

NEUROBIOLOGICAL TECHNOLOGIES INC /CA/

Form 10-K

September 28, 2005

Table of Contents

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended June 30, 2005

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)

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

2000 Powell Street, Suite 800, Emeryville, California 94608

(Address of Principal Executive Offices)

(510) 595-6000

(Registrant's telephone number, including area code)

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

None

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

Common stock, \$.001 Par Value

Preferred Share Purchase Rights

(Title of Class)

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

Indicate by check mark 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 an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes No

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

As of September 26, 2005, the issuer had outstanding 27,077,418 shares of common stock.

The aggregate market value of the shares of common stock held by non-affiliates as of December 31, 2004, the registrant's most recently completed second fiscal quarter, was approximately \$119,577,000 based upon the last sale price of the issuer's common stock reported on The NASDAQ SmallCap Market on that date.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2005 Annual Meeting of Stockholders, to be held December 6, 2005 and expected to be filed with the Commission no later than October 28, 2005, are incorporated by reference into Part III of this report.

Table of Contents

Table of Contents

Part I

Item 1	<u>Business</u>	1
Item 2	<u>Properties</u>	16
Item 3	<u>Legal Proceedings</u>	16
Item 4	<u>Submission of Matters to a Vote of Security Holders</u>	16

Part II

Item 5	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	16
Item 6	<u>Selected Financial Data</u>	17
Item 7	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
Item 7A	<u>Quantitative and Qualitative Disclosure about Market Risk</u>	37
Item 8	<u>Financial Statements and Supplementary Data</u>	38
Item 9	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	60
Item 9A	<u>Controls and Procedures</u>	60
Item 9B	<u>Other Information</u>	62

Part III

Item 10	<u>Directors and Executive Officers of the Registrant</u>	63
Item 11	<u>Executive Compensation</u>	66
Item 12	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	67
Item 13	<u>Certain Relationships and Related Transactions</u>	67
Item 14	<u>Principal Accountant Fees and Services</u>	67

Part IV

Item 15	<u>Exhibits, Financial Statements and Financial Statement Schedules</u>	68
	<u>Signatures</u>	71

Table of Contents

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 may, will, should, expects, plans, anticipates, be, estimates, predicts, potential, or continue, 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 the caption Other Factors that May Affect Future Results. Except as may be required by law, we undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

OVERVIEW

Neurobiological Technologies, Inc., alternatively referred to in this report as NTI, we, us, our, or the Company, is a biotechnology company engaged in the business of acquiring and developing central nervous system (CNS) related drug candidates. The Company is focused on therapies for neurological conditions that occur in connection with dementia, Alzheimer's disease, ischemic stroke, neuropathic pain and brain cancer.

Our strategy is to in-license and develop later stage drug candidates that target major medical needs and that can be rapidly commercialized. Our experienced management team oversees the human clinical trials necessary to establish preliminary evidence of efficacy and then seeks partnerships with pharmaceutical and biotechnology companies for late-stage development and marketing of our product candidates. Currently, we receive revenues on the sales of one approved product and have two product candidates in clinical development. The approved product, Memantine, is an orally dosed compound that is approved for the treatment of moderate-to-severe Alzheimer's disease and is marketed in the United States and Europe by our marketing partners. As of the end of our fiscal 2005, Memantine was also being developed for the treatment of neuropathic pain. In September 2005, we entered into a definitive agreement for the sale of our rights and assets related to XERECEPT[®], a compound for the treatment of peritumoral brain edema, or swelling around brain tumors, to two subsidiaries of Celtic Pharma Holdings, L.P., or Celtic, and these entities will assume responsibility for the clinical development of XERECEPT. We are also developing Viprinex[®] for the treatment of acute ischemic stroke.

MEMANTINE

In April 1998, we entered into a strategic research and marketing cooperation agreement with Merz Pharmaceuticals GmbH, or Merz, and Children's Medical Center Corporation (CMCC) to further the clinical development and commercialization of Memantine. Pursuant to this agreement, we share in revenues from worldwide sales of Memantine for Alzheimer's disease and all indications covered by the CMCC patents, including AIDS-related dementia and diabetic neuropathy. However, we do not receive royalties on Merz's sales of Memantine for dementia syndrome or for Alzheimer's disease in certain countries where Merz had pre-existing marketing or other commercial arrangements, including Japan, Korea and China; Germany, Italy, Spain and several other smaller European markets; and much of Latin America, but excluding Brazil. We have no significant ongoing obligations under the

Table of Contents

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 neuropathic pain.

In June 2000, Merz entered into an agreement with Forest Laboratories, Inc., or Forest, for the development and marketing of Memantine in the United States for the treatment of Alzheimer's disease, neuropathic pain and AIDS-related dementia. In August 2000, Merz entered into a strategic license and cooperation agreement with H. Lundbeck A/S of Copenhagen, Denmark, or Lundbeck, for the further development and marketing of Memantine for the treatment of Alzheimer's disease, neuropathic pain and AIDS-related dementia. Lundbeck acquired exclusive rights to Memantine in certain European markets, Canada, Australia and South Africa, as well as semi-exclusive rights to co-market Memantine with Merz in other markets worldwide, excluding the United States and Japan, where Merz has granted development rights to Forest and Daiichi Suntary Pharma Co., Ltd., or Suntary, respectively. While we are not a party to any of these agreements, we are entitled to receive a share of the license fees and royalties Merz receives from Forest, Lundbeck and Suntary pursuant to our strategic research and marketing cooperation agreement with Merz and CMCC.

In May 2002, Merz announced that Memantine (Ebixa®) was approved by the regulatory authorities in the European Union for the treatment of Alzheimer's disease. In October 2003, Forest announced that Memantine (Namenda®) was approved by the Food and Drug Administration (FDA) for the treatment of moderate to severe Alzheimer's disease. Memantine became commercially available in the United States in January 2004.

During the period from August 2002, when commercial sales of Memantine commenced, to June 30, 2005, we have received total license fee and royalty payments of \$7,865,729 from Merz. Subsequent to our fiscal year end in June 30, 2005, we received an additional \$1,052,448 in royalty payments on sales of Memantine.

Forest has conducted three additional placebo-controlled studies in either mild-to-moderate or moderate-to-severe Alzheimer's disease. In June 2003, Forest announced that one of these trials did not demonstrate statistically significant effects on cognitive or global outcomes compared to control. This trial combined Memantine with Acetyl cholinesterase inhibitors for mild-to-moderate Alzheimer's disease. In an additional trial, patients with moderate-to-severe Alzheimer's disease who received the combined therapy of Memantine with the Acetyl cholinesterase inhibitor donepezil showed greater cognitive, functional, global and behavioral benefits over those with donepezil alone. These results were published in the Journal of the American Medical Association, or JAMA, a peer review journal, in January 2004. In January 2004, Forest announced positive results of a Phase III study using Memantine as a monotherapy in mild-to-moderate Alzheimer's disease. Forest has announced that it plans to seek approval for Memantine for a mild-to-moderate indication.

We conducted the first pivotal trial of Memantine for the treatment of neuropathic pain with an enrollment of 400 patients and reported positive results in January 2000. In July 2001, Forest initiated the second of two trials necessary for registration of a new drug application, or NDA, for Memantine for the treatment of diabetic neuropathy. In May 2003, Forest announced that Memantine had failed to demonstrate a statistically significant difference versus placebo with regards to the primary endpoint of this trial. In October 2003, Forest announced the resumption of its clinical development of Memantine for the neuropathic pain indication with an expanded clinical program to examine various neuropathic pain conditions at different dosages. Forest has stated that it would make an announcement by October 2005 regarding its further development plans for Memantine for this indication.

Table of Contents

XERECEPT[®]

We have developed XERECEPT, a synthetic preparation of the natural human peptide, Corticotropin-Releasing Factor, as a potential treatment for brain swelling due to brain tumors (peritumoral brain edema). In April 1998, XERECEPT received orphan drug designation for this indication from the FDA. Orphan drug designation permits us to obtain seven years market exclusivity upon approval and makes us eligible to receive Orphan Drug Grants to fund clinical research.

In April 2004, we began enrollment in one of the two planned pivotal Phase III trials of XERECEPT for peritumoral brain edema needed for the submission of an NDA. This trial has a target enrollment of 200 patients and is expected to be completed in the first quarter of calendar 2007. The second pivotal trial is expected to begin by the end of calendar 2005, to enroll 120 patients and to be completed in the first quarter of calendar 2007. We will also conduct an extended-use trial, where patients completing one of the other two Phase III trials can elect to continue to receive XERECEPT.

Subsequent to fiscal year end, on September 19, 2005, we entered into an agreement to sell all our rights and assets related to XERECEPT to two subsidiaries of Celtic Pharma Holdings, L.P., or Celtic. That transaction is expected to close in by early October 2005. Pursuant to that agreement, we will receive a total of \$33 million in upfront payments between closing and January 2007, be entitled to receive up to \$15 million in milestone payments and be eligible to receive profit sharing on sales of XERECEPT in the United States, if regulatory approval is obtained, as well as royalties on any sales of XERECEPT elsewhere in the world. We also entered into an agreement with Celtic, pursuant to which we will provide certain services in connection with the development of XERECEPT, with the Celtic entities reimbursing us for our direct costs.

VIPRINEX[®]

With our acquisition of Empire Pharmaceuticals, Inc. in July 2004, we acquired the exclusive worldwide rights to Viprinex, which is a late-stage reperfusion therapy for use in the treatment of acute ischemic stroke, a life-threatening condition caused by the blockage of blood vessels supplying blood and oxygen to portions of the brain. A reperfusion therapy is a treatment, and in this case a drug, that breaks up the blood clot causing the stroke and enables normal blood flow to return to the affected areas of the brain. The Viprinex program will evaluate a new dosing regimen that is expected to optimize efficacy and improve safety when compared to previous experience with the drug, which, to date, has resulted in the evaluation of approximately 2000 stroke patients.

Empire acquired the exclusive worldwide rights to Viprinex in a royalty-bearing license from Abbott Laboratories in March 2002. Viprinex was being developed by Knoll AG, prior to its acquisition by Abbott in 2001.

In September 2005 or shortly thereafter, we expect to commence enrollment in the first of two 650 patient Phase III clinical trials of Viprinex for ischemic stroke. These trials are expected to run simultaneously, and take 18 months to conclude.

MATERIAL AGREEMENTS

Edgar Filing: NEUROBIOLOGICAL TECHNOLOGIES INC /CA/ - Form 10-K

Set forth below is a summary of the principal terms of our material agreements relating to our products and product candidates. These agreements have been filed as exhibits to our periodic reports and the following summaries are qualified by the text of these agreements, copies of which are available from the company upon request.

Table of Contents

Merz Pharmaceuticals and Memantine

Pursuant to our 1998 strategic research and marketing cooperation agreement with Merz and CMCC, we gave up the rights previously exclusively licensed to us by CMCC to patents covering Memantine for the treatment of neuropathic pain and AIDS-related dementia, and CMCC licensed those rights to Merz. In exchange, we and CMCC are entitled to share in revenues from sales of Memantine in certain countries for Alzheimer's disease and all indications covered by the CMCC patents, including AIDS-related dementia and diabetic neuropathy. Through June 30, 2005, we have received approximately \$14.7 million from Merz under this agreement.

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 neuropathic pain. In the event that we were to conduct any further research and development on Memantine or derivatives of Memantine during the term of the agreement, Merz would have the right to license any inventions resulting from such research and development and we and Merz would be required to negotiate in good faith the payment to us of a share of the revenues received by Merz from the commercialization and marketing of any such products. Currently, we have no plans to develop Memantine that would trigger these obligations.

The agreement will expire on a country-by-country basis on the later of ten years after the first commercial sale of a covered product or the last to expire patent covering products in that country. Merz or CMCC can terminate the agreement upon six months' notice in the event that Merz does not meet certain conditions relating to the clinical development of Memantine.

Abbott Laboratories and Viprinex

Upon our acquisition of Empire Pharmaceuticals in July 2004, we acquired the rights to an exclusive license from Abbott Laboratories, or Abbott, for Viprinex. Under this license, we have the exclusive worldwide rights to Viprinex for all human therapeutic indications.

We have an obligation to use commercially reasonable efforts to develop Viprinex for the treatment of ischemic stroke and, if Viprinex receives regulatory approval from the FDA, to market the product for that indication. We will be required to make milestone payments to Abbott upon receiving regulatory approval in each of the United States, Europe, Latin America and Asia. We will also be required to make royalty payments to Abbott based on worldwide Viprinex sales. Our royalty obligations will terminate on a country-by-country basis as the applicable patents for Viprinex expire in each such country. To date, we have made no payments to Abbott under this agreement. Prior to our acquisition in July 2004, Empire Pharmaceuticals had paid Abbott a total of \$500,000 in license fees under this agreement.

Our agreement with Abbott will continue until terminated by either party. Abbott has the right to terminate the agreement in the event of our breach and we have the right to terminate the agreement for our convenience upon providing 90 days' notice.

In June 2005, we entered into an agreement with SCIREX Corporation, pursuant to which SCIREX will serve as our contract research organization to manage our Phase III clinical program for Viprinex. The agreement provides for aggregate payments to SCIREX of \$9,815,000 over the period of the program, which is anticipated to take 18 months.

Information regarding our supply arrangements for Viprinex is set forth below under the caption Suppliers.

Table of Contents

ICON Clinical Research, L.P. and XERECEPT

We entered into a master services agreement effective December 2003 with ICON Clinical Research, L.P. or ICON, providing for ICON to perform clinical research and related services in connection with our clinical research projects with respect to XERECEPT. In May 2004 and January 2005, we entered into project agreements with ICON for our Phase III clinical trial for XERECEPT for the treatment of peritumoral braid edema. These agreements, which were entered into pursuant to the master services agreement between us and ICON, set forth the terms on which ICON will oversee the XERECEPT Phase III trials. Our aggregate payment obligations to ICON under the two project agreements are estimated to be approximately \$827,000 and \$609,000, respectively. We intend to assign these agreements to the buyers of XERECEPT following the closing of the transaction described below under the heading Celtic Pharma Holdings, L.P. and XERECEPT.

Celtic Pharma Holdings, L.P. and XERECEPT

Subsequent to fiscal year end, on September 19, 2005, we entered into an agreement to sell all our rights and assets related to XERECEPT to Celtic. That transaction is expected to close in early October 2005. Pursuant to that agreement, we will receive a total of \$33 million in payments between closing and January 2007, be entitled to receive up to \$15 million in payments for achievement of certain regulatory objectives and be eligible to receive profit sharing on sales of XERECEPT in the United States, if regulatory approval is obtained, as well as royalties on any sales of XERECEPT elsewhere in the world. We also entered into an agreement with Celtic, pursuant to which we will provide certain services in connection with the development of XERECEPT with the Celtic entities reimbursing us for our direct costs.

PRODUCT DEVELOPMENT STATUS

The following table summarizes the development status of product candidates for each indication in which regulatory approval has been obtained or is being sought. The results of the clinical trials summarized below are not conclusive and early evidence of safety and/or efficacy may not be supported by subsequent clinical trials. Further, no definitive conclusions regarding safety or efficacy can be obtained until the FDA approval process is complete. For more information on the approval process and risks of drug development, please refer to Government Regulation and Other Factors That May Affect Future Results. Our product candidates are based on new technologies and therefore are subject to numerous inherent risks of failure.

<u>Product/Indication</u>	<u>Development Status</u>	<u>Primary Benefit Sought</u>
MEMANTINE Neuropathic Pain	Phase IIB trial completed by NTI. Results showed statistically significant improvement of 40mg of Memantine over placebo in reducing chronic pain. The FDA accepted trial as one of two pivotal trials. In May 2003, Forest announced that primary endpoint results in the second pivotal trial did not demonstrate a statistically significant difference versus placebo. In October 2003, Forest announced its plans to resume development of neuropathic pain indication.	Treatment of chronic pain associated with diabetic neuropathy or other neuropathic pain conditions.

Table of Contents

Product/Indication	Development Status	Primary Benefit Sought
Mild-to-Moderate Vascular Dementia	Forest has stated it will make an announcement by October 2005 regarding its development plans for Memantine for this indication.	
Mild-to-Moderate Dementia and Alzheimer's Disease	Phase III trials completed by Merz in the United Kingdom and France. Results showed significantly improved cognitive abilities compared to patients who received placebo, as demonstrated by the Activities of Daily Living and cognitive performance evaluations.	Functional and cognitive improvement.
Moderate-to-Severe Dementia and Alzheimer's Disease	Combination of Memantine with Acetyl cholinesterase inhibitors showed no significant improvement of Acetyl cholinesterase inhibitors alone. Monotherapy trial with Memantine versus placebo demonstrated a statistically significant difference with respect to primary efficacy measures. In January 2004, Forest announced its plan to file an NDA.	Functional and cognitive improvement.
XERECEPT (CORTICOTROPIN-RELEASING FACTOR)	Marketed in Europe by Merz and Lundbeck as Ebixa® since May 2002. Marketed in U.S. by Forest as Namenda since October 2003. Combination of Memantine with donepezil (an acetyl cholinesterase inhibitor) showed greater cognitive, functional, global and behavioral benefit over donepezil alone. Results were published in JAMA in January 2004.	Functional and cognitive improvement.
Peritumoral Brain Edema	Enrollment begun in April 2004 in the first of two pivotal Phase III trials, and the second pivotal trial is anticipated to start by the end of 2005. We will also conduct an extended-use trial for patients who complete one of the two other Phase III trails and who wish to continue receiving XERECEPT.	Stabilization or improvement of neurological function with substantial dexamethasone sparing.
VIPRINEX Acute Ischemic Stroke	Phase III study completed in U.S. by Knoll AG in 1998 with positive results. Phase III trial in Europe was halted in March 2000 by Knoll AG due to lack of efficacy and intracranial hemorrhaging. We anticipate that we will commence the first of two Phase III trials in September 2005, or shortly thereafter.	Reperfusion to restore blood flow and oxygen to affected portions of the brain during ischemic stroke.

Table of Contents

Our therapeutic focus is neuroprotection and neuromodulation, which is the prevention and treatment of neurological impairment by preserving or restoring neurological function of damaged neurons. We are developing neuroprotective and neuromodulatory agents that may slow or reverse the progressive neurological impairment associated with multiple nervous system disorders, including diabetic neuropathy and brain cancer.

Because neuronal impairment contributes significantly to functional impairment in many nervous system disorders, scientists believe that neuroprotective compounds are potentially powerful and flexible therapeutic agents. There has been much interest in the business and academic communities to develop such agents.

Mechanisms common to progressive neuronal impairment in various medical conditions are thought to result in multiple neurologic symptoms such as chronic pain, motor difficulties, memory loss and other cognitive deficits. By modulating such mechanisms, neuroprotective agents may prevent or restore loss of neurological function. Our current scientific focus is on two mechanisms contributing to progressive neuronal impairment, excitotoxicity and edema. There is evidence that Memantine prevents or reduces excitotoxicity, a cascade of neuronal cell injury and death associated with the release of abnormal levels of excitatory neurotransmitters. XERECEPT has the potential to prevent the progressive neuronal impairment resulting directly from cerebral edema (swelling of the brain), damage that more frequently results in clinical impairment than the damage resulting from the presence of a tumor.

