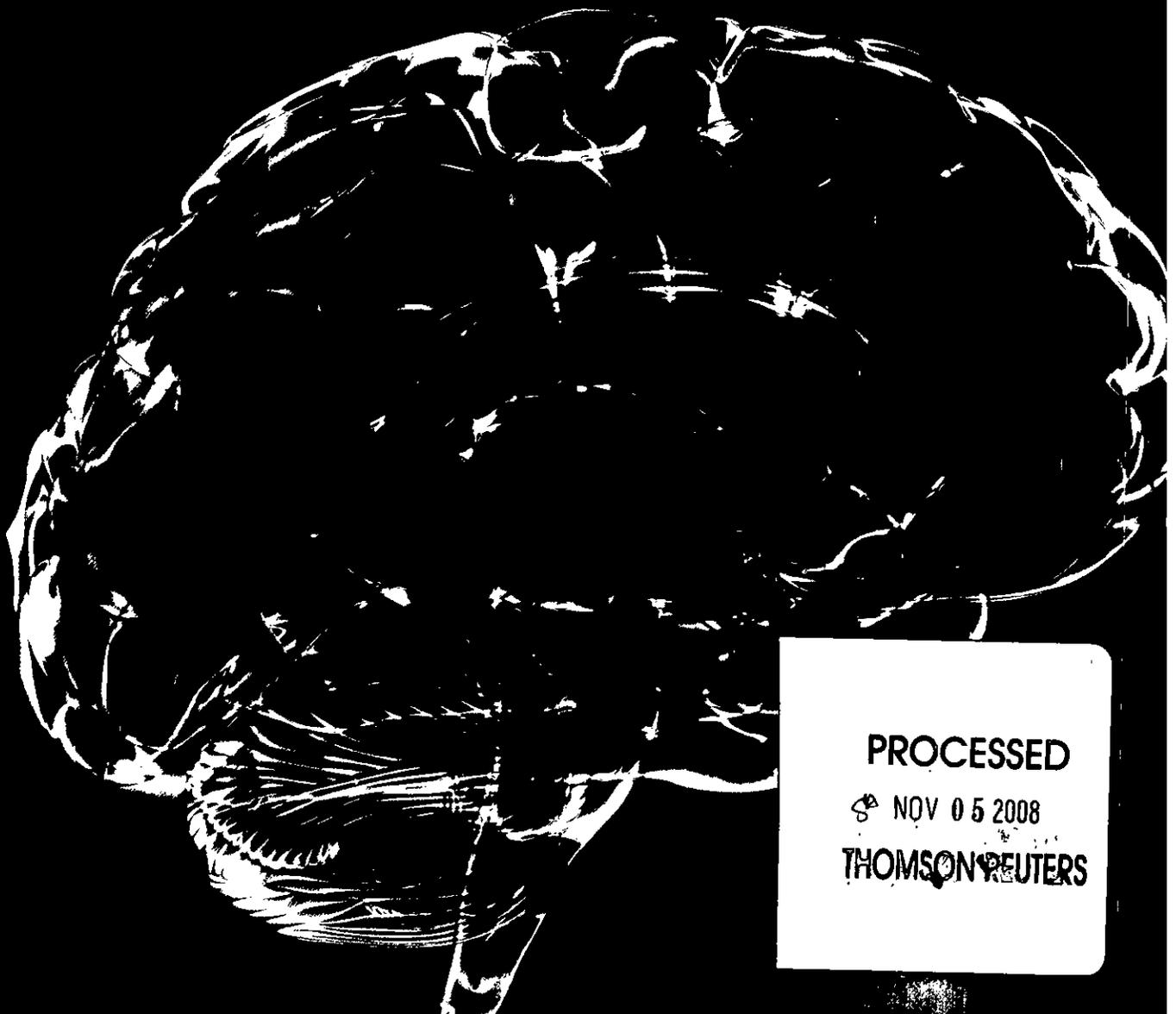




Section
Health Processing
Section
2008 ANNUAL REPORT
UCL 0 2500
UCL 0 2500

Ischemic stroke

- 3rd leading cause of death in the United States
- 87% of all strokes are ischemic
- 3 million Americans are currently disabled due to stroke
- Every 45 seconds someone suffers a stroke
- \$65 billion spent annually for stroke-related medical costs & disability
- One emerging biotechnology company focused on the fight against stroke



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To our stockholders

September 30, 2008

As we send you this annual report for our fiscal year ended June 30, 2008, we wanted to take this occasion to share with you news of recent developments affecting our business and to keep you informed about actions that we are taking to work to maximize stockholder value.

Viprinex™ continues to be the key driver of our company. It is an investigational new drug for the treatment of acute ischemic stroke and is moving forward in our clinical trial program. We are pleased that we have surpassed the number of patients required to conduct an interim futility analysis and we continue to energetically enroll patients. We expect the interim results by January 2009, thanks to the vigorous effort put forth by our dedicated management and staff. Some of you may ask, "What is a futility analysis?" Quite simply, when an independent Data Safety Monitoring Board (DSMB) conducts this analysis, if the treatment effect observed for the Viprinex patients is not considerably better than that observed for the placebo patients, we will stop the trials for futility. We have already had five safety reviews from our DSMB and have been advised by them at each review to continue forward. However, the upcoming futility analysis will provide the basis for an efficacy review by the DSMB for the first time. As you know, other products have had a checkered past in stroke trials, so a positive recommendation to continue the trials should open a number of doors for the company and determine our strategic path.

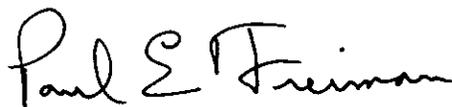
We remain focused on the speed and cost of the Viprinex trials, and for the past year have been working to accelerate the pace of enrollment by expanding our program internationally and adding new sites. We have recently seen this investment pay off in higher monthly patient enrollment numbers. In addition, the board and management are continually working to identify areas where we can trim expenditures so that we can conserve capital and focus our spending on value-added activities.

With a touch of sadness, I recently announced my desire to retire from an operational role at NTI. The decision was based on chronology, not on any doubts about the merits of Viprinex, a product candidate in which I have great faith. I would like to remain on our board and leverage my knowledge and connections in the industry to the benefit of NTI. Our board has instituted a search for a successor by forming a search committee, headed by William Fletcher and which includes myself. I am confident that our management team is solid and highly professional and will continue on its high energy journey.

The capital markets have been very difficult recently and we are disappointed with the performance of our stock. A majority of the board purchased shares in our last public stock offering (up to certain limitations under SEC regulations) and we have suffered losses along with our other stockholders. However, we continue to believe that we have a potentially very valuable asset with Viprinex and are committed to maximizing the value of this asset through our ongoing clinical development work. We expect to have more information about the prospects for Viprinex soon following the interim analysis and, if we receive a recommendation to continue the trial, we would hope to see some recovery in our stock price and market capitalization.

We appreciate your patience and continued support.

Sincerely,



Paul E. Freiman
President & Chief Executive Officer

*This report contains the accompanying disclosure regarding statements regarding the full value and value of the business. The full value and value of the business is not a financial statement and should not be used as a basis for investment decisions. The full value and value of the business is not a financial statement and should not be used as a basis for investment decisions. The full value and value of the business is not a financial statement and should not be used as a basis for investment decisions.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the fiscal year ended June 30, 2008

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: 0-23280

NEUROBIOLOGICAL TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware (State of incorporation)

2000 Powell Street, Suite 800, Emeryville, California (Address of principal executive office)

94-3049219 (I.R.S. Employer Identification No.) 94608 (Zip Code)

(510) 595-6000

(Registrant's telephone number, including area code)

Securities registered under Section 12(b) of the Act:

Table with 2 columns: Title of Each Class, Name of Each Exchange on Which Registered. Rows include Common Stock and Preferred Share Purchase Rights.

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

None

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] 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 definitive proxy 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 the 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 [X] (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 Exchange Act). Yes [] No [X]

The aggregate market value of the voting stock held by non-affiliates of the registrant based upon the closing price of the Common Stock on the NASDAQ Capital Market on December 31, 2007 was \$38 million. Shares of Common Stock held by each executive officer and director and by each person or group who owns 10% or more of the outstanding Common Stock at December 31, 2007 have been excluded. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

On September 10, 2008 there were 26,924,124 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Proxy Statement for Registrant's Annual Meeting of Stockholders to be held November 13, 2008 are incorporated herein by reference into Part III.

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PART I

ITEM 1. BUSINESS

This report contains forward-looking statements. These forward-looking statements are based on our current expectations about our business and industry. In some cases, these statements may be identified by terminology such as "anticipates," "believes," "continue," "estimates," "expects," "may," "plans," "potential," "predicts," "should," "will," or the negative of such terms and other comparable terminology. These statements involve known and unknown risks and uncertainties that may cause our results, levels of activity, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Factors that may cause or contribute to such differences include, among others, those discussed in this report under Item 1A. — "Risk Factors." Except as may be required by law, we do not intend to update any forward-looking statement to reflect events after the date of this report.

Overview

We are a biopharmaceutical company focused on developing novel, first-in-class treatments for central nervous system conditions and other serious unmet medical needs. Our most advanced product candidate, Viprinex™, is in Phase 3 clinical testing as a novel investigational drug for treating acute ischemic stroke. Stroke is one of the most prevalent, debilitating and costly diseases in the world, and there are few acceptable treatment options. Viprinex is a fibrinogen-reducing agent that is designed to expand the treatment window from three hours to six hours. In addition to Viprinex, we have rights to receive royalty payments from the sales of memantine, an approved drug marketed for Alzheimer's disease. We also have rights to receive payments from the development of XERECEPT®, another investigational drug which is in Phase 3 clinical trials for the treatment of swelling associated with brain tumors. Our earlier stage pipeline also includes rights to two proteins in preclinical development for the treatment of Alzheimer's disease and Huntington's disease.

In the most recent fiscal year, Viprinex accounted for approximately 94% of the research and development expenses for which we were not reimbursed by other parties. Viprinex is designed to restore blood flow to areas of the brain impacted by an ischemic stroke. Known generically as ancrod, Viprinex is an enzyme derived from the venom of the Malayan pit viper. Five human clinical trials, including two Phase 3 clinical trials, were conducted with this investigational drug before we acquired the rights in 2004. These trials enrolled a total of nearly 2,000 patients and were sponsored by the German pharmaceutical company Knoll AG, or Knoll, before Abbott Laboratories, or Abbott, purchased Knoll and subsequently discontinued the Knoll stroke program (and later their own stroke program). The first of the two Knoll Phase 3 trials met its primary efficacy endpoint of improvement in stroke outcome measured 90 days after the stroke with statistical significance. The second Knoll Phase 3 trial was discontinued after an interim analysis concluded that the trial was unlikely to reach its primary efficacy endpoint. Our retrospective analyses of the safety and efficacy data from the Knoll clinical trials led us to believe that the dosing strategy used by Knoll was flawed, accounting for the inability of the second Knoll Phase 3 trial to meet its primary endpoint.

Based on our analyses, we made significant changes to the Knoll dosing regimen when we initiated our pivotal Phase 3 clinical trials in 2005. We provide the drug in a single infusion given over a period of up to three hours, as compared to Knoll which had provided the drug in multiple infusions for up to five days. Based on our analysis of data from hundreds of patients that were given Viprinex in the earlier clinical studies, we believe that our dosing regimen in the current Phase 3 studies has the potential to demonstrate that Viprinex is safe and effective when treatment is initiated within six hours of stroke onset. We expect to announce results of an interim futility analysis for the Phase 3 clinical trials no later than the first quarter of calendar year 2009.

Over 1.4 million patients suffer from stroke each year in the United States and Europe. The only approved drug treatment for acute ischemic stroke is recombinant tissue plasminogen activator, or rt-PA, which is currently approved for use within three hours of stroke onset. In addition, there are safety concerns regarding increased risks of intracranial hemorrhage for patients that receive rt-PA. We believe that Viprinex

would be used to treat a substantially broader population of stroke patients than rt-PA if we are able to demonstrate it is safe and effective in treating acute ischemic stroke in the current clinical trials.

Consequences of Stroke and Current Medical Care

Stroke Background

Stroke is an acute medical condition caused by blockage or rupture of the blood vessels leading to or within the brain. When a stroke occurs, blood flow and the supply of nutrients and oxygen to an area of the brain are interrupted, leading to death of brain tissue. There are two major types of stroke: ischemic and hemorrhagic. Ischemic stroke is caused by blockage of a blood vessel in the brain due to a clot. The lack of blood flow, or ischemia, leads to cell death. Hemorrhagic stroke is caused by the sudden rupture of a blood vessel in the brain which causes bleeding into the surrounding tissue.

Clot formation in an ischemic stroke results from a chain of events that is often triggered by the disruption of the smooth lining of a blood vessel by the formation of cholesterol plaque, which activates the blood coagulation system. Fibrinogen, a protein found in the blood, is a primary component in the clotting process. As part of the blood coagulation process, fibrinogen is converted into fibrin, a smaller protein. Fibrin strands form a web of fibers that create the backbone of the clot. Red blood cells, platelets and other blood components then become trapped in the web and form the solid clot. Drugs that are called fibrinolytic drugs, such as rt-PA, operate by breaking up the fibrin web of the blood clot, and thus destroy the clot and restore blood flow to the area that was compromised by the clot formation.

According to the American Heart Association, 87% of the 700,000 annual strokes in the United States are ischemic. Stroke is the third leading cause of death in the United States, behind heart disease and cancer, and the leading cause of disability.

Investigative Drug Treatments

Drug treatments that have been investigated for acute ischemic stroke fall into two broad categories: neuroprotectants and reperfusion agents.

Neuroprotectants. Neuroprotectants are designed to protect brain cells from damage triggered by a stroke. Typically these compounds attempt to block one of the various biochemical pathways that lead to neuronal death. To date, more than 100 neuroprotectants have been studied in clinical trials in the United States and Europe. None of these compounds has demonstrated efficacy in Phase 3 trials with one exception, which was subsequently negated by a larger Phase 3 trial. One reason cited for the failure of neuroprotectants is that, in general, they target only one among many pathways leading to cell death.

Reperfusion Agents. Reperfusion agents are designed to reverse the primary cause of stroke by removing the obstructing blood clot and restoring blood flow to the affected area of the brain. In contrast to neuroprotectants, fewer than 15 reperfusion agents have been studied in clinical trials in the United States and Europe, three of which, including Viprinex, have resulted in successful Phase 3 trials. Most reperfusion agents tested belong to a class called fibrinolytic agents. These agents are used as "clot-busters" to dissolve existing clots by generating plasmin, which dissolves the fibrin in the clot through a process called fibrinolysis. A significant concern with reperfusion therapy is the potential for intracranial bleeding, in particular, symptomatic intracranial hemorrhage, or SICH, which can lead to death.

The only drug approved today for the treatment of acute ischemic stroke is the reperfusion agent rt-PA (recombinant tissue plasminogen activator), known as Activase in the United States. The use of rt-PA for stroke involves a variety of risks and potential side effects that are common for fibrinolytic drugs and limit its use:

- *Risk of Bleeding* — Fibrinolytic drugs dissolve blood clots, including those formed naturally as a protective response to vessel injury, which can result in bleeding. The risk of intracranial hemorrhaging increases as the dosage increases. Patients who are already taking other medications to prevent formation of clots, such as anticoagulants or antiplatelets, may not be good candidates for the use of

fibrinolytic drugs due to the increased difficulty of controlling bleeding. In the study that led to FDA approval of rt-PA, the incidence of SICH in rt-PA patients was 6.4%, compared to 0.6% in the placebo group. As a result, rt-PA is subject to strict limitations on when, how long and in what dosages it may be administered.

- *Time Window for Administration* — Due to its decreasing efficacy the later it is administered, rt-PA is approved for administration to acute ischemic stroke patients when started within three hours of stroke onset. This three-hour window is considered to be a limiting factor in treating acute ischemic stroke with rt-PA, and is one of the reasons a small percentage of U.S. acute ischemic stroke patients receive rt-PA.

Our Product Candidate for Stroke — Viprinex

Mechanism of Action

The formation of a blood clot is a natural process by which blood coagulates into a mass of blood cells, platelets and strands of fibrin. Fibrin is the protein that provides the structural scaffold of a clot. Most reperfusion agents utilize a single mechanism of action, fibrinolysis, or the break-up of fibrin in clots. In contrast, Viprinex's direct mechanism of action is to break up fibrinogen, the precursor to fibrin. This has several effects on blood clotting and blood flow that may be beneficial for the treatment of acute ischemic stroke:

- *Anticoagulation* — By removing fibrinogen, a key requirement of clot formation, Viprinex impairs further growth of the clot. The reduction of fibrinogen levels also reduces the likelihood of further clot formation, including reocclusion, or re clotting, after use of fibrinolytic drugs, a concern in stroke patients treated with rt-PA.
- *Decreased blood viscosity* — By removing fibrinogen, an abundant protein in human plasma, Viprinex decreases the protein content of blood plasma and reduces blood viscosity. The reduction in blood viscosity generally improves blood flow. We believe this should enhance blood flow to the affected areas of the brain even before a clot has been broken up.
- *Clot break-up* — The proteins formed by Viprinex's break-up of fibrinogen appear to indirectly stimulate the conversion of plasminogen to plasmin, which dissolves clots by removing the fibrin within the clot.

By breaking up fibrinogen, Viprinex not only produces a fibrinolytic effect similar to rt-PA, but also improves blood viscosity and anticoagulation. We believe that this mechanism of action will prove more effective than rt-PA and, at the current lower dose used in our current trials, will also lower the risk of SICH relative to rt-PA.

Market Opportunity

According to the World Health Organization, 15 million people worldwide suffer a stroke each year, including 1.4 million in the United States and Europe. Stroke is the third leading cause of death in the United States, behind heart disease and cancer, and the leading cause of disability. 87% of the strokes that occur in the United States are ischemic. Approximately three million Americans are currently disabled from stroke. The American Stroke Association estimates that approximately \$65 billion will be spent in the United States in 2008 for stroke-related medical costs and disability.

rt-PA is the only drug therapy approved in the United States and Europe for acute ischemic stroke. However, the potential to treat patients with rt-PA is limited, as the treatment currently must be initiated within three hours of stroke onset and the treatment poses a risk of symptomatic intracranial bleeding. As a result of these and other factors, fewer than 10% of acute ischemic stroke patients receive rt-PA. We believe that, if Viprinex proves safe and effective in treating acute ischemic stroke when initiated within six hours of stroke onset, it has potential to treat a substantially broader population of acute ischemic stroke patients than rt-PA.

Viprinex History

Beginning in the late 1980s and ending in 2000, Knoll and independent investigators conducted five clinical trials of Viprinex for the treatment of acute ischemic stroke, including two Phase 3 trials, one in the United States and one in Europe. The North American trial, STAT, met its primary efficacy endpoint. The European trial, ESTAT, was terminated after an interim analysis concluded that Viprinex was unlikely to reach the primary efficacy endpoint. Subsequent to the trials, Knoll undertook extensive retrospective analyses to understand the cause of failure in ESTAT and identify the factors that would result in a more favorable safety and efficacy profile in future Phase 3 clinical trials. However, when Abbott acquired Knoll in 2001, Abbott chose not to pursue any further clinical development activity of Viprinex.

In 2002, Empire Pharmaceuticals Inc., or Empire, a company whose founders included a former Knoll employee, acquired the exclusive worldwide rights to Viprinex from Abbott in a royalty-bearing license. Empire received the data from the clinical trials conducted by Knoll, including the retrospective analyses referenced above. Empire then expanded the retrospective analysis done by Knoll, examining the clinical trial data from multiple perspectives to develop better dosing regimens.

In July 2004, we acquired Empire, including all of its rights to Viprinex and the associated clinical trial data. We then conducted our own review of Knoll’s clinical trial data and further expanded on the prior retrospective analysis. Based on the cumulative analysis of the prior trials, we finalized our new dosing strategy, developed the protocol for our new Phase 3 clinical trials, and subsequently received permission from the FDA to commence the Ancrod Stroke Program, or ASP, trials.

Previous Clinical Trials Conducted by Knoll

The clinical trials conducted by Knoll enrolled nearly 2,000 acute ischemic stroke patients, as shown in the chart below:

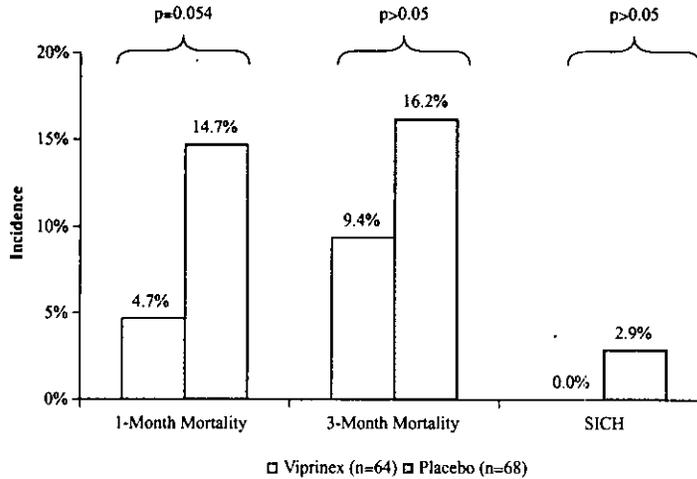
<u>Study</u>	<u>Phase</u>	<u>Number of Patients</u>		
		<u>Viprinex</u>	<u>Placebo</u>	<u>Total</u>
Single Institution	Not Applicable	10	10	20
Single Institution	Not Applicable	15	15	30
A-20	2	64	68	132
STAT (North America).....	3	248	252	500
ESTAT (Europe)	3	<u>604</u>	<u>618</u>	<u>1,222</u>
TOTAL		<u>941</u>	<u>963</u>	<u>1,904</u>

A-20 Phase 2 Clinical Trial Conducted by Knoll

The A-20 Phase 2 clinical trial was a double-blind, randomized trial conducted by Knoll from 1989 to 1992 that included 132 patients. Patients received either intermittent intravenous Viprinex or placebo over a period of seven days, initiated within six hours of stroke onset. The dosing regimen was designed to keep the target fibrinogen levels between 70 and 100 mg/dL over several days. The primary endpoint of the clinical trial was based on the Scandinavian Stroke Scale, or SSS, in which lower scores represent increasingly severe stroke outcomes.

Patients treated with Viprinex had a three-month unadjusted median SSS score of 39, while patients treated with placebo had a median SSS score of 35. Knoll initially analyzed the A-20 clinical trial data using a center-weighted analysis of the primary endpoint, rather than the patient-weighted analysis that was used in subsequent STAT and ESTAT clinical trials. The published center-weighted analysis, which gives each stroke center equal weight, showed that the median total SSS score at three months for the Viprinex-treated group was not statistically different from the placebo group. However, a patient-weighted analysis undertaken by Knoll, which gives each patient equal weight, showed that the trial results were statistically significant.

At one-month follow-up, mortality was 4.7% in the Viprinex-treated group compared to 14.7% for the placebo group. At three-month follow-up, mortality was 9.4% for the Viprinex-treated group compared to 16.2% for the placebo group. None of the patients in the Viprinex-treated group had a symptomatic intracranial hemorrhage, compared to 2.9% of patients in the placebo group. The trial results are summarized in the graph below. References to a “p-value” in this and other graphs contained in this Annual Report on Form 10-K are references to a statistical measure of significance, with a p-value less than 0.05 indicating a statistically significant difference and smaller values indicating an increasingly greater difference.

