agreements, or may result in terminations of existing collaborations.

Furthermore, even if we do establish collaborative relationships, it may be difficult for us to maintain or perform under such collaboration arrangements, as our funding resources may be limited or our collaborators may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, a change in business strategy, or other reasons. If we or any collaborator fails to fulfill any responsibilities in a timely manner, or at all, our research, clinical development or commercialization efforts related to that collaboration could be delayed or terminated. It may also become necessary for us to assume responsibility for activities that would otherwise have been the responsibility of our collaborator. Further, if we are unable to establish and maintain collaborative relationships on acceptable terms, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of funding.

We depend on our partners and other third parties to conduct our clinical trials.

We are highly dependent on third parties to conduct our clinical trials. Our collaborative partners are solely responsible for conducting the clinical trials on our lead product candidates, GlycoPEG-GCSF and Factors VII, VIII and IX. They in turn contract with other third parties, generally referred to as clinical research organizations or CROs, to oversee the operations of such clinical trials and to perform data collection and analysis, including finding investigators to conduct the clinical study; encouraging patient enrollment in the study; collecting the data and entering the data into computer systems; cleaning, outputting and analyzing the data from the study; and writing the Clinical Study Report(s). We are subject to the risk that these third parties could fail to perform their obligations properly, in a timely fashion, and/or in compliance with applicable FDA and other governmental regulations. The failure of any of these third parties to perform all of their obligations to us or our partners could substantially delay our development efforts, and delay or prevent regulatory approval of our product candidates. Furthermore, the decision of our partners to delay or discontinue the development of our product candidates would seriously adversely affect our ability to complete the development of those product candidates, and may prevent us or other potential collaborators from commercializing such product candidates.

Non-clinical and clinical trial results for our products may not be favorable.

In order to obtain regulatory approval for the commercial sale of any of our product candidates, we must conduct both non-clinical studies and human clinical trials that demonstrate the product is safe and effective for the use for which we are seeking approval. We may suffer significant setbacks in clinical trials, even after promising results in earlier trials. For example, Phase II activity may not replicate Phase I results or Phase III efficacy data may not replicate Phase II data. Adverse results from studies, including clinical trials, could have a negative effect on our ability to obtain the approval of the FDA or other regulatory agencies.

We and our collaboration partners also may not be permitted to undertake or continue clinical trials for any of our product candidates in the future or may otherwise be unable to do so because acceptable candidates to participate in such trials are unavailable. Even if we or our collaboration partners are able to conduct such trials, we or our collaboration partners may not be able to demonstrate satisfactorily that the products are safe and effective and thus qualify for the regulatory approvals necessary to commercialize them.

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

Safety and efficacy results from non-clinical studies involving animals and other models and from early clinical trials are often not accurate indicators of results of later-stage clinical trials that involve larger human populations, and, moreover, may not always be representative of results obtained while marketing an approved drug, particularly with regard to safety.

Unfavorable results of clinical trials conducted by our competitors or other biotechnology companies could also adversely affect our ability to gain regulatory approval of our product candidates by increasing government examination and complexity of clinical trials. Government and public concerns over safety issues associated with pharmaceutical and biological products could potentially result in termination of clinical trials on entire classes of drug candidates, lengthen the trial process for product categories, increase legal and production costs relating to certain drug categories, and/or expand the safety labeling for approved products.

Our and our partners' clinical trials may be delayed.

One potential cause of a delay in product development is a delay in clinical trials. Many factors could delay clinical trials, including, without limitation:

the failure to obtain or maintain regulatory clearance to conduct clinical trials;

insufficient supplies of clinical trial materials;

slow rate of patient enrollment and early discontinuation of patient participation;

adverse events occurring during clinical trials;

adverse results from non-clinical studies; and

changes in regulatory requirements.

We have no commercial manufacturing capability and rely on third parties to manufacture our product candidates and the materials used to make them.

Completion of our clinical trials and commercialization of our product candidates require access to, or the development of, facilities to manufacture a sufficient supply of our proteins, enzymes, sugar nucleotides and other reagents needed to produce and commercialize our technology. We are typically responsible under our collaboration agreements for the supply of reagents and other materials required for the collaborations. Since we currently have no manufacturing capability of our own, we are highly dependent on contract manufacturers to produce these materials for us or our collaborators for non-clinical, clinical and/or commercial purposes. Our success depends on our ability to have these compounds manufactured on a commercial scale or to obtain commercial quantities, in either case, at reasonable cost. We may not be able to procure sufficient quantities of the products we develop, or the materials used to make them, to meet our or our collaborators' needs for non-clinical or clinical development or commercialization. We may compete with other parties for access to manufacturing facilities and suitable alternatives may be unavailable to us. As a result, our product candidates may suffer delays in manufacture if our CMOs give other products greater priority than our product candidates or the materials needed to make them. It is time-consuming and expensive to change contract manufacturers for pharmaceutical products, particularly when the products are under regulatory review in a New Drug Application process. If we fail to maintain essential manufacturing and service relationships, we may not be able to replace an important CMO or to develop our own manufacturing capabilities, either of which could impede our ability to obtain regulatory approval for our products candidates and delay or prevent our or our collaborators' product development and commercialization. If we do find replacement CMOs, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a considerable delay before a new facility could be qualified and registered with the appropriate authorities. If we encounter delays or difficulties in connection with manufacturing, commercialization of our products and technology could

be delayed, we could breach our obligations under our collaborative agreements and we could have difficulty obtaining necessary financing.

The manufacture of our product candidates is a complex and highly-regulated process. If any of our CMOs encounters problems manufacturing materials for us, our business could suffer.

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with current Good Manufacturing Practices (cGMP) or similar requirements that the FDA or foreign regulators establish. The manufacture of product candidates and key reagents at any facility 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, our CMOs, or other suppliers may not meet these requirements. Our CMOs may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or they may not be able to maintain compliance with the FDA's cGMP requirements, or those of foreign regulators, necessary to continue manufacturing our product candidates and materials. Any failure to comply with cGMP requirements or other FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products candidates.

Additionally, we and the third parties with whom we contract to manufacture our proteins face the significant, normal scale-up risks associated with protein manufacturing: proteins are difficult to produce; it is difficult to scale up protein manufacturing processes; and it is expensive to produce proteins. These process manufacturing and/or regulatory problems could increase the cost, delay the timeline, or render unfeasible the commercial launch of our product candidates.

Proteins are uniquely susceptible to neutralizing antibodies that could result in diminished efficacy of our products.

Proteins that are foreign to a living body often provoke an immune response. Protein drugs produced by recombinant technology, even though they have the same primary amino acid sequence as a native human protein, sometimes provoke formation of antibodies that bind to the protein drug. Some such antibodies bind so as to prevent the protein drug from engaging its receptor, and thus neutralize the drug activity of the protein. Furthermore, neutralizing antibodies provoked by administration of a protein drug may react with endogenous proteins whose natural activity the drug was intended to supplement, thereby inducing a total lack of both therapeutic and natural activities in the patient. Such a condition can prove fatal. We will not know if the proteins we develop as product candidates will provoke neutralizing antibody responses in humans until they are evaluated in clinical trials. It is possible that our product candidates may be rendered ineffective for the therapeutic purpose for which they are intended or could induce harm to patients because of the neutralizing effect of antibodies to endogenous proteins in humans in response to our proteins.

Additionally, all protein drugs, or reagents used in the manufacture of the protein drugs, that are expressed by recombinant technology retain some trace of contaminating proteins from the host cells used to express the protein drug. These host cell proteins may increase the chances of an immunogenic response that could diminish the therapeutic efficacy of the protein.

Developments in our product categories may adversely affect our ability to commercialize our product candidates.

Our business focus is on the development of next-generation therapeutic proteins that we believe will be competitive with best-in-class protein drugs currently on the market. Because we seek to introduce products into already established markets, we are subject to the positive and negative effects of those marketplaces, including public and regulatory developments related to the product categories as a whole. For instance, the success of a large number of competitive products in our product categories would likely reduce or eliminate the commercial opportunity for our product candidates.

(See the risk factor in this report entitled "*Our competitors may develop better or more successful products.*") Likewise, the failure or negative results of products similar to ours could diminish the commercial opportunity for our product candidates by, among other factors, increasing public safety concerns or imposing governmental restrictions applicable to all products in the drug category. Failed or less than favorable clinical trial results of other drugs in our product categories could adversely affect our ability to gain regulatory approval of our product candidates by increasing government examination and complexity of clinical trials. Government and public concerns over safety issues associated with pharmaceutical and biological products could potentially result in termination of clinical trials on entire classes of drug candidates, lengthen the trial process for product categories, increase legal and production costs relating to certain drug categories, and/or expand the safety labeling for approved products. Such was the case with our NE-180 product candidate, which suffered from the increased safety concerns in the ESA drug category, resulting in that product candidate's decreased marketability and our discontinuation of its development.

We may be exposed to product liability and related risks.

The use in humans of compounds developed by us or incorporating our technology may result in product liability claims. Product liability claims can be expensive to defend, and may result in large settlements of claims or judgments against us. Even if a product liability claim is not successful, the adverse publicity, time, and expense involved in defending such a claim may interfere with our business. We may not be able to obtain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

Risks Related to Intellectual Property

Blocking patents or claims of infringement may stop or delay the development of our proprietary products.

Our commercial success depends in part on avoiding claims of infringement of the patents or proprietary rights of third parties. We have devoted significant resources to investigating the patent protection surrounding the proteins that are the subject of our development programs. The numerous patents, each with multiple claims, may be difficult to uncover and interpret, leading to uncertainty about our freedom to operate. It is possible that we will not be aware of issued patents or pending patent applications that are relevant to our product candidates because our searches do not find them, or pending patent applications because they are not yet publicly available. Our interpretation of patents could be challenged, leading to litigation, and we could face claims of infringement of rights of which we are unaware.

There have been significant litigation and interference proceedings regarding patent rights, and the patent situation regarding particular products is often complex and uncertain. As we proceed with the development of our product candidates, we may face uncertainty and litigation could result, which could lead to liability for damages, prevent our development and commercialization efforts, and divert resources from our business strategy.

The cost of any litigation challenging our right to pursue our target proteins or technology could be substantial. Others seeking to develop next-generation versions of proteins, or the holders of patents on our target proteins, may have greater financial resources, making them better able to bear the cost of litigation. In particular, one company that produces products that will likely be in direct competition with our current product candidates has aggressively defended the patents related to its products and this could increase the likelihood of litigation or the cost of litigation. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to develop, manufacture, and market products, form strategic alliances, and compete in the marketplace.

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

Third parties from time to time may assert that we are infringing their patents, trade secrets or know-how. In addition, our technology may infringe patents that may issue in the future to third parties. We could incur substantial costs in defending ourselves and our partners against any such claims. Furthermore, parties making such claims may be able to obtain injunctive or other equitable relief, which could effectively block our ability or our partners' ability to further develop or commercialize some or all of our products or technology in the U.S. and abroad, and could result in the award of substantial damages. If we are found to infringe, we may be required to obtain one or more licenses from third parties or be unable to proceed. There can be no assurance that we will be able to obtain such licenses at a reasonable cost, if at all. Defense of any lawsuit or failure to obtain any such required license could have a material adverse effect on us.

The failure to obtain, maintain or protect patents and other intellectual property could impact our ability to compete effectively.

To compete effectively, we need to develop and maintain a proprietary position with regard to our own technology, products and business. We are seeking to develop patent protection for therapeutic proteins that include numerous claims for composition of matter, methods of use, and methods of making. Legal standards relating to the validity and scope of claims in our technology field are still evolving. Therefore, the degree of future protection in the U.S. and other countries for our proprietary rights in our core technology and products made using this technology is also uncertain. The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

the pending patent applications we have filed, or to which we have exclusive rights, may not result in issued patents, or may take longer than we expect to result in issued patents;

changes in U.S. or foreign patent laws may adversely affect our ability to obtain or maintain our patent protection;

we may be subject to interference proceedings;

we may be subject to opposition proceedings in foreign countries;

the claims of any patents that are issued may not provide meaningful protection;

we may not be able to develop additional proprietary technologies that are patentable;

the patents licensed or issued to us or our collaborators may not provide a competitive advantage;

other companies may challenge patents licensed or issued to us or our collaborators;

other companies may independently develop similar or alternative technologies, or duplicate our technology;

other companies may design around technologies we have licensed or developed; and

enforcement of patents is complex, uncertain and expensive.

We cannot be certain that patents will be issued as a result of any of our pending applications, and we cannot be certain that any of our issued patents will give us adequate protection from competing products. For example, issued patents may be circumvented or challenged, declared invalid or unenforceable, or narrowed in scope. In addition, since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make our inventions or to file patent applications covering those inventions. In the event that another party has also filed a patent application relating to an invention claimed by us, we may be required to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial uncertainties and costs for us, even if the eventual outcome were favorable to us. It is also possible that others may obtain issued patents that

could prevent us from commercializing our products or require us to obtain licenses requiring the payment of significant fees or royalties in order to enable us to conduct our business. As to those patents that we have licensed, our rights depend on maintaining our obligations to the licensor under the applicable license agreement, and we may be unable to do so. Furthermore, patent protection available to us may vary in different jurisdictions. In particular, the laws in some countries provide little patent protection.

The cost to us of any patent litigation or other proceeding relating to our patents or applications, even if resolved in our favor, could be substantial. Our ability to enforce our patent protection could be limited by our financial resources, and may be subject to lengthy delays. If we are unable to effectively enforce our proprietary rights, or if we are found to infringe the rights of others, we may be in breach of our license agreements with our partners.

In addition to patents and patent applications, we depend upon trade secrets and proprietary know-how to protect our proprietary technology. We require our employees, consultants, advisors, and collaborators to enter into confidentiality agreements that prohibit the disclosure of confidential information to any other parties. We require our employees and consultants to disclose and assign to us their ideas, developments, discoveries, and inventions. These agreements may not, however, provide adequate protection for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use or disclosure.

We may have to develop or license alternative technologies if we are unable to maintain or obtain key technology from third parties.

We have licensed patents and patent applications from a number of institutions. Some of our proprietary rights have been licensed to us under agreements that have performance requirements or other contingencies. The failure to comply with these provisions could lead to termination or modifications of our rights to these licenses. Additionally, we may need to obtain additional licenses to patents or other proprietary rights from other parties to facilitate development of our proprietary technology base. The ownership of patents exclusively licensed to us may be subject to challenge if inventorship was not adequately investigated and represented. If our existing licenses are terminated or if we are unable to obtain such additional licenses on acceptable terms, our ability to perform our own research and development and to comply with our obligations under our collaborative agreements may be delayed while we seek to develop or license alternative technologies.

Risks Related to Competition

Our competitors may develop better or more successful products.

Our business is characterized by extensive research efforts and rapid technological progress. New developments in molecular biology, medicinal chemistry and other fields of biology and chemistry are expected to continue at a rapid pace in both industry and academia. Our potential competitors include both public and private pharmaceutical and biotechnology companies, as well as academic institutions, governmental agencies and other public and private research organizations that are also conducting research activities and seeking patent protection.

A number of these competitors are working on the development of next-generation protein therapeutics. Some companies have programs focused on developing next-generation or improved versions of G-CSF and Factors VIIa, VIII and IX, and some are already marketing improved versions of these products. These companies include Amgen, Maxygen, CoGenesys, Bayer Healthcare, Wyeth and Biogen Idec. Other companies are active in this area, and we expect that competition will increase.

In addition, we may compete with companies commercializing first-generation protein therapeutics, as a result of pricing practices or reimbursement limitations. Even if we succeed in developing and marketing products that have significant advantages over first-generation products, if first-generation

products are available at a lower out-of-pocket cost to the consumer, health-care providers and consumers may choose first-generation products instead of next-generation versions.

Compared to us, many of our likely and potential competitors have more:

financial, scientific and technical resources;

product development, manufacturing and marketing capabilities;

experience conducting non-clinical studies and clinical trials of new products; and

experience in obtaining regulatory approvals for products.

Competitors may succeed in developing products and technologies that are more effective or less costly than ours and that would render our products or technology, or both, obsolete or noncompetitive. We know that other companies with substantial resources are working on the development of next-generation proteins, and they may achieve better results in enzymatically modifying our target proteins or the target proteins of our potential collaborators.

Competitors also may prove to be more successful in designing, manufacturing and marketing products. If we are successful in developing our own drug candidates or versions of drugs that are no longer patented, we will compete with other drug manufacturers for market share. If we are unable to compete successfully, our commercial opportunities will be diminished.

In addition, while there is no proven abbreviated regulatory pathway for follow-on biologics, this possibility is under discussion in the U.S. and other jurisdictions and has been adopted in part in Europe. If an abbreviated regulatory process is adopted for the approval of follow-on biologics in any major market, competition could increase in related segments of the therapeutic protein market.

We may be unable to retain key employees or recruit additional qualified personnel.

Because of the specialized scientific nature of our business, we are highly dependent upon qualified scientific, technical and managerial personnel, including our research and development team. The advancement of our business is dependent upon our management team's ability to evaluate collaboration opportunities and on their ability to focus our company's efforts. Our anticipated research and development activities will require a sustained level of expertise and the retention and/or addition of experienced personnel.

There is intense competition for qualified management and research and development personnel in the biotechnology field. In addition, we have a history of operating losses and declines in our stock price and cash position, and we have implemented four workforce reductions in the past few years. Manpower may be constrained in certain areas of our business, and the departures of existing personnel could be disruptive, and lead to the departure of other employees. These factors may affect employee morale and retention, including making us a target of recruitment agencies seeking to hire our highly specialized personnel. Therefore, we may not be able to attract and retain the qualified personnel necessary for our business. The loss of the services of existing personnel, as well as the failure to recruit additional key scientific, technical and managerial personnel in a timely manner, could harm our research and development programs and our ability to manage day-to-day operations, attract collaboration partners, attract and retain other employees, and generate revenues. We do not maintain "key person" life insurance on any of our employees.

Risks Related to Government Regulation

We are subject to extensive government regulation, and we or our collaborators may not obtain necessary regulatory approvals or may encounter long delays and large expenditures in obtaining such approvals.

The research, development, manufacture and control, marketing, and sale of our reagents and product candidates manufactured using our technology are subject to significant, but varying, degrees of regulation by a number of government authorities in the U.S. and other countries.

Pharmaceutical product candidates manufactured using our technology must undergo an extensive regulatory approval process before commercialization. This process is regulated by the FDA and by comparable agencies in Europe and in other countries. The U.S. and foreign regulatory agencies have substantial discretion to delay or withhold approval of the initiation of clinical trials, terminate clinical trials, require additional testing, delay or withhold registration and marketing approval, and mandate product withdrawals. In addition, the U.S. or other regulatory agencies could, at any time in the regulatory approval process, place the regulatory submission for a product candidate on "hold" pending the receipt, review and approval of additional information.

We and our collaborators intend to base our submissions for regulatory approval and the information contained in such submissions on our understanding of the requirements of the FDA and its foreign counterparts. If additional information is required in other jurisdictions, including EMEA countries, or if the submitted information is deemed insufficient, we may face delays and additional costs.

Neither we nor our collaborators have submitted any product candidates incorporating our technology for marketing approval to the FDA or any other regulatory authority. If any product candidate manufactured using our technology is submitted for regulatory approval, it may not receive the approvals necessary for commercialization, the desired labeling claims, or adequate levels of reimbursement. Any delay in receiving, or failure to receive, these approvals would adversely affect our ability to generate product revenues or royalties, and we will have already spent significant sums in pursuing approval.

We anticipate that the development of our next-generation proprietary proteins will involve a traditional development program, including clinical trials. Any new governmental regulations may delay or alter regulatory approval of any product candidate manufactured using our technology. If an abbreviated regulatory process is adopted for the approval of follow-on biologics in any major market, competition could increase in related segments of the therapeutic protein market. We cannot predict the impact of adverse governmental action that might arise from future legislative and administrative action.