PRODUCTS AND PRODUCTS IN DEVELOPMENT

Memantine

Memantine is one of a class of agents referred to as NMDA receptor antagonists. Scientific research has indicated that modulating the NMDA receptor may protect against the neuronal impairment and death associated with a number of medical conditions. Accumulating evidence from various studies indicates that over stimulation of NMDA receptors contributes to the impairment and death of neurons. This occurs in a variety of chronic neurodegenerative diseases, including neuropathic pain, dementia, Alzheimer's disease, and Huntington's disease. Other than Memantine, there are currently no approved neuroprotective treatments for any of the pathologies associated with NMDA receptor overstimulation.

Estimates are that approximately 1,000,000 patients in the United States suffer from intractable neuropathic pain. Nerve cells in the brain communicate by sending signals to excite or inhibit each other. Compounds known as neurotransmitters initiate these signals. The principal excitatory neurotransmitter, glutamate, binds to the NMDA receptor embedded in the cell membrane of the neuron. When glutamate binds to the receptor, a channel in the neuron opens which enables charged calcium molecules to flow freely into the neuron. Normally, the influx of calcium triggers chemical reactions that cause the neuron to change its electrical charge and fire a message to neighboring neurons. This basic function of the NMDA receptor is essential for normal movement, sensation, memory, and cognition. In certain medical conditions, glutamate levels surrounding neurons are elevated, which results in over stimulation of the NMDA receptor. In these situations, excessive amounts of calcium enter the neuron, releasing internally stored glutamate into the surrounding area. This glutamate further stimulates NMDA receptors on neighboring neurons, causing a cascade of neuronal cell impairment and/or death throughout the area, referred to as excitotoxicity.

Table of Contents

Neuroscientists have been developing ways to prevent the damaging influx of excess calcium into neurons. One approach is to prevent glutamate from binding to the receptor. This can be accomplished by using either a competitive NMDA receptor antagonist, which prevents glutamate from binding to the receptor, or a closed NMDA receptor channel blocker, which binds to the entrance of the closed channel. However, if such compounds prevent the channel from opening for too long, they may impede the normal functioning of the NMDA receptor, causing side effects including hallucinations, paranoia, delirium, and amnesia.

Scientists affiliated with Children's Hospital of Boston, Massachusetts working on understanding the function of the NMDA receptor found Memantine to modulate the NMDA receptor's calcium ion channel. Memantine binds uncompetitively to the NMDA receptor and appears to interfere relatively little with normal functioning, while reducing abnormal signals associated with excessive calcium influx. Rather than blocking the NMDA receptor for long periods of time, Memantine appears to restore regulation of the channel to near normal activity, while permitting routine neurotransmission.

Product Development Status

The Neuropathic Pain of Diabetes

Diabetes mellitus is a chronic disorder that affects an estimated 16 million Americans. One of its most common complications is nerve damage, particularly damage to peripheral nerves that send sensory signals from the extremities to the central nervous system, or CNS. This condition, referred to as peripheral diabetic neuropathy, or PDN, is a large, unmet medical need. This condition most frequently damages nerves in the feet, making walking or standing painful and difficult. We estimate that approximately 800,000 patients in the United States currently receive treatment for the symptoms of PDN, including severe, chronic pain known as neuropathic pain (persistent pain in the absence of an obvious stimulus). As the neuropathy progresses, the sensation of pain may become more intense, encompass more areas, and become increasingly difficult to treat with available therapeutic agents.

Peripheral nerve damage disrupts pain pathways in the nervous system, causing nerves to send abnormal signals that the brain interprets as pain. In effect, neurons in the CNS are bombarded with abnormal signals until their ability to process pain signals is compromised. This leads to hyper-sensitization of neurons to pain impulses and results in progressive neuronal impairment in the CNS. Although the precise mechanisms of these events are not completely understood, there is evidence that over activation of NMDA receptors in the CNS plays an important role.

Memantine has been shown to inhibit abnormal pain signals by modulating the NMDA receptor in several animal models of neuropathic pain. Based on the results of these studies, we sponsored and completed in 1998, a 122-patient placebo-controlled Phase IIA human clinical trial of Memantine in patients with neuropathic pain due to diabetes or post-herpetic neuralgia (a complication of shingles). No treatment benefit was observed in patients with post-herpetic neuralgia. However, trends indicating efficacy of Memantine were observed in patients with PDN. The strongest efficacy trend was the reduction of nocturnal pain associated with PDN. Nocturnal pain is a major problem for these patients, frequently leading to insomnia and other associated health and psychological problems. After eight weeks of treatment in our clinical trial, the Memantine-treated subjects had 42% less nocturnal pain than those treated with placebo. The results for the other primary variables of daytime pain and pain relief, although not statistically significant, exhibited consistent trends representative of analgesic benefit with Memantine compared to placebo.

Table of Contents

Based on the results from our Phase IIA trial of Memantine in patients with neuropathic pain, we initiated a Phase IIB trial of Memantine in the second quarter of fiscal 1999, exclusively in patients with PDN. In May 2000, we presented results of our placebo-controlled Phase IIB dose ranging human clinical trial of Memantine. Results of this 421 patient Phase IIB clinical trial of Memantine as a treatment for painful diabetic neuropathy showed that 44% of the patients receiving 40 mg dosages experienced a 50% or greater pain reduction, compared to 29% in the placebo group at the end of eight weeks. Although positive trends were seen in the groups treated with 20 mg of Memantine compared to placebo, no statistical significance were observed.

In July 2001, Forest initiated an additional year-long, large-scale, multi-center, double-blind placebo controlled trial to assess the safety and efficacy of Memantine in the treatment of diabetic neuropathy. In May 2003, Forest announced that Memantine had failed to demonstrate a statistically significant difference versus placebo with regards to the primary endpoint of this trial. In October 2003 Forest announced that based on a recently completed analysis of a clinical trial evaluating Memantine for neuropathic pain, Forest has decided to proceed with an expanded clinical program with the objective of obtaining approval for this indication. Although the results did not achieve statistical significance at week 16 (the protocol-defined endpoint), the recently completed analysis found that weekly assessments did show a statistically significant effect for Memantine compared to placebo on nocturnal pain, on every time point from week 1 through week 14. In addition, patients with more severe pain at baseline demonstrated a statistically superior effect of Memantine on pain scores compared to placebo from week 3 through week 16.

XERECEPT (Human Corticotropin-Releasing Factor)

XERECEPT is our synthetic preparation of the human peptide Corticotropin-Releasing Factor, or hCRF that we have been developing as a potential treatment for brain swelling due to brain tumors (peritumoral brain edema). There is clinical evidence that XERECEPT may be a safer treatment than synthetic corticosteroids, which are associated with serious adverse side effects including muscle wasting, weight gain, immunosuppression, osteoporosis, hyperglycemia, glaucoma and psychosis. Results from our pre-clinical studies and pilot human clinical trials have demonstrated the compound's potential to reduce swelling in brain tissue and to be well-tolerated. However, the compound's safety and efficacy have not yet been established or approved by the FDA and subsequent clinical trials may not support our earlier findings. Thus, based on our clinical development of XERECEPT to date, this compound appears to have the potential to significantly improve the quality of life for brain cancer patients with dysfunction due to brain swelling. In the United States, approximately 30,000 patients are diagnosed every year with primary brain tumors, and 120,000 with metastatic brain tumors. Patients with this condition are in need of a safe alternative to corticosteroids, which have serious adverse effects at the high, chronic doses required for efficacy.

The FDA has granted an orphan drug designation for XERECEPT to treat this unmet medical need. Orphan drug designation provides the opportunity for us to obtain seven years market exclusivity and makes us eligible to receive orphan drug grants to fund clinical research.

hCRF is a natural neuroendocrine peptide hormone found in humans both centrally (within the brain) and peripherally (outside the brain). Researchers discovered anti-edema effects of hCRF through systemic administration. Additionally XERECEPT has been shown to have anti-neoplastic properties. Research by our scientific collaborators has revealed that XERECEPT significantly reduces edema, or swelling of damaged tissue, in animal models. Edema is a condition characterized by swelling after

Table of Contents

tissue injury when fluid, plasma proteins, and white blood cells flow from small blood vessels into the surrounding tissues, further contributing to the destruction of these tissues. Our pre-clinical studies have shown that XERECEPT reduces the flow of fluid through blood vessels at sites of traumatic tissue injury. Specifically, these studies have shown that XERECEPT injected systemically into animals can reduce brain edema after injury, brain edema associated with cancer tumors, and swelling in muscle tissue following surgical trauma.

Product Development Status

Peritumoral Brain Edema

We have been evaluating XERECEPT for the treatment of cerebral edema caused by brain tumors. In these patients, the tumor promotes increased permeability of the small blood vessels in the brain, which results in the excess flow of fluids into the brain, swelling of brain tissue, and a consequent impairment of neurological function. Current treatment of peritumoral brain edema, primarily corticosteroids, results in serious adverse side effects at the high chronic doses required for efficacy. Reactions can include muscle wasting, weight gain, immunosuppression, osteoporosis, hyperglycemia, glaucoma, psychosis and other potentially dose-limiting side effects.

Potential benefits of hCRF in patients with brain tumors have been demonstrated in laboratory testing. To date six pre-clinical studies with Corticotropin-Releasing Factor, or CRF have demonstrated an anti-cancer effect by inhibiting new cell growth. One publication has shown that CRF induces programmed cell death, which may represent one of the underlying mechanisms for the anti-neoplastic effects observed with CRF. It is of interest to note that dexamethasone, the drug of choice for peritumoral brain edema, has been shown to interfere with this programmed cell death in malignant glioma (brain) cells making them less resistant to chemotherapy and radiation. However, these data are laboratory findings and may have no similar effects in the clinic. XERECEPT is not being developed as an anti-cancer agent.

Although endogenous hCRF is involved in stimulating the release of natural corticosteroids, studies sponsored by us have shown that XERECEPT exerts its anti-edema action independent of cortisol release when administered systemically.

Based on the pharmacologic profile of XERECEPT, there is evidence that the compound may be efficacious without many of the adverse side effects associated with current corticosteroid therapies. Recently completed three month animal toxicity studies with XERECEPT support the concept of reduced side effects with XERECEPT over standard corticosteroid therapy. There is also evidence that XERECEPT may enhance radiation therapy, whereas cortisols appear to interfere with this conventional brain tumor therapy. To date, XERECEPT has been safely administered to several hundred healthy volunteers and patients according to numerous studies published by third parties. In human clinical trials sponsored by us, XERECEPT was well tolerated and appeared to be safe in more than 230 courses of treatment. These findings are only preliminary and the apparent safety and efficacy of XERECEPT may not be supported by subsequent clinical trials.

We are currently conducting two pivotal Phase III clinical trials of XERECEPT for peritumoral brain edema needed for the submission of an NDA. In September 2005, we entered into an agreement to sell all our rights and assets to XERECEPT to two wholly-owned subsidiaries of Celtic Pharma Holdings, L.P.

Table of Contents

Viprinex

Viprinex has been studied in more than 2,000 patients in various clinical studies in the U.S. and Europe and has the potential to at least double the available treatment window following the onset of stroke symptoms. Currently, the only available therapy for stroke must be administered within the initial three hours, significantly limiting the number of patients that may be treated.

One of the primary goals for the treatment of acute ischemic stroke is improving blood flow through a blocked vessel so that the flow of oxygen and nutrient supply to brain tissue is not interrupted or compromised. Brain tissue starved of oxygen can cause loss of neurological function such, as speech and mobility. Fibrinogen, a protein involved in blood clotting, has been known to contribute to high blood viscosity, which in turn may impede blood flow to critical regions of the brain. Thus, an agent that reduces fibrinogen levels may significantly impact stroke treatment.

Derived from the venom of the Malayan pit viper, Viprinex is a thrombin-like enzyme that is highly specific to fibrinogen. When administered systemically, Viprinex has been shown to rapidly deplete plasma fibrinogen (it is a defibrinogenating agent). The effects are anticoagulation, improved blood viscosity and a secondary fibrinolytic or clot lysing action. Combined, these effects constitute a reperfusion strategy that appears to restore and enhance oxygen flow to the affected area of the brain. Studies have shown that in patients receiving Viprinex within six hours of stroke onset, blood viscosity is progressively reduced by 20-30% from pretreatment levels, resulting in an improvement in blood flow and microcirculation. After stopping treatment with Viprinex, viscosity levels have been shown to return to pretreatment levels very slowly, within about 10 days.

Product Development Status

Ischemic Stroke

According to the American Stroke Association, every 45 seconds someone in the U.S. suffers a stroke and every three minutes someone dies of one. It is the nation's third leading cause of death after diseases of the heart and all forms of cancer and is the leading cause of serious, long-term disability.

A stroke occurs when a blood vessel that carries oxygen and nutrients to the brain is either blocked (ischemic) by a clot or ruptures (hemorrhagic). When the tissues are deprived of needed blood they begin to die, affecting various parts of the body and causing paralysis, speech, vision and other problems. It is estimated that less than ten percent of stroke patients are suitable for current therapies and less than five percent actually receive treatment.

Knoll AG completed a randomized, double-blind, placebo-controlled Phase III clinical study in the United States in 1998 to evaluate the safety and efficacy of Viprinex given within three hours after the onset of acute, ischemic stroke in 500 patients. In that study, Viprinex was shown to be effective in preserving neurological function in this patient population. A separate randomized, double-blind, placebo-controlled Phase III study in Europe enrolling patients within six hours of onset of acute ischemic stroke was stopped by Knoll AG after a planned interim analysis indicated lack of efficacy and increased incidence of intracranial hemorrhage. We believe that the higher dosing levels in the European trial and the use of protocol criteria that permitted entry of patients at higher risk of hemorrhage contributed to the trial's failure. In September 2005 or shortly thereafter, we anticipate that we will commence enrollment in the first of two Phase III clinical trials to evaluate a revised dosage

strategy, which we believe will confirm the results of the US trial. These trials are expected to enroll a

Table of Contents

total of 650 patients each and are expected to be complete in 2007. Although this revised dosing strategy is expected to optimize safety and efficacy, the earlier results suggesting that Viprinex may be safe and effective may not be supported by these new clinical trials.

COMPETITION

Competition in the biopharmaceutical industry is intense and is expected to increase. There are other therapies under development for each of our therapeutic targets and the development and sale of drugs for the treatment of the therapeutic targets that we and our collaborative partners are pursuing is highly competitive. Specifically, we face known competition from the following companies for each of the indications listed below.

<u>Indication</u>	<u>Principal known competing products and competitors</u>
Alzheimer's disease (Memantine)	ARICEPT® (donepezil HCl) <i>Eisai Inc. and Pfizer Inc.</i>
	Exelon® (rivastigmine tartrate) <i>Novartis</i>
	Reminyl® (galantamine HBr) <i>Janssen Pharmaceutica</i>
Neuropathic pain (Memantine)	Neurontin® (gabapentin) <i>Parke-Davis</i>
	Cymbalta® (duloxetine HCl) <i>Lilly</i>
	Lyrica® (pregabalin) <i>Pfizer, Inc.</i>
Peritumoral brain edema (XERECEPT)	Decadron® (dexamethasone)

Merck & Co. Inc.

Acute ischemic stroke (Viprinex)

Activase® (alteplase, recombinant)

Genentech, Inc.

We may not be able to develop products that will be as 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.

We and our collaborative partners will face intense competition from pharmaceutical, chemical and biotechnology companies both in the United States and abroad. Companies that complete clinical trials, obtain required regulatory approvals and first commence commercial sales of their products before their competitors may achieve a significant competitive advantage. In addition, significant levels of research in biotechnology and medicine occur in universities and other nonprofit research institutions. These entities have become increasingly active in seeking patent protection and licensing revenues for their research results.

Table of Contents

SUPPLIERS

Merz and Forest have the responsibility of supplying Memantine for their clinical trials and for commercial sale.

Pursuant to our agreements with Celtic, we will be required to continue to supply XERECEPT for clinical development. We currently have single source supply arrangements for production of XERECEPT and have experienced delays in the past in obtaining sufficient clinical supply. See, *Other Factors that Could Affect Future Operations* Because we do not have our own manufacturing facilities, we face risks from outsourcing.

In March 2005, we executed an agreement with Nordmark Arzneimittel GmbH & Co. KG for supply of the active pharmaceutical ingredient of Viprinex that is manufactured in accordance with cGMP. The term of this supply agreement will expire in October 2019. In June 2005, we entered into a drug product development and clinical supply agreement with Baxter Pharmaceutical Solutions LLC for fill and finish of the Viprinex product for development and clinical use. This agreement will continue until such Viprinex product production is completed. In addition, we have taken steps to ensure an adequate supply of raw Malayan pit viper venom, from which the Viprinex active pharmaceutical ingredient is prepared (including steps towards the establishment of a colony of Malayan pit vipers in the United States). Any difficulties in obtaining raw Malayan pit viper venom in necessary quantities and potencies could adversely affect our ability to manufacture clinical and commercial supplies of Viprinex.

Alternative cGMP suppliers of the bulk drugs and of finished dosage from products are available to us. We currently have no plans to build or develop an in-house manufacturing capability.

We face certain risks by outsourcing manufacturing, including:

the delay of market introduction and subsequent sales if we encounter difficulties establishing relationships with manufacturers to produce, package and distribute products; and

adverse effects on FDA pre-market approvals of potential products and contract manufacturers if they do not adhere to cGMP regulations.

Because of these risks, our dependence on third parties for the manufacture of products may adversely affect our results of operations and our ability to develop and deliver products on a timely and competitive basis.

PATENTS AND PROPRIETARY INFORMATION

Set forth below is a summary of our material patent and other proprietary rights. Summaries of our material license agreements relating to these proprietary rights are set forth above under the caption, *Material Agreements*.

Pursuant to the agreement we entered into with Celtic on September 19, 2005, upon the closing of the transaction, we will be assigning our exclusive licenses to patents covering the use of XERECEPT and transferring our rights to our patents, which cover certain liquid formulations of XERECEPT, to the Celtic entities.

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

Table of Contents

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 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 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.

A number of pharmaceutical and biotechnology companies and research institutions have developed competing technologies and may have patent rights that conflict with our patent rights. If such a conflict were to develop, the scope of our patent rights could be limited and we may be unable to obtain additional patent rights needed to permit the continuing use of the subject technologies.

In addition to patent protection, we rely upon trade secret protection for our confidential and proprietary information. It is our policy that each employee enter into a confidentiality agreement which contains provisions generally prohibiting the disclosure of confidential information to anyone outside NTI 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

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.

A company generally must conduct pre-clinical testing on laboratory animals of new pharmaceutical products prior to 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 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:

In Phase I, a company conducts clinical trials with a small number of subjects to determine a drug's early safety profile and its pharmacokinetic pattern.

Table of Contents

In Phase II, a company conducts clinical trials with groups of patients afflicted with a specific disease in order to determine preliminary effectiveness, optimal dosages and further evidence of safety.

In Phase III, a company conducts large-scale, multi-center, comparative trials with patients afflicted with a target disease in order to provide enough data to demonstrate the effectiveness and safety required by the FDA prior to commercialization.

The FDA closely monitors the progress of each phase of clinical testing. The FDA may, at its discretion, re-evaluate, alter, suspend, or terminate testing based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to patients.

The results of the pre-clinical and clinical testing are submitted to the FDA in the form of a new drug application or NDA for approval prior to commercialization. In responding to an NDA, the FDA may grant marketing approval, request additional information, or deny the application. 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 domestic manufacturer of the product conform to the FDA's cGMP regulations, which must be followed at all times. 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 technical compliance.