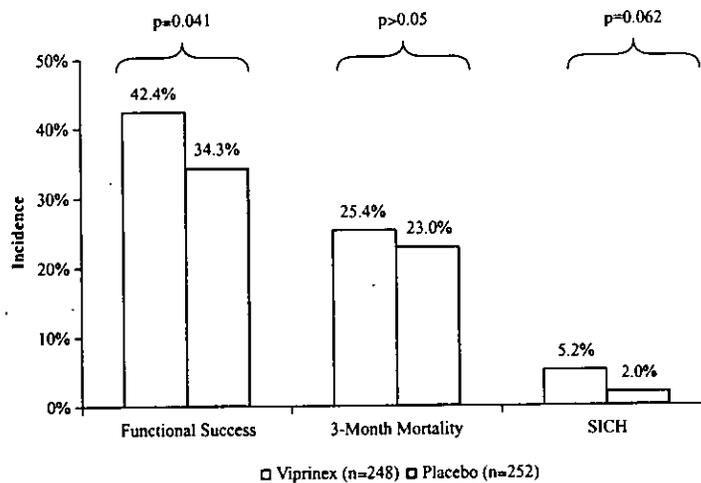


The results of this clinical trial suggested that the use of Viprinex for the treatment of acute ischemic stroke within six hours of stroke onset was safe and potentially effective. Following the encouraging results of this Phase 2 clinical trial, Knoll moved forward into Phase 3 trials.

STAT: Phase 3 North American Clinical Trial Conducted by Knoll

The STAT Phase 3 clinical trial was a double-blind, randomized trial conducted by Knoll that included 500 patients. Within three hours of stroke onset, patients received a three-day continuous intravenous infusion of either placebo or Viprinex, followed by two days of intermittent intravenous administration of placebo or Viprinex. In this clinical trial, the dosing regimen was designed to keep target fibrinogen levels between 40 and 69 mg/dL over several days. The primary endpoint of this trial was functional success, which was defined as three-month survival with a Barthel’s Index, or BI score, of at least 95 or a return to prestroke levels, adjusted for age and pretreatment stroke severity, which are strong prognostic factors for outcome. The BI scores various components of daily living, with higher scores representing better outcomes, and scores of at least 95 suggest that there are no limitations in basic functions. The results of the clinical trial met the primary endpoint and were statistically significant. The functional success score for the Viprinex-treated group was 42.2% compared to 34.3% for the placebo group. The Viprinex-treated group demonstrated numerically higher rates of functional success than the placebo group regardless of patient age, pretreatment stroke severity, gender, race, time-to-treat or prestroke disability.

As shown in the chart below, mortality was similar for both the Viprinex-treated and placebo groups at three-month follow-up. SICH occurred in Viprinex-treated patients at a rate of 5.2% compared to the 2.0% placebo rate. This was less than the difference noted in a trial of rt-PA conducted by the National Institute of Neurological Disorders and Stroke, or the NINDS, where SICH occurred in 6.4% of rt-PA-treated patients compared to 0.6% of placebo patients.

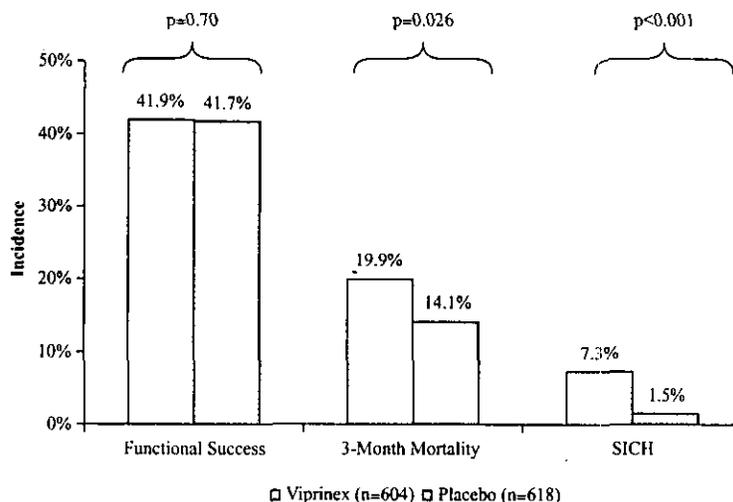


The improvement in functional success from the STAT trial suggested that the use of Viprinex was effective for the treatment of acute ischemic stroke. Results of STAT were unblinded after Knoll initiated the ESTAT trial.

ESTAT: Phase 3 European Clinical Trial Conducted by Knoll

The ESTAT Phase 3 clinical trial, a double-blind, randomized trial initiated by Knoll in 1996, was designed to include 1,680 patients. ESTAT was designed to assess the efficacy and safety of Viprinex in treating acute ischemic stroke patients starting within six hours of stroke onset in contrast to the three hours used in STAT. Patients received a three-day continuous intravenous infusion of either placebo or Viprinex, followed by two days of intermittent intravenous administration of placebo or Viprinex. The Data Safety Monitoring Board, or DSMB, halted enrollment in the clinical trial in 2000 after 1,222 patients had been enrolled. The DSMB's decision to halt the trial was based on a conclusion that Viprinex was unlikely to reach the primary efficacy endpoint after an interim analysis of the first 670 patients tested in the trial.

As in the STAT trial, the primary endpoint of the ESTAT trial was functional success, defined as three-month survival with a BI score of at least 95 or a return to prestroke levels. In this study, Viprinex treatment did not differentiate from placebo for efficacy. In contrast to previous studies, there was a statistically significant increase in mortality and SICH among the Viprinex-treated patients. The trial results are summarized in the graph below:



Retrospective Analysis: ESTAT

The authors of a publication on the results of ESTAT attributed the trial's lack of success to its six-hour treatment window. However, our analysis of the data from the patient records leads us to believe that time was not the primary reason for failure of the trial. We believe that if the time-to-treat had been the cause for the trial not meeting its primary endpoint, then patients treated later in the six-hour window (greater than 3 hours) should have had a worse outcome relative to placebo than patients treated early (less than 3 hours) in the six-hour window. Our analysis of time-to-treat data shows that patients treated with Viprinex earlier in the window actually had a worse outcome than placebo-treated patients, while patients treated later in the window had an outcome similar to placebo. Thus, the patients treated with Viprinex early had more negative impact on the overall results in ESTAT than the patients treated later.

The retrospective analysis made several other key findings regarding the failure of the ESTAT trial. For patients randomized to receive Viprinex, the median dose received was 23% higher in the ESTAT trial than in the STAT trial. In addition to the higher median dose, there was a statistically significant age imbalance between treatment groups. The mean age of patients in the Viprinex-treated group was 69.3 years compared to 67.7 years for the placebo group. While the age difference may initially appear to be relatively small, it is substantial in stroke treatment due to the significant influence of age on stroke outcome. A further analysis of the age data showed that there was a greater proportion of younger patients, defined as younger than 65 years of age, in the placebo group than in the Viprinex-treated group. Conversely, there was a greater proportion of older patients, defined as greater than or equal to 85 years of age, in the Viprinex-treated group. In addition, although not statistically significant, 22.9% of Viprinex-treated patients were categorized in the most severe pretreatment stroke severity group, defined as SSS scores of 0 to 19, compared to 19.6% for the placebo group.

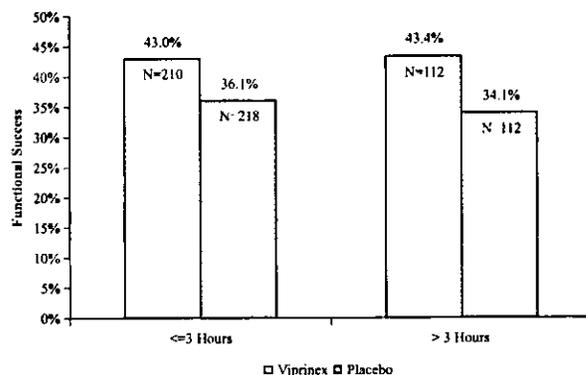
The ESTAT trial also enrolled patients with pretreatment blood pressure of up to 220/120 in contrast to many other trials for acute ischemic stroke, including rt-PA trials and STAT, where the maximum pretreatment blood pressure was 185/105. Additionally, ESTAT permitted concomitant use of low-dose prophylactic heparin, a blood thinner, while in STAT, use of heparin was not permitted. ESTAT Viprinex-treated patients who would have exceeded the STAT systolic blood pressure entry criteria had a SICH rate of 10.1% compared to 6.9% for Viprinex-treated patients who met the STAT criterion. SICH in these ESTAT Viprinex-treated patients carried a high 90-day mortality rate of 59%, which was not published in the trial manuscript. We believe the high

90-day mortality rate in the ESTAT Viprinex-treated patients emphasizes the importance of minimizing any controllable variable like blood pressure that might contribute to an increased incidence of SICH.

Although ESTAT was designed to be similar to STAT, the higher median dose and the difference in age, pretreatment stroke-severity and higher blood pressure entry criteria are notable differences that we believe played a critical role in the different outcome of ESTAT.

Retrospective Analysis: Pooled Analysis; Time-to-Treat

In contrast to ESTAT, a pooled covariate-adjusted analysis of the A-20 and STAT clinical trials and an earlier single-institution study with 20 patients indicates that the treatment effect of Viprinex as measured by functional success was similar whether Viprinex treatment began before three hours of stroke onset or between three and six hours of stroke onset, as shown in the chart below. Although not statistically significant, these trends compare favorably to rt-PA, which demonstrated in clinical trials that it loses its efficacy by the end of its approved time-to-treat window of three hours. We do not believe that time-to-treat explains the unsuccessful ESTAT efficacy outcome.



Retrospective Analysis: Key Lessons from Viprinex-treated Patients in the Knoll Clinical Trials

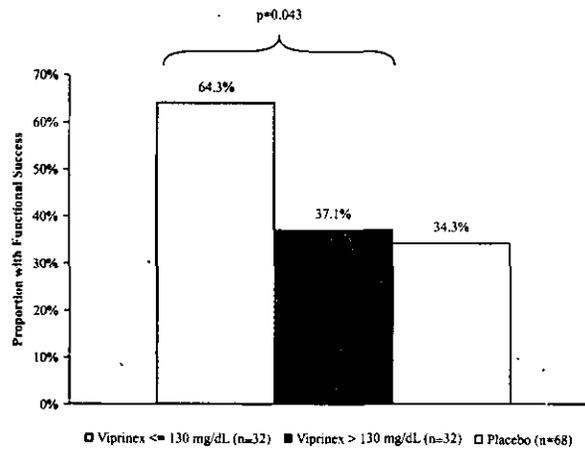
Knoll and Empire conducted a retrospective analysis of the prior Viprinex clinical trials to identify controllable factors, specifically dosing, that might have meaningful impact on efficacy and safety in future clinical trials. This analysis was adjusted for known determinants of stroke outcome, such as age and pre-treatment stroke severity.

The retrospective analysis of the data from the Knoll clinical trials resulted in two key hypotheses, which are the basis for our clinical trial strategy in the ASP trials:

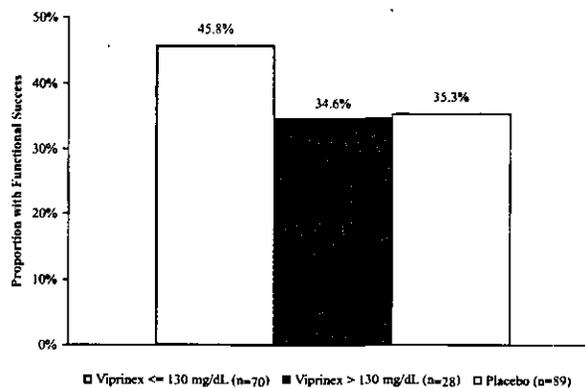
- *Efficacy* — the initial rapid lowering of fibrinogen levels, or defibrinogenation rate, appeared to have resulted in better functional success outcomes than slower initial rates of defibrinogenation.
- *Safety* — SICH occurred more frequently in patients with prolonged low fibrinogen levels.

Efficacy

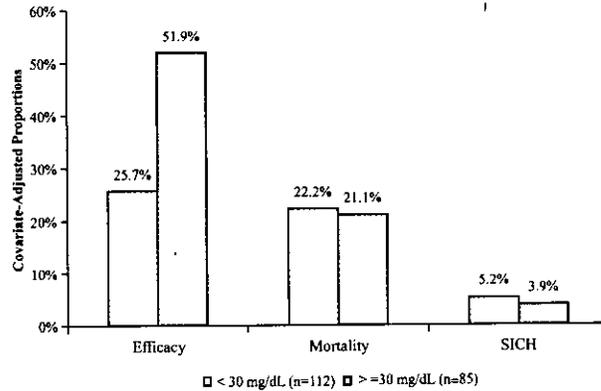
Although the target patient fibrinogen levels in the A-20 clinical trial were 70 to 100 mg/dL, the median patient fibrinogen level six hours from the beginning of the Viprinex infusion was 130 mg/dL, and levels remained there for the duration of Knoll's seven-day treatment. The retrospective analysis that our physicians conducted compared the functional success in patients whose six-hour fibrinogen levels were at or below the median value of 130 mg/dL to those whose fibrinogen level was above 130 mg/dL. Functional success was achieved by 64.3% of patients with six-hour median fibrinogen levels at or below 130 mg/dL compared to only 37.1% of patients with levels above 130 mg/dL. Since the placebo group had a functional success rate of 34.3%, this analysis suggests that Viprinex exhibited its effect only in those patients whose fibrinogen levels had fallen below 130 mg/dL at six hours. In those patients, the effect was statistically significant, representing an absolute improvement of 27.2 percentage points. The results of this retrospective analysis are shown in the chart below:



A retrospective analysis using the same criteria as the A-20 analysis, fibrinogen levels greater than or less than or equal to 130 mg/dL at six hours, was conducted on the STAT trial data and is shown in the chart below. The results of this analysis were similar to the A-20 analysis. Functional success was achieved by 45.8% of patients with six-hour median fibrinogen levels below 130 mg/dL compared to only 34.6% for patients with levels above 130 mg/dL. As in A-20, patients with fibrinogen levels greater than 130 mg/dL had efficacy comparable to that of the placebo group.



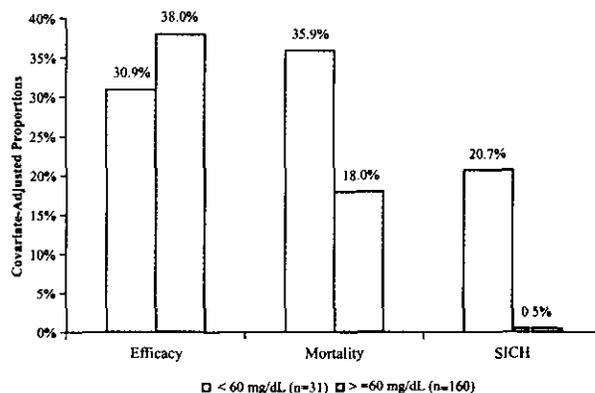
Although these observations suggested that a low six-hour fibrinogen level was important for efficacy, a multivariate analysis controlling for age and pretreatment stroke disability indicated that it was the actual rate at which fibrinogen fell in the first few hours of dosing that emerged as the most important variable. Specifically, what differentiated patients was a defibrinogenation rate of at least 30 mg/dL per hour. As shown in the chart below, 51.9% of patients whose zero to three-hour defibrinogenation rate was at least 30 mg/dL per hour achieved functional success compared to only 25.7% of patients with a slower defibrinogenation rate. In other words, twice as many patients with rapid defibrinogenation achieved functional success as did those with slower defibrinogenation. Moreover, a more rapid decline in fibrinogen levels did not adversely affect the incidence of SICH or mortality.



Based on the retrospective analysis, we concluded that optimal dosing should achieve rapid initial defibrinogenation. We believe that the best method to achieve the best patient outcome would be to use a rapid and controlled infusion of Viprinex. In both the STAT and ESTAT trials, three different initial infusion rates were used, based on the pretreatment fibrinogen levels. In STAT, 85% of patients who began therapy at the most rapid initial infusion rate, 0.167 IU/kg per hour, achieved defibrinogenation rates of at least 30 mg/dL per hour. In addition, Viprinex-treated patients in the ESTAT trial whose pretreatment fibrinogen levels required an initial infusion rate of 0.167 IU/kg per hour achieved a statistically significantly higher level of efficacy, 34.2%, compared to 21.7% for placebo patients who received the same initial infusion rate. This analysis was adjusted for age and pretreatment stroke severity, but was not adjusted for multiple comparisons. Nonetheless, both the STAT and ESTAT trials data suggest that a rapid initial defibrinogenation is associated with greater efficacy.

Safety (Symptomatic Intracranial Hemorrhage)

The absence of SICH in A-20 patients and the 5.2% incidence in STAT trial patients suggested that avoiding sustained low average fibrinogen levels over several days was the most important determinant for SICH. Analyzed most specifically in STAT, the key SICH risk factor appears to have been the average fibrinogen level, measured from the time the target fibrinogen was generally reached, nine hours after start of Viprinex infusion, to the end of the multi-day treatment period used. As shown in the chart below, the risk of SICH was greatly reduced in STAT patients who had an average fibrinogen level over the full course of treatment above 60 mg/dL. Additionally, mortality rate was approximately 50% lower in patients with higher average treatment-period fibrinogen levels. Finally, overall efficacy was greater in the group with a higher average fibrinogen level.



In a further analysis pooling all North American trials, STAT, A-20 and an earlier single-institution study with 20 patients, there were 220 acute stroke patients who received intravenous Viprinex and had average maintenance fibrinogen levels from nine hours to the end of treatment that were above 70 mg/dL. None of these 220 patients experienced a SICH. We saw a similar relationship between SICH and average maintenance fibrinogen levels in ESTAT. In ESTAT, SICH occurred in 14.5% of Viprinex-treated ESTAT patients with average maintenance fibrinogen levels at or below 70 mg/dL, but in only 3.6% of patients with average maintenance fibrinogen levels above 70 mg/dL.

Conclusion & Summary of Knoll Trials

Based upon the information from these retrospective analyses, we developed the dosing regimen in our current ASP trials, in which patients receive an infusion of placebo or Viprinex at a rate of 0.167 IU/kg per hour. This is equivalent to the highest initial infusion rate used in STAT and ESTAT, but in our trials the infusion is used for only two or three hours, after which it is stopped. As a result, the total dose and the duration of the infusion have been reduced substantially from that used in STAT and ESTAT. We believe that this dosing will result in high initial defibrinogenation rates which we believe is associated with better efficacy results. We also believe that this shorter-duration dosing will subsequently allow fibrinogen levels to return to normal much more quickly than in the Knoll trials, reducing the risk of SICH and thus improving safety.

ASP 1 and ASP 2 Phase 3 Clinical trials

In January 2005, Viprinex was granted fast track status. A drug designated as a fast track product by the FDA must be intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs for the condition. Fast track status enables the sponsor to have more frequent and timely communication and meetings with the FDA regarding the clinical development plans and results in eligibility for priority review for the marketing application, under which the FDA's review period for final approval is six rather than ten months.

Prior to initiating the ASP clinical trials, we held two End-of-Phase 2 meetings with the FDA. In March 2005 we discussed the clinical aspects of the program and in April 2005 we discussed the chemistry, manufacturing and controls for the investigational product.

We enrolled our first patient in the ASP trials in November 2005, and have been adding investigator sites since that time as we seek to increase enrollment into the trials. As of August 31, 2008, we had approximately 145 clinical sites eligible to enroll patients into the trials in 14 countries. We monitor the U.S. and Canadian sites through a combination of our own employees and independent contractors. We monitor the foreign sites through several different Clinical Research Organizations, or CROs.

Trial Design and Statistical Considerations

The primary endpoint for our ASP trials is the modified Rankin Score (“mRS”) score at 90 days. The mRS, which is a measure of global disability, is a more robust scale than those previously used in earlier trials and has become the most frequently used scale to measure treatment outcomes for new stroke treatments.

ASP 1 and ASP 2 are identical, randomized, double-blind, placebo-controlled studies designed to assess efficacy and safety of Viprinex in the treatment of acute ischemic stroke when initiated within six hours of stroke onset. Each study has been designed to enroll 650 patients, who will receive either a placebo or Viprinex. As a regular part of the drug development process, we periodically evaluate the conduct of our clinical studies, as well as plans for analysis, in consultation with advisors, consultants and regulatory agencies, when appropriate.

We designed the clinical trial inclusion criteria to include the general ischemic stroke population with as few restrictions as possible. Patients at least 18 years old (no upper age limit) and with mild, moderate or severe neurologic deficits can be enrolled in the studies provided they have a National Institute of Health Stroke Scale (“NIHSS”) score of five or greater and they are conscious at the time of presentation.

These studies are being monitored by a DSMB comprised of two neurologists and one statistician. The DSMB reviews unblinded data during the course of the trial and makes recommendations as to the conduct of the trial. The DSMB can recommend changes to the protocol or, if it identifies a safety issue that cannot be addressed through changes to the protocol, that the trial be stopped. To date, the DSMB has met to review the data five times, and each time has recommended the trials continue as planned.

The DSMB will conduct an interim analysis on the efficacy and safety of Viprinex when approximately 500 patients in the two studies have received study medication and completed their 90 day evaluation. We expect the data from these patients to be available for review by the DSMB no later than the first quarter of 2009. We intend to have the DSMB perform a “futility” analysis and a “superiority” analysis of the unblinded data in the trial, comparing the outcome of the group receiving Viprinex and the group receiving placebo:

- If the treatment effect observed in the group receiving Viprinex falls within a specified range as compared to the placebo group, the DSMB will recommend continuing the trials to their conclusion (with continued periodic DSMB safety reviews, but no additional interim efficacy reviews).
- If the treatment effect observed in the group receiving Viprinex is not greater than a specified minimum threshold, as compared to placebo (which would indicate that the trials are unlikely to show benefit for Viprinex if the trials are continued), the DSMB will recommend halting the trials for futility.
- If the treatment effect observed in the group receiving Viprinex is substantially greater than the placebo group, the DSMB has authority to recommend halting the trials for superiority. This recommendation would indicate that the DSMB does not feel it is ethical to continue to dose patients on placebo because of the benefits observed in the Viprinex group. In order for the DSMB to stop the trial for superiority, efficacy of the drug would need to be greatly superior to placebo, and as a result it is relatively uncommon for clinical studies to be halted for superiority at an interim analysis.

Dosing

Viprinex dosing is based on the patient's fibrinogen level at the time of presentation. Fibrinogen levels are frequently elevated in patients with vascular disease and thus most stroke patients will have fibrinogen levels over 200 mg/dl. These patients will receive a three-hour intravenous infusion of Viprinex, receiving a total Viprinex dose of 0.5 IU/kg. For patients with fibrinogen levels less than 200 mg/dl, the infusion lasts for two hours and the patient receives a total dose of 0.33 IU/kg.

Primary and Secondary Endpoints

The primary endpoint of the ASP studies is the percentage of patients with a favorable outcome, referred to as responders, as determined by a mRS score 90 days after stroke onset. The primary analysis of the mRS is a responder analysis that takes into consideration the patient's NIHSS score on admission and the patient's mRS score prior to the stroke.

The scores are used to create groups of responders and non-responders, or a responder analysis. Since outcome of stroke is strongly correlated with initial stroke severity, as measured by the NIHSS, the responder analysis is designed to account for this variable. The percent of responders for Viprinex will be compared to placebo. The responder definition is shown in the table below.

<u>Pretreatment NIHSS Score</u>	<u>Prestroke mRS Score</u>	<u>Day 90 mRS Score</u>	
		<u>Responder</u>	<u>Non-Responder</u>
5-15.....	0-1	0-1	2-6
≥ 16.....	0-1	0-2	3-6
Any.....	≥ 2	0-2	3-6

The secondary endpoints of the trial include the NIHSS score and BI score at day 90.

Memantine

In April 1998, we entered into a strategic research and marketing cooperation agreement with Merz and Children's Medical Center Corp., or CMCC, for the clinical development and commercialization of memantine. Pursuant to this agreement, we have the right to share in revenues from sales of of Namenda/ Ebixa (memantine) in certain territories for Alzheimer's disease and any future sales for the indications covered by specified CMCC patents, which include AIDS-related dementia and neuropathic pain. We have no significant ongoing obligations under the agreement and rely on Merz and its marketing partners for the commercialization of memantine for Alzheimer's disease and for the clinical development of memantine for other indications.