Even if we or our collaborators are successful in obtaining regulatory approvals for any of our product candidates, our or their manufacturing processes will be subject to continued review by the FDA and other regulatory authorities. Any later discovery of unknown problems with our products, products incorporating our technology, or manufacturing processes could result in restrictions on such products or manufacturing processes, including potential withdrawal of the products from the market. In addition, if regulatory authorities determine that we or our collaborators have not complied with regulations in the research and development of a product candidate or the manufacture and control of our product candidates or the materials used to make them, then we or our collaborators may not obtain necessary approvals to market and sell the product candidate.

Third-party reimbursement for our collaborators' or our future product candidates may not be adequate.

Even if regulatory approval is obtained to sell any product candidates incorporating our technology, our future revenues, profitability, and access to capital will be determined in part by the price at which we or our collaborators can sell such products. There are continuing efforts by

governmental and private third-party payors to contain or reduce the costs of health care through various means. We expect a number of federal, state, and foreign proposals to control the cost of drugs through governmental regulation. We are unsure of the form that any health care reform legislation may take or what actions federal, state, foreign, and private payors may take in response to the proposed reforms. Therefore, we cannot predict the effect of any implemented reform on our business.

Our and our collaborators' ability to commercialize our products successfully will depend, in part, on the extent to which reimbursement for the cost of such products and related treatments will be available from government health administration authorities, such as Medicare and Medicaid in the U.S., private health insurers, and other organizations. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Adequate third-party coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product research and development. Inadequate coverage and reimbursement levels provided by government and third-party payors for use of our or our collaborators' products may cause these products to fail to achieve market acceptance and would cause us to lose anticipated revenues and delay achievement of profitability. It is possible that reimbursement may be limited to that which is available for first-generation versions of one or more of our or our collaborator's products, making it harder for us and our collaborators to realize an appropriate return.

Risk Related to Stock Market and Foreign Exchange Rates

We currently fail to meet one of Nasdaq's listing requirements and if our common stock is delisted it could negatively impact the price of our common stock and our ability to access the capital markets.

Our common stock is currently listed on the Global Market of The NASDAQ Stock Market LLC. On February 19, 2008, we received a Staff Deficiency Letter from The NASDAQ Stock Market LLC stating that for the last 30 consecutive business days the bid price of our common stock has closed below the minimum \$1.00 per share required for continued inclusion on the NASDAQ Global Market, and consequently we are not in compliance with the requirements for continued listing of our common stock. If we fail to regain compliance with the minimum bid price requirement prior to August 18, 2008, or if at any time we fail to satisfy any of the other requirements for continued listing, our common stock could be delisted from the NASDAQ Global Market. The delisting of our common stock would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock.

If delisted from the NASDAQ Global Market, our common stock will likely be quoted in the over-the-counter market in the so-called "pink sheets" or quoted in the OTC Bulletin Board. In addition, our common stock would be subject to the rules promulgated under the Securities Exchange Act of 1934 relating to "penny stocks." These rules require brokers who sell securities that are subject to the rules, and who sell to persons other than established customers and institutional accredited investors, to complete required documentation, make suitability inquiries of investors and provide investors with information concerning the risks of trading in the security. These requirements could make it more difficult to buy or sell our common stock in the open market. In addition, the delisting of our common stock could materially adversely affect our ability to raise capital on terms acceptable to us or at all. Delisting from the NASDAQ Global Market could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities.

Our stock price may continue to experience fluctuations.

The market prices of securities of thinly-traded biotechnology companies such as ours generally are highly volatile. For example, since January 1, 2007, the price of our common stock reached a high of \$3.00 per share in April 2007 and a low of \$0.47 per share on March 7, 2008.

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

In this market environment, the sale of a substantial number of shares of our common stock in the public market or the perception that such a sale might occur would likely have an adverse effect on the market price of our common stock, at least for the short term. We have a number of investors who hold relatively large positions in our securities. A decision by any of these investors to sell all or a block of their holdings of our common stock could cause our stock price to drop significantly.

The market also continues to experience significant price and volume fluctuations, some of which are unrelated to the operating performance of particular companies. In recent years, the price of our common stock has fluctuated significantly and may continue to do so in the future. Many factors could have a significant effect on the market price for our common stock, including:

non-clinical and clinical trial results;

product development delays;

regulatory delays;

discontinuation of the development program for a product candidate;

an announcement or termination of a collaborative relationship by us or any of our partners or competitors;

developments relating to our patent position or other proprietary rights;

announcements of technological innovations or new therapeutic products;

government regulations;

public concern as to the safety of products developed by us or others; and

general market conditions.

Any litigation brought against us as a result of this volatility could result in substantial costs and a diversion of our management's attention and resources, which could negatively impact our financial condition, revenues, results of operations, and the price of our common stock.

If we raise additional capital by issuing equity securities in a fluctuating market, many or all of our existing stockholders may experience substantial dilution, and if we need to raise capital by issuing equity securities at a time when our stock price is down, we may have difficulty raising sufficient capital to meet our requirements. If any of the risks described in these "Risk Factors" occurred, or if any unforeseen risk affected our performance, it could have a dramatic and adverse impact on the market price of our common stock.

Changes in foreign currency exchange rates could result in increased costs.

We have entered into some agreements denominated, wholly or partly, in Euros or other foreign currencies, and, in the future, we may enter into additional, significant agreements denominated in foreign currencies. If the values of these currencies increase against the dollar, our costs would increase. To date, we have not entered into any contracts to reduce the risk of fluctuations in currency exchange rates. In the future, depending upon the amounts payable under any such agreements, we may enter into forward foreign exchange contracts to reduce the risk of unpredictable changes in these costs. However, due to the variability of timing and amount of payments under any such agreements, foreign exchange contracts may not mitigate the potential adverse impact on our financial results.

Risks Related to Facilities, Business Interruption, and the Environment

The use of hazardous materials in our operations may subject us to environmental claims or liability.

Our research and development processes involve the controlled use of hazardous materials, chemicals, and radioactive compounds. We conduct experiments that are quite common in the biotechnology industry, in which we use small quantities of corrosive, toxic and flammable chemicals, and trace amounts of radioactive materials. The risk of accidental injury or contamination from these materials cannot be entirely eliminated. We do not maintain a separate insurance policy for these types of risks. In the event of an accident or environmental discharge, we may be held liable for any resulting damages, and any liability could exceed our resources. We are subject to federal, state, and local laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations could be significant.

Destructive actions by activists or terrorists could damage our facilities, interfere with our research activities, and cause ecological harm.

Activists and terrorists have shown a willingness to injure people and damage physical facilities, equipment and biological materials to publicize or otherwise further their ideological causes. Our or our collaborators' operations and research activities, and manufacturing and other services conducted for us by third parties, could be adversely affected by such acts. Any such damage could delay our research projects and decrease our ability to conduct future research and development. Damage caused by activist or terrorist incidents could also cause the release of hazardous materials, including chemicals, radioactive and biological materials.

Any significant interruption to our ability to conduct our business operations, research and development activities, or supply activities could reduce our revenue and increase our expenses.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

We lease office space for our headquarters and operations at 102 Rock Road in Horsham, Pennsylvania (Rock Road Facility), consisting of approximately 40,000 square feet. We entered into the lease agreement for the Rock Road Facility in February 2002. The initial term of the lease ends in July 2022, at which time we have an option to extend the lease for an additional five years, followed by another option to extend the lease for an additional four and one-half years. We also lease warehouse space nearby in Horsham.

ITEM 3. LEGAL PROCEEDINGS.

We are not a party to any material legal proceedings.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

We did not submit any matters to a vote of security holders during the fourth quarter of 2007.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

Our common stock is listed on the Global Market of The NASDAQ Stock Market LLC under the symbol NTEC. We commenced trading on NASDAQ on February 15, 1996. The following table sets forth the high and low sale prices of our common stock for the periods indicated.

	Common Stock Price	
	High	Low
Year Ended December 31, 2006		
First Quarter	\$ 3.95	\$ 1.85
Second Quarter	4.18	2.18
Third Quarter	4.34	1.90
Fourth Quarter	2.89	1.78
Year Ended December 31, 2007		
First Quarter	2.73	1.56
Second Quarter	3.00	1.95
Third Quarter	2.54	1.40
Fourth Quarter	1.70	0.78

As of February 28, 2008, there were approximately 200 record holders and 2,800 beneficial holders of our common stock. We have not paid any cash dividends on our common stock and we do not anticipate paying any in the foreseeable future.

Common Stock Performance Graph

The following Common Stock Performance Graph shall not be deemed incorporated by reference into any of our filings under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent we specifically incorporate it by reference therein.

The following graph assumes that \$100 was invested on December 31, 2002 in our common stock. The graph compares the cumulative return, which includes the reinvestment of dividends, of this investment with an equivalent investment on that date in the NASDAQ Stock Market U.S. Index (the "NASDAQ Composite") and the NASDAQ Stock Market Biotech Index (the "NASDAQ Biotech Index").

ITEM 6. SELECTED FINANCIAL DATA.

The following Statements of Operations and Balance Sheet Data for each of the years in the five-year period ended December 31, 2007 are derived from our audited financial statements. The financial data set forth below should be read in conjunction with the sections of this Annual Report on Form 10-K entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," and the financial statements and notes included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2007	2006	2005	2004	2003
	(in thousands, except per share data)				
Statements of Operations Data:					
Revenue from collaborative agreements	\$ 8,805	\$ 6,184	\$ 6,137	\$ 5,070	\$ 1,435
Operating expenses:					
Research and development	34,918	29,013	33,136	34,672	26,821
General and administrative	10,855	11,551	10,878	11,711	11,148
Restructuring charges			14,206		
Total operating expenses	45,773	40,564	58,220	46,383	37,969
Gain on sale of Witmer Road Facility		7,333			
Operating loss	(36,968)	(27,047)	(52,083)	(41,313)	(36,534)
Decrease in fair value of warrant liability	6,560				
Other income			22		
Impairment of equity securities					(1,250)
Interest income (expense), net	1,357	(60)	222	(329)	103
Loss before income tax benefit	(29,051)	(27,107)	(51,839)	(41,642)	(37,681)
Income tax benefit	533				
Net loss	\$ (28,518)	\$ (27,107)	\$ (51,839)	\$ (41,642)	\$ (37,681)
Basic and diluted net loss per share	\$ (0.57)	\$ (0.82)	\$ (1.64)	\$ (1.82)	\$ (2.14)
Weighted-average shares outstanding used in computing basic and diluted net loss per share	50,262	32,857	31,590	22,898	17,611
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	\$ 19,282	\$ 16,388	\$ 37,738	\$ 45,048	\$ 53,060
Total assets	36,239	31,243	65,363	90,731	94,845
Total debt and capital lease obligations	840	1,831	14,454	18,345	10,601
Accumulated deficit	(294,845)	(266,327)	(239,220)	(187,381)	(145,739)
Total stockholders' equity	18,916	15,559	40,117	60,854	72,213

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are not historical facts and include, but are not limited to, statements about our plans, objectives, representations and contentions that typically may be identified by use of terms such as "anticipate," "believe," "estimate," "plan," "may," "expect," "intend," "could," "potential," and similar expressions, although some forward-looking statements are expressed differently. These forward-looking statements include, among others, the statements about our:

estimate that our existing cash and cash equivalents, expected proceeds from collaborations and license agreements, and interest income should be sufficient to meet our operating and capital requirements at least into the third quarter of 2009;

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, procure commercial quantities of reagents and products, and commercialize our technology;

expectations regarding the scope and expiration of patents;

expectations regarding the timing of non-clinical activities, regulatory meetings and submissions, as well as the progression of clinical trials, for GlycoPEG-GCSF and GlycoPEG-Factor VIIa;

expectations for the development of long-acting versions of G-CSF, Factor VIIa, Factor VIII and Factor IX, and subsequent proprietary drug candidates;

expectations regarding our stock price and listing qualifications;

expectations regarding net cash utilization;

expectations for generating revenue; and

expectations regarding the timing and character of new or expanded collaborations and for the performance of our existing collaboration partners in connection with the development and commercialization of products incorporating our technology.

You should be aware that the forward-looking statements included in this report represent management's current judgment and expectations, but our actual results, events and performance could differ materially from those in the 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 meet forecasted timelines due to internal or external causes;

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

unfavorable non-clinical and clinical results for our product candidates or product categories;

regulatory developments that adversely affect our ability to market our products or obtain government approvals;

our ability to develop commercial-scale manufacturing processes for our products and reagents, either independently or in collaboration with others;

the performance of our contract manufacturers;

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

our ability to enter into and maintain collaborative arrangements;

our ability to obtain adequate sources of proteins and reagents;

our ability to develop and commercialize products without infringing the patent or intellectual property rights of others;

our ability to expand and protect our intellectual property and to operate without infringing the rights of others;

our ability and our collaborators' ability to develop and commercialize therapeutic proteins and our ability to commercialize our technology;

our ability to attract and retain key personnel;

our ability to satisfy the continued listing requirements of The NASDAQ Stock Market LLC;

our ability to compete successfully in an intensely competitive field; and

general economic conditions.

These and other risks and uncertainties that could affect our actual results are discussed in this report, particularly in Item 1A of Part I of this Annual Report on Form 10-K in the section entitled "Risk Factors."

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance, or achievements. We do not assume responsibility for the accuracy and completeness of the forward-looking statements other than as required by applicable law. We do not undertake any duty to update any of the forward-looking statements after the date of this report to conform them to actual results, except as required by the federal securities laws.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion should be read in conjunction with our financial statements and related notes included in this Annual Report on Form 10-K.

Overview

We are a clinical-stage biopharmaceutical company focused on the development of next-generation therapeutic proteins, which we believe will be competitive with best-in-class protein drugs currently on the market. We have two therapeutic protein candidates in clinical trials: GlycoPEG-GCSF and GlycoPEG-FVIIa, and two therapeutic protein candidates in the research stage: GlycoPEG-FVIII and GlycoPEG-FIX.

GlycoPEG-GCSF is a long-acting version of G-CSF that we are co-developing with BioGeneriX AG, a company of the ratiopharm Group. G-CSF is prescribed to stimulate production of neutrophils (a type of white blood cell) and is approved for sale in major markets around the world for treatment of neutropenia associated with myelosuppressive chemotherapy. In November 2006, BioGeneriX initiated the first of two planned Phase I clinical trials for GlycoPEG-GCSF. In March 2007, BioGeneriX initiated the second Phase I clinical trial for GlycoPEG-GCSF. In November 2007, we reported data from both of these Phase I clinical trials. That data demonstrated that GlycoPEG-GCSF is a potent stimulator of neutrophils and mobilizer of peripheral blood progenitor cells, and that at comparable doses to Neulasta® (Amgen's marketed, long-acting G-CSF), GlycoPEG-GCSF demonstrates a 60% greater bioavailability, leading to a 30% increase in the generation of neutrophils. We expect BioGeneriX to commence a Phase II study in the first half of 2008.

GlycoPEG-FVIIa is a long-acting form of recombinant Factor VIIa that is being developed by our partner, Novo Nordisk, utilizing our GlycoPEGylation technology. Factor VIIa is used in the treatment of bleeding episodes and for the prevention of bleeding during surgery or invasive procedures in patients with congenital hemophilia with inhibitors to coagulation Factors VIII or IX. In June 2007, Novo Nordisk initiated a Phase I clinical study for GlycoPEG-Factor VIIa to assess the safety and pharmacokinetics of GlycoPEG-FVIIa in healthy volunteers. During 2007, poster presentations of preclinical data for GlycoPEG-FVIIa were presented at annual meetings of the International Society on Thrombosis and Haemostasis and the American Society of Hematology. Novo Nordisk is also developing long-acting forms of recombinant Factor VIII and recombinant Factor IX utilizing our GlycoPEGylation technology. Factor VIII products are used in the treatment of Hemophilia A, and Factor IX products are used in the treatment of Hemophilia B.

In January 2008, we announced the discontinuation of further development of GlycoPEG-EPO (NE-180), our product candidate intended for the treatment of anemia in patients with chronic kidney disease and cancer patients receiving chemotherapy. The decision to discontinue development was not due to any safety or efficacy concerns about NE-180, but was based on an evaluation of commercial prospects and the likelihood of entering into a timely collaboration for the compound in the context of increased safety concerns in the erythropoiesis-stimulating agent (ESA) category. In connection with the discontinuation of the NE-180 program, we reduced our workforce by approximately 35%. These actions allowed us to significantly reduce our expected cash expenditures and extend our cash runway by approximately one year. We anticipate paying cash severance benefits of approximately \$0.9 million in connection with the workforce reduction, most of which will be paid in the first quarter of 2008. We do not expect to incur any material contract termination charges or non-cash impairment charges in connection with the program discontinuation.

We believe that our enzymatic pegylation technology, GlycoPEGylation, can improve the drug properties of therapeutic proteins by building out, and attaching polyethylene glycol (PEG) to, carbohydrate structures at specific sites on the proteins. We are using our technology to develop

proprietary versions of protein drugs with proven safety and efficacy and to improve the therapeutic profiles of proteins being developed by our partners. We expect these modified proteins to offer significant advantages, including less frequent dosing and possibly improved efficacy, over the original versions of the drugs now on the market, as well as to meet or exceed the pharmacokinetic profile of next-generation versions of the drugs now on the market. We believe this strategy of targeting drugs with proven safety and efficacy allows us to lower the risk profile of our proprietary development portfolio as compared to *de novo* protein drug development. We intend to continue to focus our research and development resources on therapeutic proteins that we believe have the greatest probability of achieving clinically meaningful therapeutic improvements from our technology and are in commercially attractive categories.

In March 2007, we sold 21.4 million shares of common stock and warrants to purchase 9.6 million shares of common stock through a private placement, including 5.0 million shares of common stock and warrants to purchase 2.2 million shares of common stock to investment funds affiliated with certain members of our board of directors, at a price of \$2.02 per unit, generating net proceeds of approximately \$40.5 million. The warrants have a five-year term and an exercise price of \$1.96 per share.

In March 2007, we implemented a restructuring of operations designed to allow for significantly higher clinical development costs for NE-180, while keeping anticipated 2007 net cash spending consistent with 2006 levels. The restructuring resulted in a workforce reduction of approximately 40%. We incurred cash restructuring costs of approximately \$1.0 million, all of which were paid by December 31, 2007.

In February 2007, we consolidated our operations into our Rock Road Facility, a 40,000 square foot facility that we currently lease in Horsham, Pennsylvania. Total costs for construction of additional laboratory and office space in the Rock Road Facility were \$3.2 million, of which \$2.1 million was included in construction-in-progress as of December 31, 2006.

We have incurred operating losses each year since our inception. As of December 31, 2007, we had an accumulated deficit of \$294.8 million. We expect additional losses over the next several years as we continue product research and development efforts and expand our intellectual property portfolio. We have financed our operations through private and public offerings of equity securities, proceeds from debt financings, and revenues from our collaborative agreements.

We believe that our existing cash and cash equivalents, expected proceeds from collaborations and license arrangements, and interest income should be sufficient to meet our operating and capital requirements at least into the third quarter of 2009, although changes in our collaborative relationships or our business, whether or not initiated by us, may cause us to deplete our cash and cash equivalents sooner than the above estimate.

Liquidity and Capital Resources

Overview

We had \$19.3 million in cash and cash equivalents as of December 31, 2007, compared to \$16.4 million as of December 31, 2006. The increase for 2007 was primarily due to the sale, through a private placement, of 21.4 million shares of our common stock and warrants to purchase 9.6 million shares of our common stock, generating net proceeds of \$40.5 million. These additional funds were partially offset by the continued funding of our operating activities, capital expenditures, and debt repayments.