Once the sale of a product is approved, FDA regulations continue to govern the manufacturing process and marketing activities. A post-marketing testing and surveillance program may be required to continuously monitor a product's usage and effects in patients. Product approvals may be suspended or withdrawn if compliance with regulatory standards is not maintained.

Foreign regulatory approval of a product must also be obtained prior to marketing the product internationally. Foreign approval procedures vary from country to country. The time required for approval may delay or prevent marketing in certain countries. In certain instances, the Company or its collaborative partners may seek approval to market and sell certain products outside of the United States before submitting an application for United States approval to the FDA. The clinical testing requirements and the time required to obtain foreign regulatory approvals may differ from those required for FDA approval.

Fulfillment of regulatory requirements for marketing human therapeutics typically takes many years and varies substantially based on the type, complexity, and novelty of the drug for which approval is sought. Government regulation may:

delay for a considerable period of time or prevent marketing of any product that we may develop; and/or

impose costly procedures upon our activities.

Either of these effects of government regulation may provide an advantage to our competitors.

For products we develop, we may not receive FDA or other regulatory approval on a timely basis or at all. Any delay in obtaining, or failure to obtain, required approvals would adversely affect the marketing of our proposed products and our ability to earn product revenues or royalties.

In addition, success in pre-clinical or early stage clinical trials does not assure success in later-stage clinical trials. For example, although our Phase II clinical trials for Memantine for the treatment

Table of Contents

of diabetic neuropathy produced positive results, subsequent clinical trials conducted by Forest did not replicate these results. Similarly, the results of Knoll AG's Phase III clinical trials for Viprinex in the United States were not replicated in subsequent European clinical trials. As with any regulated product, additional government regulations may be instituted which could delay regulatory approval of our potential products. Additional government regulations that might result from future legislation or administrative action cannot be predicted.

EMPLOYEES

Currently, we employ 26 people, of whom 23 employees are full-time employees. 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 report 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, by providing a hyperlink to the SEC's website directly to our reports. The contents of our website are not incorporated by reference into this report.

ITEM 2. PROPERTIES

In August 2005, we relocated our executive offices to a 9,650 square foot facility in Emeryville, California. The lease for that facility runs through November 2010. We also lease approximately 5,900 square feet of office space in Edgewater, New Jersey, where our operations relating to the development of Viprinex are based. The lease for that facility runs through October 31, 2009.

ITEM 3. LEGAL PROCEEDINGS

We are not currently involved in any legal proceedings.

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

No matters were submitted to a vote of our security holders during the fourth quarter of the fiscal year ended June 30, 2005.

PART II.

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

NTI's common stock is traded on The NASDAQ SmallCap Market under the symbol NTII.

As of June 30, 2005, there were approximately 245 holders of record of our common stock and 27,077,418 shares of common stock outstanding. No dividends have been paid on our common stock to date, and we do not anticipate paying any dividends in the foreseeable future.

Table of Contents

The following table sets forth the high and low closing prices of our common stock during the past two fiscal years.

Fiscal 2004	High	Low
First Quarter	\$ 6.57	\$ 3.18
Second Quarter	\$ 6.68	\$ 4.20
Third Quarter	\$ 7.00	\$ 4.33
Fourth Quarter	\$ 5.02	\$ 3.35
Fiscal 2005	High	Low
First Quarter	\$ 4.35	\$ 2.37
Second Quarter	\$ 5.05	\$ 3.37
Third Quarter	\$ 4.79	\$ 3.05
Fourth Quarter	\$ 3.69	\$ 2.71

ITEM 6. SELECTED FINANCIAL DATA

The following table sets forth certain financial data with respect to our business. The information set forth below is not necessarily indicative of results of future operations and should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations in Item 7 and the consolidated financial statements and related notes thereto in Item 8.

	Year Ended June 30,				
	2005	2004	2003	2002	2001
	<i>(in thousands, except per share data)</i>				
Statement of Operations Data:					
Total revenue	\$ 3,100	\$ 2,786	\$ 1,980	\$	\$ 4,781
Expenses:					
Research and development	11,493	2,098	2,317	2,013	1,194
Acquired in-process research and development	4,251				
General and administrative	4,927	3,101	2,493	2,637	2,556
Total expenses	20,671	5,199	4,810	4,650	3,750
Operating income (loss)	(17,571)	(2,413)	(2,830)	(4,650)	1,031
Investment income, net	249	128	144	342	599
Other non-cash income		477			
Income (loss) before income tax	(17,322)	(1,808)	(2,686)	(4,308)	1,630
Income tax benefit (provision)				42	(42)
Net income (loss)	\$ (17,322)	\$ (1,808)	\$ (2,686)	\$ (4,266)	\$ 1,588
Basic net income (loss) per share	\$ (0.65)	\$ (0.09)	\$ (0.15)	\$ (0.24)	\$ 0.10

Edgar Filing: NEUROBIOLOGICAL TECHNOLOGIES INC /CA/ - Form 10-K

Diluted net income (loss) per share	\$ (0.65)	\$ (0.09)	\$ (0.15)	\$ (0.24)	\$ 0.08
Weighted average shares of common stock outstanding basic	26,530	20,679	18,016	17,570	16,532
Weighted average shares of common stock outstanding diluted	26,530	20,679	18,016	17,570	21,071

Table of Contents

	Year Ended June 30,				
	2005	2004	2003	2002	2001
	<i>(in thousands)</i>				
Balance Sheet Data:					
Cash, cash equivalents and investment securities	\$ 8,506	\$ 20,734	\$ 4,402	\$ 7,259	\$ 11,044
Working capital	5,490	20,446	4,238	6,607	10,667
Total assets	17,470	21,384	4,813	7,665	11,458
Total current liabilities	3,816	661	566	1,052	762
Accumulated deficit	(59,647)	(42,325)	(40,517)	(37,830)	(33,564)
Stockholders' equity	13,654	20,723	4,248	6,613	10,696

Selected quarterly financial information is summarized below:

	Quarterly Periods in the Year Ended June 30, 2005				
	September 30	December 31	March 31	June 30	Total
	<i>(in thousands, except per share data)</i> <i>(unaudited)</i>				
QUARTERLY RESULTS OF OPERATIONS					
Total revenue	\$ 517	\$ 694	\$ 765	\$ 1,124	\$ 3,100
Research and development expense	1,164	2,269	3,135	4,924	11,493
Acquired in-process research and development	4,251				4,251
General and administrative expense	931	1,090	1,200	1,706	4,927
Investment income (loss)	77	(10)	109	73	249
Net loss	\$ (5,752)	\$ (2,675)	\$ (3,461)	\$ (5,433)	\$ (17,322)
Basic and diluted net loss per share	\$ (0.23)	\$ (0.10)	\$ (0.13)	\$ (0.20)	\$ (0.65)
Shares used in basic and diluted net loss per share calculation	25,170	26,847	27,054	27,065	26,530

	Quarterly Periods in the Year Ended June 30, 2004				
	September 30	December 31	March 31	June 30	Total
	<i>(in thousands, except per share data)</i> <i>(unaudited)</i>				
QUARTERLY RESULTS OF OPERATIONS					
Total revenue	\$ 10	\$ 300	\$ 2,302	\$ 174	\$ 2,786
Research and development expense	(328)	(513)	(725)	(532)	(2,098)
General and administrative expense	(576)	(855)	(890)	(780)	(3,101)
Interest income	21	9	21	77	128
Other non-cash income			431	46	477
Net loss	\$ (873)	\$ (1,059)	\$ 1,139	\$ (1,015)	\$ (1,808)

Edgar Filing: NEUROBIOLOGICAL TECHNOLOGIES INC /CA/ - Form 10-K

Basic and diluted net loss per share	\$ (0.05)	\$ (0.06)	\$ 0.05	\$ (0.04)	\$ (0.09)
Shares used in basic and diluted net loss per share calculation	18,833	19,206	20,795	23,918	20,679

Table of Contents

CHANGE IN RESULTS FROM REPORTED EARNINGS

On August 24, 2005, we reported preliminary, unaudited results for fiscal 2005. These preliminary results differed slightly from the results reported in this report on Form 10-K. The changes from the preliminary report are as follows.

Research and Development Expenses increased by \$226,000 to \$11,492,463, and Accrued Clinical Trial Expenses increased by \$226,000, due to increasing the accrual for clinical expenses.

The change discussed immediately above had the following effect.

Operating loss of \$(17,345,661) increased to \$(17,571,661);

Net loss of \$(17,096,176) increased to \$(17,322,176); and,

Basic and diluted net loss per share is unchanged.

Table of Contents

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

Except for the historical information contained herein, the matters discussed in this Management's Discussion and Analysis of Financial Condition and Results of Operations, and elsewhere in this Form 10-K are forward-looking statements that involve risks and uncertainties. The factors listed in the section captioned Risk Factors, as well as any cautionary language in this Form 10-K, provide examples of risks, uncertainties and events that may cause our actual results to differ materially from those projected. Except as may be required by law, we undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

OVERVIEW

Neurobiological Technologies, Inc. is a biotechnology company engaged in the business of acquiring and developing central nervous system (CNS) related drug candidates. The Company is focused on therapies for neurological conditions that occur in connection with dementia, Alzheimer's disease, ischemic stroke, neuropathic pain and brain cancer.

Our strategy is to in-license and develop later stage drug candidates that target major medical needs and that can be rapidly commercialized. Our experienced management team oversees the human clinical trials necessary to establish evidence of efficacy and then seeks partnerships with pharmaceutical and biotechnology companies for marketing of our product candidates. Currently, we receive royalty revenues on the sales of one approved product and have two product candidates in clinical development. The approved product, Memantine, is an orally dosed compound that is approved for the treatment of moderate to severe Alzheimer's disease and is marketed in the United States and Europe by our marketing partners. Memantine is also being developed by our partners for the treatment of neuropathic pain. In September 2005, we entered into an agreement to sell our rights and assets related to XERECEPT[®], a compound we are developing for the treatment of peritumoral brain edema, or swelling around brain tumors to two subsidiaries of Celtic Pharma Holdings L.P., or Celtic, and these entities will assume responsibility for the clinical development of XERECEPT. We are also developing Viprinex[®], a compound we are developing for the treatment of acute ischemic stroke.

In July 2004, we acquired Empire Pharmaceuticals, Inc., a privately held corporation, through the merger of Empire Pharmaceuticals into Empire Acquisition Corp., a wholly-owned subsidiary of NTI. Pursuant to the transaction, we acquired worldwide rights to Viprinex (ancrod), a late-stage reperfusion therapy for use in treatment of ischemic stroke. The acquisition of Empire Pharmaceuticals is accounted for as a purchase of assets in accordance with accounting principles generally accepted in the United States and this resulted in a larger loss in the quarter ended September 30, 2004 and the fiscal year ended June 30, 2005 relative to prior periods.

We expect to incur additional operating losses through at least fiscal 2007 as we continue our drug development efforts. Our development expenses were higher in fiscal 2005 as a result of the commencement of the clinical trials for XERECEPT and preparation for clinical trials of Viprinex. We expect to commence enrollment in the first of two planned Phase III clinical trials for Viprinex in September 2005 or shortly thereafter, and these trials are expected to continue through 2007. Upon the closing of our sale of our rights and assets to XERECEPT to Celtic, which is expected to occur by early October 2005, Celtic will assume all the costs for the clinical development of XERECEPT.

Our general and administrative expenses have increased as a result of our acquisition of Empire Pharmaceuticals which has resulted in our leasing an additional office facility in New Jersey in order to

Table of Contents

support the management of development activities for Viprinex. Our general and administrative expenses have also increased as we have added management and operating staff to support these activities and independent consultants to assist with documenting and assessment of our internal controls. Except for fiscal 2001, we have incurred significant losses each year since our inception.

We anticipate that our development and operational expenses will exceed revenues through at least June 2007, and that we may seek to raise additional capital in order to fund our development and operational activities or seek additional partnerships or collaborative agreements with pharmaceutical companies under which they will share the cost of our development and operational activities. As of June 30, 2005, our accumulated deficit was \$59.6 million and total stockholders' equity was \$13.7 million.

CRITICAL ACCOUNTING POLICIES

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities, if any, at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We consider our accounting policies related to revenue recognition, research and development expenses, and valuation of long-lived and intangible assets to be critical.

Revenue recognition

Revenues are recorded according to the terms of formal agreements to which we are a party, when our performance requirements have been fulfilled, the fee is determinable and when collection of the fee is probable or reasonably assured. Revenue related to license fees with non-cancelable, non-refundable terms and no future performance obligations are recognized when collection is assured. Revenues associated with milestone payments, pursuant to the non-cancelable and non-refundable terms of agreements to which we are a party, are recognized when we have fulfilled development milestones and when collection of the fee is assured. Revenues resulting from royalty fees earned from the sale of the product are based upon the sales reported by our licensees and determined in accordance with the specific terms of the license agreements. We record royalty revenue when it is received because we are unable to estimate and accrue royalty revenue due to the limited sales history of the product. We have made no material adjustments to date for revenue recorded from royalty fees. During the quarter ended March 31, 2005, Merz adjusted revenues previously paid to us by approximately \$108,000 as a result of the overpayment of royalty fees in previous quarters for sales in certain European countries.

Research and development expenses

Our 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 related clinical manufacturing costs, and license fees for use of third-party intellectual property rights. Management assesses how much of these multi-period costs should be charged to research and development expense in each reporting period by assessing the level and

Table of Contents

related costs of the services provided during each reporting period. In determining whether clinical trial activities performed by third parties should be recognized in a specific reporting period, management considers:

estimates of the percentage of work completed through the applicable reporting period in accordance with agreements established with the third-party service providers; and

estimates of the percentage of work completed through the applicable reporting period in accordance with discussions with internal clinical and preclinical personnel and independent service providers as to the progress or stage of completion of trials or services and the agreed upon fee to be paid for such services.

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 requires significant judgment, and could have a material impact on our balance sheet and results of operations. Management applies judgment and bases its estimates with the benefit of historical experience with the development of similar drugs and with third party contracts structured with similar performance and payment terms. While our historic estimates have been materially accurate, we recognize that estimates of expense incurred during current and future periods are determined greatly by patient enrollment levels and related activities, which may vary from historic patterns. We monitor service providers' activities to the extent possible in order to assess current enrollment levels and related activities; however, if we under- or overestimate activity levels associated with various studies at a given point in time, we could materially under- or overestimate research and development expenses in future periods.

Valuation of Long-Lived and Intangible Assets

Intangible assets acquired, including acquired in-process research and development, are recorded at their estimated fair values at the date of acquisition. The fair values of acquired intangible assets are determined by management using relevant information and assumptions, which process is assisted by an independent, professional appraiser. Fair value is generally calculated as the present value of estimated future cash flows using a risk-adjusted discount rate, which requires significant judgment with respect to revenue and expense growth rates, and the selection and use of an appropriate discount rate. Amortization of intangibles with defined lives is calculated using the straight-line method over the period that we estimate to be the economic useful life of the related asset.

We assess the impairment of intangible and long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If it is determined that the carrying value of intangible and long-lived assets might not be recoverable based upon the existence of one or more indicators of impairment, we would measure any impairment based on a projected discounted cash flow method if the undiscounted cash flows did not exceed the carrying value of such assets. No such impairment charges have been recorded to date. At June 30, 2005, we had \$6,840,000 and \$815,000 of net intangible and tangible long-lived assets, respectively. An impairment of our intangible or tangible long-lived assets could result in the recording of a material, non-cash expense in our consolidated statement of operations during the period in which such a charge could occur.

RECENT ACCOUNTING PRONOUNCEMENT

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment (SFAS 123(R)) which requires all share-based payments to employees, including grants of stock options, to be recognized in the financial statements based on

Table of Contents

their fair values. As a result, the cost of employee services received in exchange for a grant of an equity instrument will be measured at fair value on the grant-date of the award and recorded as expense over the period during which the employee is required to provide service in exchange for the award. Pro forma disclosure of such cost is no longer an alternative for disclosing the cost share-based payments to employees. According to the requirements of SFAS 123(R) and a rule issued by the Securities and Exchange Commission in April 2005, SFAS 123(R) is effective for the Company at the beginning of our 2006 fiscal year, which commences on July 1, 2005.

SFAS 123 (R) may be adopted using either the Modified-Prospective Transition method or the Modified-Retrospective Transition method of application. Using the Modified-Prospective Transition method, the Company would recognize the cost of share-based payments based on their grant-date fair value from the beginning of the fiscal period in which the provisions of SFAS 123(R) are first adopted. Measurement and assignment of compensation cost for share-based payments granted prior to, but not vested as of the date of adopting SFAS 123(R) would be based upon the same estimate of grant-date fair value used previously under SFAS 123, whether the estimate was recognized in the financial statements or disclosed only in a pro forma manner. Recognizing a liability for share-based payments made prior to, but not vested as of the date of adopting SFAS 123(R) will be recognized as the cumulative effect of a change in accounting principle. Using the Modified-Retrospective Transition method of application, the Company would be allowed to restate previously reported periods by recognizing compensation expense in the amounts previously reported as pro forma disclosure under the earlier provisions of SFAS 123. New awards and vested awards would be accounted for in the same manner as the Modified-Prospective Transition method.

We have adopted the requirements of SFAS 123(R) effective July 1, 2005, utilizing the Modified-Prospective Transition method and expect the adoption will have a material effect on our consolidated financial position and results of operations. We anticipate that the effect of adopting SFAS 123(R) effective July 1, 2005, will increase total stock-based compensation expense in fiscal 2006 by approximately \$468,000, of which \$101,000 and \$367,000 will represent increased stock-based compensation in Research and Development and General and Administrative expenses, respectively.

RESULTS OF OPERATIONS*REVENUES*

Year Ended June 30,			Increase (Decrease) From	
2005	2004	2003	2005/2004	2004/2003
\$3,100,000	\$2,786,000	\$1,980,000	\$314,000	\$806,000

Revenues of \$3,100,000 in the year ended June 30, 2005, increase by \$314,000 over revenues of \$2,786,000 in 2004. Our 2005 revenues consisted entirely of royalty fees earned from the sale of Memantine in certain European countries and the United States by Merz and its marketing partners.

Revenues were \$2,786,000 in 2004 compared to \$1,980,000 in 2003. Our 2004 revenues included \$2,531,000 in license fees and \$255,000 in royalty fees. During 2004, we received license fee revenue of \$2,250,000 and \$281,000 related to the approval of Memantine in the U.S. and in certain European countries, respectively.

Table of Contents

In October 2003, Forest announced that it had received approval of Namenda (Memantine) in the United States for the treatment of Alzheimer's disease. Merz received a payment from Forest relating to this approval, which triggered a \$2.25 million payment from Merz in January 2004 under our 1998 strategic research and marketing cooperation agreement. We also received payments from Merz of \$281,000 in October 2003, which represent a portion of the payments that Merz received pursuant to its agreement with Lundbeck for the approval of Memantine for the treatment of Alzheimer's disease.

Our 2003 revenue included \$1,969,000 in license fees and \$11,000 in royalty fees, which were earned for the approval and sales, respectively, of Memantine in the European Union.

We expect to continue to receive royalty payments from Merz on sales of Memantine in certain European countries and in the United States. Royalty revenues result from sales of Memantine by Merz and its marketing partners who do not make anticipated future sales volumes available to us, nor, given the limited history of Memantine sales, are we able to estimate future royalty revenues.