Merz has entered into agreements with Forest Laboratories, Inc., or Forest, for the development and marketing of memantine in the United States, with H. Lundbeck A/S, or Lundbeck, of Denmark for Europe and certain other countries, and with Daiichi Suntory Pharma Co., Ltd., or Suntory, for Japan. While we are not a party to any of these agreements, under our agreements with Merz and CMCC we are entitled to receive a share of the royalties Merz receives from Forest, Lundbeck and Suntory.

In February 2008, we amended our agreement with Merz and CMCC. In the amendment, Merz and CMCC agreed that they would not provide us notice of termination of the agreement before an effective date of January 1, 2010. In return, Merz discontinued paying us royalties on sales of memantine for Alzheimer's disease outside of the United States beginning in the fourth quarter of calendar 2007, and we agreed to a schedule of staged reductions in the royalty rates for sales in the United States beginning in the third quarter of calendar 2008.

XERECEPT

XERECEPT is a synthetic preparation of Corticotropin-Releasing Factor, a natural human peptide, which is being developed as a treatment for swelling around brain tumors. XERECEPT has received orphan drug

designation for this indication from the FDA, which generally provides for seven years of market exclusivity from time of approval.

In November 2005, we sold all of our worldwide rights and assets related to XERECEPT to two subsidiaries of Celtic Pharmaceuticals. In addition to the cash we received at the time of sale, under the terms of the sales agreement we are entitled to receive up to an additional \$15 million in payments upon the approval of XERECEPT in key areas of the world. Because a portion of the milestones are only payable in the event XERECEPT receives approval within specified timeframes, we believe the milestones we are entitled to receive will not exceed \$7.5 million. In addition, if XERECEPT is approved for commercial sale we are entitled to receive profit-sharing payments of 22% on gross margins in the United States and royalty payments of 15-20% on sales elsewhere in the world.

We have also entered into a collaboration and services agreement with Celtic, pursuant to which we agreed to provide certain services in connection with Celtic's development of XERECEPT, and the Celtic entities reimburse us for the direct costs we incur. During fiscal 2008, we transitioned the majority of the XERECEPT drug development work to Celtic, reducing our direct involvement in the development of XERECEPT.

Alzheimer's Disease

We have licensed the rights to develop and commercialize products under patent rights related to a naturally occurring protein that are held by the Buck Institute for Age Research, or Buck. The protein licensed from Buck has been shown in animals to reverse the symptoms of Alzheimer's disease, or AD. AD is a neurodegenerative disease that generally occurs in people over 65 years old and is the most common cause of dementia afflicting approximately 24 million people worldwide. AD Research at Buck focuses on signal transduction pathways that may explain the different, yet seemingly opposed theories of AD, namely that AD is caused by either an overabundance of amyloid-B (AB) peptide, or by neurofibrillary tangles that build up inside the nerve cells. The protein we licensed has been shown in both cell culture and mice to inhibit the production of amyloid-B (AB) peptides while simultaneously facilitating the growth and preservation of nerve fibers in the brain. Work on the Alzheimer's program is in the preclinical stage, and we are working with Buck to meet the requirements to file an IND and move into human testing.

Fibroblast growth factor

We have licensed the rights to develop and commercialize products that incorporate fibroblast growth factor-2, or FGF, for the treatment of human diseases from Buck. Buck possesses certain patent rights related to FGF and the potential use of FGF to treat certain human diseases, and has conducted various studies in support of these patent rights. For example, preclinical studies have shown that mice with Huntington's Disease, or HD, that are treated with FGF showed a significant increase in new nerve cells. HD is caused by genetically programmed degeneration of nerve cells in the brain. In addition to growing nerve cells, treatment with FGF extended the lifespan of the affected mice, the animals exhibited improved motor performance, decreased cell death and a reduction in the amount of toxic aggregates that typically form in the brains of those affected by HD. Work on the FGF program is in the preclinical stage, and we are working with Buck to meet the requirements to file an IND and move into human testing.

Competition

We face significant competition from various other biopharmaceutical companies, as well as government-sponsored entities such as the National Institute of Neurological Disorders and Stroke, or NINDS, with respect to the development of drug candidates for the treatment of central nervous system conditions, including acute ischemic stroke. Many of the companies involved in these research and development activities and the manufacture, commercializing and/or distribution of products that compete with Viprinex and any other product candidates that we may develop have substantially greater drug development, manufacturing, sales and marketing experience than we do, as well as significantly greater financial resources.

In stroke, our primary competitor is Genentech, Inc., which markets Activase® (alteplase), or rt-PA, the only currently approved drug treatment for acute ischemic stroke in the United States and Europe, as well as other markets throughout the world. A Phase 3 study evaluating the use of rt-PA treatment of acute ischemic stroke when given between 3 and 4½ hours after stroke has completed, and results are expected to be available in September 2008.

In addition, the NINDS is currently conducting several stroke trials, including a Phase 3 trial of albumin in 1,800 patients for acute ischemic stroke. Albumin is considered a potential neuroprotectant that we believe will be used in combination with a reperfusion agent. The NINDS is also studying tenecteplase, a reperfusion agent that has been approved for the treatment of acute myocardial infarction, or heart attack, in a Phase 2 clinical trial for acute ischemic stroke that will enroll 600 patients.

We also face competition from companies that are developing medical devices for the treatment of stroke. Concentric Medical, Inc., manufacturer of the Merci® Retriever, received FDA approval of this mechanical device to be used to remove blood clots from blood vessels in the brain. This device is now under study in three different clinical trials by the NINDS to determine if this treatment approach improves stroke outcome, which is the standard endpoint for ischemic stroke. Additionally, in January 2008, the FDA granted approval of the Penumbra System™ which is intended for use in revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease.

Business Strategy

We are focused on developing drug candidates for the treatment of central nervous system conditions. Key elements of our strategy include:

- *Successfully completing the clinical development of Viprinex.* We have designed our current clinical trials to establish that Viprinex has a better efficacy and safety profile than the only treatment currently available for acute ischemic stroke, rt-PA. These trials are designed to show that Viprinex can be safe and effective in treating patients with acute ischemic stroke when initiated within six hours of stroke onset. If these trials are successful and we receive approval, the six hour treatment window would make Viprinex available to a greater proportion of the people who suffer acute ischemic strokes than rt-PA, which currently is approved for use within three hours of stroke onset.
- *Seeking a partner to commercialize Viprinex, but maintaining significant interest in commercial success, if the drug is approved.* We intend to partner with a major pharmaceutical company, or with several strong regional pharmaceutical companies, to commercialize Viprinex for ischemic stroke. We also intend to retain a significant continuing interest in the success of the product, such as through retained co-promotion rights or significantly high royalty rates. By retaining these rights, we expect to be able to secure a greater share of potential revenues from the commercialization of Viprinex.
- *Continuing to in-license and acquire new product candidates.* We seek to in-license and acquire promising drug candidates that target major medical needs and that can be rapidly commercialized, if our financial resources are sufficient. For example, we do not intend to in-license any new products or potential products until our clinical trials are funded to completion. Thereafter, we intend to continue to use the expertise of our experienced team in advancing drug candidates through human clinical trials and the regulatory approval process. Our focus is likely to be on acquiring and developing later-stage CNS drugs, but we may also acquire earlier-stage drug candidates in this area, if we believe our expertise could advance their development and they would complement our existing products.

Manufacturing and Supply

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of Viprinex. We rely on a small number of third-party manufacturers to produce our compounds and expect to continue to do so for our clinical requirements and for our commercial needs, if any. We do not have long-term agreements with any of these third parties for commercialization.

We require in our manufacturing and processing agreements that all third-party contract manufacturers and processors produce active pharmaceutical ingredients, or APIs, and finished products in accordance with current Good Manufacturing Practices, or cGMP, regulations, and all other applicable laws and regulations. We maintain confidentiality agreements with potential and existing manufacturers in order to protect our proprietary rights related to our drug candidates.

Nordmark Arzneimittel GmbH & Co. KG, or Nordmark, manufactures ancrod concentrate, the API in Viprinex. Ancrod concentrate is derived from the venom of the Malayan pit viper. As part of the acquisition of Empire, we acquired an inventory of dried venom and currently have enough dried venom to manufacture the quantities of API needed to complete our Phase 3 clinical program. Nordmark currently begins the manufacturing process by reconstituting dried venom, then uses a proprietary process that involves a series of chromatographic and filtration steps to produce a highly purified and concentrated solution of the fibrinogen-reducing active ingredient in Viprinex. This purification process is designed to remove any impurities or other potentially active compounds that may exist in raw snake venom. As part of the ongoing development work, Nordmark houses and breeds Malayan pit vipers to create raw, fresh venom. Nordmark has established a highly controlled snake facility and cGMP purification suite in Germany for the housing of our snakes and the purification and production of the active ingredient in Viprinex.

Baxter Pharmaceutical Solutions, Inc., or Baxter, performs filling and finishing procedures to produce the final Viprinex product from the purified solution manufactured by Nordmark. The final product is prepared by diluting the concentrated Viprinex solution and aseptically filling the finished drug product into sterilized glass vials in accordance with cGMP requirements.

Patents

We hold the exclusive worldwide marketing rights to Viprinex through a license from Abbott, which we acquired with our purchase of Empire in July 2004. Viprinex is protected by three patents covering the composition of matter and synthesis of the compound.

The patent position of biotechnology firms generally is highly uncertain because:

- patents involve complex legal and factual issues that have been the subject of much litigation;
- no consistent policy has emerged from the United States Patent and Trademark Office regarding the breadth of claims allowed or the degree of protection afforded under biotechnology patents; and
- others may independently develop similar products, duplicate potential products, or design around the claims of potentially patented products.

In addition, because of the time delay in patent approval and the secrecy afforded United States patent applications, we do not know if other applications, which might have priority over our applications, have been filed.

In addition to patent protection, we employ specialized technologies in the process of manufacturing the finished Viprinex product and the particular requirements of housing snakes to create our key drug's active ingredient. We rely upon trade secret protection for our confidential and proprietary information. It is our policy that vendors and employees enter into a confidentiality agreement which contains provisions generally prohibiting the disclosure of confidential information to anyone outside our company and requiring disclosure to us of ideas, developments, discoveries or inventions conceived during employment and assignment to us of proprietary rights to such matters related to our business and technology. However, it is possible that these agreements could be breached. In addition, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology.

Government Regulation

Governmental authorities in the United States and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage,

record-keeping, promotion, advertising, distribution, marketing and export and import of drug and biological products. In order to clinically test, produce, and market products for therapeutic use, a company must comply with mandatory procedures and safety standards established by the FDA and comparable agencies in foreign countries. Drug and biological products must be approved by the FDA before they may be legally marketed in the United States.

In the United States, the FDA regulates drugs and some biologics under the Federal Food, Drug, and Cosmetic Act, or FDCA, and other biologics under the Public Health Service Act. Failure to comply with the applicable regulatory requirements at any time during the product development process, approval process or after approval, may subject an applicant to sanctions which could include the FDA's refusal to approve pending applications, the withdrawal of an approval, a clinical hold, warning letters, product recalls or seizures, total or partial suspension of production or distribution, injunctions, fines, restitution, disgorgement, civil penalties and/or criminal prosecution. Any such action would be likely to materially harm our business.

A company generally must conduct preclinical laboratory tests, animal studies and formulation studies of new pharmaceutical products according to Good Laboratory Practices, or GLP, prior to the commencement of clinical studies involving humans. These studies evaluate the potential efficacy and safety of the product. The company then submits the results of these studies, together with manufacturing information and analytical data, to the FDA as part of an investigational new drug application, or IND, which must become effective before clinical testing in humans can begin.

Typically, human clinical evaluation involves a time-consuming and costly three-phase process that may overlap:

- In Phase 1, a company conducts clinical trials with a small number of subjects to determine a drug's early safety profile, dosage tolerance and its pharmacokinetic pattern.
- In Phase 2, a company conducts clinical trials with a limited number of patients afflicted with a specific disease in order to determine preliminary effectiveness, optimal dosages and further evidence of safety.
- In Phase 3, a company conducts large-scale, well-controlled, multi-center trials with patients afflicted with a target disease in order to provide enough data to demonstrate effectiveness and safety prior to commercialization.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with Good Clinical Practices, or GCP. An Institutional Review Board, or IRB, at each institution participating in the clinical trial must review and approve the plan for a clinical trial before it commences at that institution. Each new clinical protocol must be submitted to the FDA as part of the IND. Progress reports, detailing safety information of ongoing clinical trials, must be submitted at least annually to the FDA. Serious adverse events that are drug-related and life-threatening are reported more frequently to the FDA and other health agencies. The FDA closely monitors the progress of each phase of clinical testing. The FDA, IRB or the sponsor may, at its discretion, re-evaluate, suspend, or terminate testing based upon the data accumulated to that point and the assessment of the risk/benefit ratio to patients.

The results of the preclinical and clinical testing, along with the descriptions of the manufacturing process, analytical data on the drug, proposed labeling and other relevant information are submitted to the FDA in the form of a new drug application, or NDA, in the case of a new drug, or a biologic license application, or BLA, in the case of new biologic, for approval prior to commercialization.

The submission of an NDA or BLA is subject to the payment of user fees, but a waiver of such fees may be obtained under certain limited circumstances. The FDA reviews all NDAs and BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an NDA or BLA for filing in which case the application must be resubmitted with the additional information. Once the application is accepted for filing, the FDA reviews it to determine, among other things, whether they believe a product is safe and effective for its intended use and whether they believe its manufacture is cGMP-compliant.

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the application does not satisfy their criteria for approval. Failure to receive approval for any of our potential products would have a material adverse effect on us. Among the requirements for product approval is the requirement that each manufacturer of the product conform to the FDA's cGMP regulations, which must be followed at all times. Before approving an NDA or BLA, the FDA will inspect the facility or facilities where the product is manufactured and tested. Compliance with the cGMP regulations requires that manufacturers continue to expend time, money and effort in the area of production and quality control to ensure full compliance. Even if a product receives regulatory approval, the approval may be significantly limited to specific diseases or dosages or the indications for use may otherwise be limited which could restrict the commercial application of the product. Also, a postmarket testing and surveillance program may be required to continuously monitor a product's usage and effects in patients.

Once the sale of a product is approved, FDA regulations continue to govern the manufacturing process and marketing activities, including requirements relating to, among other things, record-keeping, reporting of adverse experiences with the product, providing updated safety and efficacy information, drug sampling and distribution, labeling, and advertising and promotion. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Drug manufacturers and their subcontractors are required to register their manufacturing facilities with the FDA and some state agencies, and are subject to periodic unannounced inspections by the FDA and some state agencies for compliance with cGMP and other laws. Future inspections may identify compliance issues that may disrupt production or distribution, or require substantial resources to correct. Product approvals may be suspended or withdrawn if compliance with regulatory requirements or standards is not maintained or if previously unknown problems with a product are discovered.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical trials and commercial sale and distribution of our products. Whether or not we obtain FDA approval for a product, regulatory approval of a product must also be obtained in each country prior to marketing the product in that country. Specific foreign regulatory requirements and approval procedures can vary significantly, but often involve the same steps as that required in the United States. Regardless of whether a product is approved in the United States, any foreign regulatory authority can decide not to approve the product for their country or countries. The time required for approval may delay or prevent marketing in certain countries. In certain instances, we or our collaborative partners may seek approval to market and sell certain products outside of the United States either before or after submitting an application to the FDA for U.S. approval. The clinical testing requirements and the time required to obtain foreign regulatory approvals may also differ from those required for FDA approval.

Reimbursement

Sales of biopharmaceutical products in the United States depend in significant part on the availability of reimbursement from third-party payors, including government health authorities, managed care providers, private health insurers and other organizations. We anticipate that third-party payors will provide reimbursement for any products for which we obtain regulatory approval. It will be a time consuming and expensive process for us to seek reimbursement from third-party payors. Reimbursement may not be available or may not be sufficient to allow us to sell our products on a competitive and profitable basis.

Different pricing and reimbursement schemes exist in other countries. In some foreign countries, including most countries in Europe, proposed pricing must be approved before a drug or biological product may be lawfully marketed. In these countries, pricing negotiations with governmental authorities can take considerable time and delay the marketing of a product.

Employees

As of June 30, 2008, we had 33 employees; 32 of these employees were full-time. Additionally, we use consultants to complement our staffing as needed. Our employees are not subject to any collective bargaining agreements, and we regard our relations with employees to be good.

Available Information and Website Address

Our website address is www.ntii.com. We make available free of charge through our website, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to these reports as soon as reasonably practicable after filing with the SEC. They also may be obtained directly from the SEC's website, www.sec.gov. The contents of our website are not incorporated by reference into this report.

ITEM 1A. RISK FACTORS

This Annual Report on Form 10-K includes forward-looking statements about our business and results of operations that are subject to risks and uncertainties. Factors that could cause or contribute to such differences include those discussed below. In addition to the risk factors discussed below, we are also subject to additional risks and uncertainties not presently known to us or that we currently deem immaterial. If any of these known or unknown risks or uncertainties actually occurs, our business could be harmed substantially.

Risks Related to Our Current Clinical Trials for Viprinex

Viprinex has failed in one of two Phase 3 clinical trials conducted by Knoll for the treatment of acute ischemic stroke, and it may not prove to be safe and effective in our current Phase 3 trials. Because Viprinex is our only product candidate, the failure of the interim analysis or any negative or inconclusive results in the ongoing trials would significantly harm our prospects and depress our stock price.

Although it has shown success in one of the two Phase 3 studies conducted by Knoll before we acquired the rights to Viprinex, Viprinex has also previously failed in a large multi-center Phase 3 clinical trial conducted by Knoll. In the failed trial, an interim analysis concluded that Viprinex was unlikely to reach its primary efficacy endpoint. Further analysis of the trial data revealed that Viprinex-treated patients suffered from higher symptomatic intracranial hemorrhaging and higher mortality rates than patients receiving the placebo treatment. Although we believe we may be able to address these problems by using a significantly changed dosing regimen in our current clinical trials, we still may not be able to demonstrate that Viprinex is a safe and effective treatment for acute ischemic stroke to the satisfaction of the FDA or other regulatory agencies. There is only one approved treatment for acute ischemic stroke, and many other drug candidates for this indication have failed in late-stage clinical trials, even after successful earlier-stage trials. If we are unable to demonstrate that Viprinex is a safe and effective treatment for acute ischemic stroke to the satisfaction of the FDA or other regulatory agencies, we will not receive regulatory approval and our business would be materially harmed.

The earlier failure of Viprinex illustrates the risks of clinical development of new drugs, including the possibility that drug candidates may be found to be unsafe and/or ineffective. If our trials do not have positive outcomes we may be forced cease further development of Viprinex or to make additional significant expenditures for further clinical trials. Additionally, because Viprinex is the focus of nearly all our current drug development efforts, the failure of Viprinex in the trials would greatly diminish our prospects and would likely cause our stock price to decline significantly.

We are scheduled to complete an interim analysis of the data gathered from the first 500 treated patients into our current Viprinex clinical trials no later than the first quarter of calendar 2009. Although the DSMB has reviewed the safety of Viprinex as studied in the current trials, they have never evaluated efficacy. New safety concerns could be identified during the analysis, or the DSMB could determine that we have not met the established efficacy hurdle to continue the study. Termination of the study because of safety concerns or because of lack of efficacy would likely result in our decision to terminate all future development of Viprinex, greatly diminishing our prospects and likely causing further declines in our stock price.

If our clinical trials for Viprinex are delayed because of patient enrollment or other problems, we would incur additional costs and experience delays in the potential receipt of revenues.

The rate of patient enrollment to date in our clinical trials for Viprinex continues to be slower than planned. These delays have caused us to revise our estimated completion dates for these trials on several occasions, and any additional delays would further impede the timely development of Viprinex and would further increase our development costs and risks. If the results of an upcoming study evaluating the use of rt-PA as a treatment for acute ischemic stroke when given between 3 and 4½ after stroke onset are positive, the enrollment into our trials may be slowed due to greater use of rt-PA among patients who would otherwise be candidates for enrollment into our trials. Delays in patient enrollment in our current or future clinical trials will result in increased costs, a delay in our ability to seek marketing approval and the loss of potential revenues. Due to the delays we have experienced to date, we are likely to require additional funds to complete the two clinical trials which are currently underway. Further, if we experience significant delays, our long-term prospects will be negatively affected due to, among other things, the limited time we would continue to have patent protection. In any such case, our prospects would be harmed and our stock price could decline.

The approval of Viprinex by the FDA or other regulatory authorities is uncertain and regulatory authorities may not approve it even if it meets the safety and efficacy endpoints in our clinical trials.

We may not receive regulatory approval from the FDA or any other regulatory body required for the commercial sale of Viprinex, or any future products in the United States or any other jurisdiction. The FDA or comparable foreign regulatory authorities might decide that our data is insufficient for approval and require additional clinical trials or other studies. In addition, even if we do obtain approval to market Viprinex, the process of obtaining FDA approval may take longer and require the expenditure of more resources than we anticipate. The regulatory approval of a new drug typically takes many years and varies substantially based on the type, complexity and novelty of the drug for which approval is sought, and the outcome is uncertain. Promising results from early clinical trials may not be replicated in later clinical trials. Interim results of a clinical trial do not necessarily predict final results. A number of pharmaceutical and biotechnology companies have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. If we fail to obtain regulatory approval for Viprinex, or any future product candidates, we will be unable to market and sell any products and therefore will not be able to generate any revenues from product sales or become profitable.

The FDA and foreign regulatory agencies can delay approval of or refuse to approve a drug application, including our potential drug application for Viprinex, for a variety of reasons, including failure to meet safety and efficacy endpoints in our clinical trials. In addition, our product candidates may not be approved even if they achieve their endpoints in clinical trials. Regulatory agencies, including the FDA, have substantial discretion in the approval process and may disagree with our trial design and our interpretations of data from preclinical studies and clinical trials. Even if a product candidate is approved, it may be approved for fewer or more limited indications than requested or the approval may be subject to meeting conditions we are not able to meet. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for successful commercialization. Any such limitation, condition or denial of approval would have an adverse affect on our business, reputation and results of operations.

We rely on third parties to conduct our clinical trials for Viprinex, and their failure to perform their obligations in a timely or competent manner may prevent or delay development and commercialization of our lead drug candidate.

We have entered into various contractual arrangements with CROs, consultants and others, and we are dependent upon the outside parties to perform their assigned responsibilities in an ethical and competent manner. Certain of our arrangements with these outside parties may place significant responsibility on them for human clinical testing and for various roles in preparing and submitting submissions for regulatory approval. We have previously experienced delays and other problems with CRO performance, and have previously changed CROs due to these problems. These difficulties have caused delays in our clinical trials and the same or new problems may occur with the current CROs we are using. If any additional problems occur, the clinical development of Viprinex could be further delayed and our business, financial condition and results would be adversely affected.

We have also relied on scientific, clinical, commercial and other data supplied and disclosed by others in entering into these agreements. We have relied on these data in support of applications for human clinical trials for Viprinex. Although we have no reason to believe that this information contains errors or omissions of fact, it is possible that there are errors or omissions of fact that would change materially our view of the future likelihood of FDA approval or commercial viability of Viprinex.

We do not have our own manufacturing facilities and are dependent on contract manufacturers and suppliers for the development and production of Viprinex.

We must procure from third parties our supplies of Viprinex for our clinical trials. We are party to agreements with Nordmark to house and maintain our colony of Malayan pit vipers, to purify the snake venom that is used to produce the active pharmaceutical ingredient of Viprinex, and to supply us with this active pharmaceutical ingredient in finished form for our clinical trials. We also have an agreement with Baxter for other aspects of the development, supply and packaging of Viprinex. Any difficulties in the manufacturing processes with the snakes, Nordmark or Baxter could delay our clinical trials and impede the development and commercialization of Viprinex. In addition, we may not be able to maintain or extend these arrangements on satisfactory terms, if at all, and we may not be able to find suitable replacements for Nordmark and/or Baxter if these arrangements are terminated.