The development of next-generation proprietary protein therapeutics, which we are pursuing both independently and in collaboration with selected partners, will require substantial expenditures by us and our collaborators. We plan to continue financing our operations through private and public offerings of equity securities, proceeds from debt financings, and proceeds from existing and future

collaborative agreements. Because our 2008 revenues could be substantially affected by entering into new collaborations and by the financial terms of any new collaborations, we cannot estimate our 2008 revenues. Other than proceeds from our collaborations with Novo Nordisk and BioGeneriX, and any future collaborations with others, we do not expect to generate significant revenues until such time as products using our technology 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 investing requirements. We believe that our existing cash and cash equivalents, expected revenue from collaborations and license arrangements, and interest income should be sufficient to meet our operating and capital requirements at least into the third quarter of 2009. Accordingly, we will need to raise substantial additional funds to continue our business activities and fund our operations until we are generating sufficient cash flow from operations. If we are unable to raise additional capital when required, we may need to delay, scale back, or eliminate some or all of our research and development programs.

Operating Activities

Net cash used in operating activities during 2007 and 2006 was \$32.5 million and \$26.8 million, respectively. The increase of \$5.7 million in net cash used in operating activities during 2007 was due to several factors. Research and development costs increased by \$5.9 million from 2006 to 2007, primarily due to \$6.8 million of additional external NE-180 costs, as well as \$3.3 million of additional external costs associated with our collaborations with Novo Nordisk and BioGeneriX, and was partially offset by lower payroll and facility-related costs resulting from the restructurings that were implemented in 2006 and 2007. Revenues were \$2.6 million higher in 2007 compared to 2006 due to the reimbursement of research and developments costs under our collaborations with Novo Nordisk and BioGeneriX. Net interest income was up by \$1.4 million in 2007 compared to 2006 due to higher cash balances during 2007 and the reduction of debt.

Investing Activities

Net cash used in investing activities during 2007 was \$3.7 million, compared to \$18.5 million of net cash provided by investing activities during 2006. In September 2006, we sold our Witmer Road Facility for approximately \$21.0 million. After payment of selling fees and expenses, we received net proceeds of approximately \$19.3 million. Concurrent with the closing, we repaid outstanding debt associated with the facility and related equipment of approximately \$9.6 million, which included accrued interest and prepayment penalties. In February 2007, we consolidated our operations into our Rock Road Facility. Total cost for construction of additional laboratory and office space in our Rock Road Facility was \$3.2 million, of which \$2.1 million was included in construction-in-progress as of December 31, 2006.

During 2007 and 2006, cash expenditures for property and equipment were \$3.7 million and \$0.9 million, respectively. The improvements to our Rock Road Facility contributed significantly to our capital expenditures during both years. For the year ended December 31, 2007, \$2.3 million cash payments were made for the Rock Road Facility. Of the \$2.1 million included in construction-in-progress as of December 31, 2006 for the Rock Road Facility, only \$0.9 million was paid out in cash as of December 31, 2006.

Financing Activities

Equity Financing Activities

In March 2007, we sold 21.4 million shares of common stock and warrants to purchase 9.6 million shares of common stock through a private placement, including 5.0 million shares of common stock and warrants to purchase 2.2 million shares of common stock to investment funds affiliated with certain members of our board of directors, at a price of \$2.02 per unit, generating net proceeds of

approximately \$40.5 million. The warrants have a five-year term and an exercise price of \$1.96 per share.

Debt Financing Activities

Our total debt decreased by \$1.0 million to \$0.8 million at December 31, 2007, compared to \$1.8 million at December 31, 2006, primarily due to planned debt principal repayments of \$1.7 million, which were partially offset by the issuance of \$0.4 million of new debt to finance insurance policy premiums and \$0.4 million of new capital leases obligations.

Note Payable Secured by Insurance Policies

In March 2007, we borrowed \$0.4 million to finance insurance policy premiums due on certain insurance policies. We made the last payment in November 2007, and, therefore, there was no outstanding principal balance under this agreement as of December 31, 2007. The interest was calculated based on an annual percentage rate of 5.7%. To secure payment of the amounts financed, we granted the lender a security interest in all of our right, title and interest to the insurance policies.

Term Loan from Landlord

In May 2004, we borrowed \$1.5 million from the landlord of our Rock Road Facility in Horsham, Pennsylvania. As of December 31, 2007, we owed the landlord \$0.2 million. The terms of the financing require us to pay monthly principal and interest payments over 48 months at an interest rate of 13%. During 2008, we expect to make principal and interest payments totaling \$0.2 million under this agreement.

Notes Payable to Equipment Lender

As of December 31, 2007, we owed \$0.3 million to an equipment lender that financed the purchase of certain equipment and facility improvements, which collateralize the amounts borrowed. In October 2006, we amended six promissory notes with our equipment lender in connection with the early repayment of a portion of the outstanding debt as a result of the sale of the Witmer Road Facility. Under the amended promissory notes, our last payment is scheduled for September 2008, and interest rates applicable to the equipment loan range from 9.1% to 9.5%. During 2008, we expect to make principal and interest payments totaling \$0.3 million under these agreements.

Capital Lease Obligations

We entered into two agreements with capital lease obligations during 2007 for furniture with a value of \$0.4 million. We entered into agreements with capital lease obligations during 2004 for equipment with a value of \$0.2 million. The terms of existing leases require us to make monthly payments through February 2012. As of December 31, 2007, the present value of aggregate minimum lease payments under these agreements was \$0.3 million. During 2008, we expect to make lease principal payments totaling \$136,000 under these agreements.

Operating Leases

We lease laboratory, office, warehouse facilities, and equipment under operating lease agreements. In 2002, we entered into a lease agreement for our Rock Road Facility. The initial term of this lease ends 2022, at which time we have an option to extend the lease for an additional five years, followed by another option to extend the lease for an additional four and one-half years. This lease contains escalation clauses, under which the base rent increases annually by 2%. We leased approximately 5,000 square feet of office and warehouse space in Horsham, Pennsylvania under a lease agreement that expired in April 2007. In January 2007, we entered into a five-year lease agreement for approximately 6,800 square feet of office and warehouse space in Horsham, Pennsylvania to replace the space subject to the expired lease described above. Our rental expense was \$0.7 million, \$1.0 million, and \$1.0 million for each of the years ended December 31, 2007, 2006, and 2005, respectively.

Summary of Contractual Obligations

The following table summarizes our obligations to make future payments under current contracts as of December 31, 2007:

Payments due by period

	Total	Less than 1 Year	1 - 3 Years	4 - 5 Years	After 5 Years
Long-term debt obligations(1)					
Debt maturities	\$ 522,000	\$ 522,000	\$	\$	\$
Contractual interest	17,000	17,000			
Capital lease obligations(2)					
Debt maturities	318,000	136,000	113,000	69,000	
Contractual interest	39,000	18,000	18,000	3,000	
Operating leases(3)	7,941,000	549,000	1,092,000	1,062,000	5,238,000
Purchase obligations(4)	470,000	396,000	74,000		
Total contractual obligations	\$ 9,307,000	\$ 1,638,000	\$ 1,297,000	\$ 1,134,000	\$ 5,238,000

- (1) See "Financing Activities Debt Financing Activities" in this Liquidity and Capital Resources section and Note 8 of the Notes to Financial Statements included in Item 8 of this Annual Report on Form 10-K for a description of the material features of our long-term debt. Contractual interest is the interest we contracted to pay on the long-term debt obligations.
- (2) See "Financing Activities Capital Lease Obligations" in this Liquidity and Capital Resources section and Note 15 of the Notes to Financial Statements included in Item 8 of this Annual Report on Form 10-K for a description of the material features of our capital lease obligations. At December 31, 2007, the present value of our capital lease obligations was \$318,000 and the amount of imputed interest, calculated using an assumed incremental borrowing rate at the time we entered into the capital lease obligations, was \$39,000.
- (3) See Note 15 of the Notes to Financial Statements included in Item 8 of this Annual Report on Form 10-K for a description of our significant operating leases.
- (4) See Note 15 of the Notes to Financial Statements included in Item 8 of this Annual Report on Form 10-K for a description of our commitments as of December 31, 2007 to purchase goods and services from various suppliers.

Off-Balance Sheet Arrangements

We are not involved in any off-balance sheet arrangements that have or are reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources.

Critical Accounting Policies and Estimates

Our Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) focuses on our liquidity, capital resources, and financial statements. The financial statements have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of financial statements requires management to make estimates and assumptions that affect the carrying amounts of assets and liabilities, and the reported amounts of revenues and expenses during the reporting period. These estimates and assumptions are developed and adjusted periodically by management based on historical experience and on various other factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates.

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

Our summary of significant accounting policies is described in Note 2 of the Notes to Financial Statements included in Item 8 of this Annual Report on Form 10-K. Management considers the following policies and estimates to be the most critical in understanding the more complex judgments that are involved in preparing our financial statements and the uncertainties that could impact our results of operations, financial position, and cash flows. Management has discussed the development and selection of these critical accounting policies and estimates with the audit committee of our board of directors, and the audit committee has reviewed our disclosure relating to it in this MD&A.

Revenue Recognition

We have entered into collaborative agreements with other companies for the development and commercialization of our product candidates. The terms of the agreements typically include non-refundable up-front license fees, funding of research and development, payments based upon achievement of development milestones, and royalties on product sales.

License Fees and Multiple Element Arrangements

Non-refundable license fees are recognized as revenue when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured, and we have no further performance obligations under the license agreement.

Multiple element arrangements, such as license and development arrangements, are analyzed to determine whether the deliverables, which often include a license and performance obligations, such as research and development services, can be separated or whether they must be accounted for as a single unit of accounting in accordance with Emerging Issues Task Force (EITF) Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. However, if the license is considered to either (i) not have stand-alone value or (ii) have stand-alone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting and the license payments and payments for performance obligations are recognized as revenue over the estimated period of when the performance obligations are performed. In our collaborative arrangements with Novo Nordisk and BioGeneriX, we have determined the license to each does not have stand-alone value.

Whenever we determine that an arrangement should be accounted for as a single unit of accounting, we must determine the period over which the performance obligations will be performed and revenue will be recognized. Significant management judgment is required in determining the period over which we are expected to complete our performance obligations under an arrangement.

Substantive Milestone Payments

Our collaboration agreements may also contain substantive milestone payments. Substantive milestone payments are considered to be performance bonuses that are recognized upon achievement of the milestone only if all of the following conditions are met:

the milestone payments are non-refundable;

achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement;

substantive effort is involved in achieving the milestone;

a reasonable amount of time passes between the up-front license payment and the first milestone payment as well as between each subsequent milestone payment; and

the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone.

Determination as to whether a payment meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone, and therefore the resulting payment would be considered part of the consideration for the single unit of accounting and be recognized as revenue as such performance obligations are performed.

Reimbursement of Research and Development Costs

Reimbursement of research and development costs is recognized as revenue provided the provisions of EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent*, are met, the amounts are fixed and determinable, and collection of the related receivable is reasonably assured. In our collaborative arrangements with Novo Nordisk and BioGeneriX, we recognize revenue as such costs are incurred because we have evidence of fair value for these delivered items.

Deferred Revenue

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying Balance Sheets. Determination as to the classification of deferred revenue as current or long-term on our balance sheets involves management's judgment. For example, in connection with our existing collaboration agreements, we have recorded on our Balance Sheets current and long-term deferred revenue based on our best estimate of when such revenue will be recognized. The current portion of deferred revenue consists of amounts that are expected to be recognized as revenue during 2008. Amounts that we expect will not be recognized during 2008 are classified as long-term deferred revenue. This estimate is based on our estimate of the periods of our involvement in certain of our collaborations. In certain instances, the timing of satisfying these obligations can be difficult to estimate. Accordingly, our estimates may change in the future. Any change to the estimated performance period would be recognized on a prospective basis. If these estimates and judgments change over the course of these agreements, it may affect the timing and amount of revenue that we recognize and record in future periods.

Stock-based Employee Compensation

We adopted Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), *Share-Based Payment* (SFAS No. 123R), effective January 1, 2006. SFAS No. 123R requires all share-based payments to employees to be recognized in the financial statements based on their fair values at the date of grant. Prior to January 1, 2006, we followed Accounting Principles Board (APB) Opinion 25, *Accounting for Stock Issued to Employees* (APB No. 25), and related interpretations in accounting for our stock-based compensation. We elected to use the modified prospective transition method for adopting SFAS No. 123R. Under this method, the provisions of SFAS No. 123R apply to all awards granted or modified after the date of adoption and to that portion of awards not fully vested as of the date of adoption. Accordingly, prior periods have not been restated.

The fair value of stock options is determined using the Black-Scholes valuation model, which is the same model we previously utilized for valuing stock options for footnote disclosures required under SFAS No. 123, *Accounting for Stock Based Compensation* (SFAS No. 123), as amended by SFAS No. 148, *Accounting for Stock-Based Compensation, Transition and Disclosure* (SFAS No. 148).

The fair value of share-based awards is recognized as expense over the requisite service period, net of estimated forfeitures. We rely primarily on historical experience to estimate expected forfeitures for stock options. We have not assumed any expected forfeitures for restricted stock units (RSUs) because those awards have been granted to a small number of individuals. For all unvested share-based awards

outstanding as of December 31, 2005, the previously measured but unrecognized compensation expense, based on the fair value at the original grant date, will be recognized on an accelerated basis in our statement of operations over the remaining vesting period, consistent with our recognition policy under SFAS No. 123. For share-based awards granted subsequent to December 31, 2005, we have elected to recognize compensation expense in the statement of operations on a straight-line basis from the date of grant. The following table contains the assumptions used in the Black-Scholes option-pricing model in each year to value stock-based compensation:

	Year Ended December 31,					
	2007		2006		2005	
Weighted average expected volatility	75%		75%		75%	
Expected term (years)	4.7	9.1	4.7	7.8	0.7	9.1
Risk-free interest rate	4.4%	4.6%	4.4%	5.1%	3.9%	4.3%
Expected dividend yield	0%		0%		0%	

Impairment of Long-Lived Assets

We evaluate our long-lived assets for impairment at least annually and whenever indicators of impairment exist. Because our history of negative operating cash flows is an indicator of impairment, we annually compare the market value of our equity and debt to the carrying value of our net assets. During 2006 we recorded a non-cash impairment charge of \$0.1 million for equipment that was no longer in use. The market value of our equity and debt exceeded the carrying value of our net assets as of December 31, 2007 and, therefore, we did not record any impairment of long-lived assets other than the impairment of the equipment mentioned above. We do not believe we will have any impairment of long-lived assets in connection with the discontinuation of NE-180 program.

Expenses from Contract Research and Development Service Providers

Some of our research and development is conducted by third parties, including contract research and development service providers. At the end of each quarter, we compare the payments made to each service provider to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the estimated service provided, we record net prepaid or accrued expense relating to these costs.

Results of Operations

Years Ended December 31, 2007 and 2006 and Outlook for 2008

Our net loss for the year ended December 31, 2007 was \$28.5 million compared to \$27.1 million for the corresponding period in 2006. The following section explains the trends within each component of net loss for 2007 compared to 2006 and provides our estimate of trends for 2008 for each component.

Revenue from Collaborative Agreements. Our revenues from collaborative agreements have historically been derived from a few major collaborators. Our collaborative agreements provide for some or all of the following elements: license fees, research and development funding, milestone revenues, and royalties on product sales. A summary of revenue recognized under our collaborative

agreements for the years ended December 31, 2007 and 2006 is presented in the following table (in thousands).

	Year Ended December 31,	
	2007	2006
Novo Nordisk		
Research and development funding	\$ 5,354	\$ 3,577
Substantive milestones		750
License fees	745	457
	6,099	4,784
BioGeneriX		
Research and development funding	2,650	1,191
License fees	56	209
	2,706	1,400
	\$ 8,805	\$ 6,184

Revenue from collaborative agreements increased in 2007 from 2006 primarily due to increased research and development funding from our agreements with Novo Nordisk and BioGeneriX. This was partially offset by a substantive milestone received under our agreement with Novo Nordisk in 2006.

Because our 2008 revenues could be substantially affected by entering into new collaborations and by the financial terms of any new collaborations, we cannot estimate our 2008 revenues. 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, if ever, 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 levels of effort committed and made by our collaborative partners. Even if we achieve technical success in developing drug candidates, our collaborative partners may discontinue development, may not devote the resources necessary to complete development and commence marketing of these products, or they may not successfully market potential products.

Research and Development Expense. We have two therapeutic protein candidates in clinical trials: GlycoPEG-GCSF and GlycoPEG-FVIIa, and two therapeutic protein candidates in the research stage: GlycoPEG-FVIII and GlycoPEG-FIX.

In January 2008, we announced the discontinuation of further development of NE-180, our product candidate intended for the treatment of anemia in patients with chronic kidney disease and cancer patients receiving chemotherapy. The decision to discontinue development was not due to any safety or efficacy concerns about NE-180, but was based on an evaluation of commercial prospects and the likelihood of entering into a timely collaboration for the compound in the context of increased safety concerns in the erythropoiesis-stimulating agent (ESA) category. Throughout 2007 we incurred costs for the development of NE-180, including process, non-clinical and clinical development. In addition, pursuant to an agreement with a vendor that was to produce bulk NE-180 on our behalf, we had the option to, on or before October 9, 2007, either terminate the agreement or execute an amendment to amend the scope of services. Under an August 2007 change order contemplating an amendment or termination of the agreement, we agreed to pay the vendor a non-refundable fee of \$2,800. On October 9, 2007, we terminated this agreement to reduce uncertainties associated with

announced ownership changes at the vendor and to defer future process development and manufacturing costs. All of the \$2,800 was included in research and development expense for the year ended December 31, 2007.

We conduct exploratory research, both independently and with collaborators, on therapeutic candidates, primarily proteins, for development using our enzymatic technologies. Successful candidates may be advanced for development through our own proprietary drug program or through our partnering and licensing program, or a combination of the two. Although our primary focus is the development of long-acting proteins, we are also conducting research to assess opportunities to use our enzymatic technologies in other areas, such as glycopeptides and glycolipids. We expect to continue this research during 2008.

Our current research and development projects are divided between two categories: (i) GlycoPEGylation and (ii) Other Glycotechnology Programs, which includes projects investigating opportunities to use our enzymatic technologies in other areas, such as glycolipids. The following chart sets forth our projects in each of these categories and the stage to which each has been developed:

	Development Stage	Status
GlycoPEGylation:		
NE-180	Clinical (Phase II)	Discontinued
GlycoPEG-GCSF	Clinical (Phase I)	Active
GlycoPEG-FVIIa	Clinical (Phase I)	Active
GlycoPEG-FIX	Research	Active
GlycoPEG-FVIII	Research	Active
Other Glycotechnology Programs:		
Non-protein therapeutic applications	Research	Active

The process of bringing drugs from the preclinical research and development stage through Phase I, Phase II, and Phase III clinical trials to FDA or other regulatory approval is time consuming and expensive. Because our announced product candidates are currently in the research or early clinical and preclinical stages, and there are a variety of potential intermediate clinical and non-clinical outcomes that are inherent in drug development, we cannot reasonably estimate either the timing or 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.

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 non-clinical development costs. Indirect expenses include depreciation expense and the costs of operating and maintaining our facilities, property, and equipment, to the extent used for our research and development projects, as well as the costs of general management of our research and development projects.