RESEARCH AND DEVELOPMENT EXPENSES

Year Ended June 30,			Increase (Decrease) From	
2005	2004	2003	2005/2004	2004/2003
\$11,493,000	\$2,098,000	\$2,317,000	\$9,395,000	\$(219,000)

Research and development expenses of \$11,493,000 in the year ended June 30, 2005, increased by \$9,395,000 compared to expenses of \$2,098,000 in 2004. The increase of \$9,395,000 included \$7,524,000 of expenses incurred to prepare for Phase III clinical trials for Viprinex, for which we anticipate to commence enrollment in September 2005 or shortly thereafter, and \$1,871,000 of expenses for the continuing Phase III clinical trials for XERECEPT, which were initiated in April 2004. The \$7,524,000 of research and development expenses incurred for Viprinex consist primarily of: \$3,414,000 of expenses for the manufacture of Viprinex clinical materials; approximately \$1,579,000 for clinical, statistical and manufacturing consulting expenses; approximately \$902,000 of compensation and related benefit expenses; approximately \$594,000 for amortization of the intangible marketing license and patent value for Viprinex; approximately \$201,000 for depreciation of clinical material production equipment, venom concentrate, raw venom and related snake-farm facilities utilized in the development of Viprinex; and, approximately \$201,000 of commercial insurance expense for the Viprinex development program. The increase of \$1,871,000 in research and development expenses for XERECEPT result primarily from: approximately \$962,000 of clinical consulting fees; approximately \$674,000 for the manufacture of XERECEPT clinical materials; and, approximately \$153,000 of compensation and related benefit expense for an increased level of personnel dedicated to the XERECEPT program.

Research and development expenses were \$2,098,000 in fiscal 2004 compared to \$2,317,000 in fiscal 2003. The decrease from 2003 to 2004 was primarily due to the completion of toxicology studies and manufacturing of clinical supplies of XERECEPT, partially offset by an increase in expenses relating to the initiation in April 2004 of a Phase III clinical trial for XERECEPT.

The table captioned "Product Development Status" in Item 1 of this report sets forth the status of regulatory approval and clinical trial for Memantine, XERECEPT and Viprinex. The expenses

Table of Contents

related to the clinical trials of XERECEPT were approximately \$3,969,000, \$2,098,000, and \$2,292,000 for the years ended June 30, 2005, 2004, and 2003, respectively. To date, we have incurred expenses of approximately \$8,947,000 in the development of Memantine, \$22,203,000 in the development of XERECEPT, and \$11,775,000, which includes the expense of \$4,251,000 associated with the charge-off of acquired in-process research and development expenses, for Viprinex. All future expenses for the development and commercialization of Memantine will be borne by Merz and its marketing partners, Forest and Lundbeck. We currently anticipate that our expenditures for completing the two planned Viprinex Phase III trials will be approximately \$33 million, of which we have incurred approximately \$6.8 million through June 30, 2005; these estimated expenditures do not include the non-cash expenses resulting from charge to expense for acquired in-process research and development, amortization of intangible assets and depreciation of tangible assets acquired with the acquisition of Empire. However, these estimates are subject to the uncertainties inherent in conducting clinical trials and seeking regulatory approval drug candidates. Pursuant to the agreement under which we have agreed to sell our rights and assets related to XERECEPT, we will continue to provide development services for XERECEPT, the direct costs of which we will be reimbursed by the buyers of these assets.

Research and development expenditures are charged to operations, as incurred. Research and development expenses, including direct and allocated expenses, consist of independent research and development costs and costs associated with sponsored research and development.

Material cash inflows resulting from the successful completion and commercialization of our current research and development projects are estimable and realizable only when clinical trials are successfully completed and the drugs are approved by the FDA. Because of the uncertainty relating to the clinical trials and receipt of regulatory approval by the FDA, we cannot estimate the amount or timing of receipt for significant cash inflows resulting from the potential successful commercialization of our research and development projects.

ACQUIRED IN-PROCESS RESEARCH AND DEVELOPMENT

Year Ended June 30,			Increase (Decrease) From	
2005	2004	2003	2005/2004	2004/2003
\$4,251,000			\$4,251,000	

We acquired Empire in July 2004 in order to secure the worldwide rights to Viprinex, a late-stage perfusion therapy for use in ischemic stroke. The acquisition of Empire is recorded as a purchase of assets and, accordingly, the purchase price was assigned to all identified tangible and intangible assets. During the identification and valuation process, we determined that in-process research and development associated with Viprinex had a fair value of \$4,251,000. This valuation was determined using risk-adjusted valuation of the cash flows anticipated with completing the research and development of Viprinex. At the date of the acquisition, the development of Viprinex had not reached technological feasibility and the research and development in progress had no alternative future uses. Accordingly, the in-process research and development acquired with the acquisition of Empire was charged to expense at the date of the acquisition. If pivotal Phase III trials for Viprinex are commenced as currently planned, we will issue an additional 2,375,170 shares of our common stock and pay an additional \$1,515,675 to the selling stockholders of Empire and will pay Empire's former principal stockholder, who is currently an officer of NTI, \$484,325 for the remainder of advances that he previously made to Empire. We anticipate that, in the event the pivotal Phase III trials for Viprinex are commenced and the additional

Table of Contents

proceeds are paid to the selling stockholders of Empire, approximately \$3,750,000 of the contingent consideration will be identified as in-process research and development based on its pro-rata allocation of the total consideration for the acquisition, assuming a per-share valuation of \$3.85 for the issued shares, and will be recorded as expense in the period during which the contingent payment is made. Otherwise, we currently do not expect to incur similar charges in future periods.

GENERAL AND ADMINISTRATIVE EXPENSES

Year Ended June 30,			Increase (Decrease) From	
2005	2004	2003	2005/2004	2004/2003
\$4,927,000	\$3,101,000	\$2,493,000	\$1,826,000	\$608,000

General and administrative expenses of \$4,927,000 for the year ended June 30, 2005, increased \$1,826,000 over \$3,101,000 of administrative expenses in 2004. The increase of \$1,826,000 in administrative expenses results primarily from \$421,000 of expenses for the administrative operations of our New Jersey office established in September 2004, together with an increase of \$623,000 for periodic public reporting requirements, including professional fees for examination of Sarbanes-Oxley assessments, an increase of approximately \$336,000 of compensation and related expenses resulting from additions to personnel and establishing an incentive compensation program, an increase of approximately \$224,000 for consulting expenses relating to the preparation of public reporting requirements and with financial management of the Company, and an increase of approximately \$125,000 for legal fees associated with pursuing various strategic alternatives including the sale of our rights and assets related to XERECEPT and compliance with the Sarbanes-Oxley Act of 2002.

General and administrative expenses were \$3,101,000 in 2004 compared to \$2,493,000 in fiscal 2003. The 2004 increase resulted primarily from increases of \$230,000 for performance-based bonus compensation and \$378,000 for additional marketing advisory and investor relation services, directors and officers insurance, increased directors fees, and professional fees related to compliance with the Sarbanes-Oxley Act.

We anticipate that general and administrative expenses will increase in the future as we expand our New Jersey facilities.

INVESTMENT INCOME

Year Ended June 30,			Increase (Decrease) From	
2005	2004	2003	2005/2004	2004/2003
\$249,000	\$128,000	\$144,000	\$121,000	\$(16,000)

Edgar Filing: NEUROBIOLOGICAL TECHNOLOGIES INC /CA/ - Form 10-K

Investment income of \$249,000 for the year ended June 30, 2005, consists of interest, amortization of principal, accretion of discount and realized gains and losses on sale of individual securities of the Company's portfolio of investment securities, all of which are classified as available for sale. The increase of investment income resulted from a greater average balance of invested funds available at the beginning of 2005 resulting from the Company's sale of common stock and warrants for net proceeds of \$18,311,000 in March 2004.

Table of Contents

Investment income was \$128,000 in 2004, compared to \$144,000 in 2003. The decrease was primarily due to lower average interest rates and lower average invested cash balances. In March 2004, we issued 3,880,000 shares of common stock and warrants to purchase 737,000 shares of common stock for net proceeds of \$18,311,000, which funds were available for investment in the final four months of the 2004 fiscal year.

OTHER NON-CASH INCOME

Year Ended June 30,			Increase (Decrease) From	
2005	2004	2003	2005/2004	2004/2003
	\$477,000		\$(477,000)	\$477,000

Non-cash income of \$477,000 in 2004 resulted from the revaluation of warrants issued with our sale of 3,880,000 shares of common stock in March 2004. The common stock and warrants were issued in a private placement and were initially unregistered. We filed a registration statement on Form S-3 with the Securities and Exchange Commission in April 2004 to register the shares issued in the private placement, as well as the shares to be issued upon the exercise of the warrants. In accordance with EITF 00-19, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, A Company's Own Stock, the warrants were reported as a liability and valued at fair value on the date of issuance. Pursuant to the terms of the private placement agreement, the Company could have delivered warrants for which the related shares were unregistered, but would have been required to pay a monthly penalty to each purchaser, with no contractual maximum, until the time that the registration statement was filed. Accordingly, because the penalty for not registering the shares related to the warrants had no contractual maximum, the Company determined that the penalty did not represent a reasonable difference between the value of registered and unregistered shares and that settling with unregistered shares was not an economically reasonable alternative. The warrants were revalued each period until the effective date of the registration statement, and the change in the fair value from the date of issuance through the date that the registration statement was effective, in the amount of \$477,000, was recorded as non-cash income.

We had no other non-cash income during 2005 and 2003.

LIQUIDITY AND CAPITAL RESOURCES

	June 30,		
	2005	2004	2003
Cash, cash equivalents, and investment securities	\$ 8,506,000	\$ 20,734,000	\$ 4,402,000
Working capital	\$ 5,290,000	\$ 20,446,000	\$ 4,238,000

Year Ended June 30,		
2005	2004	2003

Edgar Filing: NEUROBIOLOGICAL TECHNOLOGIES INC /CA/ - Form 10-K

Cash (used in) provided by:			
Operating activities	\$ (9,404,000)	\$ (2,078,000)	\$ (3,110,000)
Investing activities	\$ 7,517,000	\$ (14,736,000)	\$ 2,625,000
Financing activities	\$ 703,000	\$ 18,760,000	\$ 274,000

Table of Contents

Since our founding in 1987, we have applied a majority of our resources to research and development programs and have generated only limited operating revenue. Except for 2001, we have incurred losses in each year since our inception and we expect to continue to incur losses in the future due to ongoing research and development efforts.

As of June 30, 2005, we had cash, cash equivalents and investment securities of \$8,506,000 which represents a decrease of \$12,228,000 compared to our balance of cash, cash equivalents and investment securities of \$20,734,000 as of June 30, 2004.

Cash Flows from Operating Activities

We used \$9,404,000 of cash for operating activities in 2005 resulting primarily from the net loss of \$17,322,000 which was partially offset by the non-cash expense resulting from the charge of approximately \$4,251,000 for acquired in-process research and development related to our acquisition of Empire Pharmaceuticals, Inc. in July 2004, and the non-cash expense of approximately \$816,000 for depreciation and amortization of tangible and intangible assets. We earned cash royalty revenue of \$3,100,000 based on sales of Memantine for the treatment of mid- to moderate-Alzheimer's disease by Merz's marketing partners in Europe and the United States. Merz and its marketing partners are responsible for sales and marketing of Memantine, and we are unable to estimate the level of royalties which may result from future sales. In the event that Merz and its marketing partners obtain regulatory approval for the commercial sale of Memantine for other indications, such as mild- to moderate-Alzheimer's disease or neuropathic pain, we may earn additional cash license fees in future periods. Our research and development operations together with our general and administrative operations, used cash of \$11,293,000 and \$4,927,000, respectively. The increase of \$3,155,000 in accounts payable and accrued liabilities and the use of cash for an increase of \$277,000 in prepaid and other assets was due to the increase in Viprinex and XERECEPT related expenditures. The increase of \$31,000 of restricted cash and \$75,000 in deposits relate to new facilities that we arranged for our corporate headquarters and New Jersey locations.

Cash Flows from Investing Activities

Investing activities provided cash flows of \$7,517,000 in 2005 resulted primarily from sales and maturities of investments of \$90,906,000, which was partially offset by investment purchases of \$79,793,000, the payment of \$2,951,000 of cash for the purchase of Empire Pharmaceuticals, net of cash received, and the purchase of property and equipment in the amount of \$645,000 related primarily to clinical production equipment.

Cash Flows from Financing Activities

Financing activities provided cash of \$703,000 in 2005 consisting of the net proceeds we received in the amount of \$689,000 from the exercise of warrants and options for our common stock, and \$14,000 from the sale of common stock pursuant to the Company's employee stock purchase plan during the year.

Table of Contents

Our contractual commitments as of June 30, 2005 are summarized below by category in the following table. As we move forward with the clinical development of Viprinex, we will enter into contractual commitments for additional expenditures relating to these clinical trials; these additional expenditures are not reflected in the following table.

	Payments due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations	\$ 1,655,000	\$ 231,000	\$ 1,031,000	\$ 393,000	
Other long-term liabilities *	14,912,000	10,584,000	4,328,000		
Total	\$ 16,567,000	\$ 10,815,000	\$ 5,359,000	\$ 393,000	

* Includes additional contingent merger cash consideration payable as of June 30, 2005 to the selling stockholders of Empire Pharmaceuticals upon commencement of Phase III clinical trials for Viprinex. These clinical trials are anticipated to commence in September 2005, or shortly thereafter, at which time our payments will be made and we will issue 2,375,170 shares of common stock to the selling stockholders.

At June 30, 2005 our balance of available cash, cash equivalents and investment securities is \$8,506,000. As described above, we expect to incur increased costs in 2006 and subsequent fiscal years primarily for Phase III clinical trials for Viprinex, along with related administrative support costs. Additionally, when the first patient is enrolled in the Phase III clinical trials for Viprinex, which we anticipate will occur in September 2005 or shortly thereafter, we will pay the former Empire stockholders an additional \$2,000,000 in cash and issue an additional 2,375,170 shares of common stock. All future development costs for Memantine will be paid by Merz, together with its marketing partners. In August 2005, we entered into a loan agreement with a commercial bank. The loan agreement provides the Company with a \$10 million revolving credit facility, which matures at the end of two years and bears interest at the bank's variable prime rate plus 1.00%. The revolving credit facility is secured by substantially all of the assets of the Company.

In September 2005, we signed a definitive agreement for the sale of our rights in XERECEPT to two wholly-owned subsidiaries of a private equity firm focused on the biotechnology and pharmaceutical industries. Under the terms of the agreement, we will receive \$20 million in cash upon closing and a promissory note requiring the buyers to pay us an additional \$13 million in non-contingent installment payments due in January and June 2006, and January 2007. We are also eligible to receive up to an additional \$15 million upon the achievement of certain regulatory objectives and are eligible to receive profit-sharing payments on sales of XERECEPT in the United States and royalties on any sales elsewhere in the world, if the product receives regulatory approval. The buyers will assume responsibility for product development and pay all product development expenses. We will provide ongoing services relating to the current clinical trials of XERECEPT.

We believe that our available cash, cash equivalents and investment balances of \$8,506,000 as of June 30, 2005, our \$10 million credit facility, the \$33 million we will receive from our sale of rights to XERECEPT between closing and January 2007, and the reimbursement of our ongoing development costs for XERECEPT, will provide adequate liquidity to fund our operations through at least the next twelve months. However we may seek to raise additional liquidity to fund our operations in periods

Table of Contents

thereafter or to acquire development projects for our pipeline. Accordingly, we may seek to raise additional funds when market conditions permit, including through the sale of up to \$25 million of common stock pursuant to our shelf registration statement. However, there can be no assurance that funding will be available or that, if available, will be on acceptable terms.

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

- the amount of payments received from marketing agreements for Memantine;
- the amount of royalties received from Merz for future sales of Memantine;
- the receipts of payments pursuant to our agreement with Celtic which we anticipate will close by early October 2005;
- the progress of our clinical development programs;
- the time and cost involved in obtaining regulatory approvals;
- 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; and
- the development of commercialization activities and arrangements.

We do not have any off-balance sheet arrangements as defined by rules recently enacted by the Securities and Exchange Commission and Financial Accounting Standards Board, and accordingly, no such arrangements are likely to have a current or future effect on our financial position, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

OTHER FACTORS THAT MAY AFFECT FUTURE RESULTS

Our product candidates are based on new technologies and therefore are subject to numerous inherent risks of failure.

Edgar Filing: NEUROBIOLOGICAL TECHNOLOGIES INC /CA/ - Form 10-K

Our product candidates are based on new and relatively unproven technologies. Viprinex has previously failed in the Phase III clinical trial in Europe conducted by Knoll AG, where patients receiving Viprinex in the trial suffered from intercranial hemorrhaging and higher mortality rates than those patients receiving the placebo treatment. A Phase III clinical trial for Memantine for neuropathic pain failed to meet the primary endpoint. As evidenced by these trials, our product candidates face numerous risks of failure, including the possibility that these drug candidates may:

be found to be unsafe, ineffective or toxic; or

fail to receive necessary regulatory clearances.

If any of these risks of failure should materialize, we may be forced to make additional significant expenditures for further clinical trials or cease further development of the drug candidate. In either case, our prospects would be harmed and our stock price could decline.

Table of Contents

We are dependent on Merz and its marketing partners Forest and Lundbeck for the successful commercialization of Memantine.

All of our revenues in fiscal 2005, 2004 and 2003 were license fee and royalty payments from Merz related to our portion of payments received by Merz pursuant to its agreements with Forest and Lundbeck, its marketing partners. The only revenues that we expect to receive in the foreseeable future are our share of payments received by Merz from Forest and Lundbeck and royalties on Memantine sales made by Merz or its marketing partners, which depends, among other things, on the continuation of our research and marketing cooperation agreement with Merz and Children's Medical Center. Although Merz has received approval to market Memantine for Alzheimer's disease in Europe, we are not entitled to receive royalty payments for Memantine sales for Alzheimer's disease in certain European countries and any commercialization efforts in these markets would not directly benefit us. If Merz is unable to successfully commercialize Memantine, or if Memantine is not commercialized for indications or in markets where we are entitled to royalty payments, our revenues would be adversely affected.

In February 2005, Merz made a royalty payment to us in the amount of \$765,000 for sales of Memantine during the quarter ended September 30, 2004, for the treatment of moderate-to-severe Alzheimer's disease. Merz informed us that the payment reflected a one-time reduction of \$108,000 to correct an apparent over-payment on royalties on certain sales outside of the U.S. in earlier quarters. We may be subject to such adjustments in the future.

Merz or Children's Medical Center can terminate our research and marketing cooperation agreement upon six months' notice in the event that Merz does not meet certain conditions relating to the clinical development of Memantine. We believe these conditions are currently being met. However, the termination of our agreement with Merz or any failure by Merz or its partners to successfully commercialize Memantine, could reduce or terminate our future royalties under the research and marketing cooperation agreement and would have a material adverse effect on our business, financial conditions and results of operations.

If we close the sale of our rights and assets related to XERECEPT pursuant to the agreement we entered into with newly-formed subsidiaries of Celtic Pharma Holdings, L.P. in September 2005, we will be dependent upon these entities for the development and commercialization of XERECEPT.