Further, although we perform audits on Nordmark and Baxter to assess their compliance with cGMP regulations, there can be no assurance that these or other contractors will meet cGMP standards or be able to synthesize, purify and deliver Viprinex in a timely fashion. Although alternative cGMP suppliers of the bulk drugs and of finished dosage form products are available to us, Viprinex is difficult and costly to produce, and we believe that there is only a limited number of manufacturers that are capable of producing the compound. The loss of our current supply arrangement could significantly delay our clinical trials for Viprinex and could impact the commercialization of the drug if it is ultimately approved by the FDA. As a result, we may face delays or we may not be able to adequately manufacture the drug for approval or commercial sale, which would harm our stock price, business and financial position.

Risks Related to Our Financial Condition

We have a history of losses, we expect to generate losses in the near future, and we may never achieve or maintain profitability.

As we have funded the development and clinical testing of our drug candidates, we have experienced operating losses in nearly every year since our inception. As of June 30, 2008, our accumulated deficit was approximately \$126 million. We expect to continue to incur operating losses for the next several years as we continue our clinical trials for Viprinex, continue to investigate new treatments for Alzheimer's and Huntington's diseases, and pursue potential acquisitions of new product candidates. To achieve profitability, we will need to successfully develop and obtain regulatory approval for our drug candidates, and thereafter successfully manufacture, market and sell the products, or we will need to generate significant revenues from

other sources, such as licensing collaborations. We may never generate sufficient revenues to become or remain profitable.

We will need to raise additional capital to reach profitability and to complete the clinical trial work that is likely to be necessary to apply for approval of Viprinex. If we succeed in raising additional capital through a debt or equity financing transaction, it may adversely affect our stock price. If we are unable to raise additional capital, we may be forced to curtail operations.

Because we do not expect to operate profitably for several years, if at all, we will need to obtain substantial additional funds to sustain our operations and may need more capital than anticipated if we acquire and develop other product candidates.

Our future capital requirements will depend on a number of factors, including:

- the time and cost involved in completing the clinical trials and obtaining regulatory approval for Viprinex;
- the amount of royalties received from Merz for future sales of memantine;
- the payments received pursuant to our agreements with Celtic;
- the progress of our clinical development program;
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the acquisition or licensing of new drug candidates;
- competing technological and market developments;
- our ability to establish partnerships to commercialize Viprinex and any future product candidates;
- future commercialization activities and arrangements; and
- the cost of our research collaborations with the Buck Institute for Age Research.

Due to the delays we have experienced enrolling patients into our current Phase 3 clinical trials, we estimate that we do not have sufficient resources to complete two pivotal clinical trials that the FDA customarily requires for approval of new drugs. Therefore, we will need to license rights to Viprinex or otherwise raise capital by issuing securities. Licensing the rights to Viprinex may be disadvantageous as we would be required reduce our economic interest in the success of the product, if approved, diminishing our potential long-term return. Alternatively, if we raise capital by issuing additional shares of common stock, preferred stock or debt, regardless of the price at which these are issued, the value of the shares of our common stock then outstanding may be reduced. In addition, the terms of a licensing agreement or financing transaction may restrict our operations.

We may not be able to raise capital on terms that we find acceptable, or at all. If we are unable to raise additional capital to fund future operations, we may be forced to reduce the scope of our operations or defer or abandon our clinical development program for Viprinex. Any of these actions could have an adverse effect on our stock price and could significantly impair our prospects.

The auction rate securities we hold in our portfolio are currently not actively trading, and we may have to sell all or some of these securities at a loss to fund our operations.

As of June 30, 2008, our investments included a variety of interest-bearing auction rate securities, or ARS, for which we paid a total of \$13.2 million and are carrying at an estimated value of \$11.9 million. These ARS investments are intended to provide liquidity via an auction process that resets the applicable interest rates at predetermined calendar intervals, allowing investors to either roll over their holdings or obtain immediate liquidity by selling such investments at par. Since February 2008, the auctions for our ARS have failed to settle on their respective settlement dates. Consequently, the investments are not currently liquid and

we are not able to access these funds until a future auction is successful, the investments are called by the issuer, or we find a buyer outside the auction process. Maturity dates for these ARS investments range from 2030 to 2045. All of these ARS investments are investment grade quality and were in compliance with our investment policy at the time of acquisition. Because we are operating at a loss while funding our Phase 3 trials for Viprinex, we are unlikely to be able to hold these ARS investments to maturity and will likely need to sell them by early fiscal 2010, although we may choose to do so at an earlier date. We may experience a loss on sale, reducing the capital we have to continue to fund our business.

Risks Related to Our Business

The approval of any future product candidate by the FDA or other regulatory authorities is uncertain and will involve the commitment of substantial time and resources.

As part of the regulatory approval process, we must conduct, at our own expense, preclinical research and clinical trials for each product candidate sufficient to demonstrate its safety and efficacy to the satisfaction of the FDA in the United States and other regulatory agencies in the countries where the product candidate will be marketed, if approved. The number of preclinical studies and clinical trials that will be required varies depending on the product, the disease or condition for which the product is in development and the regulations applicable to any particular product. The regulatory process typically also includes a review of the manufacturing process to ensure compliance with applicable regulations and standards, including the FDA's current Good Manufacturing Practice, or cGMP, regulations. The FDA can delay, limit or decline to grant approval for many reasons, including:

- their determination that a product candidate is not safe or effective;
- their determination that the manufacturing processes or facilities do not meet specified requirements; or
- changes to their approval policies, guidelines or new regulations that affect us in an unfavorable manner.

Any denial of approval or any delay or limitation on approval of any of our product candidates will substantially harm our business prospects, financial condition and results of operations.

Even if Viprinex is approved for commercialization, it may not be successfully commercialized or generate meaningful product revenues for us.

If Viprinex is approved for commercialization, we would be required either to market the drug directly, which would require the recruitment and training of a direct sales force, or to enter into a collaborative arrangement with a larger biotechnology or pharmaceutical company with an existing sales force to sell, market and distribute our products. Our current strategy is to retain some portion of the commercial rights to Viprinex, which may ultimately require us to build an internal sales force. However, we may not succeed in directly marketing Viprinex because the building of a direct sales force is costly, and we have no experience in sales, marketing and distribution. If we elect to license Viprinex to a larger company with an existing sales force, we would be required to share the revenues from commercialization and would lose a significant degree of control over the commercialization and further development of the drug. In addition, any licenses or collaborative arrangements that we may enter into may not be effective in generating meaningful product royalties or other revenues to us.

If Viprinex does not attain adequate market acceptance by health care professionals and patients, our business prospects and results of operations will suffer.

Even if Viprinex receives regulatory approval for commercial sale, our revenues from sales of the product may not be significant and will depend on many factors that are outside of our control. Factors that may affect revenue from Viprinex, if and when approved, include:

- perception of physicians and other members of the health care community of its safety and efficacy relative to that of competing products;

- cost-effectiveness;
- patient and physician satisfaction with the product;
- ability to successfully manufacture commercially and on a timely basis;
- cost and availability of raw materials;
- reimbursement policies of governments and third-party payors;
- unfavorable publicity concerning Viprinex or similar drugs;
- the introduction, availability and acceptance of competing products, including those of any future partners;
- adverse event information relating to the product;
- product labeling or product inserts required by the FDA or regulatory authorities in other countries;
- regulatory developments related to the manufacture or continued use of the product; and
- extent and effectiveness of sales and marketing and distribution support for the product.

Our product revenues will be adversely affected if, due to these or other factors, Viprinex does not gain significant market acceptance.

If government and third party payors fail to provide coverage and adequate payment rates for Viprinex, if approved, our revenues and prospects for profitability will suffer.

In the United States and other countries, our sales of Viprinex will depend in part on the availability of reimbursement from third-party payors. These third-party payors include government health programs such as Medicare, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. Reimbursement may not be available at all or sufficient enough to allow us to sell Viprinex or the other product candidates in our pipeline on a competitive and/or profitable basis.

Even if we are granted approval for our product candidates, we may not be able to maintain that approval, which would reduce our revenues.

Even if we are granted regulatory approval for a product candidate, the FDA and corresponding foreign regulatory agencies can limit or withdraw approvals for a variety of reasons, often at their sole discretion. If we are ever able to obtain any product approvals, the approvals may be limited or withdrawn or we may be unable to remain in compliance with regulatory requirements. Limitations upon or withdrawals of any approvals we or our licensees obtain will reduce our revenues and harm our business and financial condition.

The royalty rate we receive for memantine product sales will decrease.

We are party to a license and cooperation agreement with Merz and CMCC, pursuant to which we have rights to share in revenues from worldwide sales of memantine for the treatment of Alzheimer's disease. In return for Merz's agreement not to terminate the license and cooperation agreement before an effective date of January 1, 2010, we have agreed to a staged reduction in royalty rates on sales of memantine in the United States beginning in the third quarter of 2008. Additionally, we agreed to discontinue the royalty on sales of memantine for Alzheimer's disease outside the United States as of the fourth quarter of 2007. This amendment will result in lower royalty payments to us. In addition, any ultimate termination of our agreement with Merz or any failure by Merz or its partners to successfully commercialize memantine or defend memantine against generic competition could reduce or eliminate the future royalties we are entitled to receive under the agreement, and would have a material adverse effect on our business, financial condition and results of operations.

We only have very limited control over the development and commercialization of XERECEPT, which we have sold to Celtic, and as a result, we may not realize a significant portion of the potential value of this product candidate.

In November 2005, we completed the sale of all our rights and assets related to XERECEPT to two newly-formed subsidiaries of Celtic. Under our agreement with the Celtic subsidiaries, we are eligible to receive milestone payments upon the achievement of certain regulatory objectives, and if XERECEPT is approved for commercial sale, we are eligible to receive profit-sharing payments on gross margins of XERECEPT in the United States and royalties on sales elsewhere in the world. However, because Celtic has assumed control of the clinical development of XERECEPT throughout the world, our ability to receive these payments largely depends on Celtic. Celtic controls the execution of clinical trials and will direct the final regulatory approval process and commercialization, if the product is approved. If Celtic is unable to successfully develop and market XERECEPT, we may not receive the potential development milestone payments and may not receive any royalty and/or profit-sharing payments, harming our financial condition and results of operations.

We face intense competition from other companies.

Our competitors are generally larger biotechnology or pharmaceutical companies, and the National Institute of Neurological Disorders and Stroke, or NINDS, all of which have significantly greater financial resources and experience. In addition, larger companies that compete with us generally have greater manufacturing, marketing, sales, distribution and managerial personnel resources than we do. Many of them also have much more experience than we do in clinical trials of new product candidates and in obtaining FDA and foreign regulatory approvals. Accordingly, we may not be able to develop products that will be as safe, efficacious or as cost-effective as currently-marketed products or those products being developed by our competitors. In addition, others may develop, manufacture and market products that could compete with those that we are developing.

For the treatment of acute ischemic stroke, the only currently approved drug treatment is marketed by Genentech, Inc., a much larger company. Additionally, other large pharmaceutical companies have pursued the development of treatments for ischemic stroke, including AstraZeneca and Forest. These companies have significantly more experience in developing new products and substantially greater financial resources. We may also face competition from medical devices that are currently used in the United States for the treatment of acute ischemic stroke.

If we do not continue to attract and retain key employees, our product development efforts and our operations will be impaired.

We depend on a small number of key management and scientific and technical personnel. There is a shortage of skilled personnel in our industry, we face intense competition in our recruiting efforts, and we may not be able to attract or train qualified personnel. In addition, Paul E. Freiman, our President and Chief Executive Officer, has informed our board that he intends to retire as of December 31, 2008. While we have initiated a search for a successor, we may not be able to find a suitable replacement before his retirement. Changes in our management team can be disruptive to our business and, if our management team cannot work together effectively, our ability to manage our business will suffer. Further, the loss of any of our other key employees, including Dr. Warren W. Wasiewski, our Chief Medical Officer; David E. Levy, M.D., our Vice President, Clinical Development, Matthew M. Loar, our Chief Financial Officer, and Karl G. Trass, our Vice President, Regulatory Affairs & Quality Assurance, could impair our product development efforts and harm our business. Our employment agreements with these individuals provide for "at-will" employment, which means that they may terminate their employment with us at any time.

Clinical trials or marketing of any of our potential products may expose us to liability claims from the use of such products, which our insurance may not cover.

We currently have a limited amount of product liability insurance for our clinical trials, with coverage limits of \$5 million per incident and \$5 million in the aggregate. It is possible that our current insurance may not be adequate to cover liabilities arising from our clinical trials. Our current product liability insurance does not cover the commercial sales of products, and we cannot be sure that we will be able to obtain product liability insurance covering commercial sales if and when they commence or, if such insurance is obtained, that sufficient coverage can be acquired at a reasonable cost. Any inability to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims could prevent or inhibit commercialization of any products we develop.

Our success will depend, in large part, on our ability to obtain or license patents, protect trade secrets and operate without infringing upon the proprietary rights of others.

The patent position of biotechnology firms generally is highly uncertain because:

- patents involve complex legal and factual issues that have recently been the subject of much litigation;
- no consistent policy has emerged from the United States Patent and Trademark Office regarding the breadth of claims allowed or the degree of protection afforded under biotechnology patents; and
- others may independently develop similar products, duplicate any of our potential products, or design around the claims of any of our potential patented products.

In addition, because of the time delay in patent approval and the secrecy afforded United States patent applications, we do not know if other applications, which might have priority over our applications, have been filed. As a result of all of these factors, there can be no assurance that patent applications relating to our potential products or processes will result in patents being issued, or that patents, if issued, will provide protection against competitors who may successfully challenge our patents, obtain patents that may have an adverse effect on our ability to conduct business, or be able to circumvent our patent position.

While no infringement claims have been brought against us by third parties, and while we are not aware of any basis on which such claims could be made, any infringement claims that are brought by a third party, even if these claims were ultimately found to be without merit, would be costly to defend against and would likely interfere with our operations while the claim was pending. If we were unsuccessful in defending against any such claims, it may be necessary for us to license certain additional rights. These licenses may be costly and may not be available on terms we find acceptable, if at all. Accordingly, the unfavorable resolution of any patent infringement claim could adversely affect our operations and prospects.

We have previously concluded that we have material weaknesses in our internal controls over accounting for certain complex transactions and other items, and we have restated financial statements from prior periods as a result of material weaknesses in our internal controls over accounting for highly complex issues and transactions.

We record certain transactions in our financial statements using complex accounting rules. Although we believe that we currently have the necessary expertise and resources to ensure that we properly account for these transactions in accordance with U.S. generally accepted accounting principles, we have had deficiencies in our internal controls over accounting for complex transactions and other items. For example, in fiscal 2007 we concluded that we had a material weakness in our internal controls over our financial reporting for stock options and accounts payable and accrued liabilities. In fiscal 2006, we concluded that we had a material weakness in our internal controls following the restatement of our financial statements for fiscal 2005 and a portion of fiscal 2006.

Although we have taken steps designed to remediate the weaknesses previously identified, the corrective actions taken may not be sufficient to correct the problems, or other accounting deficiencies could arise in the future. If our internal controls over financial reporting are deficient, we may not properly account for

transactions which could lead to another restatement of our financial statements. A restatement could have a negative impact on our stock price and negatively affect the credibility of our financial reporting in future periods.

Risks Related to Our Common Stock

The market price of our common stock has been, and is likely to continue to be, highly volatile.

The average daily trading volume of our common stock has historically been low, even when compared to that of other biopharmaceutical companies. Because of our relatively low trading volume, our stock price can be highly volatile. Any large sales of our stock could have a negative effect on the stock price. Additional factors that may affect the price include:

- announcements of the results of our clinical trials of Viprinex;
- announcements of our plans regarding clinical trials of Viprinex;
- announcements of the results of clinical trials of competitors or Celtic;
- other evidence of the safety or efficacy of our products, or those of Celtic, Merz or its marketing partners, or our competitors (such as rt-PA for stroke);
- announcements of technological innovations or new therapeutic products by us or our competitors;
- developments in patent or other proprietary rights of us or our competitors, including litigation;
- our need for additional capital or fluctuations in our operating results;
- government regulation and health care legislation; and
- market conditions for life science companies' stocks in general;

We may not continue to meet the listing standards of the NASDAQ Capital Market, which could result in our delisting and negatively impact the price of our common stock and our ability to access the capital markets.

Our common stock is listed on the NASDAQ Capital Market. The NASDAQ Capital Market provides various continued listing requirements that a company must meet in order for its stock to continue trading on NASDAQ. The requirements state that a company's stock may be delisted if the bid price of its stock drops below \$1.00 for a period of 30 consecutive business days or if the company fails to maintain (i) stockholders' equity of at least \$2.5 million, (ii) total market value of listed securities of at least \$35 million or (iii) net income from continuing operations of at least \$500,000 in the latest fiscal year or in two of the last three fiscal years. If we fail to comply with the continued listing standards of the NASDAQ Capital Market, our common stock may be delisted. The delisting of our common stock would significantly affect the ability of investors to trade our securities and would significantly negatively affect the value and liquidity of our common stock. In addition, the delisting of our common stock could materially adversely affect our ability to raise capital on acceptable terms acceptable or at all. Delisting from The NASDAQ Capital 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 certificate of incorporation, our bylaws, Delaware law and our stockholder rights plan contain provisions that could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current board and/or management.

Provisions of Delaware law, our certificate of incorporation, our bylaws and our stockholder rights plan may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current

management by making it more difficult for stockholders to replace or remove our Board of Directors. These provisions include:

- authorizing the issuance of “blank check” preferred stock without any need for action by stockholders; and
- providing for dilutive issuance of preferred stock, commonly referred to as a “poison pill,” which can generally be triggered after a person or a group acquires 15% or more of our common stock.

In addition, Section 203 of Delaware General Corporation Law may discourage, delay or prevent a change in control of our company by prohibiting stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us, unless certain approvals are obtained.

There may be issuances of shares of preferred stock in the future.

Although we currently do not have preferred shares outstanding, the board of directors could authorize the issuance of a series of preferred stock that would grant holders preferred rights to our assets upon liquidation, the right to receive dividends before dividends would be declared to common stockholders, and the right to the redemption of such shares, possibly together with a premium, prior to the redemption of the common stock. To the extent that we do issue preferred stock, the rights of holders of common stock could be impaired thereby, including without limitation, with respect to liquidation.

FORWARD-LOOKING STATEMENTS

This report, including the sections entitled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and “Business,” contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may, in some cases, use words such as “project,” “believe,” “anticipate,” “plan,” “expect,” “estimate,” “intend,” “should,” “would,” “could,” “potentially,” “will,” or “may,” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements in this report may include statements about:

- our ability to complete clinical trials for Viprinex;
- the timing and results of the interim analysis for the clinical trials for Viprinex;
- the timing and outcome of the final analysis for the current clinical trials of Viprinex;
- the completion, announcement and success of any other clinical trials that we commence and the progress of those trials;
- our receipt of regulatory approvals;
- our ability to maintain and establish intellectual property rights in our product candidates;
- whether any product candidate we commercialize is safer or more effective than other marketed products, treatments or therapies;
- our development activities, including development of Viprinex, and projected expenditures;
- our ability to have manufactured sufficient supplies of active pharmaceutical ingredient and drug product for clinical testing and commercialization;
- our ability to obtain licenses to any necessary third-party intellectual property;
- our ability to retain and hire necessary employees and appropriately staff our development programs;
- our cash requirements; and
- our financial performance.

There are a number of important factors that could cause actual results to differ materially from the results anticipated by these forward-looking statements. These important factors include those that we discuss in this report under the caption "Risk Factors." You should read these factors and the other cautionary statements made in this report as being applicable to all related forward-looking statements wherever they appear in this report. If one or more of these factors materialize, or if any underlying assumptions prove incorrect, our actual results, performance or achievements may vary materially from any future results, performance or achievements expressed or implied by these forward-looking statements. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal executive offices are located in an approximately 10,000 square foot facility in Emeryville, California that is occupied under an operating lease expiring in November 2010. In addition, we lease approximately 6,000 square feet of office space in Edgewater, New Jersey, where our operations relating to the development of Viprinex are based under an operating lease that expires in October 2009. We believe that our existing facilities are adequate to meet our needs for the foreseeable future and that suitable alternative space is readily available should we choose to or be unable to renew our leases at the conclusion of their terms.

ITEM 3. LEGAL PROCEEDINGS

While we are not currently a party to any material pending legal proceedings, from time to time we are named as a party to lawsuits in the normal course of our business.

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

On May 30, 2008, we held a special meeting of stockholders at which our stockholders approved amendments to our Equity Incentive Plan, increasing the number of shares authorized for issuance under the plan, increasing the size of annual non-employee director grants and making certain other changes. Aggregated results of the voting were 10,496,141 shares for the proposal, 9,800,261 shares against the proposal and 24,865 shares abstaining.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock is traded on the NASDAQ Capital Market under the symbol "NTII." The following table sets forth the high and low reported intraday sale prices of our common stock during the past two fiscal years as reported by the NASDAQ Capital Market.

	<u>High</u>	<u>Low</u>
Fiscal Year 2008		
Fourth Quarter	\$ 2.73	\$1.15
Third Quarter	\$ 3.15	\$2.00
Second Quarter	\$ 5.19	\$2.06
First Quarter	\$12.60	\$3.46

	<u>High</u>	<u>Low</u>
Fiscal Year 2007		
Fourth Quarter	\$15.68	\$ 9.94
Third Quarter	\$19.95	\$14.42
Second Quarter	\$22.54	\$13.93
First Quarter	\$22.40	\$15.47

As of August 31, 2008, there were approximately 210 holders of record of our common stock and a total of 26,924,124 shares of common stock outstanding. The number of holders of record does not include holders in "street name" which comprise the majority of our stockholders. No dividends have been paid on our common stock to date, and we do not anticipate paying any dividends in the foreseeable future.

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data presented below summarize certain financial information from the consolidated financial statements. The information below is not necessarily indicative of results of future operations. This information should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and notes in Item 8 of this Annual Report on Form 10-K in order to fully understand factors that may affect the comparability of the information presented below.