Our research and development expenses increased to \$34.9 million in 2007 from \$29.0 million in 2006. During 2008, we expect our research and development expenses to be significantly lower than they were in 2007 as a result of discontinuing further development of NE-180. The following table

illustrates research and development expenses incurred during 2007 and 2006 for our significant groups of research and development projects (in thousands):

	Year ended December 31,	
	2007	2006
GlycoPEGylation	\$ 26,438	\$ 18,846
Other Glycotechnology Programs	75	435
Indirect expenses	8,405	9,732
	\$ 34,918	\$ 29,013

GlycoPEGylation

Our GlycoPEGylation research and development expenses result primarily from development activities, including process, non-clinical and clinical development, associated with our proprietary drug development programs. These expenses increased during the 2007 period primarily due to \$1.8 million of additional reimbursable costs incurred under our collaborative agreement with Novo Nordisk for GlycoPEG-FVIIa, \$1.5 million of additional reimbursable costs incurred under our collaborative agreement with BioGeneriX for GlycoPEG-GCSF, as well as additional costs for non-clinical and clinical development associated with NE-180, including a \$2.8 million non-refundable fee to a vendor that was contracted to produce bulk NE-180 on our behalf. These increases were partially offset by lower payroll and related personnel costs due to the restructurings that were implemented in 2006 and 2007.

Other Glycotechnology Programs

Research and development expenses related to our other glycotechnology programs decreased during 2007, compared to 2006, primarily due to lower payroll and decreased supplies for early stage research.

Indirect expenses

Our indirect research and development expenses decreased during 2007, compared to 2006, primarily due to lower payroll and facility costs related to the restructurings that were implemented in 2006 and 2007.

General and Administrative Expense. General and administrative expenses for the year ended December 31, 2007 were \$10.9 million, compared to \$11.6 million for the corresponding period in 2006. The decrease in 2007 was primarily attributable to lower payroll and related personnel costs due to the restructurings that were implemented in 2006 and 2007, and was partially offset by increased consulting costs. During 2008, we expect our general and administrative expenses to remain relatively consistent with the 2007 expense amounts.

Decrease in Fair Value of Warrant Liability. In connection with the sale of our common stock and warrants to purchase shares of our common stock in March 2007, we recorded the warrants as a liability at their initial fair value using the Black-Scholes option-pricing model and revalue them at each reporting date until they are exercised or expire. Changes in the fair value of the warrants are reported in our Statements of Operations as non-operating income or expense. During the year ended December 31, 2007, we recorded non-operating income of \$6.6 million related to the change in fair value of these warrants. The market price for our common stock has been and may continue to be volatile. Consequently, future fluctuations in the price of our common stock may cause significant increases or decreases in the fair value of these warrants.

Interest Income. Interest income for the year ended December 31, 2007 was \$1.5 million, compared to \$1.2 million for the corresponding period in 2006. The increase was due to higher cash balances during 2007. Our interest income during 2008 is difficult to project, and will depend largely on whether we enter into any new collaborative agreements, complete any equity or debt financings, and prevailing interest rates during 2008.

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

Interest Expense. Interest expense for the year ended December 31, 2007 was \$0.1 million compared to \$1.3 million for the corresponding period in 2006. Lower average debt balances in the 2007 period accounted for the decrease, due to the repayment of \$9.6 million of outstanding debt in September 2006 in connection with the sale of the Witmer Road Facility. Our interest expense during 2008 is difficult to project and will depend largely on whether we complete any new debt financings and prevailing interest rates during 2008. See "Financing Activities Debt Financing Activities" in the Liquidity and Capital Resources section of this Annual Report on Form 10-K for a description of the material features of our debt financings.

Years Ended December 31, 2006 and 2005

Our net loss for the year ended December 31, 2006 was \$27.1 million compared to \$51.8 million for the corresponding period in 2005. The following section explains the trends within each component of net loss for 2006 compared to 2005.

Revenue from Collaborative Agreements. A summary of revenue recognized under our collaborative agreements for the years ended December 31, 2006 and 2005 is presented in the following table (in thousands).

	Year ended December 31,	
	2006	2005
Novo Nordisk		
Research and development funding	\$ 3,577	\$ 2,027
Substantive milestones	750	
License fees	457	769
	4,784	2,796
BioGeneriX		
Research and development funding	1,191	2,939
License fees	209	402
	1,400	3,341
	\$ 6,184	\$ 6,137

Revenue from collaborative agreements increased slightly in 2006 from 2005. Increased research and development funding and milestone revenue recognized during 2006 under our Novo Nordisk agreements were largely offset by decreased research and development funding during 2006 from BioGeneriX.

Research and Development Expense. Our research and development expenses decreased to \$29.0 million in 2006 from \$33.1 million in 2005. The following table illustrates research and development expenses incurred during 2006 and 2005 for our significant groups of research and development projects (in thousands).

	Year ended December 31,	
	2006	2005
GlycoPEGylation	\$ 18,846	\$ 18,170
Other Glycotechnology Programs	435	978
Indirect expenses	9,732	13,988
	\$ 29,013	\$ 33,136

GlycoPEGylation

Our GlycoPEGylation research and development expenses increased during 2006, compared to 2005, primarily due to increased non-clinical study costs associated with NE-180 and GlycoPEG-GCSF, as well as increased clinical trial costs associated with NE-180. These increases were partially offset by lower payroll and related personnel costs due to reduced headcount in 2006. Increased purchases of laboratory services and research supplies also contributed to the overall increase.

Other Glycotechnology Programs

Research and development expenses related to our other glycotechnology programs decreased during 2006, compared to 2005, primarily due to reduced research efforts during 2006 for early stage research.

Indirect expenses

Our indirect research and development expenses decreased during 2006, compared to 2005, primarily due to decreased depreciation resulting from the August 2005 impairment of our Witmer Road Facility and the closure of our leased facility in San Diego. Further contributing to the decrease during 2006 were lower amounts spent for indirect outside laboratory services and consulting, and was partially offset by \$0.8 million of non-cash compensation costs for share-based payment arrangements accounted for under SFAS No. 123R.

General and Administrative Expense. General and administrative expenses for the year ended December 31, 2006 were \$11.6 million, compared to \$10.9 million for the corresponding period in 2005. The increase in 2006 was primarily attributable to \$1.6 million of non-cash compensation costs for share-based payment arrangements accounted for under SFAS No. 123R, and was partially offset by lower consulting costs, lower patent legal expenses and reduced depreciation resulting from the August 2005 impairment of our Witmer Road Facility and the closure of our leased facility in San Diego.

Restructuring Charges. Restructuring charges for the year ended December 31, 2005 were \$14.2 million, which included \$13.2 million of non-cash property and equipment impairment charges and \$1.0 million of payments for employee severance and facility closure costs. We did not incur any restructuring charges during 2006.

Gain on Sale of Witmer Road Facility. During 2006, we recognized a gain from the sale of the Witmer Road Facility of \$7.3 million. In September 2006, we sold the Witmer Road Facility for approximately \$21.0 million. After payment of selling fees and expenses, we received net proceeds of approximately \$19.3 million. The carrying value of the property and equipment sold was \$12.4 million. We continued to occupy a portion of the facility on a rent-free basis for six months after the closing. We estimated the rental fair value for the space we continued to occupy to be \$0.4 million, which was included in the calculation of the \$7.3 million gain on the sale of the Witmer Road Facility and was amortized as rent expense to our Statements of Operations over the period of our occupancy.

Interest Income. Interest income for the year ended December 31, 2006 was \$1.2 million, compared to \$1.5 million for the corresponding period in 2005. The decrease was due to lower interest rates during 2005.

Interest Expense. Interest expense for each of the years ended December 31, 2006 and 2005 was \$1.3 million.

Recent Accounting Pronouncements

In June 2007, the Financial Accounting Standards Board (FASB) issued Emerging Issues Task Force (EITF) 07-03, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used*

in Future Research and Development Activities-(EITF 07-03). EITF 07-03 specifies that nonrefundable advance payments for future research and development activities should be deferred and capitalized and should be recognized as an expense as the related goods are delivered or the related services are performed. If, subsequent to an advance payment, an entity no longer expects the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. EITF 07-03 is effective for fiscal years beginning after December 15, 2007. As the guidance in EITF 07-03 is consistent with our existing policy we do not believe EITF 07-03 will have any impact on our financial statements or related disclosures.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* (SFAS No. 159), which allows companies to choose, at specific election dates, to measure eligible financial assets and liabilities at fair value that are not otherwise required to be measured at fair value. If a company elects the fair value option for an eligible item, changes in that item's fair value in subsequent reporting periods must be recognized in current earnings. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. We are currently evaluating the impact of SFAS No. 159 on our financial statements and related disclosures.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS No. 157), which is applicable for fiscal years beginning after November 15, 2007. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 applies under other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Although SFAS No. 157 does not require any new fair value measurements, its application may, for some entities, change current practices related to the definition of fair value, the methods used to measure fair value, and the expanded disclosures about fair value measurements. We are currently evaluating the impact of the adoption of SFAS No. 157 on our financial statements and related disclosures.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK.

Interest Rate Risk

We are exposed to market risk from changes in interest rates. We are currently not engaged in hedging activities and we do not use derivative financial instruments for speculation or trading purposes. We do not believe that our exposure to interest rate risk is material to our results of operations. The analysis below presents the sensitivity of our interest income and expense to selected changes in market interest rates.

The primary objective of our investment activities is to preserve our capital to fund operations and maximize income from our investments without assuming significant risk. We seek the safety of principal and market liquidity by investing in high credit quality institutional money market funds and fixed income securities. 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. Because our investments are short-term in duration, we believe our exposure to interest rate risk is not significant. We held no marketable securities as of December 31, 2007. The approximate principal amount of our investment portfolio as of December 31, 2007 was \$19.3 million, and the weighted-average annualized interest rate and interest income earned on the portfolio during the year ended December 31, 2007 were 5.3% and \$1.5 million, respectively. The sensitivity analysis as it relates to our investment activities assumes an instantaneous 100 basis point move in interest rates from their weighted-average levels during the year ended December 31, 2007. A 100 basis point move up or down in market interest rates would have caused a corresponding change of \$0.3 million in interest income during the year ended December 31, 2007.

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

As of December 31, 2007, the principal components of our debt portfolio were (1) a term loan from our landlord of \$0.2 million that accrues interest at a fixed annual rate of 13.0%; (2) aggregate equipment financing of \$0.3 million that accrues interest at fixed annual rates ranging from 9.1% to 9.5%; and (3) capital lease obligations with a present value of \$0.1 million, for which we imputed interest at fixed annual rates ranging from 7.2% to 11.5%. Our aggregate interest expense for the year ended December 31, 2007 was \$0.1 million. By modifying the interest expense associated with fixed rate debt entered into during the year ended December 31, 2007 by a 100 basis point move up or down in market interest rates, it would have caused a corresponding change of \$10,000 in interest expense during the year ended December 31, 2007.

Foreign Exchange Risk

We have entered into some agreements denominated, wholly or partly, in Euros or other foreign currencies, and, in the future, we may enter into additional, significant agreements denominated in foreign currencies. If the values of these currencies increase against the dollar, our costs would increase. To date, we have not entered into any contracts to reduce the risk of fluctuations in currency exchange rates. In the future, depending upon the amounts payable under any such agreements, we may enter into forward foreign exchange contracts to reduce the risk of unpredictable changes in these costs. However, due to the variability of timing and amount of payments under any such agreements, foreign exchange contracts may not mitigate the potential adverse impact on our financial results.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The financial statements and supplementary data required by this item are attached to this Annual Report on Form 10-K beginning on page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Disclosure 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 (Exchange Act)), as of December 31, 2007. Based on that evaluation, our principal executive officer and principal financial officer concluded that these controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported as specified in SEC 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 SEC. 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.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial and accounting officers and effected by our board of directors and management to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of our company are being made only in accordance with authorizations of our management and board of directors; and

provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2007. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework*. Based on our assessment, our management believes that, as of December 31, 2007, our internal control over financial reporting is effective. In addition, no changes in our internal control over financial reporting have occurred during the three months ended December 31, 2007 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. The following is the audit report on our assessment of our internal control over financial reporting issued by our independent registered public accounting firm.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Neose Technologies, Inc.:

We have audited Neose Technologies, Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Neose Technologies, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on Neose Technologies, Inc.'s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Neose Technologies, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control - Integrated Framework issued by the COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Neose Technologies, Inc. as of December 31, 2007 and 2006, and the related statements of operations, stockholders' equity and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2007, and our report dated March 10, 2008 expressed an unqualified opinion on those financial statements.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 10, 2008

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

The information concerning directors and executive officers, appearing under the caption "Governance of the Company" in our Proxy Statement (the Proxy Statement) to be filed with the SEC in connection with our 2008 Annual Meeting of Stockholders; the information concerning executive officers, appearing under the caption "Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement; the information concerning stockholder nominations for director candidates, appearing under the captions "Governance of the Company Committees of our Board of Directors Corporate Governance Committee" and "Requirements for Advance Notification of Nominations and Stockholder Proposals" in the Proxy Statement; and the information concerning the Audit Committee of our Board of Directors and the audit committee financial expert thereon, appearing under the caption "Governance of the Company Committees of our Board of Directors Audit Committee" in the Proxy Statement are incorporated herein by reference in response to this Item 10.

Code of Conduct

We have a Code of Business Conduct and Ethics, which can be viewed on our website at www.neose.com (under "About Neose Corporate Governance"). We require all employees to adhere to the Code in addressing the legal and ethical issues encountered in conducting their work. The Code of Business Conduct and Ethics requires that our employees avoid conflicts of interest, comply with all laws and other legal requirements, conduct business in an honest and ethical manner, and otherwise act with integrity and in our best interest. All of our employees were required to certify that they reviewed and understood the Code when they received it during 2003 or upon their later hire date, and are required to renew this certification annually thereafter and when the Code is changed. The Code of Business Conduct and Ethics is intended to comply with Item 406 of the SEC's Regulation S-K and the rules of NASDAQ.

The Code of Business Conduct and Ethics includes procedures for reporting violations of the Code, which are applicable to all employees. The Sarbanes-Oxley Act of 2002 requires companies to have procedures to receive, retain and treat complaints received regarding accounting, internal accounting controls or auditing matters and to allow for the confidential and anonymous submission by employees of concerns regarding questionable accounting or auditing matters. The Code of Business Conduct and Ethics also includes these required procedures.

Any waiver or amendment of the Code of Business Conduct and Ethics for designated senior officers, including our chief executive officer and chief financial officer, will be disclosed promptly on our Internet website.

Copies of the Code of Business Conduct and Ethics, which appears on our website, are also available upon request by any stockholder addressed to our Corporate Secretary, 102 Rock Road, Horsham, PA 19044.

ITEM 11. EXECUTIVE COMPENSATION.

The information contained in the sections titled "Executive Compensation" and "Governance of the Company Compensation of Directors" in the Proxy Statement is incorporated herein by reference in response to this Item 11.

Compensation Committee Interlocks and Insider Participation

The current members of the Compensation Committee of our Board of Directors are Douglas J. MacMaster, Jr., L. Patrick Gage and H. Stewart Parker. None of these individuals has ever been an officer or employee of ours. In addition, none of our executive officers serves as a member of the

board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our Board of Directors or the Compensation Committee of our Board of Directors.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.

The information contained in the section titled "Stock Ownership of our Directors, Executive Officers and 5% Beneficial Owners" in the Proxy Statement is incorporated herein by reference in response to this Item 12.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

The information contained in the section titled "Certain Relationships and Related Transactions" in the Proxy Statement, and the information concerning director independence under the captions "Governance of the Company Independence of Directors" and "Governance of the Company Committees of our Board of Directors" in the Proxy Statement is incorporated herein by reference in response to this Item 13.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information contained in the section titled "Relationship with Independent Registered Public Accounting Firm" in the Proxy Statement is incorporated herein by reference in response to this Item 14.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) 1. Financial Statements.

The Financial Statements filed as part of this Annual Report on Form 10-K are listed on the Index to Financial Statements on page F-1.

2. Financial Statement Schedules.

All financial statement schedules have been omitted here because they are not applicable, not required, or the information is shown in the Financial Statements or Notes thereto.

3. Exhibits.

The following is a list of exhibits filed as part of this Annual Report on Form 10-K. We are incorporating by reference to our previous SEC filings each exhibit that contains a footnote. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated in parentheses.

Exhibit Number	Description
2.1	Purchase and Sale Agreement and Joint Escrow Instructions by and between ARE-PA Region No.6, LLC and Neose Technologies, Inc. dated September 1, 2006. (Exhibit 2.1)(11)
3.1	Fourth Amended and Restated Certificate of Incorporation. (Exhibit B)(10)
3.2	First Amendment of the Fourth Amended and Restated Certificate of Incorporation. (Exhibit 3.1)(17)
3.3	Second Amended and Restated By-Laws. (Exhibit 3.2)(2)
4.1	See Exhibits 3.1, 3.2 and 3.3 for instruments defining rights of holders of common stock.
10.1	1995 Amended and Restated Stock Option/Stock Issuance Plan, as amended. (Appendix B)(4)
10.2	Agreement of Lease, dated as of February 15, 2002, between Liberty Property Leased Partnership and Neose Technologies, Inc. (Exhibit 10.40)(1)
10.3	Master Security Agreement between General Electric Capital Corporation and Neose Technologies, Inc., dated as of December 19, 2002. (Exhibit 10.33)(3)
10.4	Amendment to Master Security Agreement between General Electric Capital Corporation and Neose Technologies, Inc., dated as of December 19, 2002. (Exhibit 10.34)(3)
10.5	Research, Co-Development and Commercialization Agreement between BioGeneriX AG and Neose Technologies, Inc., dated April 20, 2004. (Exhibit 10.5)(5)
10.6	First Amendment to Lease between Liberty Property Limited Partnership and Neose Technologies, Inc., dated May 18, 2004. (Exhibit 10.7)(5)
10.7	Promissory Note of Neose Technologies, Inc. to Liberty Property Limited Partnership, dated May 7, 2004. (Exhibit 10.8)(5)
10.8	Promissory Note of Neose Technologies, Inc. to General Electric Capital Corporation dated August 20, 2004. (Exhibit 10.11)(6)

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

- 10.9 Form of Incentive Stock Option Award Agreement under the Neose Technologies, Inc. 2004 Equity Incentive Plan. (Exhibit 10.12)(6)
- 10.10 Form of Non-Qualified Stock Option Award Agreement under the Neose Technologies, Inc. 2004 Equity Incentive Plan. (Exhibit 10.13)(6)
- 10.11 Form of Annual Director Grant Agreement under the Neose Technologies, Inc. 2004 Equity Incentive Plan. (Exhibit 10.14)(6)
- 10.12 Form of Director Fee Option Grant Agreement under the Neose Technologies, Inc. 2004 Equity Incentive Plan. (Exhibit 10.15)(6)
- 10.13 Promissory Note of Neose Technologies, Inc. to General Electric Capital Corporation, dated December 16, 2004. (Exhibit 10.47)(7)
- 10.14 Form of Restricted Stock Unit Agreement (cliff vesting) between Neose Technologies, Inc. and Certain Employees, Officers and Directors. (Exhibit 10.1)(8)
- 10.15 Form of Restricted Stock Unit Agreement (quarterly vesting) between Neose Technologies, Inc. and Certain Employees, Officers and Directors. (Exhibit 10.2)(8)
- 10.16 Promissory Note of Neose Technologies, Inc. to General Electric Capital Corporation dated July 12, 2005. (Exhibit 10.1)(9)
- 10.17 Post-Closing Property Access Agreement by and between Auxilium Pharmaceuticals, Inc. and Neose Technologies, Inc. dated September 1, 2006. (Exhibit 10.1)(11)
- 10.18 Consent to Property Access Agreement by and among ARE-PA Region No.6, LLC, Auxilium Pharmaceuticals, Inc. and Neose Technologies, Inc. dated September 1, 2006. (Exhibit 10.2)(11)
- 10.19 Modification Agreement by and between Neose Technologies, Inc. and General Electric Capital Corporation dated October 31, 2006. (Exhibit 10.1)(12)
- 10.20 Amendment Number 1 to Research, Co-Development and Commercialization Agreement and Research License and Option Agreement between Neose Technologies, Inc. and BioGeneriX AG dated October 20, 2006. (Exhibit 10.41)(13)
- 10.21 Amended and Restated Research, Development and License Agreement among Neose Technologies, Inc. and Novo Nordisk A/S and Novo Nordisk Health Care AG dated October 31, 2006. (Exhibit 10.42)(13)
- 10.22 Bioprocessing Services Agreement by and between Neose Technologies, Inc. and Diosynth RTP Inc. dated December 7, 2006. (Exhibit 10.43)(13)
- 10.23 Commercial Premium Finance Agreement and Promissory Note from Neose Technologies, Inc. to AFCO Credit Corporation dated March 6, 2007. (Exhibit 10.44)(13)
- 10.24 Securities Purchase Agreement by and among Neose Technologies, Inc. and the purchasers appearing on the signature pages thereto dated March 8, 2007. (Exhibit 10.1)(14)
- 10.25 Registration Rights Agreement by and among Neose Technologies, Inc. and the purchasers appearing on the signature pages thereto dated March 8, 2007. (Exhibit 10.2)(14)
- 10.26 Form of Common Stock Purchase Warrant (U.S.), dated March 8, 2007. (Exhibit 10.3)(14)
- 10.27 Form of Common Stock Purchase Warrant (Non-U.S.), dated March 8, 2007. (Exhibit 10.4)(14)

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

- 10.28 Amended and Restated Employment Agreement between Neose Technologies, Inc. and George J. Vergis, Ph.D. dated April 30, 2007. (Exhibit 10.6)(15)
- 10.29 Form of Change of Control Agreement between Neose Technologies, Inc. and Certain Executive Officers dated April 30, 2007. (Exhibit 10.7)(15)
- 10.30 Change of Control Agreement between Neose Technologies, Inc. and Debra J. Poul dated April 30, 2007. (Exhibit 10.8)(15)
- 10.31 Neose Technologies, Inc. 2004 Equity Incentive Plan, as amended. (Exhibit 99.1)(16)
- 10.32*# Research, Development and License Agreement between Neose Technologies, Inc. and Novo Nordisk A/S dated November 2, 2007.
- 10.33*# Research, Development and License Agreement between Neose Technologies, Inc. and Novo Nordisk A/S dated November 2, 2007.
- 23.1* Consent of KPMG LLP.
- 24* Powers of Attorney (included as part of signature page hereof).
- 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 13-14(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.