Subsequent to fiscal year end, on September 19, 2005, we entered into an agreement to sell all our rights and assets related to XERECEPT to two newly-formed subsidiaries of Celtic Pharma Holdings, L.P. or Celtic. That transaction is expected to close in September or early October 2005. Under the terms of the agreement, we will receive \$20 million upon closing and an additional \$13 million in non-contingent installment payments due in January and June 2006, and January 2007. We are also eligible to receive up to an additional \$15 million upon the achievement of certain regulatory objectives and are eligible to receive profit-sharing payments on sales of XERECEPT in the United States and royalties on any sales elsewhere in the world, if the product receives regulatory approval. The buyers will assume responsibility for product development and pay all product development expenses. We will provide ongoing services relating to the current clinical trials of XERECEPT. The failure of these entities to do so could harm our operating prospects and results.

We have a history of losses and we may never achieve or maintain profitability.

Except for fiscal 2001, we have experienced operating losses every year since inception in funding the research, development and clinical testing of our drug candidates. As of June 30, 2005, our

Table of Contents

accumulated deficit was approximately \$59.6 million and we expect to continue to incur operating losses in the next several years as we continue our clinical trials for Viprinex. To achieve profitability, we would need to generate significant additional revenue with positive gross margins. Although we expect that our royalty revenues from the sales of Memantine will increase in future periods, these increases may not occur and, even if they do increase in line with our expectations, we do not expect that these increases will be sufficient to allow us to operate profitably at any time in the foreseeable future.

Even if Viprinex is approved for commercialization, it may not be successfully commercialized.

If Viprinex is approved for commercialization, we will be required either to market the drug directly, which would require the recruitment and training of a direct sales force, or license the drug to a larger biotechnology or pharmaceutical company with an existing sales force. The building of a direct sales force is costly and we may not succeed in directly marketing any approved drug. If we elected to license the approved drug 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 of the drug.

Our industry is highly competitive

Competition in the biopharmaceutical industry is intense and is expected to increase. There are other therapies under development for each of our therapeutic targets and the development and sale of drugs for the treatment of the therapeutic targets that we and our collaborative partners are pursuing is highly competitive. Specifically, we face known competition from the following companies for each of the indications listed below.

Indication / Principal known competing products and competitors Alzheimer's disease (Memantine)

ARICEPT® (donepezil HCl) Eisai Inc. and Pfizer Inc.

Exelon® (rivastigmine tartrate) Novartis

Reminyl® (galantamine HBr) Janssen Pharmaceutica

Neuropathic pain (Memantine)

Neurontin® (gabapentin) Parke-Davis

Cymbalta® (duloxetine HCl) Lilly

Lyrica® (pregabalin) Pfizer Inc.

Peritumoral brain edema (XERECEPT)

Decadron® (dexamethasone) Merck & Co. Inc.

Acute ischemic stroke (Viprinex)

Activase® (alteplase, recombinat) Genentech, Inc.

Our competitors are generally larger biotechnology or pharmaceutical companies with significantly greater financial resources and experience and have more internal development, sales and marketing personnel. Accordingly, we may not be able to develop products that will be as efficacious or as cost-effective as currently-marketed products or those products being developed by our

Table of Contents

competitors. In addition, others may develop, manufacture and market products that could compete with those that we are developing.

It is difficult to integrate acquired companies, products, technologies and personnel into our operations and our inability to do so could greatly lessen the value of any such acquisitions.

In July 2004, we acquired Empire Pharmaceuticals in a merger transaction and we may make additional strategic acquisitions of companies, products or technologies in the future in order to complement our product pipeline or to implement our business strategy. In connection with the Empire acquisition, we added two new members to our senior management team and we established offices and added personnel in New Jersey. The management of two facilities has required us to implement new internal controls and the distance between the facilities has required frequent travel for our management team. If we are unable to successfully integrate acquired businesses, products, technologies or personnel with our existing operations, we may not receive the intended benefits of such acquisitions.

Additionally, disputes may arise following the consummation of an acquisition regarding representations and warranties, indemnity, earn-out and other provisions in the acquisition agreement. For these reasons, acquisitions may subject us to unanticipated liabilities or risks, disrupt our operations or divert management's attention from day-to-day operations.

Because we do not have our own manufacturing facilities, we face risks from outsourcing.

Although Merz and its marketing partners have the responsibility of supplying Memantine for the clinical trials and commercialization of the drug, we must procure our own supplies of Viprinex for our clinical trials.

In March 2005, we executed an agreement with Nordmark Arzneimittel GmbH & Co. KG for supply of the active pharmaceutical ingredient of Viprinex that is manufactured in accordance with cGMP. The term of this supply agreement will expire in October 2019. In June 2005, we entered into a drug product development and clinical supply agreement with Baxter Pharmaceutical Solutions LLC for fill and finish of the Viprinex product for development and clinical use. This agreement will continue until such Viprinex product production is completed. In addition, we have taken steps to ensure an adequate supply of raw Malayan pit viper venom, from which the Viprinex active pharmaceutical ingredient is prepared (including steps towards the establishment of a colony of Malayan pit vipers in the United States). Any difficulties in obtaining raw Malayan pit viper venom in necessary quantities and potencies could adversely affect our ability to manufacture clinical and commercial supplies of Viprinex.

Pursuant to our agreement with Celtic, we will be required to supply XERECEPT for clinical trials. We have previously experienced delays obtaining the necessary clinical supplies of XERECEPT due to manufacturing difficulties. We may experience further delays in obtaining clinical supplies of XERECEPT, which could cause us to fail to meet our obligations to Celtic and delay the XERECEPT clinical trials.

Further, although we perform audits on our contractors who supply our drug candidates to assess compliance with their current Good Manufacturing Practice, or cGMP, regulations, there can be no assurance that our suppliers will meet cGMP standards or be able to synthesize and deliver our drug compounds 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

Table of Contents

there is only a limited number of manufacturers who are capable of producing the compound. The loss of our current supply arrangement could significantly delay our planned clinical trials for Viprinex and could impact the commercialization of the drug, if it is approved by the FDA.

As a result of our reliance on manufacturers, we face the following outsourcing risks:

the delay of our preclinical and human clinical testing if our contractors are unable to supply sufficient quantities of product candidates manufactured in accordance with cGMP on acceptable terms;

the delay of market introduction and subsequent sales if we should encounter difficulties establishing relationships with manufacturers to produce, package and distribute products; and

adverse effects on FDA pre-market approval of potential products if contract manufacturers do not adhere to cGMP regulations.

Because of these risks, our dependence on third parties for the manufacture of products may adversely affect our ability to develop and deliver products on a timely and competitive basis and our results of operations.

The FDA and state and local agencies, and comparable agencies and entities in foreign countries impose substantial requirements on the manufacturing and marketing of human therapeutics through lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time consuming procedures.

Fulfillment of regulatory requirements for marketing human therapeutics typically takes many years and varies substantially based on the type, complexity, and novelty of the drug for which approval is sought. Government regulation may:

delay for a considerable period of time or prevent marketing of any product that we may develop; and/or

impose costly procedures upon our activities.

Either of these effects of government regulation may provide an advantage to our competitors.

There can be no assurance that FDA or other regulatory approval for any products developed by us will be granted on a timely basis or at all. Any delay in obtaining, or failure to obtain, required approvals would adversely affect the marketing of our proposed products and our ability to earn product revenues or royalties.

In addition, success in pre-clinical or early stage clinical trials does not assure success in later-stage clinical trials. For example, although our Phase II clinical trials for Memantine for the treatment of diabetic neuropathy produced positive results, a subsequent clinical trial conducted by Forest did not replicate these results. Similarly, the results of Knoll AG's Phase III clinical trials for Viprinex in the United States were not

replicated in the subsequent European clinical trial, and we cannot be certain that the Phase III clinical trials that we anticipate to commence in September 2005 or shortly thereafter, will not encounter similar difficulties. Similar variations in later-stage clinical trial results may also occur in XERECEPT, as longer trials and larger patient populations are used. Further, since we began the first Phase III clinical trial of XERECEPT in April 2004, patient enrollment has been slow and we have not yet commenced the second Phase III trial. Any further delays in patient enrollment could impede the development of XERECEPT and make it less likely that we or Celtic will be able to further develop or successfully commercialize the drug.

Table of Contents

As with any regulated product, additional government regulations may be instituted which could delay regulatory approval of our potential products. Additional government regulations that might result from future legislation or administrative action cannot be predicted.

We may need to raise additional capital to fund ongoing operations. If we are unable to raise additional capital, we may be forced to curtail operations. If we succeed in raising additional capital through a financing transaction, it may adversely affect our stock price.

In order to maintain sufficient cash and investments to fund future operations, we may need to raise additional capital. Although we obtained a \$10 million revolving credit facility in August 2005, and expect to receive aggregate payments of \$33 million under our agreement with Celtic, we may seek to raise up to \$25 million in additional capital over the next 12 to 24 months through various alternatives, including selling shares of our common stock.

If we raise capital by issuing additional shares of common stock at a price per share less than the then-current market price per share, the value of the shares of our common stock then outstanding may be reduced. Further, even if we were to sell shares of common stock at prices equal to or higher than the current market price, the issuance of additional shares may depress the market price of our common stock and dilute voting rights.

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, then we might have to reduce operations or defer or abandon one or more of our clinical or preclinical research programs. Any of these actions could be expected to have an adverse effect on our stock price.

We have relied and will continue to rely on others for research, development and commercialization of our potential products.

We have periodically entered into various contractual arrangements (which are generally non-exclusive) with consultants, academic collaborators, licensors, licensees and others, and we are dependent upon the level of commitment and subsequent success of these outside parties in performing their responsibilities. Certain of these agreements may place significant responsibility on the collaborator, licensor or contractor for pre-clinical testing and human clinical trials and for preparing and submitting submissions for regulatory approval for potential products on the collaborator, licensor or contractor. In the quarter ended June 30, 2005, we entered into an agreement with SCIREX Corporation for the design and management of our anticipated Phase III clinical trials for Viprinex. We expect to rely substantially on SCIREX for these clinical trials. If this organization or any other collaborator, licensor or contractor fails to perform, our business, financial conditions and results may be adversely affected.

We have also relied on scientific, mechanical, clinical, commercial and other data supplied and disclosed by others in entering into these agreements. We have relied on this data in support of applications for human clinical trials for our potential products. 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 these potential products.

Table of Contents

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 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.

No infringement claims have been brought by third parties and we are not aware of any basis on which such claims could be made. Any infringement claims 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.

If the members of our expanded management team are unable to work together effectively, our ability to manage our business will suffer.

Since our acquisition of Empire Pharmaceuticals in July 2004, we have expanded our management team. Stephen J. Petti joined us as Vice President, Product Development in July 2004; David E. Levy joined us as Vice President, Clinical Development in September 2004; Jonathan R. Wolter joined us as Vice President and Chief Financial Officer in December 2004; and, Karl G. Trass joined us as Director of Regulatory Affairs in January 2005 and was promoted to Vice President, Regulatory Affairs in September 2005. In addition, we may seek to hire other executive officers in the future. Consequently, most of the members of our management team have recently joined the company and have not worked together before. If these employees cannot work together effectively our ability to manage our business will suffer.

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.

Table of Contents

Our current product liability insurance does not cover the commercial sales of products. 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. An 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.

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.

We issued 2,399,163 shares of common stock in connection with our acquisition of Empire Pharmaceuticals and, if we commence Phase III clinical trials for Viprinex in September 2005, or shortly thereafter as expected, we will be required to issue an additional 2,375,170 shares. These shares have been registered for resale and are, or upon issuance will be, freely tradable. The issuance of these additional shares and any large sales that may be made by former stockholders of Empire or otherwise could have a negative effect on the price and volatility of our stock price.

Additional factors that may affect the volatility of our stock price include:

announcements of the results of pre-clinical studies and clinical trials by us, Merz or its marketing partners, Celtic or our competitors;

other evidence of the safety or efficacy of our products, or those of Merz or its marketing partners, Celtic or our competitors;

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;

fluctuations in our operating results;

government regulation and health care legislation; and

market conditions for life science companies' stocks in general.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE 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 to protect against these and other exposures. As a result, we do not anticipate material potential losses in these areas.

The primary objective for our investment activities is to preserve principal while maximizing yields without significantly increasing risk. This is accomplished by investing in widely diversified short-term investments, consisting primarily of investment grade securities. As of June 30, 2005, the fair value of our investments was approximately \$7.7 million, 6% of our total portfolio will mature in one year or less, and the total portfolio had a duration of approximately 2.7 years. 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. We have no investments denominated in foreign country currencies and therefore our investments are not subject to foreign currency exchange risk.

Table of Contents

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

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, 2005 and 2004, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended June 30, 2005. 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 the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Neurobiological Technologies, Inc. at June 30, 2005 and 2004, and the consolidated results of its operations and its cash flows for each of the three years in the period ended June 30, 2005, in conformity with the U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Neurobiological Technologies, Inc.'s internal control over financial reporting as of June 30, 2005, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated September 27, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California

September 27, 2005

Table of Contents**Neurobiological Technologies, Inc.****CONSOLIDATED BALANCE SHEETS**

	June 30,	
	2005	2004
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 828,416	\$ 2,012,452
Investment securities	7,677,818	18,721,107
Interest receivable	52,648	103,259
Prepaid expenses and other current assets	546,796	269,444
	<u>9,105,678</u>	<u>21,106,262</u>
Total current assets	9,105,678	21,106,262
Restricted cash	30,933	
Deposits	82,117	7,583
Property and equipment, net	596,021	6,209
Acquisition-related tangible and intangible assets	7,655,391	
Deferred acquisition costs		263,544
	<u>\$ 17,470,140</u>	<u>\$ 21,383,598</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 579,647	\$ 258,855
Accrued compensation-related expenses	364,500	
Accrued clinical trial expenses	573,520	42,550
Accrued professional expenses	503,068	210,025
Accrued toxicology and manufacturing expenses	1,551,049	42,284
Other accrued liabilities	244,251	106,835
	<u>3,816,034</u>	<u>660,549</u>
Total current liabilities	3,816,034	660,549
Commitments		
Stockholders' equity:		
Convertible Series A Preferred stock, \$.001 par value, 5,000,000 shares authorized, 2,332,000 issued in series, 504,000 and 534,000 outstanding at June 30, 2005 and 2004, respectively (aggregate liquidation preference of \$252,000 at June 30, 2005)	252,000	267,000
Common stock, \$.001 par value, 50,000,000 and 35,000,000 shares authorized, at June 30, 2005 and 2004, respectively, and 27,077,418 and 23,993,938 outstanding at June 30, 2005 and 2004, respectively	73,051,935	62,880,926
Deferred stock compensation		(27,376)
Accumulated deficit	(59,646,803)	(42,324,627)
Accumulated other comprehensive loss	(3,026)	(72,874)
	<u>13,654,106</u>	<u>20,723,049</u>
Total stockholders' equity	13,654,106	20,723,049
	<u>\$ 17,470,140</u>	<u>\$ 21,383,598</u>

See accompanying notes.

Table of Contents**Neurobiological Technologies, Inc.****CONSOLIDATED STATEMENTS OF OPERATIONS**

	Year ended June 30,		
	2005	2004	2003
REVENUES:			
License	\$	\$ 2,531,210	\$ 1,968,690
Royalty	3,099,511	255,369	10,949
Total revenues	3,099,511	2,786,579	1,979,639
EXPENSES:			
Research and development	11,492,463	2,098,404	2,316,978
Acquired in-process research and development	4,251,335		
General and administrative	4,927,374	3,101,033	2,492,971
Total expenses	20,671,172	5,199,437	4,809,949
Operating loss	(17,571,661)	(2,412,858)	(2,830,310)
Investment income	249,485	127,516	143,842
Other non-cash income		477,239	
Net Loss	\$ (17,322,176)	\$ (1,808,103)	\$ (2,686,468)
Basic and diluted net loss per share	\$ (0.65)	\$ (0.09)	\$ (0.15)
Shares used in basic and diluted net loss per share calculation	26,529,564	20,678,914	18,015,644

See accompanying note

Table of Contents**Neurobiological Technologies, Inc.****STATEMENTS OF STOCKHOLDERS EQUITY**

	Convertible Preferred Stock		Common Stock		Deferred Stock Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders Equity
	Shares	Amount	Shares	Amount				
Balances at June 30, 2002	1,372,000	\$ 686,000	17,783,571	\$ 43,876,705	\$ (136,876)	\$ (37,830,056)	\$ 16,930	\$ 6,612,703
Issuance of common stock upon exercise of options and warrants			769,955	320,422				320,422
Repurchase of common stock			(32,000)	(86,950)				(86,950)
Amortization of deferred stock compensation					54,750			54,750
Conversion of preferred stock to common stock	(218,000)	(109,000)	218,000	109,000				
Issuance of common stock under employee stock purchase plan			16,027	40,357				40,357
Comprehensive loss:								
Net loss						(2,686,468)		(2,686,468)
Unrealized loss on securities							(7,199)	(7,199)
Total comprehensive loss								(2,693,667)
Balances at June 30, 2003	1,154,000	577,000	18,755,553	44,259,534	(82,126)	(40,516,524)	9,731	4,247,615
Issuance of common stock upon exercise of options and warrants			729,005	423,917				423,917
Issuance of common stock in private equity financing net of issuance costs			3,880,000	13,274,669				13,274,669
Issuance of warrants with common stock in private equity financing				4,558,923				4,558,923
Issuance of warrants for services				28,200				28,200
Amortization of deferred stock compensation					54,750			54,750
Conversion of preferred stock to common stock	(620,000)	(310,000)	620,000	310,000				
Issuance of common stock under employee stock purchase plan			9,380	25,683				25,683
Comprehensive loss:								
Net loss						(1,808,103)		(1,808,103)
Unrealized loss on securities							(82,605)	(82,605)
Total comprehensive loss								(1,890,708)
Balances at June 30, 2004	534,000	267,000	23,993,938	62,880,926	(27,376)	\$ (42,324,627)	(72,874)	20,723,049
Issuance of common stock upon exercise of options and warrants			649,109	689,054				689,054
Amortization of deferred stock compensation					27,376			27,376
Conversion of preferred stock to common stock	(30,000)	(15,000)	30,000	15,000				
Issuance of common stock under employee stock purchase plan			5,208	14,253				14,253
Issuance of common stock at \$3.94 per share in connection with acquisition			2,399,163	9,452,702				9,452,702

Edgar Filing: NEUROBIOLOGICAL TECHNOLOGIES INC /CA/ - Form 10-K

Comprehensive loss:								
Net loss						(17,322,176)		(17,322,176)
Unrealized gain on securities							69,848	69,848
Total comprehensive loss								(17,252,328)
Balances at June 30, 2005	504,000	\$ 252,000	27,077,418	\$ 73,051,935	\$	\$ (59,646,803)	\$ (3,026)	\$ 13,654,106

See accompanying notes.