	<u>Fiscal Year Ended June 30,</u>				
	<u>2008</u>	<u>2007</u>	<u>2006</u>	<u>2005</u>	<u>2004</u>
	(In thousands, except per share data)				
Statement of Operations Data:					
Total revenues	<u>\$ 14,760</u>	<u>\$ 17,673</u>	<u>\$ 12,339</u>	<u>\$ 3,100</u>	<u>\$ 2,786</u>
Expenses:					
Research and development	24,581	26,737	22,808	10,749	2,098
Acquired in-process research and development ..	—	—	11,501	12,650	—
General and administrative	<u>6,876</u>	<u>6,537</u>	<u>5,968</u>	<u>4,927</u>	<u>3,101</u>
Total expenses	<u>31,457</u>	<u>33,274</u>	<u>40,277</u>	<u>28,326</u>	<u>5,199</u>
Operating loss	(16,697)	(15,601)	(27,938)	(25,226)	(2,413)
Interest income	1,254	493	399	249	128
Interest expense	(2,479)	—	—	—	—
Other income	<u>1,600</u>	<u>980</u>	<u>—</u>	<u>—</u>	<u>477</u>
Loss before income taxes	(16,322)	(14,128)	(27,539)	(24,977)	(1,808)
Provision for income taxes	—	—	(300)	—	—
Net loss	<u>\$(16,322)</u>	<u>\$(14,128)</u>	<u>\$(27,839)</u>	<u>\$(24,977)</u>	<u>\$(1,808)</u>
Basic and diluted net loss per share	<u>\$ (0.84)</u>	<u>\$ (3.26)</u>	<u>\$ (6.84)</u>	<u>\$ (6.59)</u>	<u>\$ (0.61)</u>
Shares used in basic and diluted net loss per share calculation	<u>19,437</u>	<u>4,338</u>	<u>4,070</u>	<u>3,790</u>	<u>2,954</u>

	As of June 30,				
	2008	2007	2006	2005	2004
	(In thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	\$ 29,980	\$ 8,957	\$ 15,248	\$ 8,506	\$ 20,734
Working capital	21,817	(3,973)	12,055	5,290	20,446
Total assets	43,187	10,921	22,499	9,815	21,384
Total current liabilities	9,042	14,222	9,609	3,816	661
Accumulated deficit	(125,591)	(109,269)	(95,141)	(67,302)	(42,325)
Stockholders' equity (deficit)	20,286	(22,093)	(11,402)	5,999	20,723

Selected quarterly financial information is summarized below:

	Quarterly Periods in the Fiscal Year Ended June 30, 2008				
	September 30	December 31	March 31	June 30	Total
	(In thousands, except per share data) (Quarterly amounts are unaudited)				
Quarterly Results of Operations:					
Total revenues	\$ 3,900	\$ 3,663	\$ 3,684	\$ 3,513	\$ 14,760
Research and development expenses	(5,460)	(7,416)	(5,945)	(5,760)	(24,581)
General and administrative expenses	(1,659)	(1,912)	(1,757)	(1,548)	(6,876)
Interest income	28	452	540	234	1,254
Other income (expense)	2,269	(1,670)	(1,585)	107	(879)
Net loss	<u>\$ (922)</u>	<u>\$ (6,883)</u>	<u>\$ (5,063)</u>	<u>\$ (3,454)</u>	<u>\$ (16,322)</u>
Basic and diluted net loss per share	<u>\$ (0.19)</u>	<u>\$ (0.36)</u>	<u>\$ (0.19)</u>	<u>\$ (0.13)</u>	<u>\$ (0.84)</u>
Shares used in basic and diluted net loss per share calculation	<u>4,772</u>	<u>19,313</u>	<u>26,913</u>	<u>26,913</u>	<u>19,437</u>

	Quarterly Periods in the Fiscal Year Ended June 30, 2007				
	September 30	December 31	March 31	June 30	Total
	(In thousands, except per share data) (Quarterly amounts are unaudited)				
Quarterly Results of Operations:					
Total revenues	\$ 4,781	\$ 4,020	\$ 4,878	\$ 3,994	\$ 17,673
Research and development expenses	(5,858)	(5,681)	(7,690)	(7,508)	(26,737)
General and administrative expenses	(1,494)	(1,565)	(1,686)	(1,792)	(6,537)
Interest income	153	116	84	140	493
Other income	—	—	—	980	980
Net loss	<u>\$ (2,418)</u>	<u>\$ (3,110)</u>	<u>\$ (4,414)</u>	<u>\$ (4,186)</u>	<u>\$ (14,128)</u>
Basic and diluted net loss per share	<u>\$ (0.57)</u>	<u>\$ (0.74)</u>	<u>\$ (1.04)</u>	<u>\$ (0.91)</u>	<u>\$ (3.26)</u>
Shares used in basic and diluted net loss per share calculation	<u>4,222</u>	<u>4,222</u>	<u>4,237</u>	<u>4,669</u>	<u>4,338</u>

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

OVERVIEW

We are a biopharmaceutical company focused on developing novel, first-in-class treatments for central nervous system conditions and other serious unmet medical needs. Our most advanced product candidate, Viprinex™ (ancrod), is in Phase 3 clinical testing as a novel investigational drug for the treatment of acute ischemic stroke. Stroke is one of the most prevalent, debilitating and costly diseases in the world, and there are few acceptable treatment options. Viprinex is a fibrinogen-reducing agent that is designed to expand the treatment window from three hours to six hours. In addition to Viprinex, we have rights to receive royalty payments from the sales of Namenda® (memantine HCL), an approved drug marketed for Alzheimer's disease. We also have rights to receive payments from the development of another investigational drug which is in Phase 3 clinical trials for the treatment of swelling associated with cerebral tumors. Our earlier stage pipeline also includes rights to two proteins in preclinical development for the treatment of Alzheimer's disease and Huntington's disease.

Below is an overview of key developments affecting our business over the course of fiscal 2008.

Financing activity

In September 2007 we implemented a one-for-seven reverse stock split and then in November 2007 completed an underwritten offering of approximately 21.8 million shares of common stock, at a price of \$2.75 per share, raising \$60.0 million in gross proceeds. After underwriting commissions and expenses, net proceeds of the offering were \$54.8 million. All share and per-share information contained in this report reflect the stock split and historical numbers have been restated to reflect the split.

Viprinex™, our Phase 3 investigational drug for acute ischemic stroke

We are currently conducting two Phase 3 clinical trials of Viprinex (ancrod) for acute ischemic stroke. The trials are referred to as Ancrod Stroke Program I and Ancrod Stroke Program II, or ASP I and ASP II. Although patient enrollment in the ASP trials in fiscal 2008 has been slower than planned, we have recently reached the number of patients required to conduct an interim analysis. We currently anticipate completing this interim analysis no later than the first quarter of calendar 2009. The interim analysis will be conducted based on the outcome of the first 500 patients treated in the studies, aggregated together as a single data set. For this interim analysis, an independent data safety monitoring board, or DSMB, will conduct a review of the outcome of the patients receiving Viprinex compared to the outcome of patients receiving placebo. If Viprinex does not meet specified minimum efficacy criteria, the DSMB has been instructed to inform us that it is futile for us to continue the trial, and we would then stop the studies. If the data indicates overwhelming efficacy, the DSMB may recommend stopping the studies for superiority. In addition to the interim efficacy analysis, the DSMB will also evaluate safety. If the trials continue following the interim analysis, we will not have access to any efficacy data until the trials are completed and full analysis on all patients has been completed.

XERECEPT®, a Phase 3 investigational drug for which we have rights to receive milestone and royalty/profit-sharing payments

Celtic continues to develop XERECEPT (corticorelin acetate) for the treatment of brain edema associated with cerebral tumors, and has informed us that it expects to report results of a Phase 3 clinical trial during late calendar 2008.

Amendment to Merz Agreement

In February 2008, we amended the agreement under which we receive royalties for sales of memantine from Merz and CMCC. We agreed to discontinue receiving royalties on sales of memantine outside of the United States, and agreed to a staged reduction in the royalty rate for sales in the United States. In return, Merz and CMCC agreed that they would not provide us notice of termination of the agreement before an

effective date of January 1, 2010. As a result, we expect that we will continue to receive royalty payments from Merz through at least January 1, 2010, but the amount of the payments will decrease from historical levels and will continue to decrease over this time.

Critical Accounting Policies

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires us to make judgments, assumptions and estimates that affect the amounts reported and the disclosures made. Actual results could differ materially from those estimates. The following are critical accounting policies and estimates that we believe are the most important and/or subjective items used in determining our financial condition and results of operations as presented in the consolidated financial statements.

Revenue recognition

Revenue from nonrefundable up-front fees where we continue involvement through a service agreement or other obligation is initially classified as "deferred revenue," a liability on our consolidated balance sheet. We subsequently amortize the deferred revenue into "collaboration service revenue" in the consolidated statement of operations over the period of our service obligations. Technology and collaboration service revenue is recognized according to the terms of the contractual agreements to which we are a party, when our performance requirements have been fulfilled, the amount is fixed and determinable, and collection is reasonably assured. Revenue from license fees with non-cancelable, non-refundable terms and no future performance obligations is recognized when collection is assured. Milestone payments are recognized when we have fulfilled development milestones and collection is also assured. Revenue from services performed for other parties is recorded during the period in which the expenses are incurred. As of June 30, 2008, we had \$18.8 million in deferred revenue related to our agreements with Celtic. We are amortizing this into the consolidated statement of operations on a straight-line basis through November 2011, when our service obligations to Celtic are scheduled to end.

Royalty revenue is generally recorded when payments are received, which is often one quarter after the period in which the products sales have occurred, because there is no information available to us on the product sales until the time we receive the royalty payment.

Revenue arrangements with multiple components are divided into separate units of accounting if certain criteria are met, including whether the delivered component has stand-alone value to the customer, and whether there is objective reliable evidence of the fair value of the undelivered items. Consideration received is allocated among the separate units of accounting based on their relative fair values, and the applicable revenue recognition criteria are identified and applied to each of the units.

Research and development expenses

Our research and development costs are expensed as incurred. Research and development includes clinical trial costs, development and manufacturing costs for investigational drugs, payments to clinical and contract research organizations, compensation expenses for drug development personnel, consulting and advisor costs, preclinical studies and other costs related to development of our product candidates. Research and development expenses include expenses that are incurred over multiple reporting periods, such as fees for contractors and consultants, patient treatment costs related to clinical trials and investigational drug manufacturing costs. We assess the level and related costs of the services provided during each reporting period, including the percentage of work completed through each reporting period, to determine the portion to expense in each period. The assessment of the percentage of work completed that determines the amount of research and development expense that should be recognized in a given period sometimes requires significant judgment. We apply our judgment and base our estimates on historical experience and the information available at the time of reporting.

Estimates Involved in Determining Fair Value of Investments

We estimate the fair value of our investments in Auction Rate Securities, or ARS, based on models of discounted cash flow and assumptions regarding future interest rates. The Company's investments in ARS were initially structured to provide liquidity via an auction process that reset the applicable interest rate at predetermined calendar intervals. Beginning in February 2008, failed auctions occurred throughout the ARS market, and since then all auctions for our ARS have been unsuccessful. While the credit rating of these securities remains high and the ARS are paying interest according to their terms, as a result of the potentially long maturity and lack of liquidity for ARS, we believe that the value of the ARS in our portfolio has been impaired. In the third quarter of fiscal 2008, we recorded an impairment charge to reduce the carrying value of the ARS by \$1,778,000, based on our judgment that the decline in value is other-than-temporary. Models estimating the value of ARS are complex and require estimates that can significantly change their value.

Equity Financing Warrants

We have issued warrants in connection with sales of our common stock to raise capital. We generally account for warrants we issue as a component of stockholders' equity when permitted under accounting rules. However, when the terms of the warrants require registered shares to be delivered to the investors, or require potential cash payments to be made under specified circumstances, we account for the estimated fair value of the warrants as a liability under the terms of Emerging Issues Task Force 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. This standard specifies that our ability to deliver registered shares upon an exercise of the warrants and our potential obligation to cash-settle the warrants are deemed to be beyond our control, and therefore the value of the warrants must be accounted for as a liability. As with stock-based compensation, there is a high degree of subjectivity involved in determining the input values needed to estimate the fair value of the warrants. Changes in these assumptions, particularly the estimated volatility, can materially affect the resulting estimates of the fair values of the warrants on our consolidated balance sheet.

Stock-based compensation

We account for stock options granted to employees using an estimate of the fair value of the stock option on the date that it is granted. This estimated fair value is recognized as an expense in the consolidated statement of operations on a straight-line basis over the vesting period of the underlying stock option, generally four years for employees and one to three years for directors. There is a high degree of subjectivity involved in estimating the input values needed to estimate the fair value of stock options. Changes in these assumptions, particularly the estimated volatility and the estimated term of the options, can materially affect the resulting estimates of the fair values of the options that are granted. In addition, the expenses recorded for stock-based compensation in our financial statements may differ significantly from the actual value realized by the recipients of the stock options — the stock options may expire worthless or otherwise result in little or no value to the recipient, or the stock options may be exercised when the stock price is significantly in excess of the option exercise price, resulting in value to the recipient greater than that estimated by the fair values reported in consolidated financial statements. Under accounting requirements, the expenses recorded in the consolidated financial statements are not adjusted to the actual amounts realized by stock option recipients. Users of the financial statements should understand that the expenses we recognize for stock-based compensation will not result in any payment of cash by us.

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements*, or SFAS 157. SFAS 157 defines fair value, establishes a market-based hierarchy for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 is applicable whenever another accounting pronouncement requires or permits assets and liabilities to be measured at fair value, but it does not expand or require any new fair value measures. The provisions of SFAS 157 are to be applied prospectively and are effective for our fiscal year beginning July 1, 2008. In February 2008, the FASB issued FASB Staff Position No. 157-2, *Effective Date of FASB Statement*

No. 157, delaying the effective date for non-financial assets and liabilities until fiscal years beginning after November 15, 2008, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis. We do not expect the adoption of SFAS 157 to have a material effect on our consolidated financial statements.

In June 2007, the Emerging Issues Task Force issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3, which requires nonrefundable advance payments for future research and development activities to be recorded as an asset and recognized as an expense as the goods are delivered or services are performed. EITF 07-3 will be effective for our fiscal year beginning July 1, 2008. We do not expect the adoption of EITF 07-3 to have a material effect on our consolidated financial statements.

In November 2007, the Emerging Issues Task Force, or EITF, issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property* ("EITF 07-1"). EITF 07-1 addresses arrangements with other companies to jointly develop, manufacture, distribute, and market products when the activities associated with these arrangements are conducted by the collaborators without the creation of a separate legal entity (that is, the arrangement is operated as a "virtual joint venture"). EITF 07-1 requires collaborators in such virtual joint venture arrangements to present the results of activities for which they act as the principal on a gross basis, and to report any payments received from or made to its other collaborators based on other applicable accounting guidance. EITF 07-1 is effective for collaborative arrangements in place at the beginning of annual periods beginning after December 15, 2008; for us this will be the fiscal year beginning July 1, 2009, and we will evaluate what effect, if any, the adoption of EITF 07-1 will have on our consolidated financial statements at a later date.

RESULTS OF OPERATIONS

Revenues

The major components of our revenue are as follows (in thousands):

	Fiscal Year Ended June 30,			Increase (Decrease) From Prior Year	
	2008	2007	2006	2008/2007	2007/2006
Royalty	\$ 8,253	\$ 6,853	\$ 5,063	\$ 1,400	\$ 1,790
XERECEPT sale	5,500	5,500	3,209	—	2,291
Collaboration services	1,007	5,320	4,067	(4,313)	1,253
Technology sale and collaboration services	6,507	10,820	7,276	(4,313)	3,544
	<u>\$14,760</u>	<u>\$17,673</u>	<u>\$12,339</u>	<u>\$(2,913)</u>	<u>\$5,334</u>

Total revenues of \$14,760,000 for fiscal year ended June 30, 2008 decreased by \$2,913,000 from revenues of \$17,673,000 in fiscal 2007. Our fiscal 2008 revenues consisted of \$8,253,000 from royalties on the commercial sales of memantine by Merz and its marketing partners, \$5,500,000 recognized from the fiscal 2006 sale of our rights and interests in XERECEPT to Celtic, and \$1,007,000 from the reimbursement of the direct expenses incurred for services provided to Celtic for administering the Phase 3 clinical trials and manufacturing of XERECEPT in the United States. Royalties were higher for fiscal year 2008 compared to fiscal 2007 because of higher sales of memantine by Merz and its marketing partners. Royalty payments we receive for future periods will be based on an amended royalty structure with Merz, and we will no longer receive royalties for sales of memantine outside the United States, which were \$1,064,000 and \$1,107,000 for fiscal 2008 and 2007, respectively. Revenues from the sale of XERECEPT were the same for fiscal 2008 and 2007 because we are recognizing the up-front payment of \$33 million we received in November 2005 on a straight-line basis over the estimated term of our obligations, which extends to November 2011. Revenues from collaboration services declined by \$4,313,000, or 81%, to \$1,007,000 for fiscal 2008 compared to fiscal 2007 because we have transitioned most of the XERECEPT drug development work to Celtic.

Revenues of \$17,673,000 in fiscal 2007 increased by \$5,334,000 compared to revenues of \$12,339,000 in fiscal 2006. All categories for which we report revenue increased from the prior year. The amount we recognize from the sale of XERECEPT increased by \$2,291,000 because our collaboration and service agreement with Celtic was in place for the full twelve months of fiscal 2007, as compared to approximately seven months during fiscal 2006. Collaboration services revenue also increased in fiscal 2007 as compared to fiscal 2006 because, likewise, there was a twelve month period in fiscal 2007 over which we provided services to Celtic as compared to seven months in fiscal 2006. Royalty revenue increased in fiscal 2007 as compared to fiscal 2006 because of higher sales of memantine by Merz and its marketing partners.

In future periods, we expect to record revenue from the sale of our rights and assets related to XERECEPT in the amount of \$5.5 million annually through November 2011, unless the agreements with Celtic are modified. We expect revenue from collaboration services to decline further since Celtic has directly assumed many of the responsibilities we previously handled on its behalf. We expect royalty revenue to decrease in future periods because we will no longer receive royalties on sales of memantine for Alzheimer's disease in Europe and there will be a staged reduction in royalty rates for sales in the United States.

Research and Development Expenses

Because we are in the business of drug development and our current drug candidates have not been approved for sale, our research and development costs are expensed as incurred. Research and development includes clinical trial costs, development and manufacturing costs for investigational drugs, payments to clinical and contract research organizations, compensation expenses for drug development personnel, consulting and advisor costs, preclinical studies and other costs related to development of our product candidates. The following table shows our research and development costs by product under development (in thousands):

	Fiscal Year Ended June 30,			Increase/(Decrease) From Prior Year	
	2008	2007	2006	2008/2007	2007/2006
Viprinex for stroke	\$22,071	\$21,208	\$15,962	\$ 863	\$ 5,246
XERECEPT	1,061	5,529	6,846	(4,468)	(1,317)
Preclinical programs for Alzheimer's and Huntington's diseases	1,449	—	—	1,449	—
	<u>\$24,581</u>	<u>\$26,737</u>	<u>\$22,808</u>	<u>\$(2,156)</u>	<u>\$ 3,929</u>

The majority of our research and development efforts are focused on Viprinex, a Phase 3 investigational drug for the treatment of acute ischemic stroke which we acquired rights to in July 2004. Since acquiring these rights we have established GMP manufacturing capability and initiated two large, international, well-controlled, double-blind, randomized Phase 3 studies designed to determine whether Viprinex is a safe and effective treatment for stroke when given within six hours of onset.

For fiscal year 2008, our expenditures on Viprinex aggregated \$22,071,000, an increase of 4% from expenses of \$21,208,000 for fiscal 2007. In fiscal year 2008 the Viprinex clinical trials and associated costs increased \$2,216,000 due to an increase in salaries and benefits as we hired additional personnel to oversee the clinical trials and qualify additional investigator sites for enrollment of patients, increased costs for training clinical investigators, increased clinical trial site expenses and lab costs. The increased clinical trial costs were partially offset by lower manufacturing expenses of \$1,243,000 following the completion of certain development work on the Nordmark snake facility in the 2007 fiscal year (the active ingredient in Viprinex is derived from the venom of the Malayan pit viper).

For fiscal year 2007, Viprinex expenses increased to \$21,208,000 compared to expenses of \$15,962,000 in fiscal 2006. The increase in our expenditures for Viprinex was due to increased manufacturing costs, related to costs of developing the snake farm, manufacturing and purification processes, and completing finished drug supply for use in the clinical trials and stability testing for the drug. Clinical costs also increased in fiscal 2007 compared to fiscal 2006 as we hired additional employees to manage the increase in enrollment and number of sites in our Phase 3 clinical trials of Viprinex.

For fiscal year 2008, our expenditures for XERECEPT of \$1,061,000 decreased \$4,468,000 from \$5,529,000 in fiscal 2007. Following our earlier sale of XERECEPT to Celtic, during fiscal 2008 we transitioned substantially all drug development activities to Celtic and are no longer incurring these costs. The decrease in our research and development costs for XERECEPT is comparable to the decrease in revenue for reimbursement of these costs by Celtic. In future periods, we expect our costs (and comparable reimbursement revenues) for XERECEPT to be similar to the levels of fiscal 2008.

Expenses for the XERECEPT program decreased in fiscal 2007 compared to fiscal 2006 because our agreement with Celtic was in place for the full fiscal 2007 compared to only a portion of fiscal 2006, and we began transitioning activities to Celtic which we previously handled directly, reducing costs that we incurred.

In fiscal 2008 we entered into two collaboration and license agreements with the Buck Institute for Age Research, or Buck, for the development of proteins in preclinical development for the treatment of Alzheimer's and Huntington's diseases. Under the agreements, we fund specified preclinical research work as performed by Buck in return for development rights to the proteins that are the subject of their research. There were no comparable costs for fiscal 2007 or 2006. If our research funding continues at the current level for fiscal 2009, we expect 2009 research costs for these proteins to be approximately \$2 million.

Through June 30, 2008, we have incurred approximately \$66 million of direct expenses on the development of Viprinex since our acquisition of Empire in July 2004, when we acquired the rights to Viprinex. These expenses are in addition to Viprinex-related expenditures of approximately \$24 million which we recorded as in-process research and development expenses related to our acquisition of Empire. We presently cannot estimate the cost of completing the development work on Viprinex required to receive approval from the FDA and begin marketing the drug candidate. These costs cannot be estimated because we are unable to reliably estimate future enrollment rates into the studies, and costs are highly dependent on the enrollment rates. If the rate of enrollment decreases from recent levels, it will take a longer period of time to complete the clinical trials, resulting in higher total costs; in such a case it is possible that we may not even be able to complete the trials. In addition, the outcome of the trials may not support an FDA approval of the drug candidate, or the FDA may require additional trials after reviewing the outcome of the current trials. We expect fiscal 2009 research and development costs to increase for the Viprinex program as additional patients are enrolled into our clinical trials, although we are still seeking to reduce expenses in areas where possible.

Acquired In-Process Research and Development Expenses

We acquired Empire Pharmaceuticals, Inc. in July 2004 to obtain the worldwide rights to Viprinex. In connection with the acquisition, a portion of the purchase price we agreed to pay was contingent upon our commencement of Phase 3 clinical trials. After we started these trials in November 2005, we made the contingency payment of \$11,501,000, consisting of cash of \$2,000,000 and 339,000 shares of common stock valued at \$9,501,000. Because the contingency was fulfilled and no further contingency payments were included in the agreement to acquire Empire, this item did not recur in fiscal 2008 or 2007.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs for executive management, finance, business development and human resources, as well as professional expenses, such as legal and audit, and facilities costs such as rent and insurance. General and administrative expenses were as follows (in thousands):

<u>Fiscal Year Ended June 30,</u>			<u>Increase from Prior Year</u>	
<u>2008</u>	<u>2007</u>	<u>2006</u>	<u>2008/2007</u>	<u>2007/2006</u>
\$6,876	\$6,537	\$5,968	\$339	\$569

General and administrative expenses, which include costs relating to our corporate operations in California and administrative operations for our office in New Jersey, were \$6,876,000 for fiscal 2008, a 5% increase from the expenses of \$6,537,000 for fiscal 2007. The increase of \$339,000 for fiscal 2008 is due primarily due to an increase in compensation and benefits after we hired additional personnel during the latter

half of fiscal 2007 to address the earlier material weaknesses in our internal control, and an increase in legal and consulting fees related to new contracts entered into during the fiscal 2008 period, both partially offset by a reduction in audit and consulting fees following our hiring of the additional administrative personnel.

General and administrative expenses of \$6,537,000 in fiscal 2007 increased by \$569,000 compared to expenses of \$5,968,000 in fiscal 2006. The increase in general and administrative expenses resulted primarily from increases for consultants and audit fees associated with a restatement of our financial statements, and higher employee salaries for employees hired during the year, partially offset by lower legal fees.

We are currently conducting a review of our operating structure and expenses, seeking areas in general and administrative expenses where there are potential cost savings.

Interest Expense

Interest expense relates to charges incurred for a bridge financing transaction in fiscal 2008 for which there was no comparable transaction in fiscal years 2007 or 2006.

Impairment Charge for Decrease in Fair Value of Investments

We recorded a charge of \$1,778,000 for the fiscal year ended June 30, 2008 for the decrease in value of our investments in ARS. ARS were structured to provide liquidity via an auction process that resets the applicable interest rate at predetermined calendar intervals. Beginning in February 2008, auctions failed to settle for the ARS held in our investment portfolio and we believe the value of these investments have been impaired. We recorded a charge for the impairment in the third quarter of our fiscal year based on a model of discounted future cash flows and assumptions regarding interest rates. There were no comparable charges for the periods in fiscal 2007 or 2006.