*
Filed herewith.

Portions of this Exhibit were omitted and filed separately with the Secretary of the SEC pursuant to an order of the SEC granting our application for confidential treatment filed pursuant to Rule 24b-2 under the Exchange Act.

Compensation plans and arrangements for executives and others.

Portions of this Exhibit were omitted and filed separately with the Secretary of the SEC pursuant to a request for confidential treatment that has been filed with the SEC.

(1)
Filed as an Exhibit to our Annual Report on Form 10-K for the year ended December 31, 2001 (Commission File No. 000-27718).

(2)
Filed as an Exhibit to our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2002 (Commission File No. 000-27718).

(3)
Filed as an Exhibit to our Annual Report on Form 10-K for the year ended December 31, 2002 (Commission File No. 000-27718).

(4)
Filed as an Exhibit to our Proxy Statement filed with the SEC on April 7, 2003.

(5)

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

Filed as an Exhibit to our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2004.

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

- (6) Filed as an Exhibit to our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2004.
- (7) Filed as an Exhibit to our Annual Report on Form 10-K for the year ended December 31, 2004.
- (8) Filed as an Exhibit to our Current Report on Form 8-K filed with the SEC on March 4, 2005.
- (9) Filed as an Exhibit to our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2005.
- (10) Filed as an Exhibit to our Proxy Statement filed with the SEC on March 30, 2006.
- (11) Filed as an Exhibit to our Current Report on Form 8-K filed with the SEC on September 6, 2006.
- (12) Filed as an Exhibit to our Current Report on Form 8-K filed with the SEC on November 2, 2006.
- (13) Filed as an Exhibit to our Annual Report on Form 10-K for the year ended December 31, 2006.
- (14) Filed as an Exhibit to our Current Report on Form 8-K filed with the SEC on March 13, 2007.
- (15) Filed as an Exhibit to our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2007.
- (16) Filed as an Exhibit to our Registration Statement on Form S-8 filed with the SEC on May 30, 2007.
- (17) Filed as an Exhibit to our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2007.

Exhibit Index

Exhibit	Description
10.32#	Research, Development and License Agreement between Neose Technologies, Inc. and Novo Nordisk A/S dated November 2, 2007.
10.33#	Research, Development and License Agreement between Neose Technologies, Inc. and Novo Nordisk A/S dated November 2, 2007.
23.1	Consent of KPMG LLP.
24	Powers of Attorney (included as part of signature page hereof).
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 13-14(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.

Portions of this Exhibit were omitted and filed separately with the Secretary of the SEC pursuant to a request for confidential treatment that has been filed with the SEC.

Index to Financial Statements

Report of Independent Registered Public Accounting Firm	F-2
Balance Sheets	F-3
Statements of Operations	F-4
Statements of Stockholders' Equity and Comprehensive Loss	F-5
Statements of Cash Flows	F-6
Notes to Financial Statements	F-7

F-1

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Neose Technologies, Inc.:

We have audited the accompanying balance sheets of Neose Technologies, Inc. as of December 31, 2007 and 2006, and the related statements of operations, stockholders' equity and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2007. These financial statements are the responsibility of the management of Neose Technologies, Inc. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Neose Technologies, Inc. as of December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the financial statements, effective January 1, 2006, the Company adopted the fair value method of accounting for stock-based compensation as required by Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Neose Technologies, Inc.'s internal control over financial reporting as of December 31, 2007, based on the criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 10, 2008 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 10, 2008

Neose Technologies, Inc.

Balance Sheets

(in thousands, except per share amounts)

	December 31,	
	2007	2006
Assets		
Current assets:		
Cash and cash equivalents	\$ 19,282	\$ 16,388
Accounts receivable, net	1,758	286
Prepaid expenses and other current assets	1,564	1,284
	<u>22,604</u>	<u>17,958</u>
Total current assets	22,604	17,958
Property and equipment, net	13,564	13,104
Intangible and other assets, net	71	181
	<u>36,239</u>	<u>31,243</u>
Total assets	\$ 36,239	\$ 31,243
Liabilities and Stockholders' Equity		
Current liabilities:		
Current portion of long-term debt and capital lease obligations	\$ 658	\$ 1,251
Accounts payable	1,309	1,848
Accrued compensation	872	1,772
Accrued expenses	2,977	4,749
Deferred revenue	1,517	645
	<u>7,333</u>	<u>10,265</u>
Total current liabilities	7,333	10,265
Warrant liability	4,205	
Long-term debt and capital lease obligations	182	580
Deferred revenue	5,055	4,329
Other liabilities	548	510
	<u>17,323</u>	<u>15,684</u>
Total liabilities	17,323	15,684
Commitments (See Note 15)		
Stockholders' equity:		
Preferred stock, par value \$.01 per share, 5,000 shares authorized, none issued		
Common stock, par value \$.01 per share, 150,000 and 75,000 shares authorized; 54,468 and 32,972 shares issued and outstanding	545	330
Additional paid-in capital	313,216	281,556
Accumulated deficit	(294,845)	(266,327)
	<u>18,916</u>	<u>15,559</u>
Total stockholders' equity	18,916	15,559
Total liabilities and stockholders' equity	\$ 36,239	\$ 31,243

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

Neose Technologies, Inc.

Statements of Operations

(in thousands, except per share amounts)

	Year ended December 31,		
	2007	2006	2005
Revenue from collaborative agreements	\$ 8,805	\$ 6,184	\$ 6,137
Operating expenses:			
Research and development	34,918	29,013	33,136
General and administrative	10,855	11,551	10,878
Restructuring charges			14,206
Total operating expenses	45,773	40,564	58,220
Gain on sale of Witmer Road Facility (see Note 6)		7,333	
Operating loss	(36,968)	(27,047)	(52,083)
Decrease in fair value of warrant liability	6,560		
Other income			22
Interest income	1,504	1,211	1,536
Interest expense	(147)	(1,271)	(1,314)
Loss before income tax benefit	(29,051)	(27,107)	(51,839)
Income tax benefit	533		
Net loss	\$ (28,518)	\$ (27,107)	\$ (51,839)
Basic and diluted net loss per share	\$ (0.57)	\$ (0.82)	\$ (1.64)
Weighted-average shares outstanding used in computing basic and diluted net loss per share	50,262	32,857	31,590

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

Neose Technologies, Inc.

Statements of Stockholders' Equity and Comprehensive Loss

(in thousands)

	Common stock		Additional paid-in capital	Deferred compensation	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance, January 1, 2005	24,717	\$ 247	\$ 248,027	\$ (39)	\$ (187,381)	\$ 60,854
Net and total comprehensive loss					(51,839)	(51,839)
Sale of common stock in a registered offering	8,050	81	29,925			30,006
Shares issued pursuant to employee stock purchase plan	15		86			86
Restricted stock units:						
Conversion of liability-classified awards to equity-classified awards			382			382
Compensation cost recognized in the Statement of Operations			609			609
Deferred compensation related to non-employee stock options			(14)	14		
Amortization of deferred compensation related to:						
Employee stock options				28		28
Non-employee stock options				(9)		(9)
Balance, December 31, 2005	32,782	328	279,015	(6)	(239,220)	40,117
Net and total comprehensive loss					(27,107)	(27,107)
Reclassification of deferred compensation upon the adoption of SFAS No. 123R			(6)	6		
Exercise of stock options	5		14			14
Restricted stock units:						
Shares issued upon vesting of restricted stock units	185	2	(2)			
Payment of withholding taxes related to restricted stock units			(175)			(175)
Conversion of liability-classified awards to equity-classified awards			129			129
Compensation costs recognized in the Statement of Operations:						
Employee stock options			2,438			2,438
Non-employee stock options			14			14
Restricted stock units			129			129
Balance, December 31, 2006	32,972	330	281,556		(266,327)	15,559
Net and total comprehensive loss					(28,518)	(28,518)
Sale of common stock through a private placement	21,415	214	40,245			40,459
Initial valuation of warrants issued through a private placement			(10,765)			(10,765)
Exercise of stock options	11		27			27
Restricted stock units:						
Shares issued upon vesting of restricted stock units	70	1	(1)			
Payment of withholding taxes related to restricted stock units			(48)			(48)
Compensation costs recognized in the Statement of Operations:						
Employee stock options			2,164			2,164
Non-employee stock options			33			33
Restricted stock units			5			5

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

	Common stock					
Balance, December 31, 2007	345	\$	313,216	\$	(294,845)	\$ 18,916
	34,166					

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

F-5

Neose Technologies, Inc.

Statements of Cash Flows

(in thousands)

	Year ended December 31,		
	2007	2006	2005
Cash flows from operating activities:			
Net loss	\$ (28,518)	\$ (27,107)	\$ (51,839)
Adjustments to reconcile net loss to cash used in operating activities:			
Impairment of property and equipment and assets held for sale		121	13,187
Decrease in fair value of warrant liability	(6,560)		
Depreciation and amortization expense	1,901	2,209	4,322
Non-cash compensation expense	2,202	2,581	628
Non-cash rent expense	130	260	
Loss (gain) on disposition of equipment and assets held for sale, net	32	(7,272)	(4)
Premiums paid on early repayment of debt		215	
Accelerated amortization of debt issuance costs on early repayment of debt		133	
Changes in operating assets and liabilities:			
Accounts receivable	(1,884)	790	1,809
Prepaid expenses and other current assets	(411)	(75)	(150)
Intangible and other assets	(13)		
Accounts payable	(24)	481	(1,043)
Accrued compensation	(900)	283	84
Accrued expenses	(116)	818	698
Deferred revenue	1,598	(318)	(691)
Other liabilities	38	47	(70)
Net cash used in operating activities	(32,525)	(26,834)	(33,069)
Cash flows from investing activities:			
Purchases of property and equipment	(3,656)	(898)	(792)
Proceeds from sale of property and equipment and assets held for sale		19,373	110
Proceeds from settlement of property and equipment dispute			75
Purchases of marketable securities			(9,845)
Proceeds from maturities of marketable securities			10,000
Net cash (used in) provided by investing activities	(3,656)	18,475	(452)
Cash flows from financing activities:			
Proceeds from issuance of debt	367	539	1,484
Repayments of debt	(1,730)	(13,154)	(5,365)
Premiums paid on early repayment of debt		(215)	
Proceeds from issuance of common stock and warrants, net	40,486	14	30,092
Payment of withholding taxes related to restricted stock units	(48)	(175)	
Net cash provided by (used in) financing activities	39,075	(12,991)	26,211

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

	Year ended December 31,		
Net increase (decrease) in cash and cash equivalents	2,894	(21,350)	(7,310)
Cash and cash equivalents, beginning of year	16,388	37,738	45,048
Cash and cash equivalents, end of year	\$ 19,282	\$ 16,388	\$ 37,738

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

F-6

Neose Technologies, Inc.

Notes to Financial Statements

(in thousands, except per share amounts)

Note 1. Background

Neose Technologies, Inc. is a clinical-stage biopharmaceutical company focused on the development of next-generation therapeutic proteins, which we believe will be competitive with best-in-class protein drugs currently on the market. We have two therapeutic protein candidates in clinical trials: GlycoPEG-GCSF and GlycoPEG-FVIIa, and two therapeutic protein candidates in the research stage: GlycoPEG-FVIII and GlycoPEG-FIX.

GlycoPEG-GCSF is a long-acting version of granulocyte colony stimulating factor (G-CSF) that we are co-developing with BioGeneriX AG, a company of the ratiopharm Group. G-CSF is prescribed to stimulate production of neutrophils (a type of white blood cell) and is approved for sale in major markets around the world for treatment of neutropenia associated with myelosuppressive chemotherapy. In November 2007, we reported data from two Phase I clinical trials. That data demonstrated that GlycoPEG-GCSF is a potent stimulator of neutrophils and mobilizer of peripheral blood progenitor cells, and that at comparable doses to Neulasta® (Amgen's marketed, long-acting G-CSF), GlycoPEG-GCSF demonstrates a 60% greater bioavailability, leading to a 30% increase in the generation of neutrophils. We expect BioGeneriX to commence a Phase II study in the first half of 2008.

GlycoPEG-FVIIa is a long-acting form of recombinant Factor VIIa that is being developed by our partner, Novo Nordisk AS, utilizing our GlycoPEGylation technology. Factor VIIa is used in the treatment of bleeding episodes and for the prevention of bleeding during surgery or invasive procedures in patients with congenital hemophilia with inhibitors to coagulation Factors VIII or IX. In June 2007, Novo Nordisk initiated a Phase I clinical study to assess the safety and pharmacokinetics of GlycoPEG-FVIIa in healthy volunteers. During 2007, poster presentations of preclinical data for GlycoPEG-FVIIa were presented at annual meetings of the International Society on Thrombosis and Haemostasis and the American Society of Hematology. Novo Nordisk is also developing long-acting forms of recombinant Factor VIII and recombinant Factor IX utilizing our GlycoPEGylation technology. Factor VIII products are used in the treatment of Hemophilia A, and Factor IX products are used in the treatment of Hemophilia B.

In January 2008, we announced the discontinuation of further development of GlycoPEG-EPO (NE-180), our product candidate intended for the treatment of anemia in patients with chronic kidney disease and cancer patients receiving chemotherapy. The decision to discontinue development was not due to any safety or efficacy concerns about NE-180, but was based on an evaluation of commercial prospects and the likelihood of entering into a timely collaboration for the compound in the context of increased safety concerns in the erythropoiesis-stimulating agent (ESA) category. In connection with the discontinuation of the NE-180 program, we will reduce our workforce by approximately 35% (see Note 14).

We believe that our enzymatic pegylation technology, GlycoPEGylation, can improve the drug properties of therapeutic proteins by building out, and attaching polyethylene glycol (PEG) to, carbohydrate structures at specific sites on the proteins. We are using our technology to develop proprietary versions of protein drugs with proven safety and efficacy and to improve the therapeutic profiles of proteins being developed by our partners. We expect these modified proteins to offer significant advantages, including less frequent dosing and possibly improved efficacy, over the original versions of the drugs now on the market, as well as to meet or exceed the pharmacokinetic profile of next-generation versions of the drugs now on the market. We believe this strategy of targeting drugs

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 1. Background (Continued)

with proven safety and efficacy allows us to lower the risk profile of our proprietary development portfolio as compared to *de novo* protein drug development. We intend to continue to focus our research and development resources on therapeutic proteins that we believe have the greatest probability of achieving clinically meaningful therapeutic improvements from our technology and are in commercially attractive categories.

We have incurred losses each year since inception. As of December 31, 2007, we had an accumulated deficit of \$294,845. We expect to spend significant amounts to expand our research and development on our proprietary drug candidates and technology, maintain and expand our intellectual property position, and expand our business development and commercialization efforts. Given our planned level of operating expenses, we expect to continue incurring losses for some time.

We believe that our existing cash and cash equivalents, expected proceeds from collaborations and license arrangements, and interest income should be sufficient to meet our operating and capital requirements at least into the third quarter of 2009, although changes in our collaborative relationships or our business, whether or not initiated by us, may cause us to deplete our cash and cash equivalents sooner than the above estimate. We will require significant amounts of additional capital in the future to fund our operations, 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. If we are unable to raise additional capital when required, we may need to delay, scale back, or eliminate some or all of our research and development programs.

We have not yet developed any products or commercialized any products or technologies, and we may never be able to do so. Even if we are successful in developing products that are approved for marketing, we will not be successful unless our products, and products incorporating our technology, gain market acceptance. Our operations are subject to risks and uncertainties in addition to those mentioned above, such as, among others, the uncertainty of product development, including our dependence upon third parties to conduct our clinical trials and to manufacture our product candidates and the materials used to make them, and unexpected delays or unfavorable results in our clinical trials; our limited product development and manufacturing experience; our dependence upon collaborative partners to develop and commercialize products incorporating our technology and the success of collaborative relationships; the uncertainty of intellectual property rights; the possibility of development and commercialization of competitive products by others that are more effective, less costly, or otherwise gain greater market acceptance; and the uncertainty of the impact of government regulation on our operations, including achieving regulatory approvals for our products or products incorporating our technology, and changes in health care reimbursement policies.

Note 2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements, in conformity with U.S. generally accepted accounting principles, requires us to make estimates and assumptions. Those estimates and assumptions affect the reported amounts of assets and liabilities as of the date of the financial statements, the disclosure of contingent assets and liabilities as of the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 2. Summary of Significant Accounting Policies (Continued)

Cash and Cash Equivalents

We consider all highly liquid investments with a maturity of three months or less on the date of purchase to be cash equivalents. As of December 31, 2007 and 2006, cash equivalents consisted of money market investments. Our cash balances have been kept on deposit primarily at one bank and in amounts greater than \$100, which is the limit of insurance provided by the Federal Deposit Insurance Corporation.

Accounts Receivable

We record accounts receivable net of an allowance for doubtful accounts. We establish an allowance for doubtful accounts that we believe is adequate to cover anticipated losses on the collection of all outstanding accounts receivable. The adequacy of the allowance for doubtful accounts is based on historical information and management's assessment of our collaborators' ability and intent to pay. We recognize revenue based on proportional performance of research and development work performed on behalf of our collaborators, which recognition may not correspond with how our customers are billed. We review the unbilled accounts receivable from our customers to determine that such amounts are expected to become billable and collectible. All unbilled receivables are expected to be billed within six months.

Property and Equipment

Property and equipment are stated at cost. Property and equipment capitalized under capital leases are recorded at the present value of the minimum lease payments due over the lease term. Expenditures for additions and improvements are capitalized, while maintenance and repairs are charged to expense as incurred. Depreciation and amortization are calculated using the straight-line method over the estimated useful lives of the assets. Laboratory and office equipment are depreciated over three to seven years. For assets acquired under capital leases and for leasehold improvements, depreciation and amortization are calculated on the straight-line method over the estimated useful lives of the assets or the lease term, whichever is shorter. Upon the disposition of assets, the cost and related accumulated depreciation are removed from the accounts and any resulting gain or loss is included on our Statements of Operations.