Table of Contents**Neurobiological Technologies, Inc.****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year ended June 30,		
	2005	2004	2003
OPERATING ACTIVITIES			
Net loss	\$ (17,322,176)	\$ (1,808,103)	\$ (2,686,468)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	815,833	5,967	8,715
Acquired in-process research and development	4,251,335		
Loss on sale of property and equipment		2,850	
Amortization of deferred stock compensation	27,376	54,750	54,750
Derivative revaluation		(477,239)	
Issuance of common stock, options and warrants for license rights and services		28,200	
Changes in assets and liabilities:			
Restricted cash	(30,933)		
Interest receivable	50,611	(52,920)	105,557
Prepaid expenses and other current assets	(277,352)	73,506	(105,999)
Deposits	(74,534)		
Accounts payable and accrued expenses	3,155,485	94,954	(486,682)
Net cash used in operating activities	(9,404,355)	(2,078,035)	(3,110,127)
INVESTING ACTIVITIES			
Acquisition, net of cash acquired	(2,950,690)		
Purchase of investments	(79,792,808)	(54,000,312)	(6,719,831)
Sales and maturities of investments	90,905,945	39,532,727	9,358,537
Purchases of property and equipment	(645,435)	(4,953)	(13,332)
Deferred acquisition costs		(263,544)	
Net cash (used in) provided by investing activities	7,517,012	(14,736,082)	2,625,374
FINANCING ACTIVITIES			
Issuance of common stock, net of issuance costs	703,307	18,760,431	360,779
Repurchase of common stock			(86,950)
Net cash provided by financing activities	703,307	18,760,431	273,829
Increase (decrease) in cash and cash equivalents	(1,184,036)	1,946,314	(210,924)
Cash and cash equivalents at beginning of period	2,012,452	66,138	277,062
Cash and cash equivalents at end of period	\$ 828,416	\$ 2,012,452	\$ 66,138
SUPPLEMENTAL DISCLOSURES:			
Issuance of common stock in connection with an acquisition	\$ 9,452,702	\$	\$

Edgar Filing: NEUROBIOLOGICAL TECHNOLOGIES INC /CA/ - Form 10-K

Conversion of preferred stock to common stock	\$ 15,000	\$ 310,000	\$ 109,000
-----------------------------------------------	-----------	------------	------------

See accompanying notes.

Table of Contents

Neurobiological Technologies, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

Description of Business

Neurobiological Technologies, Inc. ("NTI", we, or the Company) is a drug development company focused on the clinical evaluation and regulatory approval of neuroscience drugs. The Company's strategy is to in-license and develop later-stage drug candidates that target major medical needs and which can be rapidly commercialized. The Company's experienced management team oversees the human clinical trials necessary to establish preliminary evidence of efficacy and seeks partnerships with pharmaceutical and biotechnology companies to complete development and marketing of our product candidates.

The accompanying Consolidated Financial Statements include the accounts of the Company and its subsidiary NTI-Empire, Inc. All significant intercompany accounts and transactions have been eliminated in consolidation.

Currently, we receive revenues on the sales of one approved product and have two product candidates in clinical development. Memantine, an orally-dosed compound, has been approved for treatment of moderate to severe Alzheimer's disease and is marketed in the United States, beginning in 2004, and in Europe, beginning in 2003, by our marketing partners Merz Pharmaceuticals GmbH (Merz) and Forest Laboratories, Inc. (Forest). Memantine is also being developed for the treatment of neuropathic pain. Our product candidates are XEREPID compound for the treatment of peritumoral brain edema, or swelling around brain tumors, and Viprinex, a compound for the treatment of acute ischemic stroke.

In the course of our development activities, we have incurred significant losses since inception and, although the Company was profitable in the year ended June 30, 2001, it will likely incur additional losses over at least the next several fiscal years. The Company may seek to raise additional funds whenever market conditions permit. However, there can be no assurance that funding will be available, or, if available, that it will be available on acceptable terms. If the Company is not able to raise adequate funds, it may be required to delay, scale back, or terminate its clinical trials or to obtain funds through entering into arrangements with collaborative partners or others.

Revenue recognition

Revenues are recorded according to the terms of formal agreements to which we are a party, when our performance requirements have been fulfilled, the fee is determinable and when collection of the fee is probable or reasonably assured. Revenue related to license fees with non-cancelable, non-refundable terms and no future performance obligations are recognized when collection is assured. Revenues associated with milestone payments, pursuant to the non-cancelable and non-refundable terms of agreements to which we are a party, are recognized when we have fulfilled development milestones and when collection of the fee is assured. Revenues resulting from royalty fees earned from the sale of the product are based upon the sales reported by our licensees and determined in accordance with the specific terms of the license agreements.

We record royalty revenue when it is received because we are unable to estimate and accrue royalty revenue due to the limited sales history of the product. We have made no material adjustments to date for revenue recorded from royalty fees. During

Table of Contents

Neurobiological Technologies, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

the year ended June 30, 2005, Merz adjusted revenues previously paid to us by approximately \$108,000 as a result of the overpayment of royalty fees in previous periods for sales in certain European countries.

Research and development expenses

Our 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 related clinical manufacturing costs, and license fees for use of third-party intellectual property rights. Management assesses how much of these multi-period costs should be charged to research and development expense in each reporting period by assessing the level and related costs of the services provided during each reporting period. In determining whether clinical trial activities performed by third parties should be recognized in a specific reporting period, management considers:

estimates of the percentage of work completed through the applicable reporting period in accordance with agreements established with the third-party service providers; and

estimates of the percentage of work completed through the applicable reporting period in accordance with discussions with internal clinical and preclinical personnel and independent service providers as to the progress or stage of completion of trials or services and the agreed upon fee to be paid for such services.

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 requires significant judgment, and could have a material impact on our balance sheet and results of operations. Management applies judgment and bases its estimates with the benefit of historical experience with the development of similar drugs and with third party contracts structured with similar performance and payment terms. While our historic estimates have been materially accurate, we recognize that estimates of expense incurred during current and future periods are determined greatly by patient enrollment levels and related activities, which may vary from historic patterns. We monitor service providers' activities to the extent possible in order to assess current enrollment levels and related activities; however, if we under- or overestimate activity levels associated with various studies at a given point in time, we could materially under- or overestimate research and development expenses in future periods.

Valuation of Long-Lived and Intangible Assets

Intangible assets acquired, including acquired in-process research and development, are recorded at their estimated fair values at the date of acquisition. The fair values of acquired intangible assets are determined by management using relevant information and assumptions, which process is assisted by an independent, professional appraiser. Fair value is generally calculated as the present value of estimated future cash flows using a risk-adjusted discount rate, which requires significant judgment with respect to revenue and expense growth rates, and the selection and use of an appropriate discount rate. Amortization of intangibles with defined lives is calculated using the straight-line method over the period that we estimate to be the economic useful life of the related asset.

Table of Contents

Neurobiological Technologies, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

We assess the impairment of intangible and long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If it is determined that the carrying value of intangible and long-lived assets might not be recoverable based upon the existence of one or more indicators of impairment, we would measure any impairment based on a projected discounted cash flow method if the undiscounted cash flows did not exceed the carrying value of such assets. An impairment of our intangible or tangible long-lived assets could result in the recording of a material, non-cash expense in our consolidated statement of operations during the period in which such a charge could occur. At June 30, 2005, we had \$6,840,000 and \$815,000 of net intangible and tangible long-lived assets, respectively. Through June 30, 2005, there has been no such instance in which circumstances indicate that the carrying value of long-lived assets may not be fully recoverable and, accordingly, no impairment in the carrying value of long-lived assets has been recorded.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. We base our estimates upon actual experience and other current indications that we believe to be reasonable under the circumstances. Actual results could differ from these estimates. Estimates in the financial statements include, but are not limited to, accrued but unbilled expenses incurred in the performance of clinical trials and pre-clinical studies, expenses incurred and to be deducted from prepayments made for services related to clinical trials, fees and expenses incurred by independent experts and consultants who assist us with clinical trials and pre-clinical studies, and useful lives of property and equipment for depreciation calculations.

Cash Equivalents and Investments

The Company's investments include securities of the U.S. government and its agencies, municipalities, corporations and mortgage-backed securities. All securities which are highly liquid and purchased with original maturities of 90 days or less are recorded as cash equivalents. The Company has classified its cash equivalent and investment securities as available for sale securities as it does not intend to hold securities with stated maturities greater than twelve months until maturity. The Company manages its investment securities to maintain a duration of approximately two years and, in response to liquidity requirements and changes in the market value of securities, will sell investment securities prior to their stated maturities. Available-for-sale securities are carried at estimated fair value, based on available market information, with unrealized gains and losses reported as a component of Accumulated Other Comprehensive Income (Loss) in Stockholders' Equity. Realized gains or losses, amortization of premiums, accretion of discounts and earned interest are included in investment income. The cost of securities when sold is based upon specific identification.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the respective asset, generally two to seven years.

Table of Contents

Neurobiological Technologies, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Net Loss per Share

Basic net loss per share is calculated using the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share includes the impact of potentially dilutive securities. As the Company's potentially dilutive securities (stock options, warrants, and convertible preferred stock) were anti-dilutive, they have been excluded from the computation of weighted-average shares used in computing diluted net loss per share for all periods presented.

The computation of diluted net loss per share for the year ended June 30, 2005 excludes the impact of options to purchase 424,640 shares of common stock, warrants to purchase 618,769 shares of common stock, and the conversion of convertible preferred stock into 521,189 shares of common stock. The computation of diluted net loss per share for the year ended June 30, 2004 excludes the impact of options to purchase 783,271 shares of common stock, warrants to purchase 294,492 shares of common stock, and the conversion of convertible preferred stock into 626,055 shares of common stock. The computation of diluted net loss per share for the year ended June 30, 2003 excludes the impact of options to purchase 788,221 shares of common stock, warrants to purchase 1,511,824 shares of common stock, and the conversion of convertible preferred stock into 1,295,462 shares of common stock.

Stock-Based Compensation

The Company grants stock options for a fixed number of shares to employees with an exercise price equal to the fair value of the shares at the date of the grant. The Company accounts for stock option grants in accordance with APB Opinion No. 25, Accounting for Stock Issued to Employees (APB 25) and related Interpretations. Under APB 25, when the exercise price of our employee stock options equals the market price of the underlying stock on the date of the grant, no compensation expense is recognized.

Stock-based compensation arrangements to non-employees are accounted for in accordance with SFAS 123, EITF 96-18, and related Interpretations, using a fair value approach, and the compensation costs of such arrangements are subject to re-measurement over their vesting terms, as earned.

As permitted by SFAS 123, and as amended by Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation Transition and Disclosure, (SFAS 148), the Company elected to continue to apply the provisions of APB 25 and related interpretations in accounting for its employee stock option and stock purchase plans. The Company is generally not required under APB 25 and related interpretations to recognize compensation expense in connection with its employee stock option and stock purchase plans when exercise prices are not less than fair value.

Edgar Filing: NEUROBIOLOGICAL TECHNOLOGIES INC /CA/ - Form 10-K

Pro forma information regarding net loss and net loss per share is required by SFAS 148 and has been determined as if the Company had accounted for its employee stock options under the fair

Table of Contents**Neurobiological Technologies, Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

value method prescribed by the SFAS 123. The fair value for these options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions: expected volatility calculations, based on historical data, of 0.606 in 2005 and 0.846 in 2004 and 2003; and, expected option lives of five years and no dividend yield for each of 2005, 2004, and 2003. Weighted average risk free interest rate assumptions were based on U.S. government bonds, with maturities equal to the expected option lives, of 3.50%, 3.07% and 4.08% in 2005, 2004 and 2003, respectively.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the vesting period of the options using the straight-line method. The Company's pro forma information follows (in thousands).

	Year ended June 30,		
	2005	2004	2003
Net loss as reported	\$ (17,322)	\$ (1,808)	\$ (2,686)
Add back:			
Deferred compensation expense	27	55	55
Deduct:			
Stock-based employee expense determined under SFAS 123	(687)	(616)	(491)
Pro forma net loss	\$ (17,982)	\$ (2,369)	\$ (3,122)
Basic and diluted net loss per share as reported	\$ (0.65)	\$ (0.09)	\$ (0.15)
Basic and diluted pro forma net loss per share	\$ (0.68)	\$ (0.11)	\$ (0.17)

Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) includes certain changes in equity that are excluded from our net income (loss), specifically, the unrealized gains and losses on available-for-sale securities. For the years ended June 30, 2005, 2004 and 2003, the components of comprehensive income (loss) have been included in the Statement of Stockholders' Equity.

Derivative Financial Instruments

Edgar Filing: NEUROBIOLOGICAL TECHNOLOGIES INC /CA/ - Form 10-K

In March 2004, the Company raised \$19,400,000 in gross offering proceeds from the sale of 3,880,000 shares of common stock at a price of \$5.00 per share. Investors also received warrants to purchase an additional 582,000 shares of common stock at a price of \$6.73 per share. The Company also issued warrants to its placement agent to purchase 155,200 shares of common stock at a purchase price of \$6.00 per share and 23,280 shares at \$8.08 per share. The common stock and warrants issued in this private placement were initially unregistered. The Company filed a registration statement on Form S-3 with the Securities and Exchange Commission on April 14, 2004, to register the shares issued in the private placement as well as the shares to be issued upon exercise of the warrants. In accordance with EITF 00-19, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock, the warrants were reported as a liability and valued at fair value on the date of issuance. Pursuant to the terms of the private placement agreement, the

Table of Contents

Neurobiological Technologies, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Company could have delivered warrants for which the related shares were unregistered, but would have been required to pay a monthly penalty to each purchaser, with no contractual maximum, until the time that the registration statement was declared effective. Accordingly, because the penalty for not registering the shares related to the warrants had no contractual maximum, the Company determined that the penalty did not represent a reasonable difference between the value of a registered and unregistered shares and that settling with unregistered shares was not an economically reasonable alternative. The warrants were revalued each period until the effective date of the registration statement, and the change in the fair value from the date of issuance through the date that the registration statement was effective in the amount of \$477,239, has been recorded as non-cash income. The warrants were transferred to permanent equity when they were registered.

Fair Value of Financial Instruments

The fair value of cash equivalents and investments is based on quoted market prices. The carrying amount of cash equivalents and investments are considered to be representative of their respective fair values at June 30, 2005 and 2004.

Reclassification

Certain balances reported in prior periods reflect the reclassification of long-term investments to short-term investments to conform with the presentation of the reported current period as we may not hold investment securities with stated maturities greater than twelve months to such stated maturity.

Recent Accounting Pronouncement

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment (SFAS 123(R)) which requires all share-based payments to employees, including grants of stock options, to be recognized in the financial statements based on their fair values. As a result, the cost of employee services received in exchange for a grant of an equity instrument will be measured at fair value on the grant-date of the award and recorded as expense over the period during which the employee is required to provide service in exchange for the award. Pro forma disclosure of such cost is no longer an alternative for disclosing the cost share-based payments to employees. According to the requirements of SFAS 123(R) and a rule issued by the Securities and Exchange Commission in April 2005, SFAS 123(R) is effective for the Company at the beginning of our 2006 fiscal year, which commences on July 1, 2005.

SFAS 123 (R) may be adopted using either the Modified-Prospective Transition method or the Modified-Retrospective Transition method of application. Using the Modified-Prospective Transition method, the Company would recognize the cost of share-based payments based on their grant-date fair value from the beginning of the fiscal period in which the provisions of SFAS 123(R) are first adopted. Measurement and assignment of compensation cost for share-based payments granted prior to, but not vested as of the date of adopting SFAS 123(R) would be

Edgar Filing: NEUROBIOLOGICAL TECHNOLOGIES INC /CA/ - Form 10-K

based upon the same estimate of grant-date fair value used previously under SFAS 123, whether the estimate was recognized in the financial statements or disclosed only in a pro forma manner. Recognizing a liability for share-based payments made prior to, but not vested as of the date of adopting SFAS 123(R) will be recognized as the

Table of Contents

Neurobiological Technologies, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

cumulative effect of a change in accounting principle. Using the Modified-Retrospective Transition method of application, the Company would be allowed to restate previously reported periods by recognizing compensation expense in the amounts previously reported as pro forma disclosure under the earlier provisions of SFAS 123. New awards and vested awards would be accounted for in the same manner as the Modified-Prospective Transition method.

We have adopted the requirements of SFAS 123(R) effective July 1, 2005, utilizing the Modified-Prospective Transition method and expect the adoption will have a material effect on our consolidated financial position and results of operations. We anticipate that the effect of adopting SFAS 123(R) effective July 1, 2005, will increase total stock-based compensation expense in fiscal 2006 by approximately \$468,000.

Note 2. Acquisition of Empire Pharmaceuticals, Inc.

On July 14, 2004, NTI acquired Empire Pharmaceuticals, Inc. (Empire), a privately held corporation, through the merger of Empire into Empire Acquisition Corp., a wholly-owned subsidiary of NTI. Pursuant to the transaction, NTI acquired worldwide rights to Viprinex (ancrod), a late-stage reperfusion therapy for use in treatment of ischemic stroke, a life-threatening condition caused by the blockage of blood vessels supplying blood and oxygen to the brain. A reperfusion therapy is a drug that breaks up the blood clot causing the stroke and enables normal blood flow to return to the affected areas of the brain. Viprinex is derived from the venom of the Malayan pit viper. The acquisition of Empire was accounted for as a purchase of assets in accordance with SFAS No. 141, *Business Combinations* and under SFAS No. 142, *Goodwill and Other Intangible Assets*. Accordingly, the results of operations of Empire have been included in the accompanying consolidated financial statements from the date of the acquisition.

As a result of the acquisition, all of Empire's issued and outstanding capital stock immediately prior to the acquisition was automatically converted into the right to receive an aggregate of 2,399,163 shares of NTI's common stock and \$1,500,020 in cash. Additionally, NTI paid \$500,000 to Empire's principal stockholder to partially reimburse advances previously made by the stockholder to Empire. The aggregate purchase price paid at the date of acquisition was \$12,669,184, which consists of the common stock valued at \$9,452,702, cash of \$2,000,020, including in-lieu payment for partial shares, and acquisition-related expenses of \$1,216,462. If pivotal Phase III trials for Viprinex are commenced as planned, NTI will issue an additional 2,375,170 shares and pay an additional \$1,515,675 in cash to the selling stockholders of Empire and will pay Empire's principal stockholder the balance of \$484,325 for the remainder of advances he made to Empire. The additional amounts due upon commencement of the Phase III clinical trials are being treated as contingent consideration.

As part of the purchase price allocation, all intangible assets were identified and valued. It was determined that certain development technology, which was in-process, had value. As a result of this identification and valuation process, the Company allocated \$4,251,335 of the purchase price to acquired in-process research and development. This allocation represents the estimated fair value based upon the estimated risk-adjusted cash flows related to research and development activities associated with the preparation for Phase III clinical trials for Viprinex. At the date of the acquisition, the development of Viprinex had not yet reached technological feasibility, and the research and

Table of Contents**Neurobiological Technologies, Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

development in progress had no alternative future uses. Accordingly, the acquired in-process research and development was charged to expense as of the date of the acquisition, in accordance with accounting principles generally accepted in the United States.

The following table summarizes the estimated fair value of the assets acquired and liabilities assumed at the date of acquisition for an aggregate purchase price of \$12,669,184, including acquisition costs.

Current assets	\$ 2,251
Property and equipment, net	16,604
Patents	78,894
Other tangible assets	965,027
License agreement	7,355,073
In-process research and development	4,251,335
	<hr/>
Total assets acquired	\$ 12,669,184
	<hr/>

Intangible assets acquired, for which no material residual value is anticipated, consist of: \$7,355,073 for a royalty-bearing license agreement with Abbott Laboratories and \$78,245 for certain patents, which will be amortized over an estimated useful life of twelve years. Tangible assets acquired, for which no residual value is anticipated, consist of \$965,027 for the snake farm, snake venom and snake venom compound concentrate from which Viprinex is derived, which will be amortized over estimated useful lives of four to eight years. The intangible and tangible assets acquired are reported, net of accumulated amortization and depreciation as Acquisition-related tangible and intangible assets in the accompanying Consolidated Balance Sheet as of June 30, 2005.