Interest Income

Interest income was \$1,254,000 for the fiscal year ended June 30, 2008; an increase of \$761,000 compared to the fiscal year ended June 30, 2007. The increased interest income in fiscal 2008 was due to our higher cash and investments balances following the underwritten public offering in November 2007, more than offsetting the decline in interest rates between the periods. Interest income increased by \$94,000 for the fiscal year ended June 30, 2007 compared to the fiscal year ended June 30, 2006 primarily due to higher cash and investment balances in fiscal 2007.

Non-cash Gain on Decrease in Fair Value of Warrants

The non-cash gain on decrease in fair value of warrants was \$3,378,000 for the fiscal year ended June 30, 2008, an increase of \$2,398,000 from the gain recorded in fiscal 2007. There was no comparable item in fiscal 2006. The non-cash gain on decrease in fair value of warrants represents changes in the Black-Scholes value of warrants we issued in April 2007, and this has occurred primarily as a result of the decrease in the price of our common stock for each of the fiscal 2008 and 2007 reporting periods. The April 2007 warrants require us to provide the investors with registered shares upon the warrants' exercise. The warrants may also require cash payments to be made in connection with certain fundamental transactions involving us or our common stock. Because accounting rules specify that delivery of registered shares is beyond the control of the company that issued the warrants, and also because in some circumstances there may be cash payments to the investors in lieu of a warrant exercise, we are required to account for the value of these warrants as a liability. We have estimated the liability based on the Black-Scholes option pricing model, and this warrant liability is re-valued on each reporting date with changes in the fair value from prior periods reported as a non-cash charge or gain to earnings.

LIQUIDITY AND CAPITAL RESOURCES

We assess liquidity primarily by the cash and investments available to fund our operations, which are primarily related to the continuation of the Phase 3 clinical trials of Viprinex for acute ischemic stroke, the

continued development of Viprinex manufacturing processes, and the administrative expenses of operating as a public company. We also assess liquidity by the working capital, modified to exclude deferred revenue and the warrant liability, available to fund operations. We exclude deferred revenue and the warrant liability from our working capital in the table below as we do not believe these items will ever require payments from our funds. The following table shows our cash and short-term investments and working capital (in thousands).

	<u>June 30,</u> <u>2008</u>	<u>June 30,</u> <u>2007</u>
Cash, cash equivalents and short-term investments.	\$29,980	\$8,957
Cash, cash equivalents, short-term and long-term investments	\$41,830	\$8,957
Working capital (excluding deferred revenue and the warrant liability).	\$27,357	\$4,945

Since our inception in 1987, we have applied the majority of our resources to our research and development programs and have generated only limited operating revenue. We have experienced operating losses in nearly every year since inception as we have funded the development and clinical testing of our drug candidates. We expect to continue to incur losses for the foreseeable future.

As of June 30, 2008, our combined balance of cash, cash equivalents and short-term investments increased by \$21.0 million from the balance at the end of our prior fiscal year at June 30, 2007. The combined balance including long-term investments increased by \$32.9 million. Our working capital (excluding deferred revenue and the warrant liability) increased by \$22.4 million. The increases were a result of \$54.8 million in net proceeds received from our sale of common stock in November 2007, partially offset by the operating activities of conducting our clinical trials and other operations as a company, which used approximately \$20.7 million in cash and short-term investments. We have classified approximately \$11.9 million of our auction-rate securities as long-term investments due to their current lack of liquidity.

We believe that our cash and investments (long and short-term combined) as of June 30, 2008 will be sufficient to fund our planned operations through at least the next twelve months. This estimate is based on the clinical trial scenario which assumes that we continue our two clinical trials beyond the interim analysis and enrollment into the trials increases from recent levels. If the DSMB recommends that the trials be stopped for futility or superiority, our cash and investments will last for a longer period of time as we would no longer incur on-going expenses for the current clinical trials. The estimates of our future liquidity will be materially impacted by our success or failure in enrolling patients into our Viprinex clinical trials. Either success or failure could increase our operating expenses, as success would involve additional incremental costs of the additional patients and a faster outflow of funds to pay these costs. Failure to enroll patients at the anticipated rate may require us to initiate additional potentially costly activities as we attempt to reach our targeted enrollment, and we will still incur fixed costs for our operations and the sites eligible to enroll patients. We may seek to raise additional funds when market conditions permit; however, there can be no assurance that funding will be available or that, if available, it will be on acceptable terms.

Our future capital requirements will depend on a number of factors, including:

- the time and cost involved in completing the clinical trials and obtaining regulatory approval for Viprinex;
- the value we are able to receive upon our disposition of the auction rate securities we hold as long-term investments;
- the royalties received from Merz for future sales of memantine;
- the receipt of milestone, royalty and profit-sharing payments pursuant to our agreements with Celtic;
- the progress of our clinical development programs;
- the cost of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights;
- the acquisition or licensing of new drug candidates;

- competing technological and market developments;
- our ability to establish collaborative relationships;
- the development of commercialization activities and arrangements; and
- the cost of our research collaborations with the Buck Institute for Age Research.

Contractual Obligations

Our total noncancelable obligations are summarized in the following table (in thousands):

	Payments Due by Period			
	Total	Less Than 1 Year	1-3 Years	Over 3 Years
Operating lease obligations	\$ 770	\$ 373	\$397	\$—
Manufacturing commitment(1)	4,410	4,410	—	—
Total	<u>\$5,180</u>	<u>\$4,783</u>	<u>\$397</u>	<u>\$—</u>

(1) Under our agreement for supply of the active pharmaceutical ingredient in Viprinex with Nordmark, we have agreed to make a termination payment of up to €2,800,000 in the event we cancel the agreement prior to the commercialization of Viprinex. Although we presently have no intention to cancel the agreement, the cancellation payment is a potential contractual obligation and is therefore included in the table. In the event that the current clinical trials are stopped for futility, we believe we would cancel the agreement as soon as we determine that further development of Viprinex is unlikely. Our obligation in Euros has been translated at a June 30, 2008 exchange rate of approximately \$1.575 per Euro.

In addition to our noncancelable contractual obligations, to develop our product candidates, particularly Viprinex, we periodically enter into agreements that require us to make regular payments to various parties in the normal course of business. Because we generally provide for our ability to terminate these agreements with a 30 day termination notice, we do not believe that our noncancelable contractual obligations at June 30, 2008 are material, except when a cancellation penalty may be required as noted in the table above. For a more thorough understanding of certain obligations relating to our business, even though they may be terminated, the following additional considerations are provided as convenience.

- *Active ingredient production/purification and operation of a snake farm.* Raw venom of the Malayan pit viper is the starting material for the active ingredient in Viprinex, and is produced by Nordmark in Germany where they maintain a colony of snakes in a manufacturing facility. We have agreed to make monthly payments to Nordmark for our supply of the active ingredient and for the fully burdened costs of operating the snake farm until such time as either 1) the agreement is terminated or 2) commercial production commences. If the agreement is terminated by us prior to commercialization, we are required to make a termination payment of up to €2.8 million (or approximately \$4.4 million) to Nordmark.
- *Finished Product Manufacturing.* The active pharmaceutical ingredient produced by Nordmark is shipped to Baxter Pharmaceutical Solutions LLC in the United States for production of the finished drug product. We make payments to Baxter based on the work performed. We have the right to cancel the agreement, provided we pay for the services performed up to the time of termination plus a portion of manufacturing work that has been scheduled but not completed.
- *Clinical Research Organizations for assistance overseeing the clinical trials.* We have agreements in place with various Clinical Research Organizations for work needed on the clinical trials in various foreign countries. We generally pay the CROs on a monthly basis for work as it is performed, and the terms of the agreements allow them to be cancelled with no obligations beyond the costs incurred by the CROs to the time of termination.

- *Medical Facilities conducting the clinical trials.* We generally pay medical facilities for each patient enrolled into our trials, and withhold a portion of total site compensation until all data required in the clinical trial protocol is received. The portion withheld is recorded as a liability in our consolidated financial statements.
- *Data Management.* We pay outside service organizations on a monthly or quarterly basis for services related to managing the data collected from the clinical trial.
- *License agreement for Viprinex.* We have an exclusive worldwide license for all human therapeutic indications for Viprinex from Abbott. Under this license, we have an obligation to use commercially reasonable efforts to develop Viprinex for the treatment of acute ischemic stroke. Milestone payments of up to \$2 million are due to Abbott upon various regulatory approvals of Viprinex, and if Viprinex is approved we will be required to make royalty payments to Abbott based on worldwide Viprinex sales. We are unable to estimate if and when Viprinex may be approved. In the event we sublicense the rights to Viprinex, additional payments may be due to Abbott based on the terms of the sublicense. We have the right to terminate the agreement for our convenience upon providing 90 days notice to Abbott, and Abbott has the right to terminate the agreement only in the event of our breach.
- *Employees.* All of our employees are employed on an "at-will" basis.
- *Buck Institute for Age Research.* We have entered into agreements with Buck for rights to preclinical proteins for the treatment of Alzheimer's disease and Huntington's disease. These agreements may be extended annually and we have the right to terminate the agreements upon 60 days notice if we determine the research program objectives cannot be substantially met. In addition, we have certain milestone obligations to Buck in the event that specified research goals are met.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

In the normal course of business, our financial position is subject to a variety of risks, including market risk associated with interest rate movements. We regularly assess these risks and have established policies and business practices designed to help us protect against these and other exposures. We do not anticipate material potential losses in these areas, but no policies or business practices can protect against all risks, and there is always a chance that unanticipated risks could arise and create losses for us.

We invest funds not needed for near-term operating expenses in diversified short-term and long-term investments, consisting primarily of investment grade securities. As of June 30, 2008, the fair value of our cash, cash equivalents and investments maturing in one year or less was \$30.0 million and represented 72% of our cash, cash equivalents and investment portfolio. A hypothetical 50 basis point increase in interest rates would not result in a material decrease or increase in the fair value of our available-for-sale securities due to the general short-term nature of our investment portfolio, or the regular resetting of interest rates on the securities we own which have an overall maturity date of more than one year. We have no investments denominated in foreign country currencies and therefore our investments are not subject to foreign currency exchange risk.

We have two offices in the United States and no offices in foreign locations. However, the manufacturer of the Active Pharmaceutical Ingredient, or API, in our lead investigational drug, Viprinex, is based in Germany and our obligations to this manufacturer are denominated in Euros. In addition, we have entered into agreements with clinical trial sites and service providers throughout the world, and as a result have payment obligations denominated in foreign currencies. Because we do not maintain any accounts in foreign currencies, decreases in the value of the United States dollar will increase our U.S. dollar costs as additional U.S. dollars would be necessary to pay the same costs denominated in the various foreign currencies.

As of June 30, 2008, we had \$11.9 million invested in ARS, issued principally by student loan agencies and generally rated AAA by a major credit rating agency. Our original purchase price for these securities was approximately \$13.2 million, which was subsequently written-down to a value of \$11.4 million during the third quarter of fiscal 2008. ARS are structured to provide liquidity via an auction process that resets the applicable interest rate at predetermined calendar intervals, which are approximately once a month. Beginning

in February 2008, auctions for the securities in our portfolio began to fail, and none have been successful since that time. We have classified all of our ARS as “long-term investments” as of June 30, 2008 and recorded a charge for the decrease in their value. We have estimated the fair value of these investments based on a model of discounted future cash flows and assumptions regarding interest rates. If the auctions for these securities continue to fail, the ARS may not be readily convertible into cash, and we may be required to take losses on the sale of the securities. Based on our expected cash usage for the next twelve months, we do not anticipate the current illiquidity of these investments will affect our ability to operate our business as usual for at least twelve months.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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All schedules are omitted because they are not required or the required information is included in the consolidated financial statements or notes thereto.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
Neurobiological Technologies, Inc.

We have audited the accompanying consolidated balance sheets of Neurobiological Technologies, Inc. as of June 30, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the three fiscal years in the period ended June 30, 2008. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements audited by us present fairly, in all material respects, the consolidated financial position of Neurobiological Technologies, Inc. at June 30, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three fiscal years in the period ended June 30, 2008, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the consolidated financial statements, on July 1, 2007, the Company adopted Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an Interpretation of FAS 109*.

Odenberg Ullakko Mumarishi & Co.

San Francisco, California
September 11, 2008

NEUROBIOLOGICAL TECHNOLOGIES, INC.
CONSOLIDATED BALANCE SHEETS

	June 30,	
	2008	2007
	(In thousands, except per share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 27,941	\$ 5,538
Short-term investments	2,039	3,419
Accounts receivable	599	430
Prepaid expenses and other current assets	280	862
Total current assets	30,859	10,249
Deposits	85	85
Long-term investments	11,850	—
Property and equipment, net	393	587
	\$ 43,187	\$ 10,921
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 588	\$ 1,623
Accrued clinical trial expenses	1,075	1,579
Accrued professional expenses	252	344
Accrued manufacturing and related expenses	581	825
Other accrued liabilities	1,006	933
Deferred revenue, current portion	5,500	5,500
Warrant liability	40	3,418
Total current liabilities	9,042	14,222
Deferred revenue, net of current portion	13,292	18,792
Long term clinical trial expenses and other liabilities	567	—
Total liabilities	22,901	33,014
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value, 5,000 shares authorized; 3,000 authorized shares designated as Series A convertible preferred stock, 2,332 shares issued, 494 shares outstanding at June 30, 2008 and 2007, with aggregate liquidation preference of \$247	247	247
Common stock, \$0.001 par value, 50,000 shares authorized, 26,924 and 4,691 shares issued and outstanding at June 30, 2008 and 2007, respectively . . .	27	5
Additional paid-in capital	145,113	86,930
Accumulated deficit	(125,591)	(109,269)
Accumulated other comprehensive income (loss)	490	(6)
Total stockholders' equity (deficit)	20,286	(22,093)
	\$ 43,187	\$ 10,921

See accompanying notes.

NEUROBIOLOGICAL TECHNOLOGIES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Fiscal Year Ended June 30,		
	2008	2007	2006
	(In thousands, except per share amounts)		
REVENUES:			
Royalty	\$ 8,253	\$ 6,853	\$ 5,063
Technology sale and collaboration services	<u>6,507</u>	<u>10,820</u>	<u>7,276</u>
Total revenues	<u>14,760</u>	<u>17,673</u>	<u>12,339</u>
EXPENSES:			
Research and development	24,581	26,737	22,808
Acquired in-process research and development	—	—	11,501
General and administrative	<u>6,876</u>	<u>6,537</u>	<u>5,968</u>
Total expenses	<u>31,457</u>	<u>33,274</u>	<u>40,277</u>
Operating loss	(16,697)	(15,601)	(27,938)
Interest expense, including non-cash amortization of \$2,336 discount on notes	(2,479)	—	—
Impairment charge for decrease in fair value of investments	(1,778)	—	—
Interest income	1,254	493	399
Non-cash gain on decrease in fair value of warrants	<u>3,378</u>	<u>980</u>	<u>—</u>
Loss before income taxes	(16,322)	(14,128)	(27,539)
Provision for income taxes	—	—	(300)
Net loss	<u><u>\$(16,322)</u></u>	<u><u>\$(14,128)</u></u>	<u><u>\$(27,839)</u></u>
Basic and diluted net loss per share	<u><u>\$ (0.84)</u></u>	<u><u>\$ (3.26)</u></u>	<u><u>\$ (6.84)</u></u>
Shares used in basic and diluted net loss per share calculation	<u><u>19,437</u></u>	<u><u>4,338</u></u>	<u><u>4,070</u></u>

See accompanying notes.

NEUROBIOLOGICAL TECHNOLOGIES, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Convertible Series A Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
	(In thousands, except per share amounts)							
Balances at June 30, 2005	504	\$252	3,868	\$ 4	73,048	\$ (67,302)	\$ (3)	\$ 5,999
Issuance of common stock upon exercise of stock options	—	—	12	—	70	—	—	70
Issuance of common stock under employee stock purchase plan	—	—	2	—	36	—	—	36
Issuance of common stock at \$28.00 per share in connection with acquisition	—	—	340	—	9,500	—	—	9,500
Conversion of preferred stock to common stock	(10)	(5)	1	—	5	—	—	—
Stock-based compensation expense	—	—	—	—	848	—	—	848
Comprehensive loss:								
Net loss	—	—	—	—	—	(27,839)	—	(27,839)
Unrealized loss on securities	—	—	—	—	—	—	(16)	(16)
Total comprehensive loss	—	—	—	—	—	—	—	(27,855)
Balances at June 30, 2006	494	247	4,223	4	83,507	(95,141)	(19)	(11,402)
Issuance of common stock upon exercise of stock options	—	—	37	—	473	—	—	473
Common stock received as consideration for exercise of stock options	—	—	(8)	—	(150)	—	—	(150)
Issuance of common stock under employee stock purchase plan	—	—	4	—	47	—	—	47
Issuance of common stock and warrants at \$16.10 per share of common stock, net of issuance costs	—	—	435	1	6,493	—	—	6,494
Reclassification of fair value of warrants issued to warrant liability	—	—	—	—	(4,398)	—	—	(4,398)
Stock-based compensation expense	—	—	—	—	958	—	—	958
Comprehensive loss:								
Net loss	—	—	—	—	—	(14,128)	—	(14,128)
Unrealized gain on securities	—	—	—	—	—	—	13	13
Total comprehensive loss	—	—	—	—	—	—	—	(14,115)
Balances at June 30, 2007	494	247	4,691	5	86,930	(109,269)	(6)	(22,093)
Issuance of common stock under employee stock purchase plan	—	—	22	—	42	—	—	42
Issuance of common stock at deemed price of \$5.95 per share in bridge financing transaction, net of issuance costs	—	—	393	—	2,326	—	—	2,326
Issuance of common stock at \$2.75 per share in public offering, net of issuance costs	—	—	21,818	22	54,809	—	—	54,831
Stock-based compensation expense	—	—	—	—	1,006	—	—	1,006
Comprehensive loss:								
Net loss	—	—	—	—	—	(16,322)	—	(16,322)
Unrealized gain on securities	—	—	—	—	—	—	496	496
Total comprehensive loss	—	—	—	—	—	—	—	(15,826)
Balances at June 30, 2008	494	\$247	26,924	\$27	\$145,113	\$(125,591)	\$490	\$ 20,286

See accompanying notes.

NEUROBIOLOGICAL TECHNOLOGIES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Fiscal Year Ended June 30,		
	2008	2007	2006
	(In thousands, except per share amounts)		
OPERATING ACTIVITIES			
Net loss	\$(16,322)	\$(14,128)	\$(27,839)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation and amortization	205	230	194
Stock-based compensation expense	1,006	958	848
Acquired in-process research and development	—	—	11,500
Impairment charge for decrease in value of investments	1,778	—	—
Amortization of note discount	2,336	—	—
Non-cash gain on decrease in fair value of warrants	(3,378)	(980)	—
Changes in assets and liabilities:			
Accounts receivable	(169)	1,140	(1,570)
Notes receivable	—	4,000	(4,000)
Prepaid expenses and other current assets	582	(45)	(271)
Deposits	—	—	30
Accounts payable and accrued expenses	(1,235)	1,195	293
Deferred revenue	(5,500)	(5,500)	29,792
Net cash provided by (used in) operating activities	(20,697)	(13,130)	8,977
INVESTING ACTIVITIES			
Acquisition of Empire Pharmaceuticals, Inc.	—	—	(2,000)
Purchase of investments	(22,918)	(52,038)	(91,201)
Sales and maturities of investments	11,166	54,172	93,375
Purchases of property and equipment	(11)	(66)	(349)
Net cash provided by (used in) investing activities	(11,763)	2,068	(175)
FINANCING ACTIVITIES			
Issuance of common stock and warrants, net of issuance costs	54,831	6,493	—
Proceeds from stock options and employee stock purchase	42	370	106
Issuance of common stock and notes in bridge financing transaction, net of issuance costs	5,990	—	—
Repayment of notes issued in bridge financing transaction	(6,000)	—	—
Net cash provided by financing activities	54,863	6,863	106
Increase (decrease) in cash and cash equivalents	22,403	(4,199)	8,908
Cash and cash equivalents at beginning of period	5,538	9,737	829
Cash and cash equivalents at end of period	\$ 27,941	\$ 5,538	\$ 9,737
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid for interest expense	\$ 143	\$ —	\$ —
Cash paid for income taxes	\$ —	\$ 275	\$ 130
SUPPLEMENTAL DISCLOSURE OF NON-CASH TRANSACTIONS:			
Issuance of common stock in connection with acquisition	\$ —	\$ —	\$ 9,500
Conversion of preferred stock to common stock	\$ —	\$ —	\$ 5

See accompanying notes.

NEUROBIOLOGICAL TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(tabular amounts in thousands, except per share amounts, percentages and years)

Note 1. Description of Business and Summary of Significant Accounting Policies

Business Description and Basis of Presentation

Neurobiological Technologies ("NTI" or "the Company") is a biopharmaceutical company focused on developing novel, first-in-class treatments for central nervous system conditions and other serious unmet medical needs. The Company's most advanced product candidate, Viprinex™, is in Phase 3 clinical testing as a novel investigational drug for the treatment of acute ischemic stroke. Stroke is one of the most prevalent, debilitating and costly diseases in the world, and there are few acceptable treatment options. Viprinex is a fibrinogen-reducing agent that is designed to expand the treatment window from three hours to six hours. In addition to Viprinex, the Company has the right to receive royalty payments from the sales of Namenda® (memantine HCL), an approved drug marketed for Alzheimer's disease. The Company also has rights to receive payments from the development of another investigational drug which is in Phase 3 clinical trials for the treatment of swelling associated with cerebral tumors. Additionally, NTI's earlier stage pipeline includes rights to two proteins in preclinical development for the treatment of Alzheimer's disease and Huntington's disease.

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, NTI-Empire, Inc. All significant intercompany accounts and transactions have been eliminated in consolidation. The Company operates in one business segment, the discovery and development of pharmaceutical products.

Reverse Stock Split

On September 17, 2007, the Company implemented a reverse stock split whereby each seven shares of common stock issued and outstanding immediately before the split were converted into one share of common stock after the split. All share and per share information contained in this filing has been adjusted to give effect to the split as if it had been in effect for all periods presented.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual amounts may differ from these estimates.

Revenue Recognition

Revenues are recognized according to the terms of contractual agreements to which NTI is a party, when the Company's performance requirements have been fulfilled, the amount is fixed and determinable, and collection is reasonably assured. Revenue from license fees with non-cancelable, non-refundable terms and no future performance obligations is recognized when collection is assured. Milestone payments are recognized when the Company has fulfilled development milestones and collection is assured. Revenue from services performed for other parties is recorded during the period in which the expenses are incurred.

Royalty revenue is generally recorded when payments are received.

Revenue arrangements with multiple components are divided into separate units of accounting if certain criteria are met, including whether the delivered component has stand-alone value to the customer, and whether there is objective reliable evidence of the fair value of the undelivered items. Consideration received is allocated among the separate units of accounting based on their relative fair values, and the applicable revenue recognition criteria are identified and applied to each of the units.

NEUROBIOLOGICAL TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued) (tabular amounts in thousands, except per share amounts, percentages and years)

Cash Equivalents and Investments

The Company's investments include securities of the U.S. government and its agencies, municipalities, corporations and auction rate securities. All securities which are highly liquid and purchased with original maturities of 90 days or less are recorded as cash equivalents. Securities which the Company does not intend to hold to maturity are generally classified as available-for-sale securities, and carried at estimated fair value, based on available market information, with unrealized gains and losses reported as a component of accumulated other comprehensive income or loss in stockholders' equity (deficit). A decline in the market value of a security below its cost that is deemed to be other than temporary is charged to earnings, and results in the establishment of a new cost basis for the security. In determining whether an impairment is other than temporary, the Company evaluates, among other factors, general market conditions, the financial condition of the investee, the duration and extent to which fair value is less than cost, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery. Realized gains or losses, amortization of premiums, accretion of discounts and earned interest are included in interest income. The cost of securities when sold is based upon specific identification.