Impairment of Long-lived Assets

Long-lived assets and certain identifiable intangibles are reviewed for impairment at least annually and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets held and used is measured by a comparison of the carrying amount of an asset to future net undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. As described in Note 14, we discontinued further development of NE-180, our product candidate intended for the treatment of anemia in patients with chronic kidney disease and cancer patients receiving chemotherapy. We do not expect to incur any impairment of long-lived assets in connection with the discontinuation of the NE-180 program. As described in Note 6, we recognized during the third quarter

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 2. Summary of Significant Accounting Policies (Continued)

of 2005 non-cash impairment charges on our property and equipment as a result of the restructuring we announced in August 2005 (see Note 14). During the year ended December 31, 2006, we recognized additional non-cash impairment charges on our property and equipment. Because our history of negative operating cash flows is an indicator of impairment, we annually compare the market value of our equity and debt to the carrying value of our net assets. The market value of our equity and debt exceeded the carrying value of our net assets as of December 31, 2007 and, therefore, we did not recognize any impairment of long-lived assets for the year ended December 31, 2007.

Financing Costs Related to Long-term Debt

Costs associated with obtaining long-term debt are deferred and amortized to interest expense over the term of the related debt. During the year ended December 31, 2006, the remaining amount of deferred financing costs was amortized to interest expense in our Statements of Operations due to the repayment in full of the related debt (see Note 8).

Warrant Liability

We follow Emerging Issues Task Force (EITF) No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock* (EITF 00-19), which provides guidance for distinguishing among permanent equity, temporary equity and assets and liabilities. EITF 00-19 requires liability classification of warrants that may be settled in cash at the option of warrant holders. Our warrants issued in March 2007 permit net cash settlement in certain change of control circumstances at the option of the warrant holders, and are, therefore, classified as a liability on our Balance Sheets (see Note 10).

We record the warrant liability at its fair value using the Black-Scholes option-pricing model and revalue it at each reporting date until the warrants are exercised or expire. Changes in the fair value of the warrants are reported in our Statements of Operations as non-operating income or expense. The fair value of the warrants is subject to significant fluctuation based on changes in our stock price, expected volatility, remaining contractual life and the risk-free interest rate. The market price for our common stock has been and may continue to be volatile. Consequently, future fluctuations in the price of our common stock may cause significant increases or decreases in the fair value of the warrants.

In connection with our March 2007 equity financing, we were obligated to file a registration statement with the Securities and Exchange Commission (SEC) for the registration of the total number of shares sold to the investors and shares issuable upon exercise of the warrants. We are required under an agreement to use commercially reasonable efforts to cause the registration to be declared effective by the SEC, which we accomplished in May 2007, and to remain continuously effective until such time when all of the registered shares are sold. In the event we fail to meet various legal requirements in regards to the registration statement, we will be obligated to pay the investors, as partial liquidated damages and not as a penalty, an amount in cash equal to 1% of the aggregate purchase price paid by investors for each monthly period that the registration statement is not effective, up to 24%. We follow Financial Accounting Standards Board (FASB) Staff Position No. EITF 00-19-2, *Accounting for Registration Payment Arrangements* (EITF 00-19-2), which specifies that registration payment arrangements should play no part in determining the initial classification of, and subsequent accounting for, securities to which the payments relate. Contingent obligations in a registration payment

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 2. Summary of Significant Accounting Policies (Continued)

arrangement are separately analyzed under Statement of Financial Accounting Standards (SFAS) No. 5, *Accounting for Contingencies*, and FASB Interpretation No. 14, *Reasonable Estimation of the Amount of a Loss*. If we determine a registration payment arrangement in connection with the securities issued in March 2007 is probable and can be reasonably estimated, a liability will be recorded. As of December 31, 2007, we concluded the likelihood of having to make any payments under the arrangements was remote, and therefore did not record any related liability.

Deferred Rent and Landlord Incentive

We have entered into various operating lease arrangements for laboratory, office and warehouse space which contain escalation clauses, under which the base rent increases annually (see Note 15). We record monthly rent expense equal to the total of the payments due over the lease term, divided by the number of months of the lease term. The difference between rent expense recorded and the amount paid is credited or charged to deferred rent, which is included in other liabilities on our Balance Sheets. In addition we received an incentive from the landlord for our Rock Road Facility for partial reimbursement for improvements we made to the facility. This incentive is also included in other liabilities on our Balance Sheets and is being amortized ratably as a reduction to rent expense over the lease term.

Revenue Recognition

We have entered into collaborative agreements with other companies for the development and commercialization of our product candidates. The terms of the agreements typically include non-refundable up-front license fees, funding of research and development, payments based upon achievement of development milestones, and royalties on product sales.

License Fees and Multiple Element Arrangements

Non-refundable license fees are recognized as revenue when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured, and we have no further performance obligations under the license agreement.

Multiple element arrangements, such as license and development arrangements are analyzed to determine whether the deliverables, which often include a license and performance obligations, such as research and development services, can be separated or whether they must be accounted for as a single unit of accounting in accordance with EITF Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. However, if the license is considered to either (i) not have stand-alone value or (ii) have standalone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting and the license payments and payments for performance obligations are recognized as revenue over the estimated period of when the performance obligations are performed. In our collaborative arrangements with Novo Nordisk and BioGeneriX, we have determined the license to each does not have stand-alone value.

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 2. Summary of Significant Accounting Policies (Continued)

Whenever we determine that an arrangement should be accounted for as a single unit of accounting, we must determine the period over which the performance obligations will be performed and revenue will be recognized. Significant management judgment is required in determining the period over which we are expected to complete our performance obligations under an arrangement.

Substantive Milestone Payments

Our collaboration agreements may also contain substantive milestone payments. Substantive milestone payments are considered to be performance bonuses that are recognized as revenue upon achievement of the milestone only if all of the following conditions are met:

the milestone payments are non-refundable;

achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement;

substantive effort is involved in achieving the milestone;

a reasonable amount of time passes between the up-front license payment and the first milestone payment as well as between each subsequent milestone payment; and

the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone.

Determination as to whether a payment meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone, and therefore the resulting payment would be considered part of the consideration for the single unit of accounting and be recognized as revenue as such performance obligations are performed.

Reimbursement of Research and Development Costs

Reimbursement of research and development costs is recognized as revenue provided the provisions of EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent*, are met, the amounts are fixed and determinable, and collection of the related receivable is reasonably assured. In our collaborative arrangements with Novo Nordisk and BioGeneriX, we recognize revenue as such costs are incurred because we have evidence of fair value for these delivered items.

Deferred Revenue

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying Balance Sheets. Determination as to the classification of deferred revenue as current or long-term on our Balance Sheets involves management's judgment. For example, in connection with our existing collaboration agreements, we have recorded on our Balance Sheets current and long-term deferred revenue based on our best estimate of when such revenue will be recognized. The current portion of deferred revenue consists of amounts that are expected to be recognized as revenue during 2008. Amounts that we expect will not be recognized during 2008 are classified as long-term deferred revenue. This estimate is based on our estimate of the periods of our

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 2. Summary of Significant Accounting Policies (Continued)

involvement in certain of our collaborations. In certain instances, the timing of satisfying these obligations can be difficult to estimate. Accordingly, our estimates may change in the future. Any change to the estimated performance period would be recognized on a prospective basis. If these estimates and judgments change over the course of these agreements, it may affect the timing and amount of revenue that we recognize and record in future periods.

Research and Development

Research and development costs are charged to expense as incurred. 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 consulting and contract research, development, and manufacturing costs. Indirect expenses include depreciation expense and the costs of operating and maintaining our facilities, property, and equipment, to the extent used for our research and development projects, as well as the costs of general management of our research and development projects.

Some of our research and development is conducted by third parties, including contract research and development service providers. At the end of each quarter, we compare the payments made to each service provider to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the estimated service provided, we may record net prepaid or accrued expenses relating to these costs.

Accounting for Restructuring Costs

In January 2008, March 2007, September 2006 and August 2005, we implemented restructurings of operations (see Note 14). SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (SFAS No. 146), addresses financial accounting and reporting for costs associated with exit or disposal activities. SFAS No. 146 requires a liability for a cost associated with an exit or disposal activity be recognized and measured initially at fair value only when the liability is incurred. SFAS No. 146 does not apply to costs associated with a disposal activity covered by SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS No. 144).

The employee severance costs incurred for the restructurings in 2007 and 2006 were payable pursuant to an employee severance plan established in August 2005. Therefore, these costs did not meet the definition for classification as a restructuring charge on our Statements of Operations. The restructuring charges recorded by us during 2005 were comprised primarily of costs to reduce property and equipment to fair value and to reduce our workforce.

Under SFAS No. 144, any impairment of property and equipment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. To determine the fair value of assets that are not likely to be used over their remaining useful economic life, we use a probability-weighted approach of estimated cash flows to be received upon a range of possible disposition outcomes. In August 2005, we announced we would evaluate alternatives relative to our headquarters and pilot manufacturing facility (Witmer Road Facility), which we owned subject to a

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 2. Summary of Significant Accounting Policies (Continued)

mortgage, including the potential disposition of the facility and further consolidation of our research, development and administrative operations into a currently leased facility also located in Horsham, Pennsylvania. As a result of the announcement, we concluded that identifiable cash flows could be assigned to the Witmer Road Facility and related equipment. We based our estimates of potential cash flows related to possible disposition outcomes on conversations with commercial real estate firms that have both knowledge of recent history of sales and expertise in marketing and selling similar facilities.

Under SFAS No. 146, employee severance costs are determined based on the estimated severance and fringe benefit charge for identified employees. In calculating the cost to exit our leased facility in San Diego, California, we estimated the future lease and operating costs to be paid until the lease is terminated, the amount of any sublease receipts, and real estate broker fees. SFAS No. 146 also required us to estimate the timing and the amount of operating costs and the timing and rate at which we might be able to sublease the facility. To form our estimates for these costs, we performed an assessment of the affected facility and considered the current market conditions.

Interest Expense

During the years ended December 31, 2007 and 2006, we incurred significant capital expenditures related to improving our leased facilities. See Note 6 for a description of our property and equipment. Accordingly, we capitalized a portion of interest incurred during each reporting period in accordance with SFAS No. 34, *Capitalization of Interest Cost*, as amended. We did not capitalize any interest incurred during the year ended December 31, 2005.

Income Taxes

We account for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. We provide a valuation allowance for the full amount of our net deferred tax assets because there is no assurance they will be realized.

Stock-based Employee Compensation

We adopted SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS No. 123R), effective January 1, 2006. SFAS No. 123R requires all share-based payments to employees to be recognized in the financial statements based on their fair values at the date of grant. Prior to January 1, 2006, we followed Accounting Principles Board (APB) Opinion 25, *Accounting for Stock Issued to Employees* (APB No. 25), and related interpretations in accounting for our stock-based compensation. We elected to use the modified prospective transition method for adopting SFAS No. 123R. Under this method, the provisions of SFAS No. 123R apply to all awards granted or modified after the date of adoption and to that portion of awards not fully vested as of the date of adoption. Accordingly, prior periods have not been restated.

Neose Technologies, Inc.

Notes to Financial Statements

(in thousands, except per share amounts)

Note 2. Summary of Significant Accounting Policies (Continued)

The fair value of stock options is determined using the Black-Scholes valuation model, which is the same model we previously utilized for valuing stock options for footnote disclosures required under SFAS No. 123, *Accounting for Stock Based Compensation* (SFAS No. 123), as amended by SFAS No. 148, *Accounting for Stock-Based Compensation, Transition and Disclosure* (SFAS No. 148).

The fair value of share-based awards is recognized as expense over the requisite service period, net of estimated forfeitures. We rely primarily on historical experience to estimate expected forfeitures for stock options. We have not assumed any expected forfeitures for restricted stock units (RSUs) because those awards have been granted to a small number of individuals. For all unvested share-based awards outstanding as of December 31, 2005, the previously measured but unrecognized compensation expense, based on the fair value at the original grant date, will be recognized on an accelerated basis in our statement of operations over the remaining vesting period, consistent with our recognition policy under SFAS No. 123. For share-based awards granted subsequent to December 31, 2005, we have elected to recognize compensation expense in the Statements of Operations on a straight-line basis from the date of grant. Our deferred stock compensation balance of \$6 as of December 31, 2005 was reclassified into additional paid-in capital upon the adoption of SFAS No. 123R.

SFAS No. 123R requires us to present pro forma information for comparative periods prior to the adoption as if we had accounted for all our stock-based employee compensation under the fair value method of SFAS No. 123. 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:

	Year ended December 31, 2005
Net loss as reported	\$ (51,839)
Add: Stock-based employee compensation expense included in reported net loss	788
Deduct: Total stock-based employee compensation expense determined under fair value-based method for all awards	(4,607)
Net loss pro forma	\$ (55,658)
Basic and diluted net loss per share as reported	\$ (1.64)
Basic and diluted net loss per share pro forma	\$ (1.76)

Net Loss 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 is computed by dividing net loss by the sum of weighted-average number of common shares outstanding for the period and the number of additional shares that would have been outstanding if dilutive potential common shares had been

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 2. Summary of Significant Accounting Policies (Continued)

issued. Potential common shares are excluded from the calculation of diluted net loss per share if the effect on net loss per share is antidilutive. Our diluted net loss per share is equal to basic net loss per share for all reporting periods presented because giving effect in the computation of diluted net loss per share to the exercise of outstanding options or granting of restricted stock units would have been antidilutive. See Note 12 for a summary of outstanding options and a description of our restricted stock units.

Comprehensive Loss

SFAS No. 130, *Reporting Comprehensive Income*, requires disclosure of comprehensive income (loss) in the financial statements. Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) includes changes to equity that are not included in net income (loss). Our comprehensive loss for the years ended December 31, 2007, 2006, and 2005 was comprised only of our net loss and is reported on our Statements of Stockholders' Equity and Comprehensive Loss.

Fair Value of Financial Instruments

The fair value of our financial instruments is the amount for which the instrument could be exchanged in a current transaction between willing parties. As of December 31, 2007, the carrying values of cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses, and accrued compensation equaled or approximated their respective fair values because of the short duration of these instruments. The fair value of our long-term debt was estimated by discounting the future cash flows of each instrument at rates recently offered to us for similar debt instruments offered by our lenders. As of December 31, 2007, the fair and carrying values of our long-term debt and capital lease obligations were \$846 and \$840, respectively.

Recent Accounting Pronouncements

In June 2007, the FASB issued EITF 07-03, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*-(EITF 07-03). EITF 07-03 specifies that nonrefundable advance payments for future research and development activities should be deferred and capitalized and should be recognized as an expense as the related goods are delivered or the related services are performed. If, subsequent to an advance payment, an entity no longer expects the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. EITF 07-03 is effective for fiscal years beginning after December 15, 2007. As the guidance in EITF 07-03 is consistent with our existing policy we do not believe EITF 07-03 will have any impact on our financial statements or related disclosures.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* (SFAS No. 159), which allows companies to choose, at specific election dates, to measure eligible financial assets and liabilities at fair value that are not otherwise required to be measured at fair value. If a company elects the fair value option for an eligible item, changes in that item's fair value in subsequent reporting periods must be recognized in current earnings. SFAS No. 159 is effective for fiscal years beginning after November 15,

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 2. Summary of Significant Accounting Policies (Continued)

2007. We are currently evaluating the impact of SFAS No. 159 on our financial statements and related disclosures.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS No. 157), which is applicable for fiscal years beginning after November 15, 2007. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 applies under other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Although SFAS No. 157 does not require any new fair value measurements, its application may, for some entities, change current practices related to the definition of fair value, the methods used to measure fair value, and the expanded disclosures about fair value measurements. We are currently evaluating the impact of the adoption of SFAS No. 157 on our financial statements and related disclosures.

Note 3. Supplemental Disclosure of Cash Flow Information

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

	Year ended December 31,		
	2007	2006	2005
Supplemental disclosure of cash flow information:			
Cash paid for interest, net of amounts capitalized (see Note 6)	\$ 147	\$ 1,164	\$ 1,302
Non-cash operating activities:			
Non-cash rent included in gain on sale of Witmer Road Facility (see Note 6)	\$	\$ 390	\$
Increase in prepaid expenses and other current assets included in accounts payable	\$	\$ 228	\$
Non-cash investing activities:			
Increase (decrease) in property and equipment included in accounts payable and accrued expenses	\$ (1,759)	\$ 1,651	\$ 45
Assets acquired under capital leases	\$ 373	\$	\$
Decrease in acquisition value of property and equipment related to cancellation of a vendor invoice as partial settlement of dispute	\$	\$	\$ 116
Decrease in acquisition value of property and equipment due to decrease in amount of remaining minimum lease payments under capital lease	\$	\$	\$ 10
Non-cash financing activities:			
Initial measurement of warrant liability (see Note 10)	\$ 10,765	\$	\$

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

Year ended December 31,

Conversion of accrued compensation from liability to equity classified award upon grant of restricted stock units (see Note 12)	\$	\$ 129	\$ 382

F-17

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 4. Accounts Receivable

Accounts receivable consisted of the following:

	December 31,	
	2007	2006
Billed receivables	\$ 670	\$ 286
Unbilled receivables	1,107	
	1,777	286
Less allowance for doubtful accounts	(19)	
	\$ 1,758	\$ 286

During the year ended December 31, 2007, we recorded an allowance for doubtful accounts of \$19 in our Statement of Operations. There were no write-offs or recoveries recorded against this allowance for doubtful accounts during 2007.

Note 5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31,	
	2007	2006
Prepaid contract research and development services	\$ 1,008	\$ 228
Prepaid maintenance agreements	159	162
Prepaid clinical trials and non-clinical studies	113	124
Prepaid rent	66	195
Prepaid insurance	57	86
Other prepaid expenses	158	262
Other current assets	3	227
	\$ 1,564	\$ 1,284

Receivable from Related Party

In 2001, we entered into a tuition reimbursement agreement with an employee who subsequently became an executive officer. Under the agreement, we agreed to lend the amounts necessary to pay for the employee's tuition payments and related costs and fees. Interest accrued on the loan at 4.71% per year, and was payable annually commencing in May 2002. We agreed to forgive repayment of the principal amount outstanding, in four equal, annual installments, commencing in May 2004, if the employee remained employed by us on each forgiveness date. We also agreed to forgive the accrued interest on each annual due date. We forgave principal and accrued interest of \$30, \$31 and \$33 during the years ended December 31, 2007, 2006, and 2005, respectively. As of December 31, 2007, there was no remaining outstanding principal or accrued interest under the agreement. As of December 31, 2006, the amount outstanding under the agreement, including accrued interest, was \$29, all of which was included in prepaid expenses and other current assets on our Balance Sheets as of December 31, 2006.

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 6. Property and Equipment

Property and equipment consisted of the following:

	December 31,	
	2007	2006
Leasehold improvements	\$ 12,984	\$ 9,817
Laboratory, manufacturing, and office equipment	6,960	5,874
Construction-in-progress		2,142
	19,944	17,833
Less accumulated depreciation and amortization	(6,380)	(4,729)
	\$ 13,564	\$ 13,104

In February 2007, we consolidated our operations into a 40,000 square foot facility that we currently lease in Horsham, Pennsylvania (Rock Road Facility). Total costs for construction of additional laboratory and office space in the Rock Road Facility were \$3,160, of which \$2,111 was included in construction-in-progress as of December 31, 2006. Of the total construction costs, \$2,890 related to leasehold improvements that will be amortized over the remaining lease term of approximately 15 years and the remaining \$270 related to laboratory and office equipment that will be depreciated over three to seven years.