Depreciation and amortization expense related to the acquired tangible and intangible assets was \$149,970 and \$593,633, respectively, during the year ended June 30, 2005. The estimated depreciation and amortization expense for each of the next five years related to the acquired tangible and intangible assets is summarized in the following table.

	<u>Depreciation</u>	<u>Amortization</u>
Year ending June 30, 2006	\$ 156,491	\$ 619,443
Year ending June 30, 2007	156,491	619,443
Year ending June 30, 2008	156,491	619,443
Year ending June 30, 2009	87,754	619,443
Year ending June 30, 2010	84,766	619,443
	<hr/>	<hr/>
Total	\$ 641,993	\$ 3,097,215
	<hr/>	<hr/>

The following unaudited pro forma financial information presents the combined results of operations of NTI and Empire as if the acquisition had occurred as of the beginning of the periods presented. The pro forma results for the years ended June 30, 2005 and 2004 include \$281,782 and \$100,000, respectively, of transaction fees and expenses incurred by Empire related to the acquisition during the periods but exclude \$4,251,335 of research and development expenses recorded as of July 14, 2004, the acquisition date. The unaudited pro forma financial information is based upon available

Table of Contents**Neurobiological Technologies, Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

information and certain assumptions that management believes to be reasonable. The unaudited pro forma financial information is not intended to represent or be indicative of the consolidated results of operations or financial condition of the company that would have been reported had the acquisition been completed as of the dates presented and should not be taken as representative of the future consolidated results of operations or financial condition of the Company.

	Year ended June 30,	
	2005	2004
Total revenues	\$ 3,099,511	\$ 2,786,579
Net loss	\$ (17,673,875)	\$ (3,037,064)
Basic and diluted net loss per share	\$ (0.67)	\$ (0.13)

Note 3. Restricted Cash

In accordance with the terms of the sublease for certain of its operating facilities, the Company, as sublessee, is required to maintain a security deposit in the approximate of \$30,900 in a separate commercial bank account of the sublessor's selection. All principal and interest in the account remain the property of the Company and all such principal and interest balances shall be returned to the Company after termination of the sublease, in October 2009, with all conditions and covenants fulfilled.

Table of Contents**Neurobiological Technologies, Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Note 4. Investments**

Available-for-sale securities were as follows (in thousands):

	Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	Market Value
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
June 30, 2005				
Corporate debt obligations:				
Maturing within 1 year	\$ 113	\$	\$ (1)	\$ 112
Maturing after 1 through 5 years	2,304		(23)	2,281
Maturing after 5 years	1,263	4		1,267
U.S. Government obligations:				
Maturing after 1 through 5 years	297			297
Maturing after 5 years	272	4		276
Municipal Securities				
Maturing within 1 year	329			329
Mortgage and asset-backed securities				
Maturing after 5 years	3,088	13		3,101
Securities issued by foreign governments and agencies denominated in \$US				
Maturing after 5 years	15			15
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Total investments	\$ 7,681	\$ 21	\$ (24)	\$ 7,678
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
June 30, 2004				
Corporate debt obligations:				
Maturing within 1 year	\$ 7,772	\$	\$ (6)	\$ 7,766
Maturing after 1 year through 5 years	2,623		(25)	2,598
U.S. Government obligations:				
Maturing within 1 year	4,097		(13)	4,084
Maturing after 1 year through 5 years	4,302		(29)	4,273
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Total investments	\$ 18,794	\$	\$ (73)	\$ 18,721
	<u> </u>	<u> </u>	<u> </u>	<u> </u>

Realized losses were \$234,355 during the year ended June 30, 2005 and there were no realized gains or losses during the years ended June 30, 2004 and 2003.

Table of Contents**Neurobiological Technologies, Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Note 5. Property and Equipment**

Property and equipment consisted of the following:

	2005	2004
Machinery and equipment	\$ 151,509	\$ 199,415
Furniture, fixtures and leasehold improvements	19,586	145,426
Clinical production equipment	500,720	
	<u>671,815</u>	<u>344,841</u>
Less accumulated depreciation	(75,794)	(338,632)
	<u>\$ 596,021</u>	<u>\$ 6,209</u>

Depreciation and amortization expense was \$72,230, \$5,967 and \$8,715 during the years ended June 30, 2005, 2004 and 2003, respectively.

Note 6. Operating Lease Commitments

In April 2005, the Company entered into a lease agreement for its executive offices in Emeryville, California, which commences in August 2005 and continues through November 2010. The Company occupied its existing executive office facilities in Richmond, California pursuant to the terms of its lease which expired in July 2005 and occupied the new facilities in Emeryville in August 2005.

In May 2005, the Company entered into a sublease in Edgewater, New Jersey, which commenced in June 2005, and continues through October 2009, for its operating staff dedicated to the Viprinex development program.

The balance of deferred rent was \$9,710 as of June 30, 2005 and there was no deferred rent as of June 30, 2004.

As of June 30, 2005, future minimum lease payments under operating leases in California and New Jersey are as follows.

Year ending June 30:	
2006	\$ 231,280
2007	311,504
2008	356,280
2009	363,228
2010	287,828
Thereafter	104,992
	<hr/>
Total minimum future lease payments	\$ 1,655,112
	<hr/>

Rent expense for the years ended June 30, 2005, 2004 and 2003 was \$247,725, \$103,000, and \$89,000, respectively.

Table of Contents

Neurobiological Technologies, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 7. Stockholders' Equity

Convertible Preferred Stock

At June 30, 2005, the Company has 504,000 shares of Series A convertible preferred stock outstanding. The holders of the Series A convertible preferred stock are entitled to receive annual noncumulative dividends of 8% per share per annum, when and if declared by the Board of Directors. These dividends are in preference to any declaration or payment of any dividend on the common stock of the Company. As of June 30, 2005, no dividends had been declared.

Each share of Series A preferred stock is convertible, at the holder's option, subject to antidilution provisions, into one share of common stock. Additionally, each share of the preferred stock will be automatically converted into one share of common stock upon the affirmative vote (or action by written consent in lieu of vote) of a majority of the then-outstanding Series A shares. 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.

In the event of any liquidation, dissolution, or winding up of the Company, the holders of the Series A preferred stock have a liquidation preference, over holders of common stock, of \$0.50 per share plus any declared but unpaid dividends. After payment has been made to the holders of Series A preferred stock, the entire remaining assets and funds of the Company legally available for distribution, if any, would be distributed ratably among the holders of common stock.

Stockholder Rights Plan

On May 19, 2005, the Company's Board of Directors declared a dividend distribution of one preferred share purchase right (the "Right") for each outstanding share of the Company's common stock to stockholders of record on May 27, 2005. The Rights were issued pursuant to, and are governed by the terms of, that certain Rights Agreement, dated May 19, 2005, by and between the Company and American Stock Transfer & Trust Company, as Rights Agent (the "Rights Agreement") and will initially trade with shares of the Company's common stock. If a person or group acquires beneficial ownership of 15% or more of the Company's common stock (the "Control Stockholder") in a transaction not approved in advance by the Company's Board of Directors, each Right will entitle its holder, other than the Control Stockholder, to acquire additional shares of the Company's capital stock at a formula price set forth in the Rights Agreement. In addition, if and after a Control Stockholder acquires more than 15% of the Company's common stock, if the Company or its business is later acquired in a merger or asset sale by the Control Stockholder or in a transaction in which all stockholders are not treated alike, stockholders with unexercised Rights, other than the Control Stockholder, will be entitled to purchase common stock of the acquiring party (or its parent entity) at a formula price as set forth in the Rights Agreement.

The Board of Directors may redeem the Rights for a nominal amount at any time prior to an event that causes the Rights to become exercisable, and the rights will expire on May 27, 2015.

Table of Contents**Neurobiological Technologies, Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)***Warrants to Purchase Common Stock*

At June 30, 2005, the Company had a total of 770,480 outstanding warrants to purchase shares of common stock as follows:

<u>Number of Shares</u>	<u>Exercise Price</u>	<u>Issue Date</u>	<u>Expiration Date</u>
10,000	\$ 5.14	December 2003	December 2006
582,000	\$ 6.73	March 2004	August 2009
155,200	\$ 6.00	March 2004	February 2007
23,280	\$ 8.08	March 2004	February 2007
<u>770,480</u>			

Stock Option Plan

In September 2003, the Board of Directors adopted the 2003 Equity Incentive Plan (the 2003 Plan). The 2003 Plan was approved by the stockholders in December 2003. The 2003 Plan provides for the issuance of options and stock awards and reserves up to 1,000,000 shares of common stock for issuance under the plan. In general, options are granted at fair market value on the date of the grant, have a term of 10 years and become exercisable over the vesting period of up to 48 months.

A summary of the Company's stock option activity, and related information for the three years ended June 30, 2005 follows:

	<u>Options Available for Grant</u>	<u>Options Outstanding</u>	
		<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>
Balance at June 30, 2002	163,936	1,789,387	\$ 2.49
Options granted	(4,000)	4,000	3.82
Options canceled	72,250	(72,250)	4.17
Options exercised		(70,108)	1.51
Balance at June 30, 2003	<u>232,186</u>	<u>1,651,029</u>	<u>\$ 2.46</u>
Options granted	(134,000)	134,000	5.98

Edgar Filing: NEUROBIOLOGICAL TECHNOLOGIES INC /CA/ - Form 10-K

Options canceled	22,420	(22,420)	3.70
Options exercised		(5,455)	3.31
Options expired	(250,606)		
Options authorized	1,000,000		
	<hr/>	<hr/>	<hr/>
Balance at June 30, 2004	870,000	1,757,154	2.71
Options granted	(544,000)	544,000	3.89
Options canceled	15,480	(24,345)	4.25
Options exercised		(33,458)	2.66
	<hr/>	<hr/>	<hr/>
Balance at June 30, 2005	341,480	2,243,351	\$ 2.98
	<hr/>	<hr/>	<hr/>

At June 30, 2005, 2004 and 2003, options to purchase 1,641,706, 1,403,308, and 1,269,988 shares of common stock were exercisable, respectively. The weighted-average exercise price of

Table of Contents**Neurobiological Technologies, Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

options exercisable at June 30, 2005 and 2004 was \$2.59, and was \$2.46 at June 30, 2003. The weighted-average fair value of options granted during 2005, 2004 and 2003 was \$3.90, \$4.14, and \$3.17, respectively.

The following table summarizes information concerning currently outstanding and exercisable options:

Options Outstanding				Options Exercisable		
Range of Exercise Prices		Shares Outstanding	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Shares Exercisable	Weighted Average Exercise Price
\$0.01	1.99	816,948	3.26	\$ 0.84	816,948	\$ 0.84
2.00	3.99	909,612	6.38	3.30	452,248	2.84
4.00	5.99	132,291	9.08	4.63	38,000	5.36
6.00	8.00	384,500	5.85	6.21	334,500	6.21
		<u>2,243,351</u>	5.31	\$ 2.98	<u>1,641,706</u>	\$ 2.59

In connection with the grant of certain stock options to senior management, we recorded deferred compensation of \$274,000 in fiscal 2000. Deferred compensation represents the difference in the market value of the stock on the date granted and the exercise price of these options. Deferred compensation is presented as a reduction of stockholders' equity and is amortized over the vesting period of the option using a straight-line method. We recognized amortization of deferred stock compensation expense of \$27,376 in the fiscal year ended June 30, 2005, and \$54,750 in 2004 and 2003.

Employee Stock Purchase Plan

In September 2003, the Board of Directors adopted, subject to stockholder approval, the 2003 Employee Stock Purchase Plan (the 2003 ESPP). The 2003 ESPP was approved by the stockholders in December 2003. The 2003 ESPP reserves up to 500,000 shares of common stock for sale under the ESPP. The 2003 ESPP permits eligible employees to purchase common stock at a discount through payroll deductions during defined accumulation periods. The price at which the stock is purchased is equal to the lower of 85% of the fair value of the common 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. Under the plan, 491,404 shares remain available for issuance at June 30, 2005. The weighted average purchase price per share for shares purchased under the 2003 ESPP was \$3.42 during the year ended June 30, 2005.

Stock Repurchase Program

In August 2002, the Board of Directors authorized a stock repurchase program of up to 500,000 shares of the Company's common stock. Depending on market conditions and other factors, repurchases will be made from time to time in the open market and in negotiated transactions, including block transactions, and may be discontinued at any time. No shares were repurchased in the

Table of Contents**Neurobiological Technologies, Inc.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

years ended June 30, 2005 and 2004. In the year ended June 30, 2003, the Company repurchased 32,000 shares of its common stock for \$87,000. All shares repurchased have been retired.

Common Stock Reserved for Future Issuance

At June 30, 2005, the Company has reserved shares of common stock for future issuance as follows:

Conversion of preferred stock into common stock	504,000
1993 Stock Plan and 2003 Equity Incentive Plan	2,584,831
Warrants	770,480
2003 Employee Stock Purchase Plan	491,404
	<u>4,350,715</u>

Note 8. Income Taxes

The Company uses the liability method to account for income taxes. Under this method, deferred tax assets and liabilities are determined based upon the differences between the financial reporting and tax bases of assets and liabilities and are measured using enacted tax rules and laws that are anticipated to be in effect when the differences are expected to reverse. Valuation allowances are established, when necessary, to reduce differed tax assets to the amounts expected to be realized.

There was no provision (benefit) for income taxes for the years ended June 30, 2005, 2004 and 2003 because the Company has incurred operating losses.

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

June 30,

Edgar Filing: NEUROBIOLOGICAL TECHNOLOGIES INC /CA/ - Form 10-K

	2005	2004	2003
	<u> </u>	<u> </u>	<u> </u>
Deferred tax assets:			
Net operating losses	\$ 12,330,000	\$ 6,830,000	\$ 6,230,000
Research credits	547,000	430,000	430,000
Other	331,000	290,000	360,000
	<u> </u>	<u> </u>	<u> </u>
Total deferred tax assets	13,208,000	7,550,000	7,020,000
Valuation allowance	(9,852,000)	(7,550,000)	(7,020,000)
Deferred tax assets	3,356,000		
Deferred tax liability:			
Purchased intangibles	(3,356,000)		
	<u> </u>	<u> </u>	<u> </u>
Net deferred tax assets	\$ <u> </u>	\$ <u> </u>	\$ <u> </u>

Table of Contents

Neurobiological Technologies, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Realization of the deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The net valuation allowance increased by \$2,302,000, \$530,000 and \$1,150,000 during 2005, 2004 and 2003, respectively.

As of June 30, 2005, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$29,530,000 which will expire in the years 2006 through 2025, and federal research and development tax credits of approximately \$275,000 which will expire in the years 2007 through 2025.

As of June 30, 2005, the Company had net operating loss carryforwards for state income tax purposes of approximately \$27,900,000 which will expire in the years 2006 through 2015, and state research and development tax credits of approximately \$378,000 which do not expire.

Utilization of the Company's net operating loss and credit carryforwards may be subject to substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such an annual limitation could result in the expiration of net operating loss and credits before utilization.

Note 9. Collaboration Agreement

In April 1998, we entered into a strategic research and marketing cooperation agreement with Merz Pharmaceuticals GmbH and Children's Medical Center Corporation to further the clinical development and commercialization of Memantine. Pursuant to this agreement, NTI and Merz share scientific, clinical and regulatory information about Memantine, particularly safety data, to facilitate regulatory review and marketing approval by the Food and Drug Administration and foreign regulatory authorities. Pursuant to this agreement, we will continue to share in future revenues from sales of Memantine for all indications.

In June 2000, Merz entered into an agreement with Forest Laboratories, Inc. for the development and marketing of Memantine in the United States for the treatment of Alzheimer's disease, neuropathic pain and AIDS-related dementia. In August 2000, Merz entered into a strategic license and cooperation agreement with H. Lundbeck A/S of Copenhagen, Denmark for the further development and marketing of Memantine for the treatment of Alzheimer's disease, neuropathic pain and AIDS-related dementia. Lundbeck has acquired exclusive rights to Memantine in certain European markets, Canada, Australia and South Africa and semi-exclusive rights to co-market Memantine with Merz in other markets worldwide, excluding the United States, where Forest has development rights, and Japan, where Merz has granted development rights to Daiichi Sanyou Pharma Co., Ltd., respectively.

Through June 30, 2005, we have received approximately \$14,100,000 from Merz under our 1998 strategic research and marketing cooperation agreement. We received \$3,099,511, \$255,369, and \$10,949 in royalty payments for the fiscal years ended June 30, 2005, 2004, and 2003,

respectively, for sales of Memantine. Commercial sales of Memantine in the United States commenced in January 2004 and revenue for 2004 includes royalty from the sale of Memantine in the United States and Europe. Royalty payments of \$10,949 in 2003 resulted from the sale of Memantine in Europe, which

Table of Contents

Neurobiological Technologies, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

commenced sales in that year. In October 2003, the FDA approved the commercial sale of Memantine in the United States for the treatment of mid- to severe-Alzheimer's disease, which triggered a payment of \$2,531,210 to the Company under the agreement. We received no license payments in 2005 and received license payments of \$2,531,210 and \$1,968,690 in 2004, and 2003, respectively.

The Company may receive additional license and royalty fees from Merz and its marketing partners, Forest and Lundbeck, from regulatory approvals in additional countries or for new indications and from sales of Memantine because the clinical development and commercial marketing of Memantine is managed by Merz and its marketing partners, the company is unable to estimate the timing or amount of potential revenues.

Note 10. 401(k) Plan

NTI maintains a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code. The 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. NTI made employer contributions to the plan, recorded as expense, of \$3,546, \$3,673 and \$3,215 in the years ended June 30, 2005, 2004 and 2003, respectively.

Note 11. Subsequent Events

In July 2005, the Company received a royalty payment in the amount of \$1,052,448 from Merz Pharmaceuticals GmbH for sale of Memantine in the quarter ended March 31, 2005.

In August 2005, the Company established a \$10 million line of credit with a large, national commercial bank. The line of credit is a revolving credit facility which is secured by the Company's assets (excluding intellectual property but including the right to receive payments pursuant to intellectual property agreements), matures in two years, bears interest at the bank's annual prime rate plus 1.00%, provides that the Company maintain one of several alternative liquidity covenants and requires payment of an annual commitment fee of 0.15% on the committed balance. As of September 27, 2005, no advances had been made on the line of credit.

In September 2005, the Company signed a definitive agreement for the sale of its rights in XERECEPT to two wholly owned subsidiaries of a private equity firm focused on the biotechnology and pharmaceutical industries. Under the terms of the agreement, the Company will receive \$20 million upon closing and an additional \$13 million in non-contingent installment payments in January and June 2006, and January 2007. The Company is also eligible to receive up to an additional \$15 million upon the achievement of certain regulatory objectives. The Company is eligible to receive profit-sharing payments on sales of XERECEPT in the United States and royalties on any sales elsewhere in the world, if the product receives regulatory approval. The buyers will assume responsibility for product development and pay all product development expenses.

The Company will provide services relating to the current clinical trials of XERECEPT.