The Company has classified its auction-rate securities ("ARS") as long-term investments due to the failed auctions for the ARS in the Company's portfolio, and has recorded an other than temporary impairment charge in the statement of operations for the decline in value of these securities.

Concentration of Credit and Other Risks and Uncertainties

Financial instruments which potentially subject the Company to concentration of credit risk consist primarily of cash, cash equivalents and investments. The Company's cash and cash equivalents are generally invested in deposit accounts, money market accounts, commercial paper, and high quality government and corporate debt securities. A deposit account balance may exceed the amount covered by insurance for loss.

The Company's lead product candidate, Viprinex, is in Phase 3 clinical development for the treatment of acute ischemic stroke. Development of new pharmaceutical products involves a high degree of risk, and failure can occur at any point in a product's development. Accordingly, Viprinex may never be successfully marketed. The business risk as a result of the Company concentrating substantially all of its efforts in a single product under development is significant.

Fair Value of Financial Instruments

The fair value of financial instruments, including cash and cash equivalents, short-term investments, accounts receivable and accounts payable and accrued liabilities, is representative of their respective fair values due to their short maturities.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is calculated on a straight-line basis over the estimated useful lives of the respective assets, generally two to seven years. Amortization of leasehold improvements is calculated on a straight-line basis over the shorter of the useful life of the asset or the remaining lease term.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, primarily its property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when future estimated cash flows expected to result from the use of the asset, and its eventual disposition, are less than the carrying amount of the asset. The

NEUROBIOLOGICAL TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued) (tabular amounts in thousands, except per share amounts, percentages and years)

impairment loss would be based on the excess of the carrying value over its respective fair value. Through June 30, 2008, the Company had not recorded any impairment losses on its long-lived assets.

Warrants Issued in Connection with Equity Financings

The Company generally accounts for warrants issued in connection with equity financings as a component of equity, unless there is a deemed possibility that the Company may have to settle warrants in cash. For the warrants issued with deemed possibility of cash settlement, the Company records the fair value of the issued warrants as a liability at each balance sheet date and records changes in the estimated fair value as a non-cash gain or loss in the consolidated statement of operations.

Research and Development Expenses

The Company's research and development costs are expensed as incurred. Research and development includes clinical trial costs, development and manufacturing costs for investigational drugs, payments to clinical and contract research organizations, compensation expenses for drug development personnel, consulting and advisor costs, preclinical studies and other costs related to development of its product candidates. Research and development expenses include certain expenses that are incurred over multiple reporting periods, such as fees for contractors and consultants, patient treatment costs related to clinical trials and investigational drug manufacturing costs. Management assesses the level and related costs of the services provided during each reporting period, including the percentage of work completed through each reporting period, to determine the portion to expense in each period. The assessment of the percentage of work completed that determines the amount of research and development expense that should be recognized in a given period sometimes requires significant judgment. Management applies its judgment and bases its estimates on historical experience and the information available at the time of reporting.

Acquired in-process research and development expenses

In July 2004, NTI acquired Empire Pharmaceuticals, Inc., or Empire, a development stage company, to obtain the rights to Viprinex for the treatment of acute ischemic stroke. The transaction was accounted for as a purchase of assets. Terms of the purchase required contingent stock and cash payments to be made to the selling shareholders upon the commencement of Phase 3 clinical trials of Viprinex. The trials were initiated in November 2005, and the Company recorded the contingent stock and cash payments of \$11,501,000 as acquired in-process research and development expense.

Stock-Based Compensation

Stock options granted to employees are accounted for using an estimate of the fair value of the stock option on the date it is granted. The estimated fair value on the grant date is recognized in the consolidated statement of operations on a straight-line basis over the vesting period of the underlying stock option.

Comprehensive loss

Components of other comprehensive loss, including unrealized gains and losses on available for sale investments, are included as part of total comprehensive loss. For all periods presented, comprehensive loss has been included in the consolidated statements of stockholders' equity (deficit).

Operating Leases

The Company recognizes rental expense on a straight-line basis over the term of each operating lease.

NEUROBIOLOGICAL TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued) (tabular amounts in thousands, except per share amounts, percentages and years)

Net Loss per Share

Net loss per share is calculated using the weighted-average number of shares of common stock outstanding during the period. Because the Company has not reported net income, whereby the impact of potentially dilutive securities would reduce the net income per share, the net loss position of the Company results in basic and diluted net loss per share being the same. The computation of diluted net loss per share for the fiscal year ended June 30, 2008 excludes the potentially dilutive impact of options to purchase 1,909,000 shares of common stock, warrants to purchase 544,000 shares of common stock, and the conversion of convertible preferred stock into 71,000 shares of common stock. The computation of diluted net loss per share for the fiscal year ended June 30, 2007 excludes the potentially dilutive impact of options to purchase 426,000 shares of common stock, warrants to purchase 544,000 shares of common stock, and the conversion of convertible preferred stock into 71,000 shares of common stock. The computation of diluted net loss per share for the fiscal year ended June 30, 2006 excludes the impact of options to purchase 369,000 shares of common stock, warrants to purchase 110,000 shares of common stock, and the conversion of convertible preferred stock into 71,000 shares of common stock.

Income Taxes

The Company uses the liability method of accounting for income taxes, and determines deferred tax assets and liabilities based on differences between the financial reporting and the tax reporting basis of assets and liabilities. The Company measures these assets and liabilities using enacted tax rates and laws that are scheduled to be in effect when the differences are expected to reverse. Because the realization of deferred tax assets is dependent upon future earnings, if any, and the Company's future earnings are uncertain, all of the Company's net deferred tax assets have been fully offset by a valuation allowance. The Company recognizes interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense.

The Company adopted the provisions of Financial Accounting Standards Board ("FASB") Interpretation No. 48, *Accounting for Uncertainty in Income Taxes — an Interpretation of FASB Statement No. 109* ("FIN 48"), on July 1, 2007. FIN 48 establishes a single model to address uncertainty in accounting for income taxes and requires a company to recognize in its financial statements the impact of a tax position if that position is more likely than not to be sustained on audit, based on the technical merits of the position. FIN 48 also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure, and transition. There was no material impact on the Company's financial condition or results of operations as a result of implementing FIN 48.

Recent Accounting Pronouncements

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* ("SFAS 157"). SFAS 157 defines fair value, establishes a market-based hierarchy for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 is applicable whenever another accounting pronouncement requires or permits assets and liabilities to be measured at fair value, but it does not expand or require any new fair value measures. The provisions of SFAS 157 are to be applied prospectively and are effective for the Company's fiscal year beginning July 1, 2008. In February 2008, the FASB issued FASB Staff Position No. 157-2, *Effective Date of FASB Statement No. 157*, delaying the effective date for non-financial assets and liabilities until fiscal years beginning after November 15, 2008, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis. The Company does not expect the adoption of SFAS 157 to have a material effect on its consolidated financial statements.

In June 2007, the Emerging Issues Task Force issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ("EITF 07-3"), which requires nonrefundable advance payments for future research and development activities

NEUROBIOLOGICAL TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)
(tabular amounts in thousands, except per share amounts, percentages and years)

to be recorded as an asset and recognized as an expense as the goods are delivered or services are performed. EITF 07-3 will be effective for the Company's fiscal year beginning July 1, 2008. The Company does not expect the adoption of EITF 07-3 to have a material effect on its consolidated financial statements.

In November 2007, the Emerging Issues Task Force issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property* ("EITF 07-1"). EITF 07-1 addresses arrangements with other companies to jointly develop, manufacture, distribute, and market products when the activities associated with these arrangements are conducted by the collaborators without the creation of a separate legal entity (that is, the arrangement is operated as a "virtual joint venture"). EITF 07-1 requires collaborators in such virtual joint venture arrangements to present the results of activities for which they act as the principal on a gross basis, and to report any payments received from or made to its other collaborators based on other applicable accounting guidance. EITF 07-1 is effective for collaborative arrangements in place at the beginning of annual periods beginning after December 15, 2008; for NTI this will be the fiscal year beginning July 1, 2009. The Company will evaluate what effect, if any, the adoption of EITF 07-1 will have on its consolidated financial statements at a later date.

Reclassifications

In order to conform to the current year's presentation, the Company has reclassified certain prior period items which were not material.

Note 2. Investments

Available-for-sale securities were as follows:

	As of June 30,			
	2008		2007	
	Cost	Market Value	Cost	Market Value
Type of security and term				
U.S government and agency obligations				
Maturing in one to five years	\$ —	\$ —	\$ 112	\$ 110
Auction rate securities ("ARS")				
Maturing in 22 to 37 years	11,372*	11,850	3,183	3,183
Corporate debt obligations				
Maturing within one year	2,027	2,039	15	15
Maturing in one to five years	—	—	20	20
Mortgage and asset-backed securities				
Maturing in over five years	—	—	95	91
Total investments	<u>\$13,399</u>	<u>\$13,889</u>	<u>\$3,425</u>	<u>\$3,419</u>
Classification				
Short-term		\$ 2,039		\$3,419
Long-term		11,850		—
Total investments		<u>\$13,889</u>		<u>\$3,419</u>

* Cost represents purchase price less impairment charge of \$1,768,000 on securities still held at June 30, 2008.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)
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The Company's investments in ARS were structured to provide liquidity via an auction process that resets the applicable interest rate at predetermined calendar intervals. Beginning in February 2008, failed auctions occurred throughout the ARS market, and all auctions for NTI's ARS have been unsuccessful. While the credit rating of these securities remains high and the ARS are paying interest according to their terms, as a result of the potentially long maturity and lack of liquidity for ARS, the Company believes the value of the ARS in NTI's portfolio has been impaired. The Company recorded an impairment charge to reduce the carrying value of the ARS by \$1,778,000 during the third quarter, based on a model of discounted future cash flows and assumptions regarding interest rates. The Company recorded an unrealized gain of \$478,000 on its ARS at June 30, 2008 based on an increase in the estimated fair value since the impairment charge was initially recorded in the third quarter of fiscal 2008. All other unrealized gains and losses were immaterial at June 30, 2008 and 2007. The Company has classified its ARS as long-term at June 30, 2008, and all other investments remain classified as short-term.

Realized losses were \$1,782,000 (including the impairment charge of \$1,778,000 for the ARS), \$4,000 and \$92,000 for the fiscal years ended June 30, 2008, 2007 and 2006, respectively. Realized gains were not material.

Note 3. Property and Equipment. Net

Property and equipment as of June 30, 2008 and 2007 consisted of the following:

	<u>2008</u>	<u>2007</u>
Manufacturing equipment	\$ 501	\$ 501
Furniture, fixtures and leasehold improvements	300	300
Machinery and equipment	289	278
	1,090	1,079
Less accumulated depreciation and amortization	(697)	(492)
	<u>\$ 393</u>	<u>\$ 587</u>

Note 4. Warrant Liability

In April 2007, the Company sold common stock and warrants in a registered direct offering. The terms of the warrants require registered shares to be delivered upon each warrant's exercise and also require possible cash payments to the warrant holders (in lieu of the warrant's exercise) upon specified fundamental transactions involving the Company's common stock, such as in an acquisition of the Company. Under Emerging Issues Task Force 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock* ("EITF 00-19"), the Company's ability to deliver registered shares upon an exercise of the warrants and the Company's potential obligation to cash-settle the warrants if specified fundamental transactions occur are deemed to be beyond the Company's control. As a result, EITF 00-19 requires the warrants to be classified as liabilities. The fair value of these warrants has been estimated based on a Black-Scholes option pricing model, and changes in the fair value are recorded in the consolidated statement of operations. The key assumptions used to value the warrants were as follows:

	<u>June 30,</u>	
	<u>2008</u>	<u>2007</u>
Volatility of common stock	0.70	0.79
Term of warrants (in years)	3.75	4.75
Risk-free interest rate	3.0%	4.9%
Dividend rate	—	—

NEUROBIOLOGICAL TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)
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Note 5. Commitments and Contingencies

The Company has operating leases in place for its two office locations. The lease for the Company's principal executive office in Emeryville, California expires in November 2010. The lease for the Company's clinical development office in Edgewater, New Jersey expires in October 2009. Future minimum lease payments due under these two operating leases are as follows at June 30, 2008:

Fiscal year ending June 30:	
2009	\$373
2010	292
2011	<u>105</u>
	<u>\$770</u>

Total lease expense for the fiscal years ended June 30, 2008, 2007, and 2006 was \$340,000, \$336,000 and \$338,000, respectively.

The Company has an exclusive worldwide license from Abbott Laboratories ("Abbott") to develop and market Viprinex for all human therapeutic indications. The Company is obligated to pay certain milestones to Abbott upon achieving key regulatory goals, such as product approval, as well as royalties on product sales. In the event NTI sublicenses the rights licensed from Abbott, additional payments may be due based on the terms of the sublicense.

Under an agreement with Nordmark Arzneimittel GmbH & Co. KG ("Nordmark"), the manufacturer and purifier of raw venom of the Malayan pit viper, the starting material for Viprinex, the Company is obligated to pay certain operating costs of a snake farm and a purification unit until the commercialization of Viprinex. In addition to the operating costs, if the Company abandons the development and/or commercialization of Viprinex before the end of 2010, NTI is required to provide Nordmark with an additional payment of up to €2.8 million, or approximately \$4.4 million based on the exchange rate at June 30, 2008.

The Company has engaged the services of various Clinical Research Organizations ("CROs") to support the Phase 3 clinical program in foreign countries. The agreements generally provide for monthly payments and reimbursements of costs incurred by the CROs, and are cancelable upon providing notice as specified in the agreements.

As permitted under Delaware law and in accordance with its Bylaws, NTI indemnifies its officers and directors for certain expenses incurred from legal or other proceedings that arose as a result of the director or officer's service to the Company. There is no limitation on the term of the indemnification and the maximum amount of potential future indemnification is unlimited. The Company has a director and officer insurance policy that limits NTI's exposure and may enable the Company to recover a portion of any future amounts paid. The Company believes the fair value of these indemnification agreements is minimal, and, accordingly, has not recorded any liabilities for these agreements as of June 30, 2008.

The Company also provides indemnifications of varying scope to clinical research organizations and investigators against claims made by third parties arising from the use of its products and processes in clinical trials. To date, costs related to these indemnification provisions have been immaterial. The Company also maintains various liability insurance policies that limit exposure under their terms. The Company believes the fair value of these indemnification agreements is minimal and, accordingly, has not recorded any liabilities for these agreements as of June 30, 2008. The Company is unable to estimate the maximum potential impact of these indemnification provisions on its future results of operations.

NEUROBIOLOGICAL TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued) (tabular amounts in thousands, except per share amounts, percentages and years)

From time to time, NTI may be involved in claims and other legal matters arising in the ordinary course of business. Management is not currently aware of any matters that it believes are likely to have a material adverse effect on the consolidated financial position, results of operations or cash flows of the Company.

Note 6. Stockholders' Equity (Deficit)

Series A Convertible Preferred Stock

Each share of Series A preferred stock is convertible, at the holder's option, into one-seventh of a share of common stock. Additionally, each share of the Series A preferred stock will be automatically converted into one-seventh of a share of common stock upon the affirmative vote of a majority of the then-outstanding shares of Series A preferred stock. The holders of preferred stock are entitled to the number of votes equal to the number of shares of common stock into which their preferred stock is convertible. Each share of Series A convertible preferred stock has a liquidation preference of \$0.50 per share plus any declared but unpaid dividends. The holders of the Series A preferred stock are entitled to receive annual noncumulative dividends of 8% per share, when and if declared by the Board of Directors.

Stockholder Rights Plan

Under a stockholder rights plan adopted in May 2005, the common stock of NTI trades with rights to acquire additional shares of the Company's common stock (the "Rights"). If a person or group acquires beneficial ownership of 15% or more of the Company's common stock (the "Acquiring Person") in a transaction not approved in advance by the Company's Board of Directors, each Right will entitle the holder, other than the Acquiring Person, to acquire additional shares of the Company's common stock at a formula price set forth in the Company's rights agreement. In November 2007, the Rights were modified to allow for an exception to the definition of Acquiring Person for a "Grandfathered Person," so long as such person does not acquire greater than a specified percentage of our common stock (initially, 20.4%), subject to certain limitations. The Rights were also modified to provide that Biotechnology Value Fund, L.P., together with its affiliates, is a "Grandfathered Person," subject to certain limitations.

The Rights will expire on May 27, 2015, and they may be redeemed by the Company's Board of Directors for a nominal amount at any time prior to an event that causes the Rights to become exercisable.

Common Stock Transactions

On November 2, 2007, the Company issued 21,818,000 shares of common stock in an underwritten offering at a public offering price of \$2.75 per share, for gross proceeds of \$60.0 million. After underwriting commissions and expenses, net proceeds were \$54.8 million.

On September 12, 2007, the Company entered into a debt and equity financing agreement under which the Company issued senior secured promissory notes with a principal amount of \$6.0 million and 393,000 shares of common stock. The gross proceeds of \$6.0 million were allocated to the promissory notes and common stock based on their relative fair values. The amount allocated to the common stock, \$2,336,000, was recorded as a discount to the notes and amortized to interest expense using the effective interest method over the term of the notes, which were repaid in November 2007. The notes provided for interest at 15% per annum. The effective annual interest rate on the notes was 326% based on the stated interest rate, the amount of the note discount, and the term of the notes.

On April 4, 2007, the Company issued 435,000 shares of common stock in a registered direct offering at a price of \$16.10 per share for gross proceeds of \$7.0 million. After placement agent fees and expenses, net proceeds were \$6.5 million. In connection with the placement, the Company also issued 461,000 warrants exercisable at \$16.80 per share to the investors and the placement agent. The warrants expire in April 2012.

NEUROBIOLOGICAL TECHNOLOGIES, INC.

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(tabular amounts in thousands, except per share amounts, percentages and years)

Securities Convertible into Common Stock

At June 30, 2008, the Company had reserved the following number of shares of common stock for future issuance:

Stock option and purchase plans	3,876
Warrants	544
Series A Convertible Preferred Stock	<u>71</u>
	<u>4,491</u>

Key terms of warrants outstanding at June 30, 2008 were as follows:

<u>Expiration Date</u>	<u>Exercise Price</u>	<u>Number of Shares</u>
August 2009	\$47.11	83
April 2012	\$16.80	<u>461</u>
		<u>544</u>

Note 7. Stock-based compensation

The Company has two stock-based compensation plans, the 2003 Equity Incentive Plan (the “Equity Plan”) and the 2003 Employee Stock Purchase Plan (the “ESPP”).

The Equity Plan provides for the issuance of stock options and stock awards to employees, officers, directors and consultants. In general, options are granted with an exercise price equal to or higher than the market price of the underlying common stock on the date of the grant, have terms of up to 10 years and become exercisable over vesting periods of up to four years. As of June 30, 2008, the Company has reserved a total of 3,835,000 shares of common stock for issuance under the Equity Plan and one additional option granted under similar terms, and 1,926,000 shares remain available for the future grant of stock options under the Equity Plan.

The ESPP permits eligible employees to purchase common stock through payroll deductions during defined six month accumulation periods. The price at which the stock is purchased is equal to the lower of 85% of the fair value of the stock on the last trading day before the commencement of the applicable offering period or 85% of the fair value of the common stock on the last trading day of the accumulation period. As of June 30, 2008, the Company has reserved a total of 71,000 shares of common stock for issuance under the ESPP, and 41,000 shares remain available for future issuance.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)
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The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model. Expected volatility for the Company's common stock is based on historical volatility of the Company's common stock for the expected term of the option granted. The expected term of options is based on the simplified method provided in Staff Accounting Bulletins 107 and 110. The Company has continued to use the simplified method for estimating the terms of options granted between January 1, 2008 and June 30, 2008 because its management believes the magnitude of the November 2007 underwritten public offering qualifies as a recapitalization of the Company, which is a significant structural change rendering historical option exercise data potentially unreasonable for estimating the expected term of options granted subsequently. Nevertheless, an expected-term analysis based on historical stock option grants for the Company's outstanding stock options at June 30, 2008 approximates the expected term under the simplified method. The risk free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The expected dividend yield is zero for all options granted, as the Company does not anticipate paying dividends in the near future. The Company's forfeiture assumptions are based on historical data. The following assumptions were used to determine the estimated fair value of the options granted under the Company's stock-based compensation plans:

	<u>4 Year Vesting 7 Year Term</u>	<u>4 Year Vesting 10 Year Term</u>	<u>3 Year Vesting 7 Year Term</u>	<u>1 Year Vesting 10 Year Term</u>
June 30, 2008:				
Expected volatility	0.75	0.90	0.80	0.82
Expected term (in years)	4.75	6.25	4.50	5.75
Risk-free interest rate	3.4%	2.9%	4.7%	3.5%
June 30, 2007:				
Expected volatility	0.79 - 0.93	1.08	0.80	0.89 - 0.90
Expected term (in years)	4.75	6.25	4.50	5.50
Risk-free interest rate	4.6% - 4.7%	4.7%	4.7%	4.6% - 4.7%
June 30, 2006:				
Expected volatility	—	1.10 - 1.27	—	1.27
Expected term (in years)	—	6.25	—	5.5
Risk-free interest rate	—	4.4 - 4.8%	—	4.4%

The weighted-average fair value of options granted during fiscal years 2008, 2007, and 2006 was \$1.29, \$13.10, and \$22.21 per share, respectively. Total stock-based compensation expense recognized in the statement of operations was as follows:

	<u>Fiscal Year Ended June 30,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
Research and development	\$ 283	\$346	\$340
General and administrative	<u>723</u>	<u>612</u>	<u>508</u>
	<u>\$1,006</u>	<u>\$958</u>	<u>\$848</u>

The Company has not recorded any income tax benefits for stock-based compensation arrangements as the Company has cumulative operating losses, for which a valuation allowance has been established. As of June 30, 2008, total compensation cost related to unvested stock options that has not yet been recognized in the financial statements was \$1.9 million, which will be expensed over the next 3.9 years.

NEUROBIOLOGICAL TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)
(tabular amounts in thousands, except per share amounts, percentages and years)

A summary of stock option activity for fiscal years 2006 through 2008 is summarized as follows:

	Options Available for Future Grant	Options Outstanding	
		Number of Shares	Weighted Average Exercise Price
Balance at June 30, 2005	49	320	\$20.86
Options granted	(67)	67	\$26.39
Options canceled and expired	6	(7)	\$26.55
Options exercised	—	(11)	\$ 6.02
Options authorized	<u>214</u>	<u>—</u>	<u>—</u>
Balance at June 30, 2006	202	369	\$22.26
Options granted	(105)	105	\$17.57
Options canceled and expired	10	(11)	\$22.35
Options exercised	<u>—</u>	<u>(37)</u>	<u>\$12.67</u>
Balance at June 30, 2007	107	426	\$21.84
Options granted	(1,417)	1,417	\$ 2.36
Option granted outside of plan	—	150	\$ 2.47
Options canceled and expired	36	(84)	\$18.39
Options exercised	—	—	—
Options authorized	<u>3,200</u>	<u>—</u>	<u>—</u>
Balance at June 30, 2008	<u>1,926</u>	<u>1,909</u>	\$ 6.04

The following table summarizes information concerning options outstanding and exercisable as of June 30, 2008:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Shares	Weighted Average Remaining Contractual Term in Years	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
\$1.35	243	7.0	\$ 1.35	—	\$ —
2.08	500	6.9	2.08	—	—
2.47 - 2.55	251	9.4	2.48	10	2.55
3.00	572	8.3	3.00	136	3.00
4.38 - 19.25	156	3.8	12.43	126	11.18
20.09 - 49.44	<u>187</u>	5.4	31.52	<u>170</u>	32.11
\$1.35-49.44	<u>1,909</u>	7.2	\$ 6.04	<u>442</u>	\$16.50

There were 288,000 and 280,000 options exercisable at June 30, 2007 and 2006, respectively. As of June 30, 2008, the aggregate intrinsic value of options outstanding was \$17,000, based on a June 30, 2008 closing stock price of \$1.42, and none of these options were exercisable.