In September 2006, we sold the Witmer Road Facility for \$21,043. After payment of selling fees and expenses, we received net proceeds of approximately \$19,322. The carrying value of the property and equipment sold was \$12,379. We owned the Witmer Road Facility subject to mortgages supporting our term loan and industrial development authority bond. We were permitted to occupy a portion of the facility on a rent-free basis for up to six months after closing. We estimated the rental fair value for the space we occupied to be \$390, which was included in the calculation of the \$7,333 gain on the sale of the Witmer Road Facility. During the years ended December 31, 2007 and 2006, we amortized \$130 and \$260, respectively, as rent expense in our Statements of Operations. As of December 31, 2006, the unamortized balance of the estimated rental fair value was \$130 and was included in prepaid expenses and other current assets on our Balance Sheets (see Note 5). Concurrent with the closing, we repaid outstanding debt associated with the Witmer Road Facility and related equipment of \$9,647, which included accrued interest and prepayment penalties.

Laboratory, manufacturing, and office equipment as of December 31, 2007 and 2006 included \$495 and \$122 respectively, of assets acquired under capital leases. Accumulated depreciation and amortization as of December 31, 2007 and 2006 includes \$148 and \$47, respectively, related to assets acquired under capital leases. During the years ended December 31, 2007 and 2006, we capitalized \$8 in each period, of interest expense in connection with our facility improvement projects. We did not capitalize any interest incurred during the year ended December 31, 2005.

Depreciation expense, which includes amortization of assets acquired under capital leases, was \$1,778, \$1,606, and \$3,751 for the years ended December 31, 2007, 2006, and 2005, respectively. During the years ended December 31, 2007, 2006 and 2005, we disposed of fully depreciated assets that had original acquisition values of \$61, \$99 and \$129, respectively. During the year ended December 31, 2006, we recorded a gain on the sale of Witmer Road Facility of \$7,333. During the years ended

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 6. Property and Equipment (Continued)

December 31, 2007, 2006 and 2005, we recorded losses on disposition of property and equipment of \$32, \$13, and \$17, respectively. In addition, during the years ended December 31, 2006 and 2005, we recorded a loss of \$48 and a gain of \$21, respectively, on the disposition of assets held for sale. There were no dispositions of assets held for sale for the year ended December 31, 2007. The aggregate proceeds from the disposition of property and equipment and assets held for sale, excluding the Witmer Road Facility, were \$51 and \$110, respectively, for the years ended December 31, 2006 and 2005. There were no proceeds from the disposition of property and equipment for the year ended December 31, 2007.

During 2006, we evaluated cash flows that could be assigned to equipment that was no longer in use. We based our estimates of potential cash flows on possible disposition outcomes if the equipment was sold at auction. Based on those estimates, we recorded a non-cash impairment charge of \$121, which was included in research and development expenses in our Statements of Operations. The aggregate acquisition value of the impaired assets was reduced by \$586 and the related accumulated depreciation was reduced by \$465.

2005 Activity

As part of the restructuring announced in August 2005 (see Note 14), we centralized research activities in Horsham, Pennsylvania by ending operations in our leased facility in San Diego, California. We recorded a non-cash impairment charge of \$187 related to property and equipment located in the San Diego facility. The aggregate acquisition value of the impaired assets was reduced by \$745 and the related accumulated depreciation and amortization was reduced by \$558. This impairment charge was included in restructuring charges on our Statements of Operations.

We also announced that we would evaluate alternatives relative to our Witmer Road Facility, including the potential disposition of the facility and further consolidation of our research, development and administrative operations into Rock Road Facility. As a result of the announcement, we concluded that identifiable cash flows could be assigned to the Witmer Road Facility and related equipment. To determine the appropriate carrying value of these assets, we used a probability-weighted approach of estimated cash flows to be received upon a range of possible disposition outcomes. We based our estimates of potential cash flows related to possible disposition outcomes on conversations with commercial real estate firms that had both knowledge of recent history of sales and expertise in marketing and selling similar facilities. Based on those estimates, we recorded during the third quarter of 2005 a non-cash impairment charge of \$13,000, which was included in restructuring charges on our Statements of Operations, on our Witmer Road Facility and related equipment. The aggregate acquisition value of the impaired assets was reduced by \$29,007 and the related accumulated depreciation and amortization was reduced by \$16,007.

During 2005, we settled a dispute with a vendor from which we had purchased property and equipment. Pursuant to the settlement agreement, the vendor canceled an outstanding invoice of \$116, which we had previously included in accounts payable, and paid us \$75. Therefore, we reduced the acquisition cost of the property and equipment by \$191.

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 7. Intangible and Other Assets**Acquired Intellectual Property**

During the year ended December 31, 2007, we completed the scheduled amortization of the carrying value of acquired intellectual property. As of December 31, 2006, the carrying value of intellectual property was \$123.

Deposits

As of December 31, 2007 and December 31, 2006, deposits were \$71 and \$58, respectively.

Deferred Financing Costs

During 2004, we entered into agreements with a bank. In connection with entering into these agreements, we incurred \$181 of legal and other costs. We recorded this amount as an asset, and began amortizing the asset to interest expense in our Statements of Operations over the ten-year repayment term to the bank. Upon the repayment of the term loan from the bank and the Industrial Development Authority bond in September 2006, we accelerated the amortization of the remaining carrying value of \$133 of deferred financing costs to interest expense. Amortization expense, including the acceleration of amortization in 2006, relating to the deferred financing costs was \$145 and \$18 for the years ended December 31, 2006 and 2005, respectively.

Note 8. Long-Term Debt and Capital Lease Obligations

Long-term debt and capital lease obligations consisted of the following:

	December 31,	
	2007	2006
Notes payable to equipment lender	\$ 327	\$ 1,101
Term loan from landlord	195	622
Subtotal	522	1,723
Capital lease obligations (see Note 15)	318	108
Total debt	840	1,831
Less current portion	(658)	(1,251)
Total debt, net of current portion	\$ 182	\$ 580

Minimum principal repayments of long-term debt and capital lease obligations as of December 31, 2007 were as follows: 2008 \$658; 2009 \$58; 2010 \$55; 2011 \$59; and \$10 thereafter. Interest expense during the years ended December 31, 2007, 2006, and 2005 was \$147, \$1,271, and \$1,314, respectively. See Note 6 for the amounts of interest capitalized during each of the three years ended December 31, 2007.

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 8. Long-Term Debt and Capital Lease Obligations (Continued)**Notes Payable to Equipment Lender**

As of December 31, 2007, we owed an equipment lender \$327 under various borrowings. The amounts owed were secured by equipment and facility improvements that had a carrying value of \$1,117 as of December 31, 2007. In September 2006, we repaid \$1,626 of the outstanding debt as a result of the sale of the Witmer Road Facility (see Note 6), and in October 2006, we amended six promissory notes with our equipment lender. Under the amended promissory notes, our last payment is scheduled for September 2008, and interest rates applicable to the equipment loans range from 9.1% to 9.5%. In connection with the early repayment of this debt, we paid \$62 of premiums to the equipment lender, which premiums were included in interest expense during the year ended December 31, 2006.

Term Loan from Landlord

In May 2004, we borrowed \$1.5 million of unsecured debt from the landlord of our Rock Road Facility. As of December 31, 2007, we owed the landlord \$195. The terms of the financing require us to pay monthly principal and interest payments over 48 months at an interest rate of 13%. The final payment is due June 2008.

Note 9. Accrued Expenses

Accrued expenses consisted of the following:

	December 31,	
	2007	2006
Clinical trials and non-clinical studies	\$ 1,544	\$ 625
Professional fees	788	1,469
Contract research and development services	390	1,283
Property and equipment		1,244
Other expenses	255	128
	\$ 2,977	\$ 4,749

Note 10. Warrant Liability

In March 2007, we sold, through a private placement, 21,415 shares of our common stock and warrants to purchase 9,637 shares of our common stock with an exercise price of \$1.96 (see Note 11). The warrants have a five-year term and are immediately exercisable. The warrant agreement contains a net cash settlement feature, which is available to the warrant holders at their option, in certain change of control circumstances. As a result, under EITF 00-19, the warrants are required to be classified as a liability at their current fair value in our Balance Sheets, estimated using the Black-Scholes option-pricing model. Warrants that are classified as a liability are revalued at each reporting date until the warrants are exercised or expire with changes in the fair value reported in our Statements of Operations as non-operating income or expense. Accordingly, we recorded non-operating income of

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 10. Warrant Liability (Continued)

\$6,560 during the year ended December 31, 2007, which represents the decrease in fair value of the warrant liability from the date of issuance, March 13, 2007, through December 31, 2007. The aggregate fair value and the assumptions used for the Black-Scholes option-pricing models as of March 13, 2007 and December 31, 2007 were as follows:

	March 13, 2007	December 31, 2007
Aggregate fair value	\$ 10,765	\$ 4,205
Expected volatility	75%	69%
Remaining contractual term (years)	5.0	4.2
Risk-free interest rate	4.4%	3.3%
Expected dividend yield	0%	0%
Common stock price	\$ 1.79	\$ 1.07

Note 11. Stockholders' Equity

Common Stock

In March 2007, we sold 21,415 shares of our common stock and warrants to purchase 9,637 shares of common stock through a private placement, including 4,950 shares of common stock and warrants to purchase 2,228 shares of our common stock to investment funds affiliated with certain members of our board of directors, at a price of \$2.02 per unit, generating net proceeds of approximately \$40,459. The warrants have a five-year term and an exercise price of \$1.96 per share.

In February 2005, we offered and sold 8,050 shares of our common stock at a public offering price of \$4.00 per share, generating net proceeds of \$30,006.

Note 12. Compensation Plans

Equity Incentive Plans

The following types of awards are available under our 2004 Equity Incentive Plan (Plan), which incorporates a predecessor plan: incentive stock options, non-qualified stock options, stock appreciation rights, restricted shares and restricted stock units (RSUs). All employees, non-employee directors, and consultants are eligible to receive awards under the Plan.

The Plan allows us to grant restricted shares and RSUs with complete discretion as to: when grants are made; the consideration, if any, to be paid for restricted shares; and when the restrictions applicable to each restricted share and RSU will lapse. The Plan also allows us to grant stock options and stock appreciation rights to eligible individuals, with complete discretion as to: when grants are made; the number of shares subject to vesting and the vesting schedule; the designation as either an incentive or a non-qualified stock option; the maximum term to remain outstanding, which term, for an incentive stock option, may not exceed ten years (and for an incentive stock option granted to a person who owns more than 10% of our voting power may not exceed five years); and the exercise price, which for a non-qualified stock option may not be less than 85% of the fair market value of the stock on the date of grant and for an incentive stock option must be at least 100% of the fair market value

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 12. Compensation Plans (Continued)

on the date of grant (unless the recipient owns more than 10% of our voting power, in which case the exercise price must be at least 110% of the fair market value on the date of grant). During the years ended December 31, 2007, 2006, and 2005, the exercise price of each option granted was equal to the market price of our common stock on the grant date. We normally issue new shares to satisfy stock option exercises and the delivery of shares pursuant to RSUs. There were no modifications to stocks options during the year ended December 31, 2007.

The following table summarizes the status of stock options as of December 31, 2007 and changes during the year then ended:

	Shares	Weighted-average exercise price	Aggregate intrinsic value	Weighted-average remaining contractual life (years)
Outstanding at January 1, 2007	5,281	\$ 11.61		
Granted	1,340	2.39		
Exercised	(11)	2.55		
Forfeited	(391)	4.42		
Expired	(1,651)	15.67		
Outstanding at December 31, 2007	4,568	\$ 8.07	\$	6.3
Vested at December 31, 2007 and expected to vest	4,045	\$ 8.75	\$	6.1
Exercisable at December 31, 2007	2,933	\$ 10.89	\$	5.4

Fair Value Disclosures

We adopted SFAS No. 123R effective January 1, 2006. Prior to January 1, 2006, we applied the intrinsic value method of accounting for all stock-based employee compensation in accordance with APB No. 25 and related interpretations. We elected to use the modified prospective transition method for adopting SFAS No. 123R. Under this method, the provisions of SFAS No. 123R apply to all awards granted or modified after the date of adoption and to awards not fully vested as of the date of adoption. Accordingly, prior periods have not been restated. For the year ended December 31, 2007, we recorded \$2,202 of compensation costs for share-based payment arrangements in our Statements of Operations, all of which related to equity-classified awards. For the year ended December 31, 2006, we recorded \$2,602 of compensation cost for share-based payment arrangements in our Statements of Operations, of which \$21 related to liability-classified awards. No tax benefit was recorded as of December 31, 2007 or 2006 in connection with compensation cost due to the uncertainty regarding ultimate realization of our net operating loss carryforwards (see Note 16). The weighted-average fair value per share of stock options granted during the years ended December 31, 2007, 2006, and 2005 was \$1.63, \$1.83, and \$2.49, respectively. The total intrinsic value of stock options exercised during the years ended December 31, 2007 and 2006 was \$4 and \$5, respectively. There were no stock options exercised during the year ended December 31, 2005.

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 12. Compensation Plans (Continued)

The fair value of stock options is determined using the Black-Scholes valuation model, which is the same model we previously utilized for valuing stock options for footnote disclosures required under SFAS No. 123 as amended by SFAS No. 148 for the year ended December 31, 2005. During the years ended December 31, 2007, 2006, and 2005 the fair value of each stock option award was determined as of the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	Year ended December 31,					
	2007		2006		2005	
Weighted average expected volatility	75%		75%		75%	
Expected term (years)	4.7	9.1	4.7	7.8	0.7	9.1
Risk-free interest rate	4.4%	4.6%	4.4%	5.1%	3.9%	4.3%
Expected dividend yield	0%		0%		0%	

Expected volatility is based solely on historical volatility of our common stock over the period commensurate with the expected term of the stock options. We rely solely on historical volatility because our traded options do not have sufficient trading activity to allow us to incorporate the mean historical implied volatility from traded options into our estimate of future volatility. The expected term calculation for stock options granted to directors and officers is based on the observed and expected time to post-vesting exercise and forfeitures of stock options by those individuals. The expected term calculation for stock options granted to all other individuals is based on the "simplified" method described in SAB No. 107, *Share-Based Payment*. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for an instrument with a maturity that is commensurate with the expected term of the stock options. The dividend yield of zero is based on the fact that we have never paid cash dividends on our common stock, and we have no present intention to pay cash dividends.

The fair value of share-based awards is recognized as expense over the requisite service period, net of estimated forfeitures. Based on our historical experience of option pre-vesting cancellations, we have assumed an annualized forfeiture rate of 17% for our stock options granted to individuals not terminated as a result of a restructuring of our operations (see Note 14). For employees terminated as a result of the restructurings in 2007 and 2006, we have assumed an annualized forfeiture rate of 100%. We have not assumed any expected forfeitures for RSUs because those awards have been granted to a small number of individuals. Under the provisions of SFAS No. 123R, we will record additional expense if the actual forfeiture rate is lower than we estimated, and will record a recovery of prior expense if the actual forfeiture is higher than we estimated. We rely primarily on historical experience to estimate expected forfeitures.

For all unvested awards outstanding as of December 31, 2005, the previously measured but unrecognized compensation expense, based on the fair value at the original grant date, is being recognized on an accelerated basis in our Statements of Operations over the remaining vesting period, consistent with our recognition policy under SFAS No. 123. For share-based awards granted subsequent to December 31, 2005, we have elected to recognize compensation expense in our Statements of Operations on a straight-line basis from the date of grant. Our deferred stock compensation balance of \$6 as of December 31, 2005 was reclassified into additional paid-in capital upon the adoption of SFAS No. 123R.

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 12. Compensation Plans (Continued)

As of December 31, 2007, there was \$1,174 of total unrecognized compensation cost, which includes the impact of expected forfeitures, related to unvested share-based compensation arrangements. That cost is expected to be recognized over a weighted-average period of 1.7 years.

Non-employee Stock Options

During the years ended December 31, 2007, 2006, and 2005 we recognized \$33, \$14, and \$(9), respectively, of compensation expense (gain), in connection with the vesting of stock options granted to non-employees. The compensation expense or gain was based on each option's estimated fair value, which was calculated using the Black-Scholes option-pricing model. Because we re-value each option over the related vesting term in accordance with EITF 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring or in Conjunction with Selling, Goods or Services*, increases in our stock price result in increased expense while decreases in our stock price result in a gain.

Restricted Stock Units

In May 2005, RSUs were granted to members of our board of directors in lieu of cash payment for services. Because these RSUs vested immediately, we charged the fair value of \$107 relating to these RSUs to operating expenses on the date of grant.

In March 2005, the Compensation Committee of our board of directors (Compensation Committee) modified our 2004 bonus program for officers, adjusted salaries for officers to reduce cash payments, granted RSUs to officers, and decided to pay any 2005 bonuses for officers by the award of RSUs instead of cash. In March 2005, the aggregate value of liability-classified awards of \$382 related to the payment of a portion of 2004 officer bonuses in RSUs instead of cash was reclassified to additional paid-in capital. In January 2006, the aggregate value of liability-classified awards of \$129 related to the payment of 2005 officer bonuses in RSUs instead of cash was reclassified to additional paid-in capital. During the years ended December 31, 2007, 2006 and 2005, we recorded \$5, \$150 and \$653, respectively, of expense for RSUs, of which \$0, \$21 and \$151, respectively, were recorded while the RSUs were liability-classified. A summary of the status of RSUs as of December 31, 2007, and changes during the year then ended, is presented in the following table:

	Shares	Weighted- average grant-date fair value	Aggregate intrinsic value	Weighted- average remaining contractual life (years)
Outstanding at January 1, 2007	128	\$ 2.34		
Awarded				
Settled	(94)	2.31		
Forfeited				
Outstanding at December 31, 2007	34	\$ 2.44	\$ 36	
Vested at December 31, 2007 and expected to vest	34	\$ 2.44	\$ 36	

F-26

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 12. Compensation Plans (Continued)

The number of shares and aggregate intrinsic value of the vested portion of RSUs outstanding at December 31, 2007 were 34 and \$36, respectively. The number of shares and aggregate fair value of RSUs that vested during the year ended December 31, 2007 were 19 and \$44, respectively. In connection with the settlement of RSUs in shares during 2007, 24 shares, with an aggregate fair value of \$48, were withheld to satisfy the award holders' minimum tax withholding obligations. In accordance with the terms of the RSUs, vested awards will be settled in shares upon the earlier to occur of 18 months after the grant date or six months after the grantee's separation from service, subject to certain conditions.

401(k) Savings Plan

We maintain a 401(k) Savings Plan (Savings Plan) for our employees. Employee contributions are voluntary, determined on an individual basis, and limited to the maximum amount allowable under federal income tax regulations. We match employee contributions up to specified limits. We contributed \$160, \$189, and \$266 to the Savings Plan for the years ended December 31, 2007, 2006, and 2005, respectively. In addition, during 2006 and 2005, we allocated \$23 and \$15, respectively, of prior year Savings Plan forfeitures to match employee contributions. There were no allocations of prior year Savings Plan forfeitures to match employee contributions during 2007.

Note 13. Collaborative Agreements and Significant Customer Concentration

A summary of revenue recognized under our collaborative agreements for the years ended December 31, 2007, 2006, and 2005 is presented in the following table.

	Year Ended December 31,		
	2007	2006	2005
Novo Nordisk			
Research and development funding	\$ 5,354	\$ 3,577	\$ 2,027
Substantive milestones		750	
License fees	745	457	769
	<u>6,099</u>	<u>4,784</u>	<u>2,796</u>
BioGeneriX			
Research and development funding	2,650	1,191	2,939
License fees	56	209	402
	<u>2,706</u>	<u>1,400</u>	<u>3,341</u>
	<u>\$ 8,805</u>	<u>\$ 6,184</u>	<u>\$ 6,137</u>

Novo Nordisk A/S Agreements

We have agreements with Novo Nordisk A/S to use our GlycoPEGylation technology to develop and commercialize next-generation versions of recombinant Factors VIIa, VIII and IX, one of which, Factor VIIa, is currently marketed by Novo Nordisk. Under these agreements, we received a non-refundable, upfront fee of \$4,300, which is being amortized to revenue over the expected

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 13. Collaborative Agreements and Significant Customer Concentration (Continued)

performance period. Novo Nordisk is responsible for funding our research and development activities under the agreements, and we may receive up to \$52,200 in milestone payments based on the progress of the programs.

In December 2005, we amended one of our agreements with Novo Nordisk to provide for an additional project related to one protein and two additional milestone payments to be made to us upon the occurrence of certain events related to the additional project. During the year ended December 31, 2006, we received both of the additional milestone payments upon the occurrence of substantive events related to the additional project.

BioGeneriX AG Agreements

We have an agreement with BioGeneriX AG to use our proprietary GlycoPEGylation technology to develop a long-acting version of G-CSF. In connection with the agreement, we received from BioGeneriX a non-refundable, upfront fee, which is being recognized to revenue over the expected performance period of 18 years. In October 2006, we entered into an amendment of this agreement. Under the agreement, as amended, we and BioGeneriX shared the expenses of preclinical development, BioGeneriX is responsible for supplying the protein and funding the clinical development program and we are responsible for supplying enzyme reagents and sugar nucleotides. As of January 1, 2007, BioGeneriX became responsible for the cost of reagent supply.

In April 2005, we entered into a research, co-development and commercialization agreement with BioGeneriX for a GlycoPEGylated erythropoietin made in CHO cells (GlycoPEG-CHO-EPO). We received a non-refundable payment in connection with the execution of this agreement. The agreement provided for us to conduct research on behalf of BioGeneriX for up to 12 months and granted to BioGeneriX the right to obtain an exclusive, worldwide license to use our enzymatic technologies to develop and commercialize a long-acting version of GlycoPEG-CHO-EPO. Under an amendment to the agreement entered into in October 2006, BioGeneriX had until December 31, 2006 to exercise the option. BioGeneriX did not exercise the option and all rights to Neose's GlycoPEGylation technology as it applies to GlycoPEG-CHO-EPO reverted to Neose.

Note 14. Restructurings and Employee Severance Costs

2008 Restructuring

In January 2008, we announced the discontinuation of further development of NE-180 (2008 Restructuring), our product candidate intended for the treatment of anemia in patients with chronic kidney disease and cancer patients receiving chemotherapy. The decision to discontinue development was not due to any safety or efficacy concerns about NE-180, but was based on an evaluation of commercial prospects and the likelihood of entering into a timely collaboration for the compound in the context of increased safety concerns in the ESA category. In connection with the discontinuation of the NE-180 program, we reduced our workforce by approximately 35%. We anticipate paying cash severance benefits of approximately \$879 in connection with the workforce reduction, most of which will be paid in the first quarter of 2008. The anticipated employee severance costs for the 2008 Restructuring are payable pursuant to an employee severance plan established in August 2005. We do

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 14. Restructurings and Employee Severance Costs (Continued)

not expect to incur any material contract termination charges or non-cash impairment charges in connection with the program discontinuation.

In connection with the 2008 Restructuring, we committed to pay future cash retention bonuses to certain employees who were not given notice of termination in January 2008, contingent on their not voluntarily terminating their employment prior to November 28, 2008. We also granted stock options to all employees as part of an employee retention program. These options vested 50% on August 4, 2008 for all holders who had not voluntarily terminated their employment prior to that date, and will vest 50% on February 4, 2009 for all holders who have not voluntarily terminated their employment prior to that date. The aggregate fair market value of the options of \$236, will be recognized ratably, net of forfeitures, as compensation expense over the vesting period.

2007 Restructuring

In March 2007, we implemented a restructuring of operations (2007 Restructuring), which included a workforce reduction of approximately 40%. The employee severance costs incurred for the 2007 Restructuring were payable pursuant to an employee severance plan established in August 2005. Our net loss for the year ended December 31, 2007 included \$619 of employee severance costs related to the 2007 Restructuring, of which \$543 was included in research and development expenses and \$76 was included in general and administrative expenses. All employee severance costs related to the 2007 Restructuring were paid by December 31, 2007.

In connection with the 2007 Restructuring, we committed to pay future cash retention bonuses to certain employees who were not given notice of termination in March 2007, contingent on their not voluntarily terminating their employment prior to December 31, 2007. Our net loss for the year ended December 31, 2007 included \$358 of expense related to these cash retention bonuses, of which \$229 was included in research and development expense and \$129 was included general and administrative expenses. All of these cash retention bonuses were paid by December 31, 2007. We also granted stock options to all employees as part of an employee retention program. These options vested 50% on September 27, 2007 for all holders who had not voluntarily terminated their employment prior to that date, and will vest 50% on March 27, 2008 for all holders who have not voluntarily terminated their employment prior to that date. The aggregate fair market value of the options was \$1,332, which is being recognized ratably, net of forfeitures, as compensation expense over the vesting period.

2006 Restructuring

In September 2006, we implemented a restructuring of operations in connection with the sale of the Witmer Road Facility (2006 Restructuring). The employee severance costs incurred for the 2006 Restructuring were payable pursuant to an employee severance plan established in August 2005. Therefore, these costs did not meet the definition for classification as a restructuring charge on our Statements of Operations. Our net loss for the year ended December 31, 2006 included \$710 of employee severance costs related to the 2006 Restructuring, of which \$575 is included in research and development expenses and \$135 is included in general and administrative expenses. Of these amounts, \$67 remained unpaid and was included in accrued compensation on our Balance Sheets as of December 31, 2006. As of December 31, 2007, all of our obligations related to the 2006 Restructuring have been satisfied.

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 14. Restructurings and Employee Severance Costs (Continued)

In connection with the 2006 Restructuring we committed to pay future cash retention bonuses to certain employees who were not given notice of termination in September 2006, contingent on their not voluntarily terminating their employment prior to the payment date. In connection with this commitment, we paid \$272 during the year ended December 31, 2007, of which \$160 was included in accrued compensation on our Balance Sheet as of December 31, 2006. We also granted stock options to certain employees as part of an employee retention program. These options vested in full either on July 1, 2007 for all holders who had not terminated their employment prior to that date or their termination date for those employees who were involuntarily terminated in the 2007 Restructuring. The aggregate fair market value of the options was \$605, which was recognized ratably, net of forfeitures, as compensation expense over the vesting period.

2005 Restructuring

In August 2005, we implemented a restructuring of operations to enable an enhanced focus on next-generation proteins, to allow for the transfer of production of proteins and reagents to our collaborative partners and contract manufacturers, and to reduce cash burn (2005 Restructuring). Upon completion of the 2005 Restructuring, we reduced the size of our workforce by approximately 25% compared to the end of the first quarter of 2005. Our net loss for 2005 included \$14,206 of charges related to the 2005 Restructuring, including \$13,187 of non-cash property and equipment impairment charges (see Note 6), \$867 of payments for employee severance costs, and \$152 of payments for facility closure costs.

As part of the 2005 Restructuring we centralized research activities in Horsham, Pennsylvania by ending operations in our leased facility in San Diego, California. During 2005, we recorded a charge of \$152 in our Statements of Operations for the operating lease related to the San Diego facility. The charge was based on an estimate of the present value of the loss we would incur over the remaining term of the lease. Because the remaining lease term extended for only five months beyond our cease-use date of the facility, we assumed no sublease income in our calculation.

Of the \$1,019 accrued during 2005 for employee severance and facility closure costs for the 2005 Restructuring, we paid \$932 during 2005 and the remaining \$87 was included in accrued expenses as of December 31, 2005. As of December 31, 2006, all of our obligations related to the 2005 Restructuring were satisfied.

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 15. Commitments

Leases

Our future minimum lease payments as of December 31, 2007 under capital leases and under non-cancelable operating leases, with initial or remaining lease terms in excess of one year, were as follows:

	<u>Capital leases</u>	<u>Operating leases</u>
2008	\$ 154	\$ 549
2009	69	549
2010	62	543
2011	62	553
2012	10	509
Thereafter		5,238
	<u>357</u>	<u>\$ 7,941</u>
		<u> </u>
Less amounts representing imputed interest	(39)	
	<u>318</u>	
Present value of minimum lease payments	318	
	<u> </u>	
Less current portion of capital lease obligations	(136)	
	<u>182</u>	
Capital lease obligations, excluding current portion	\$ 182	
	<u> </u>	

Capital Lease Obligations

In February 2007, we entered into a capital lease obligation for equipment with a book value of \$257, which was calculated using an assumed incremental annual borrowing rate of 7.2%. The terms of the lease require us to make monthly payments through February 2012. This equipment had an aggregate net book value of \$214 as of December 31, 2007.

In January 2007, we entered into a modification to an operating lease obligation for equipment with a fair market value of \$116 at the time of the modification, which was calculated using an assumed incremental annual borrowing rate of 7.3%. This modification resulted in the lease being classified as a capital lease. The terms of the lease require us to make monthly payments through May 2008. This equipment had an

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

aggregate net book value of \$95 as of December 31, 2007.

In February 2004, we entered into a capital lease obligation for equipment with a book value of \$184, which was calculated using an assumed incremental annual borrowing rate of 8.7%. The terms of the lease require us to make monthly payments through February 2009. This equipment had an aggregate net book value of \$29 as of December 31, 2007.

In September 2003, we entered into a capital lease obligation for software with a book value of \$60, which was calculated using an assumed incremental annual borrowing rate of 11.5%. The terms of the lease require us to make monthly payments through September 2008. As of December 31, 2007, this software had a net book value of \$9.

F-31

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 15. Commitments (Continued)

Operating Leases

We lease laboratory, office, warehouse facilities, and equipment under operating lease agreements. In February 2002, we entered into a lease agreement for our Rock Road Facility, which consists of approximately 40,000 square feet of laboratory and office space. The initial term of the lease ends in July 2022, at which time we have an option to extend the lease for an additional five years, followed by another option to extend the lease for an additional four and one-half years. Pursuant to the lease, we received \$250 from the landlord in September 2004 as a partial reimbursement for improvements we made to the facility. This landlord incentive, which is included in other liabilities on our Balance Sheets, is being amortized ratably as a reduction to rental expense over the lease term. In January 2007, we entered into a five-year lease agreement for approximately 6,800 square feet of office and warehouse space in Horsham, Pennsylvania to replace similar space that we had leased under an agreement that expired in April, 2007. Our laboratory, office, and warehouse facility leases contain escalation clauses, under which the base rent increases annually by 2%. Our rental expense for the years ended December 31, 2007, 2006, and 2005 was \$710, \$967, and \$951, respectively.

Purchase Obligations and Employment Agreements

As of December 31, 2007, we had non-cancelable purchase obligations for 2008 in the amount of \$396, which all relate to goods or services. As of December 31, 2007, our non-cancelable purchase obligations for 2009 were \$74, and we had no non-cancelable purchase obligations for 2010 and thereafter.

In May 2006, we entered into an employment agreement with our chief executive officer, George J. Vergis, Ph.D. Under the terms of the agreement we are required to pay Dr. Vergis an annual base salary of at least \$350 for continuing his employment with us.

Note 16. Income Taxes

During the year ended December 31, 2007, we sold Pennsylvania research and development tax credits, resulting in the recognition of \$533 of income tax benefit. We had no income taxes payable as of December 31, 2007 and 2006. As of December 31, 2007, we had \$172,512 of federal and \$60,000 of state net operating loss (NOL) carryforwards potentially available to offset future taxable income. As of December 31, 2007, our federal NOL carryforward included \$9,002 related to equity-based compensation, which will be recorded as additional paid-in capital upon recognition of the tax benefit associated with these deductions. As of December 31, 2007, we had federal and state research and development tax credit carryforwards of \$8,252 and \$515, respectively, potentially available to offset future taxable income.

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* an interpretation of FASB Statement No. 109 (FIN 48), which is applicable for fiscal years beginning after December 15, 2006. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109, *Accounting for Income Taxes*. FIN 48 prescribes a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position reported or expected to be reported on a tax

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 16. Income Taxes (Continued)

return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. We adopted the provisions of FIN 48 on January 1, 2007. Upon adoption of FIN 48 and through December 31, 2007, we determined that we had no liability for uncertain income taxes as prescribed by FIN 48. Our policy is to recognize potential accrued interest and penalties related to the liability for uncertain tax benefits, if applicable, in income tax expense. The tax years back to 2004 remain open to examination by the major taxing jurisdictions where we file. NOL and credit carryforwards from earlier periods also remain open to examination by taxing authorities, and will for a period post utilization.

The Tax Reform Act of 1986 (Tax Reform Act) provided for a limitation on the annual use of NOL and research and development tax credit carryforwards following certain ownership changes. Because we may have experienced various ownership changes, as defined by the Tax Reform Act, as a result of past equity financings, our ability to utilize federal and Pennsylvania NOL and credit carryforwards in any given year may be limited. In addition, federal tax law limits the time during which carryforwards may be applied against future taxes, and Pennsylvania tax law could limit the utilization of state NOL carryforwards to \$3,000 annually. Therefore, we may not be able to take full advantage of these carryforwards to offset future taxable income. The federal and state NOL and tax credit carryforwards will expire as follows:

	Net operating loss carryforwards		Research and development tax credit carryforwards	
	Federal	State	Federal	State
2008	\$ 638	\$	\$ 146	\$
2009	385		207	
2010	110		83	
2011	150		104	
2012			207	
Thereafter	171,229	60,000	7,505	515
	<u>\$ 172,512</u>	<u>\$ 60,000</u>	<u>\$ 8,252</u>	<u>\$ 515</u>

We have incurred a loss in each period since our inception. Due to the uncertainty surrounding the realization of the tax benefit associated with our federal and state carryforwards, we have provided

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 16. Income Taxes (Continued)

a full valuation allowance against these tax benefits. The approximate income tax effect of each type of carryforward and temporary difference is as follows:

	<u>Current</u>	<u>Noncurrent</u>	<u>Total</u>
December 31, 2007			
Net operating loss carryforwards	\$	\$ 62,610	\$ 62,610
Research and development tax credit carryforwards		8,767	8,767
Capitalized research and development expenses	7,533	36,240	43,773
Property and equipment	(123)	1,503	1,380
Deferred revenue	373	2,052	2,425
Deferred compensation		2,144	2,144
Impairment of equity securities		647	647
Accrued expenses not currently deductible	254	237	491
	<u>8,037</u>	<u>114,200</u>	<u>122,237</u>
Total deferred tax assets	8,037	114,200	122,237
Less valuation allowance	(8,037)	(111,537)	(119,574)
	<u></u>	<u></u>	<u></u>
Net deferred tax assets		2,663	2,663
Decrease in fair value of warrant liability		(2,663)	(2,663)
	<u></u>	<u></u>	<u></u>
Net deferred tax liability	\$	\$	\$
	<u></u>	<u></u>	<u></u>
December 31, 2006			
Net operating loss carryforwards	\$	\$ 43,269	\$ 43,269
Research and development tax credit carryforwards		8,888	8,888
Capitalized research and development expenses		51,862	51,862
Property and equipment		1,448	1,448
Capitalized start-up costs	3,404		3,404
Deferred revenue	262	1,757	2,019
Deferred compensation		1,461	1,461
Impairment of equity securities		647	647
Accrued expenses not currently deductible	538	219	757
	<u>4,204</u>	<u>109,551</u>	<u>113,755</u>
Total deferred tax assets	4,204	109,551	113,755
Less valuation allowance	(4,204)	(109,551)	(113,755)
	<u></u>	<u></u>	<u></u>
Net deferred tax assets	\$	\$	\$
	<u></u>	<u></u>	<u></u>

Neose Technologies, Inc.

Notes to Financial Statements (Continued)

(in thousands, except per share amounts)

Note 17. Quarterly Data (unaudited)

The following tables summarize our quarterly results of operations for each of the quarters in 2007 and 2006. These quarterly results are unaudited, but in the opinion of management have been prepared on the same basis as our audited financial information and include all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of our results of operations.

	2007 Results				
	First quarter	Second quarter	Third quarter	Fourth quarter	Full year
Revenue from collaborative agreements	\$ 1,237	\$ 2,231	\$ 2,631	\$ 2,706	\$ 8,805
Operating expenses	12,777	10,290	13,295	9,411	45,773
Operating loss	(11,540)	(8,059)	(10,664)	(6,705)	(36,968)
Decrease (increase) in fair value of warrant liability	(6,350)	1,920	7,772	3,218	6,560
Interest income, net	232	454	386	285	1,357
Loss before income tax benefit	(17,658)	(5,685)	(2,506)	(3,202)	(29,051)
Income tax benefit		533			533
Net loss	\$ (17,658)	\$ (5,152)	\$ (2,506)	\$ (3,202)	\$ (28,518)
Basic and diluted net loss per share	\$ (0.47)	\$ (0.09)	\$ (0.05)	\$ (0.06)	\$ (0.57)*
Weighted-average shares outstanding used in computing basic and diluted net loss per share	37,493	54,402	54,449	54,468	50,262
	2006 Results				
	First quarter	Second quarter	Third quarter	Fourth quarter	Full year
Revenue from collaborative agreements	\$ 2,396	\$ 1,715	\$ 1,477	\$ 596	\$ 6,184
Operating expenses	10,239	10,145	9,839	10,341	40,564
Gain on sale of Witmer Road Facility			7,335	(2)	7,333
Operating loss	(7,843)	(8,430)	(1,027)	(9,747)	(27,047)

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

2006 Results

	2006 Results				
Interest income (expense), net	58	(17)	(323)	222	(60)
Net loss	\$ (7,785)	\$ (8,447)	\$ (1,350)	\$ (9,525)	\$ (27,107)
Basic and diluted net loss per share	\$ (0.24)	\$ (0.26)	\$ (0.04)	\$ (0.29)	\$ (0.82)*
Weighted-average shares outstanding used in computing basic and diluted net loss per share	\$ 32,783	32,804	32,866	32,972	32,857

*

The net loss per share in each quarter is computed using the weighted-average number of shares outstanding during the quarter. The net loss per share for the full year, however, is computed using the weighted-average number of shares outstanding during the year. Thus, the sum of the quarterly net loss per share amounts does not equal the full-year net loss per share.

QuickLinks

DOCUMENTS INCORPORATED BY REFERENCE

TABLE OF CONTENTS

PART I

ITEM 1. BUSINESS.

ITEM 1A. RISK FACTORS.

Financial Risks

Risks Related to Development of Products and Technologies

Risks Related to Intellectual Property

Risks Related to Competition

Risks Related to Government Regulation

Risk Related to Stock Market and Foreign Exchange Rates

Risks Related to Facilities, Business Interruption, and the Environment

ITEM 1B. UNRESOLVED STAFF COMMENTS.

ITEM 2. PROPERTIES.

ITEM 3. LEGAL PROCEEDINGS.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

ITEM 6. SELECTED FINANCIAL DATA.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

ITEM 9A. CONTROLS AND PROCEDURES.

ITEM 9B. OTHER INFORMATION.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

ITEM 11. EXECUTIVE COMPENSATION.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

SIGNATURES

Exhibit Index

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

Edgar Filing: NEOSE TECHNOLOGIES INC - Form 10-K

Neose Technologies, Inc. Balance Sheets (in thousands, except per share amounts)

Neose Technologies, Inc. Statements of Operations (in thousands, except per share amounts)

Neose Technologies, Inc. Statements of Stockholders' Equity and Comprehensive Loss (in thousands)

Neose Technologies, Inc. Statements of Cash Flows (in thousands)

Neose Technologies, Inc. Notes to Financial Statements (in thousands, except per share amounts)

Neose Technologies, Inc. Notes to Financial Statements (in thousands, except per share amounts)