Note 8. Collaboration Agreements

In July 2004, the Company acquired Empire to obtain the rights to Viprinex, which Empire had licensed from Abbott. Under the terms of the license agreement, NTI has an obligation to use commercially reasonable

NEUROBIOLOGICAL TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued) (tabular amounts in thousands, except per share amounts, percentages and years)

efforts to develop Viprinex for the treatment of acute ischemic stroke and, if Viprinex receives regulatory approval from the FDA, to market the product for that indication. The Company is required to make milestone payments to Abbott upon meeting specified regulatory objectives and will also be required to make royalty payments based on product sales. In the event the Company sublicenses rights to Viprinex, additional payments may be due to Abbott based on the terms of the sublicense. NTI has the right to terminate the agreement upon providing 90 days' notice and Abbott has the right to terminate the agreement only in the event of the Company's breach. During the fiscal years ended June 30, 2008, 2007 and 2006, no payments were made to Abbott under the license.

In April 1998, the Company entered into a license and cooperation agreement with Children's Medical Center Corp. ("CMCC") and Merz + Co. GmbH & Co. ("Merz") covering certain uses of memantine, an approved drug sold for the treatment of Alzheimer's disease. Merz in turn has licensed rights covering memantine to Forest Laboratories, Inc., H. Lundbeck A/S and Daiichi Suntory Pharma Co., Ltd., who are marketing the drug in different territories. Under terms of the agreement, as amended in February 2008, the Company receives royalties from Merz on the sales of memantine in the United States; and through September 30, 2007 also received royalties from sales of memantine for Alzheimer's disease in Europe. Beginning July 1, 2008, there will be a staged reduction in royalty rates for product sales in the United States. Merz has the right to terminate the license agreement upon six months notice, but not before an effective date of January 1, 2010. During the fiscal years ended June 30, 2008, 2007 and 2006, the Company recognized royalty revenue of \$8.3 million, \$6.9 million and \$5.1 million, respectively.

In November 2005, the Company sold its worldwide rights and assets related to XERECEPT, an investigational drug for brain swelling, to two subsidiaries of Celtic Pharma Holdings, L.P. ("Celtic"). Under the terms of the sale, the Company has received \$33 million in non-refundable upfront payments from Celtic. The Company is also entitled to receive payments upon the achievement of certain regulatory objectives and to receive profit-sharing payments or royalties if the product is approved and commercialized. In connection with the agreement to sell its rights to XERECEPT, the Company has entered into a collaboration and services agreement under which the Company provides on-going services to Celtic in exchange for reimbursement of the expenses incurred. The Company recognizes the costs incurred for the collaboration and services agreement in its operating expenses, and recognizes the reimbursement from Celtic as revenue when the expenses are incurred. The Company is recognizing the \$33 million in up-front payments as revenue on a straight-line basis over the term the Company is obligated to provide on-going services to Celtic, which extends to November 2011. During the fiscal years ended June 30, 2008, 2007 and 2006, the Company recognized \$1.0 million, \$5.3 million and \$4.1 million, respectively, as revenue for Celtic's reimbursement of NTI's expenses associated with the development of XERECEPT. During the fiscal years ended June 30, 2008, 2007 and 2006, the Company also recognized \$5.5 million, \$5.5 million and \$3.2 million, respectively, as revenue from the up-front payments received in fiscal year 2006. As of June 30, 2008, unearned contract revenue from the sale of rights and assets to Celtic was \$18.8 million.

In November 2007, the Company entered into a research collaboration and license agreement with the Buck Institute for Age Research ("Buck") to develop pre-clinical proteins for the treatment of Huntington's disease ("HD"). Under the terms of the agreement, the Company received a license to various patent rights for the use of specified proteins to treat HD. In return, the Company has agreed to fund specified research activities at Buck involving the proteins underlying the patent rights. The Company records the payments made to Buck as a component of its research and development expenses. Upon the achievement of specified events, the Company has agreed to make milestone payments to Buck, which will be accounted for as an expense in the period in which the milestones are earned. The Company has also agreed to pay royalties on the net sales of any proteins that are ultimately developed and approved under the collaboration. During the fiscal year ended June 30, 2008, the Company paid \$0.6 million to Buck under the license.

NEUROBIOLOGICAL TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)
(tabular amounts in thousands, except per share amounts, percentages and years)

In February 2008, the Company entered into a research collaboration and license agreement with Buck to develop pre-clinical proteins for the treatment of Alzheimer's disease ("AD"). Under the terms of the agreement, the Company received a license to various patent rights for the use of specified proteins to treat AD. In return, the Company has agreed to fund specified research activities at Buck involving the proteins underlying the patent rights. The Company records the payments made to Buck as a component of its research and development expenses. Upon the achievement of specified events, the Company has agreed to make milestone payments to Buck, which will be accounted for as an expense in the period in which the milestones are earned. The Company has also agreed to pay royalties on the net sales of any proteins that are ultimately developed and approved under the collaboration. During the fiscal year ended June 30, 2008, the Company paid \$0.7 million to Buck under the license.

Note 9. Income Taxes

There is no provision for income taxes for the fiscal years ended June 30, 2008 and 2007 because the Company has incurred operating losses. During the fiscal year ended June 30, 2006, the Company recorded a provision of \$300,000 for California alternative minimum tax and New Jersey state taxes.

Deferred tax assets reflect the net tax effects of net operating loss and tax credit carryforwards and temporary differences between the carrying amounts of assets for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows:

	<u>June 30,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
Deferred tax assets:			
Net operating losses	\$ 15,834	\$ 12,418	\$ 5,845
Deferred revenue	7,443	9,622	11,797
Research credits	18	1,298	898
Other	<u>1,386</u>	<u>546</u>	<u>400</u>
Total deferred tax assets	24,681	23,884	18,940
Valuation allowance	<u>(24,681)</u>	<u>(23,884)</u>	<u>(18,940)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

Realization of the deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the Company's net deferred tax assets have been fully offset by a valuation allowance. During the fiscal years ended June 30, 2008, 2007, and 2006, the valuation allowance increased by \$797,000, \$4,944,000 and \$5,969,000, respectively.

As of June 30, 2008, the Company had net operating loss ("NOL") carryforwards for federal income tax purposes of approximately \$41.5 million, which will expire in fiscal years 2024 through 2027, and federal research and development tax credits ("R&D credits") of approximately \$0.1 million which will expire in fiscal years 2020 through 2027. As of June 30, 2008, the Company also had NOL carryforwards for state income tax purposes in California of approximately \$25.8 million, which will expire in fiscal years 2013 through 2017, and state R&D credits in California of approximately \$0.7 million, which do not expire. The Internal Revenue Code (the "Code") provides limitations on the use of NOL carryforwards and R&D credit carryforwards when the Company's ownership changes, as defined in the Code. The Company has determined that an ownership change occurred on November 2, 2007, which will result in the expiration of certain NOL carryforwards and R&D tax credits before they can be used. The NOL and R&D credits available to the Company have been reduced to reflect the limitations provided in the Code. In addition, federal and state NOLs totaling \$41.5 million and \$25.8 million, respectively, at June 30, 2008 are subject to annual limitations

NEUROBIOLOGICAL TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)
(tabular amounts in thousands, except per share amounts, percentages and years)

as a result of ownership changes. Future ownership changes may result in additional annual limitations of NOL carryforwards and R&D credit carryforwards.

A reconciliation of the statutory U.S. federal income tax rate to the Company's effective income tax rate is as follows:

	Fiscal Year Ended June 30,		
	2008	2007	2006
Tax expense (benefit) at federal statutory rate	(35.0)%	(35.0)%	(35.0)%
Effect of:			
State tax expense (benefit), net	(5.3)%	(4.1)%	1.1
Share-based compensation expenses	1.9%	1.7%	1.1
In-process research and development expense	—	—	14.6%
Warrant gain	(7.2)%	(2.4)%	—
Losses not benefited	45.6%	39.8%	19.3%
Total provision for income taxes	—%	—%	1.1%

On July 1, 2007, the Company adopted FIN 48. Upon adoption, the Company reversed certain fully reserved deferred tax assets for uncertain tax benefits related to R&D credits totaling \$660,000 and the related valuation allowance. The following is a tabular reconciliation of the total amount of unrecognized tax benefits for the fiscal year ended June 30, 2008:

Balance at July 1, 2007	\$660
Increase (decrease) for current period tax positions	—
Balance at June 30, 2008	\$660

The Company does not currently expect any significant changes to the unrecognized tax benefits within 12 months of June 30, 2008. As of June 30, 2008, the Company's U.S. federal income tax returns remain subject to examination by tax authorities for fiscal years 1991 through 2008, and its state income tax returns remain subject to examination for fiscal years 1999 through 2008.

Note 10. 401(k) Savings Plan

The Company maintains a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code (the "Savings Plan"). The Savings Plan covers substantially all full-time employees. Participating employees may defer a portion of their pretax earnings, up to the limit established by the Internal Revenue Service, and are fully vested in their salary deferrals at all times. The Company currently matches the first \$500 of each employee's contributions, which vests over 2 years, and records these matching contributions as expense. The Company's matching contributions to the plan were \$15,000, \$13,000 and \$11,000 for the fiscal years ended June 30, 2008, 2007, and 2006, respectively.

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

None.

ITEM 9A(T). CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal accounting officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as of the end of the period covered by this report (the "Evaluation Date"). Based on this evaluation, our principal executive officer and principal accounting officer concluded as of the Evaluation Date that our disclosure controls and procedures were effective such that the material information required to be included in our Securities and Exchange Commission (SEC) reports is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms relating to us, including our consolidated subsidiary, and was made known to them by others within those entities, particularly during the period when this report was being prepared.

There were no changes in our internal controls or in other factors that could significantly affect these controls subsequent to the Evaluation Date.

Management's Report on Internal Control over Financial Reporting

We are responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) or 15d-15(f) under the Exchange Act). Under the supervision and with the participation of our management, including our principal executive officer and chief financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Controls — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and the related guidance provided in *Internal Control Over Financial Reporting — Guidance for Smaller Public Companies* also issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the preparation and fair presentation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) 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. 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.

Based on our evaluation under the framework in *Internal Controls — Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of June 30, 2008.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Our internal control over financial reporting was not subject to attestation by our independent registered public accounting firm pursuant to temporary rules of the SEC that permit us to provide only management's report in this annual report.

ITEM 9B. OTHER INFORMATION

In our fiscal fourth quarter which ended June 30, 2008, we had no events that were required to be reported on Form 8-K that were not filed to date. On September 11, 2008, the Board of Directors approved an increase in the annual base salaries for the Company's executive officers, effective as of September 1, 2008, and awarded annual bonuses to the executive officers based on performance for fiscal 2008. The adjusted base salaries and annual bonus amounts are summarized on Exhibit 10.32 filed herewith and incorporated herein by reference.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to the sections entitled "Proposal No. 1, Election of Directors," "Corporate Governance," "Board Meetings and Committees," "Executive Officers," and "Section 16(a) Beneficial Ownership Reporting Compliance" in our Proxy Statement for the Annual Meeting of Stockholders to be held November 13, 2008.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is hereby incorporated by reference to the section entitled "Executive Compensation" in our Proxy Statement for the Annual Meeting of Stockholders to be held November 13, 2008.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is hereby incorporated by reference to the section entitled "Security Ownership of Certain Beneficial Owners and Management" in our Proxy Statement for the Annual Meeting of Stockholders to be held November 13, 2008.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is hereby incorporated by reference to the section entitled "Certain Relationships and Related Transactions" in our Proxy Statement for the Annual Meeting of Stockholders to be held November 13, 2008.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is hereby incorporated by reference to the section entitled "Audit Fees" in our Proxy Statement for the Annual Meeting of Stockholders to be held November 13, 2008.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) *Financial Statements and Schedules:*

Financial statements as of June 30, 2008 and 2007, and for the three years ended June 30, 2008, are included in Item 8. All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

(b) *Exhibits:*

The following exhibits are incorporated by reference or filed as part of this report.

<u>Exhibit No.</u>	<u>Description</u>	<u>Incorporated by Reference</u>		<u>Filed Herewith</u>
		<u>Form</u>	<u>Date of Filing</u>	
3.1	Amended and Restated Certificate of Incorporation.	S-3	2/25/2005	
3(i).1	Certificate of Amendment to Amended and Restated Certificate of Incorporation.	10-Q	2/10/2006	
3.2	Amended and Restated Bylaws of Neurobiological Technologies, Inc.	8-K	6/20/2007	
3.3	Certificate of Designation, Preferences and Rights of Series RP Preferred Stock of Registrant.	8-A	5/20/2005	
4.1	Form of Common Stock Certificate.			x
4.2	Form of Warrant to Purchase Common Stock, issued March 1, 2004 to investors in a private placement transaction.	8-K	3/4/2004	
4.3	Form of Rights Certificate for RP Preferred Stock.	8-A	5/20/2005	
4.4	Form of Common Stock Warrant issued to certain institutional investors as a component of the units in a private placement transaction on April 4, 2007.	8-K	4/2/2007	
10.1	Form of Indemnity Agreement between the Company and its directors and officers.*			x
10.2	Rights Agreement, dated May 19, 2005, by and between American Stock Transfer & Trust Co., as Rights Agent, and the Company.	8-A	5/20/2005	
10.3	Amendment No. 1 to Rights Agreement	8-A	11/5/2007	
10.4	1993 Stock Plan.*	14A	10/9/2001	
10.5	Amended and Restated 2003 Equity Incentive Plan.*	14A	4/3/2008	
10.6	2003 Employee Stock Purchase Plan.*	14A	10/9/2003	
10.7	Office Lease Agreement, dated April 22, 2005, by and between CA-Emeryville Properties Limited Partnership and the Company.	10-Q	5/10/2005	
10.8	Commercial Sublease, dated May 18, 2005, between the Company and Refac.	10-K	9/28/2005	
10.9	License Agreement, dated as of March 29, 2002, by and between Abbott Laboratories and Empire Pharmaceuticals, Inc.+	10-K	9/28/2005	
10.10	First Amendment to License Agreement, dated as of October 22, 2003, by and between Abbott Laboratories and Empire Pharmaceuticals, Inc.+	10-K	9/28/2005	
10.11	Cooperation and Supply Agreement, dated March 1, 2005, by and between the Company and Nordmark Arzneimittel GmbH & Co. KG.+	10-Q	5/10/2005	
10.12	Agreement on the Establishment of a Snake Farm and Purification Unit, dated January 18, 2006, by and between the Company and Nordmark Arzneimittel GmbH & Co. KG.	10-K	11/6/2006	
10.13	Amendment to the Agreement on the Establishment of a Snake Farm and Purification Unit, dated March 6, 2006, by and between the Company and Nordmark Arzneimittel GmbH & Co. KG.	10-K	11/6/2006	
10.14	Drug Product Development and Clinical Supply Agreement, dated as of April 1, 2005, by and between the Company and Baxter Pharmaceutical Solutions LLC+	10-K	9/28/2005	
10.15	Project Contract, dated May 1, 2004, by and between the Company and ICON Clinical Research, L.P.	10-K	9/28/2005	

<u>Exhibit No.</u>	<u>Description</u>	<u>Incorporated by Reference</u>		<u>Filed Herewith</u>
		<u>Form</u>	<u>Date of Filing</u>	
10.16	Project Contract, dated January 1, 2005, by and between the Company and ICON Clinical Research, L.P.	10-K	9/28/2005	
10.17	Master Clinical Services Agreement, dated January 16, 2007, by and between the Company and ICON Clinical Research Limited.	10-K	9/13/2007	
10.18	Master Clinical Development Agreement, dated as of July 25, 2005, by and between the Company and SCIREX Corporation.	10-K	9/28/2005	
10.19	Amendment to Agreement by and between the Company and SCIREX Corporation, dated April 26, 2006.	10-K	11/6/2006	
10.20	Agreement between the Company and Children's Medical Center Corp., effective as of April 16, 1998.+	10-KSB	9/29/1998	
10.21	License and Cooperation Agreement among the Company, Merz+ Co. GmbH & Co. and Children's Medical Center Corp., effective as of April 16, 1998.+	10-Q	2/8/2007	
10.22	Amendment to License and Cooperation Agreement among the Company, Merz+ Co. GmbH & Co. and Children's Medical Center Corp., dated as of February 20, 2008.+	10-Q	5/12/2008	
10.23	Asset Purchase Agreement, dated September 19, 2005, by and between the Company, Neutron ROW Ltd. and Neutron Ltd.	10-Q	11/9/2005	
10.24	Collaboration and Services Agreement, dated November 28, 2005, by and between Neutron Ltd. and the Company.	8-K	12/1/2005	
10.25	Collaboration and License Agreement, entered into as of November 29, 2007, by and between Buck Institute for Age Research and the Company for the fibroblast growth factor-2.+	10-Q	5/12/2008	
10.26	Collaboration and License Agreement, entered into as of February 29, 2008, by and between Buck Institute for Age Research and the Company for the Netrin-1 protein.+	10-Q	5/12/2008	
10.27	Securities Purchase Agreement between the Company and certain institutional investors, dated March 30, 2007.	8-K	4/2/2007	
10.28	Securities Purchase Agreement, dated as of September 12, 2007, by and among the Company and the purchasers listed therein.	8-K	9/12/2007	
10.29	Security Agreement, dated as of September 12, 2007, by and between the Company and U.S. Bank National Association, as Trustee under the Indenture.	8-K	9/12/2007	
10.30	Consulting Agreement between the Company and Lisa U. Carr, M.D., Ph.D., dated July 1, 2007.*	8-K	7/6/2007	
10.31	Employment Offer Letter, dated March 18, 2008, by and between the Company and Matthew M. Loar.*	8-K	4/3/2008	
10.32	Fiscal 2009 executive officer base salaries and fiscal 2008 bonus amounts.*			x
21.1	Subsidiary of the Company.			x
23.1	Consent of Odenberg, Ullakko, Muranishi & Co. LLP, Independent Registered Public Accounting Firm.			x
24.1	Powers of Attorney. (Contained on Signature Page)			x
31.1	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			x
31.2	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			x

<u>Exhibit No.</u>	<u>Description</u>	<u>Incorporated by Reference</u>		
		<u>Form</u>	<u>Date of Filing</u>	<u>Filed Herewith</u>
32.1	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			X
32.2	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			X

+ Confidential treatment has been granted with respect to portions of this exhibit pursuant to an application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934. A complete copy of this exhibit, including the redacted terms, has been separately filed with the Securities and Exchange Commission.

* This exhibit is a management contract or compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Neurobiological Technologies, Inc.

By: /s/ PAUL E. FREIMAN

Paul E. Freiman
President and Chief Executive Officer

Dated: September 16, 2008

POWERS OF ATTORNEY AND SIGNATURES

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Paul E. Freiman and Matthew M. Loar, and each of them, as his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them or their substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ PAUL E. FREIMAN</u> Paul E. Freiman	Director, President and Chief Executive Officer (Principal Executive Officer)	September 16, 2008
<u>/s/ MATTHEW M. LOAR</u> Matthew M. Loar	Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	September 16, 2008
<u>/s/ ABRAHAM E. COHEN</u> Abraham E. Cohen	Chairman of the Board	September 16, 2008
<u>/s/ THEODORE L. ELIOT, JR.</u> Theodore L. Eliot, Jr.	Director	September 16, 2008
<u>/s/ WILLIAM A. FLETCHER</u> William A. Fletcher	Director	September 16, 2008
<u>/s/ F. VAN KASPER</u> F. Van Kasper	Director	September 16, 2008
<u>/s/ ABRAHAM D. SOFAER</u> Abraham D. Sofaer	Director	September 16, 2008
<u>/s/ JOHN B. STUPPIN</u> John B. Stuppin	Director	September 16, 2008

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BOARD OF DIRECTORS

Abraham E. Cohen
Chairman of the Board,
Neurobiological Technologies, Inc.
Chairman and President, Kramex Company

Theodore L. Eliot, Jr.
Retired US Foreign Service
Officer and Ambassador

William A. Fletcher
Former President and CEO, Teva
Pharmaceutical Industries Ltd.
North America

Paul E. Freiman
President and Chief Executive Officer,
Neurobiological Technologies, Inc.

F. Van Kasper
Retired Chairman, Wells Fargo Securities

Abraham D. Sofaer
Senior Fellow, Hoover Institution,
Stanford University

John B. Stuppin
Independent Investment Banker
and Venture Capitalist

MANAGEMENT

Paul E. Freiman
President and Chief Executive Officer

David E. Levy, M.D.
Vice President, Clinical Development

Matthew M. Loar
Vice President, Chief Financial Officer

Karl G. Trass
Vice President, Regulatory Affairs &
Quality Assurance

Warren W. Wasiewski, M.D.
Vice President, Chief Medical Officer

CORPORATE COUNSEL

Goodwin Procter LLP
San Diego, California

**INDEPENDENT REGISTERED
PUBLIC ACCOUNTING FIRM**

Odenberg, Ullakko, Muranishi & Co. LLP
San Francisco, California

TRANSFER AGENT

American Stock Transfer and Trust Co.
Brooklyn, New York
www.amstock.com
800-937-5449

ANNUAL MEETING

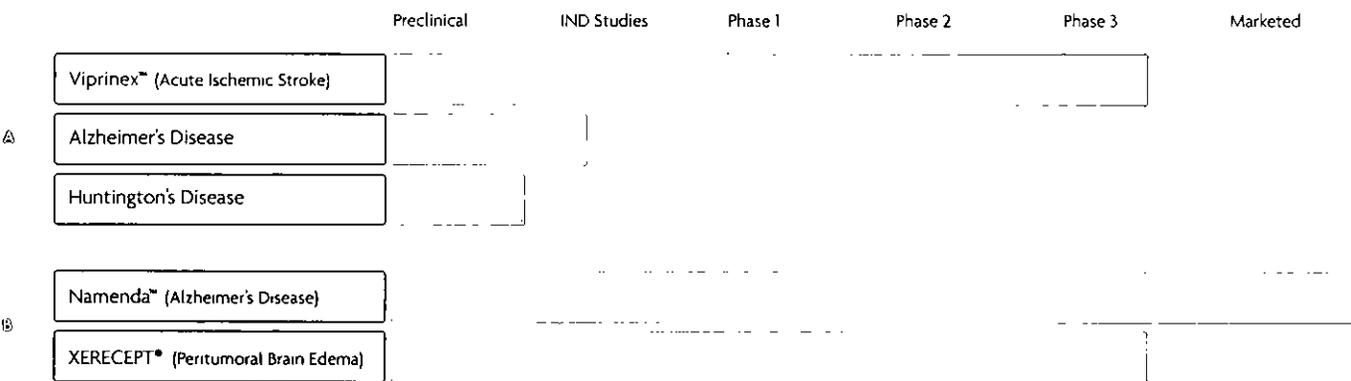
The 2008 Annual Meeting of Stockholders
will take place on November 13 at 10:00 am
at the Grand Hyatt San Francisco, 345
Stockton Street, San Francisco, California.

STOCKHOLDER INFORMATION

As of September 30, 2008, there were
26,924,124 shares of common stock
outstanding. The common stock of
Neurobiological Technologies, Inc. is
traded on the NASDAQ Capital Market
under the symbol NTII.

Neurobiological Technologies, Inc.
2000 Powell Street, Suite 800
Emeryville, CA 94608
Telephone 510-595-6000

Pipeline



A. Development of the drug is ongoing. Rights Reserved by the Company.

B. Development of the drug is ongoing. Rights Reserved by the Company.

www.ntii.com



Neurobiological Technologies, Inc.

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Emeryville, California 94608
510-595-6000 Telephone
510-595-6006 Facsimile

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