Table of Contents

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures.

Based on their evaluation as of June 30, 2005, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) were effective to ensure the information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of June 30, 2005. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Our management has concluded that, as of June 30, 2005, our internal control over financial reporting was effective based on these criteria.

Management's assessment of the effectiveness of our internal control over financial reporting as of June 30, 2005 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included elsewhere herein.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2005 that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Edgar Filing: NEUROBIOLOGICAL TECHNOLOGIES INC /CA/ - Form 10-K

Our management, including our chief executive officer and chief financial officer, does not expect that our procedures or our internal controls will prevent or detect all error and all fraud. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of our controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected.

Table of Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Neurobiological Technologies, Inc.

We have audited management's assessment, included in the accompanying Management's Report on Internal Controls over Financial Reporting, that Neurobiological Technologies, Inc. maintained effective internal control over financial reporting as of June 30, 2005, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Neurobiological Technologies, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, management's assessment that Neurobiological Technologies, Inc. maintained effective internal control over financial reporting as of June 30, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Neurobiological Technologies, Inc. maintained, in all material respects, effective internal control over financial reporting as of June 30, 2005, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Neurobiological Technologies, Inc. as of June 30, 2005 and 2004, and the related consolidated statements of operations, stockholders' equity,

Table of Contents

and cash flows for each of the three years in the period ended June 30, 2005, of Neurobiological Technologies, Inc. and our report dated September 27, 2005 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California

September 27, 2005

ITEM 9B. OTHER INFORMATION

In the fourth quarter ended June 30, 2005, the Company had no events that were required to be reported on Form 8-K but that were not filed to date.

Subsequent to the end of the fourth fiscal quarter of 2005, the Company in August 2005 established a \$10 million line of credit with Comerica Bank. The line of credit is a revolving credit facility secured by the Company and, maturing in two years, with an interest rate equal to the bank's annual prime rate plus 1.00%.

Subsequent to the end of the fourth fiscal quarter of 2005, in September 2005, the Company signed a definitive agreement (the "Sale Agreement") for the sale of its rights in XERECEPT to two wholly-owned subsidiaries of a private equity firm focused on the biotechnology and pharmaceutical industries. Under the terms of the agreement, the Company will receive \$20 million upon closing and an additional \$13 million in non-contingent installment payments due in January and June 2006, and January 2007. The Company is also eligible to receive up to an additional \$15 million upon the achievement of certain regulatory objectives and is eligible to receive profit-sharing payments on sales of XERECEPT in the United States and royalties on any sales elsewhere in the world, if the product receives regulatory approval. The buyers will assume responsibility for product development and pay all product development expenses. The Company will provide ongoing services relating to the current clinical trials of XERECEPT.

Table of Contents**PART III.****ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

The directors and executive officers of the Company, their ages and positions as of September 13, 2005 are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Paul E. Freiman	71	President and Chief Executive Officer and Director
Lisa U. Carr, M.D., Ph.D.	50	Senior Vice President, Chief Medical Officer
Stephen J. Petti	58	Vice President, Product Development
David E. Levy, M.D.	64	Vice President, Clinical Development
Jonathan R. Wolter	55	Vice President and Chief Financial Officer
Abraham E. Cohen	69	Chairman of the Board of Directors
Ronald E. Cape, Ph.D.	72	Director
Enoch Callaway, M.D.	81	Director
Theodore L. Eliot, Jr.	77	Director
Abraham D. Sofaer	67	Director
John B. Stuppin	72	Director
F. Van Kasper	68	Director

Paul E. Freiman joined the Company as a director in April 1997 and was elected President and Chief Executive Officer in May 1997. He is the former chairman and chief executive officer of Syntex Corporation, where he had a long and successful career and was instrumental in the sale of Syntex to Roche Holdings for \$5.3 billion. He is credited with much of the marketing success of Syntex's lead product Naprosyn and was responsible for moving the product to over-the-counter status, marketed by Proctor & Gamble as Aleve. Mr. Freiman currently serves as chairman of the board of SciGen Pte. Ltd. and serves on the boards of Penwest Pharmaceutical Co., Calypte Biomedical Corporation, Phytos Inc., Otsuka America Pharmaceuticals, Inc. and NeoPharm. He has been chairman of the Pharmaceutical Manufacturers Association of America (PhARMA) and has also chaired a number of key PhARMA committees. Mr. Freiman is also an advisor to Burrill & Co., a San Francisco merchant bank. Mr. Freiman holds a B.S. degree from Fordham University and an honorary doctorate from the Arnold & Marie Schwartz College of Pharmacy.

Lisa U. Carr, M.D., Ph.D. was appointed Vice President of Medical Affairs in September 1998 and Chief Medical Officer in September 2004. Prior to joining the Company in June 1998 as Director of Medical Affairs, Dr. Carr was Associate Medical Director at the Institute of Clinical Immunology and Infectious Diseases at Syntex Development Research in Palo Alto, California. Dr. Carr has more than eight years of international industry experience in conducting clinical drug trials in immunosuppression, nephrology, neurology, gastroenterology and cardiovascular disorders. She was Lead Clinical Research Physician at Syntex, directing a pivotal clinical trial of mycophenolate mofetil, for which an IND and NDA were approved for solid organ transplantation. Dr. Carr holds a medical degree and a Ph.D. degree *magna cum laude* from the University of Munich in Germany.

Stephen J. Petti was appointed Vice President of Product Development in July 2004 and President of NTI-Empire, Inc., our wholly owned subsidiary in June 2005. Mr. Petti founded Empire Pharmaceuticals in February 2001 and served at its Chief Executive Officer until its acquisition in July 2004. From February 1998 until Empire's founding in February 2001, Mr. Petti served as Vice President, Drug Development at Dov Pharmaceuticals. From October 1995 to December 1997, he was

Table of Contents

Vice President of Global Consulting Operations at Barnett International/PAREXEL, a contract research organization in the pharmaceutical industry. He established a European presence for Barnett International/PAREXEL by starting its first overseas office in Paris. From July 1980 to August 1995, Mr. Petti held a variety of clinical research management positions with American Cyanamid, now Wyeth-Ayerst, including the position of Director of Global Clinical Research Training and Process Development. He is a member of the Drug Information Association and the Society of Research Administrators. Mr. Petti received his B.B.A. from St. John's University in 1968 and a B.S.N (Nursing) in 1973 from Dominican College.

David E. Levy, M.D. was appointed Vice President of Clinical Development in September 2004 following the Company's acquisition of Empire Pharmaceuticals. Prior to joining NTI, Dr. Levy was international project team leader at Eisai Medical Research, Inc. where he directed a clinical program to develop a novel, new therapy in Alzheimer's disease as well as acute ischemic stroke programs. He had previously served as an advisor to Empire Pharmaceuticals and as senior director of medical research at DOV Pharmaceutical, where he directed several clinical development programs. From 1991 to 2001, Dr. Levy was with Knoll Pharmaceuticals, serving initially as senior director and therapeutic head of clinical CNS and then as senior director of cardiovascular/internal medicine. Dr. Levy served as executive vice chair of neurology from 1988 to 1991 at Weill-Cornell Medical College and New York Presbyterian Hospital and continues to serve as adjunct associate professor of neurology and adjunct associate attending neurologist at these institutions. Dr. Levy is a fellow of the American Academy of Neurology, the American College of Physicians, and the Stroke Counsel of the American Heart Association. Dr. Levy holds a B.A. degree from Harvard College and an M.D. degree Harvard Medical School.

Jonathan R. Wolter was appointed Vice President and Chief Financial Officer in November 2004. Prior to his engagement by the Company, Mr. Wolter served as a consultant to several public companies. Previously, he worked for BearingPoint, Inc. (formerly KPMG Consulting), where he was first CFO of its Latin America Region and was promoted to International Controller. Prior to that, he held vice president and CFO positions for Tom Sawyer Software Corporation, Bindco Corporation and Tanon Manufacturing. Upon the merger of Tanon Manufacturing and Electronic Associates, he was appointed CFO of Electronic Associates. Mr. Wolter also held senior financial positions at Exponent, Inc., First Republic Bancorp, and was a senior audit manager at Arthur Andersen & Co. He holds a B.S. degree in Business Administration from the University of California, Berkeley, and is a Certified Public Accountant.

Abraham E. Cohen has been a director of the Company since March 1993 and has been chairman of the Board since August 1993. From 1982 to 1992, Mr. Cohen served as Senior Vice President of Merck & Co. and from 1977 to 1988 as President of the Merck Sharp & Dohme International Division (MSDI). While at Merck, he played a key role in the development of Merck's international business, initially in Asia, then in Europe and, subsequently, as President of MSDI, which manufactures and markets human health products outside the United States. Since his retirement from Merck and MSDI in January 1992, Mr. Cohen has been active as an international business consultant. He was a director of Agouron Pharmaceuticals, Inc. until its merger with Warner-Lambert Company. He is currently Chairman and President of Kramex Corporation and serves as a director of four other public companies: Akzo Nobel N.V., Chugai Pharmaceutical Co., Teva Pharmaceutical Industries, Ltd. and Vasomedical, Inc.

Ronald E. Cape, Ph.D. has worked in the biotechnology industry for more than 30 years and currently serves as a consultant for several public and private biotechnology companies. He co-

Table of Contents

founded Cetus Corporation in 1971 and served as chairman for 20 years and Chief Executive Officer for 13 years until the company merged with Chiron Corporation in 1991. Cetus was a world leader and pioneer in genetic engineering, developing a technology that was ultimately awarded a Nobel Prize. He was the founding chairman of Darwin Molecular Corporation, which was later sold to Chiroscience plc, and serves on the board of EntreMed, Inc. Dr. Cape also serves as a director for several privately held biotechnology companies, including Caprion, Inc. and Neugenes Corp. Dr. Cape was a founding member of the Industrial Biotechnology Association (now the Biotechnology Industry Organization, or BIO), where he served as President from 1983 until 1985. Dr. Cape is a fellow of the American Academy of Arts and Sciences, the American Academy of Microbiology and the American Association for the Advancement of Science and has served as a board member of a number of arts and charitable organizations, including the San Francisco Opera. He has also served on the boards of Princeton University, Rockefeller University, and the Whitehead Institute at MIT. He holds a Ph.D. degree in biochemistry from McGill University, an M.B.A. degree from Harvard University and an A.B. degree from Princeton University. He has served on the Company's Business Advisory Board for several years, and was elected to the Board of Directors in November 2004.

Enoch Callaway, M.D. is a founder of the Company and has served as a director of the Company since September 1987. Dr. Callaway previously served as chairman of the Board of the Company from September 1987 to November 1990, as co-chairman of the Board of the Company from November 1990 until August 1993, as Vice President of the Company from September 1988 until August 1993 and as Secretary of the Company from September 1988 until September 1991. Dr. Callaway has been Emeritus Professor of Psychiatry at the University of California, San Francisco since 1986, where he also served as Director of Research at the Langley Porter Psychiatric Institute from 1959 to 1986. Dr. Callaway was Staff Psychiatrist, SFVAMC, 1996-1997. He is a member of the Institutional Review Board for SAM Technologies, Inc. and Abratek, Inc. Dr. Callaway is a former director of Phytos, Inc., a biotechnology company. He holds A.B. and M.D. degrees from Columbia University.

Theodore L. Eliot, Jr. has served as a director of the Company since August 1992. Previously, he served as a director of the Company from September 1988 until April 1992, and as a Vice President of the Company from September 1988 until September 1991. Mr. Eliot retired from the United States Department of State in 1978, after a 30-year career in which he held senior posts in Washington and was Ambassador to Afghanistan. He was Dean of the Fletcher School of Law and Diplomacy from 1978 to 1985 and a director of Raytheon Co. from 1983 to 1998. He is currently a director of several non-profit organizations. Mr. Eliot holds B.A. and M.P.A. degrees from Harvard University.

Abraham D. Sofaer has served as a director of the Company since April 1997. Mr. Sofaer is the first George P. Shultz Distinguished Scholar & Senior Fellow at the Hoover Institution, Stanford University, appointed in 1994. He has also been a Professor of Law (by courtesy) at Stanford Law School. From 1990 to 1994, Mr. Sofaer was a partner at the legal firm of Hughes, Hubbard & Reed in Washington, D.C., where he represented several major U.S. public companies. From 1985 to 1990, he served as the Legal Adviser to the United States Department of State, where he was principal negotiator on several international disputes. From 1979 to 1985, he served as a federal judge in the Southern District of New York. Mr. Sofaer is registered as a qualified arbitrator with the American Arbitration Association and is a member of the National Panel of the Center for Public Resolution of Disputes (CPR), a leading organization in the area of resolution of disputes outside litigation. He has mediated major commercial cases. Additionally, he acts regularly as an arbitrator in merger-acquisition disputes, commercial cases involving valuation of technology, and securities class action suits. Mr.

Table of Contents

Sofaer is on the board of directors of Gen-Probe, Inc., and Rambus, Inc. and the International Advisory Committee of Chugai Biopharmaceuticals, Inc., and is an advisor to Soligence Corp., a start-up company with expertise in efficiency analysis. He is president of American Friends of the Koret Israel Economic Development Fund and a director of the Koret Foundation and as a Trustee of the National Museum of Jazz. Mr. Sofaer holds a B.A. degree from Yeshiva College and a L.L.B. degree from New York University.

John B. Stupp is a founder of the Company and has served as a director of the Company since September 1988. From September 1987 until October 1990, Mr. Stupp served as President of the Company, from November 1990 to August 1993 as co-chairman of the Board, from October 1990 until September 1991 as Executive Vice President, and from April 1991 until July 1994 as Treasurer. He also served as acting Chief Financial Officer of the Company from the Company's inception through December 1993 and has continued to serve as an employee of the Company in a business development capacity since that time. Mr. Stupp is an investment banker and a venture capitalist. He has over 25 years experience in the start up and management of companies active in emerging technologies and has been the president of a manufacturing company. He is chairman of the board of Fiberstars, Inc. Mr. Stupp holds an A.B. degree from Columbia University.

F. Van Kasper was appointed as a director and chairman of NTI's audit committee in January 2004. Mr. Kasper served as Chairman of Wells Fargo Securities, the institutional brokerage and investment bank for Wells Fargo and Company, prior to his retirement in March 2003. Mr. Kasper entered the brokerage business in 1964 with Merrill Lynch and in 1978 co-founded Van Kasper and Company, a regional investment bank. As Chairman and CEO of Van Kasper, he guided its growth from a handful of employees to a bank with over 350 employees in 15 offices in 4 states when it was sold in 1999. During his investment career, Mr. Kasper was elected as a Governor of the National Association of Securities Dealers (NASD) and as a Director and Vice Chairman of the Securities Industry Association (SIA). Mr. Kasper is active in San Francisco, California area non-profit community, most recently as a director and member of the Investment Committee for the University of California San Francisco Foundation (UCSF) and serves as Chairman Emeritus for San Francisco's Exploratorium Museum. Mr. Kasper holds a B.S. degree from California State University.

Section 16(a) Beneficial Ownership Reporting Compliance

The information required by Item 405 of Regulation S-K is hereby incorporated by reference to the Section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" in our Proxy Statement for the Annual Meeting of Stockholders to be held December 6, 2005.

Code of Conduct

We have adopted a code of business conduct, which applies to all directors and officers. A copy of this code of conduct is available on our website at www.ntii.com and any waivers from or amendments to the code of conduct will be posted on our website.

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 December 6, 2005.

Table of Contents

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 December 6, 2005.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

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 December 6, 2005.

ITEM 14. PRINCIPAL ACCOUNTANT 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 December 6, 2005.

Table of Contents**PART IV.****ITEM 15. EXHIBITS, FINANCIAL STATEMENTS and FINANCIAL STATEMENT SCHEDULES**

(a) *Financial Statements and Schedules:* Financial Statements for the three years ended June 30, 2005 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.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation. (10)
3.2	Amended and Restated Bylaws. (9)
3.3	Certificate of Designation, Preferences and Rights of Series RP Preferred Stock of Registrant. (13)
4.1	Form of Common Stock Certificate. (1)
4.2	Form of Warrant to Purchase Common Stock. (3)
4.3	Form of Warrant, issued March 1, 2004, to Purchase Common Stock. (5)
4.4	Form of Rights Certificate for RP Preferred Stock. (13)
10.1	1993 Stock Plan. (4)*
10.2	Form of Indemnity Agreement between the Company and its directors and officers. (1)*
10.3	License Agreement between the Company and Research Corporation Technologies, Inc. dated May 30, 1990. (1)+
10.4	License Agreement between the Company and The Salk Institute for Biological Studies dated March 31, 1989, as amended. (1)+
10.5	License Agreement between the Company and the Regents of the University of California dated June 13, 1990, as amended. (1)+
10.7	License and Cooperation Agreement among the Company, Merz + Co. GmbH & Co. and Children's Medical Center Corp., effective as of April 16, 1998. (2)+
10.8	Payment Agreement between the Company and Children's Medical Center Corp., effective as of April 16, 1998. (2)+
10.9	2003 Equity Incentive Plan. (7)*
10.10	2003 Employee Stock Purchase Plan. (7)*
10.11	Agreement and Plan of Reorganization, dated as of July 14, 2004, by and among the Company, Empire Acquisition Corp. and Empire Pharmaceuticals, Inc. (8)
10.12	Stockholders Agreement, dated as of July 14, 2004, by and among the Company, Empire Acquisition Corp., Biotech Value Fund, LP, as Stockholder Representative and the stockholders of Empire Pharmaceuticals, Inc. (8)

Table of Contents

Exhibit Number	Description
10.13	Employment Agreement, dated July 14, 2004, by and between the Company and Stephen J. Petti. (11)
10.14	Services Agreement, dated August 30, 2004 between HQ Global Workplaces and the Company. (11).
10.15	Rights Agreement, dated May 19, 2005, by and between American Stock Transfer & Trust Co., as Rights Agent, and the Company. (13)
10.16	Project Contract, dated January 1, 2005, by and between the Company and ICON Clinical Research, L.P. (protocol NTI 302) +
10.17	Project Contract, dated May 1, 2004, by and between the Company and ICON Clinical Research, L.P. (protocol NTI 303) +
10.18	License Agreement, dated as of March 29, 2002, by and between Abbott Laboratories and Empire Pharmaceuticals, Inc. +
10.19	First Amendment to License Agreement, dated as of October 22, 2003, by and between Abbott Laboratories and Empire Pharmaceuticals, Inc. +
10.20	Drug Product Development and Clinical Supply Agreement, dated as of April 1, 2005, by and between the Company and Baxter Pharmaceutical Solutions LLC +
10.21	Master Clinical Development Agreement, dated as of May 31, 2005, by and between the Company and SCIREX Corporation
10.22	Cooperation and Supply Agreement, dated March 1, 2005, by and between the Company and Nordmark Arzneimittel GmbH & Co. KG. (12)
10.23	Office Lease Agreement, dated April 22, 2005, by and between CA-Emeryville Properties Limited Partnership and the Company. (12)
10.24	Commercial Sublease, dated May 18, 2005, between the Company and Refac.
10.25	Employment Agreement, dated April 1, 2003, by and between the Company and Paul Freiman, as amended. *
21.1	Subsidiary of the Company.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Powers of Attorney. (Contained on Signature Page)
31.1	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

- (1) This exhibit is filed as an exhibit to Issuer's Registration Statement on Form SB-2 (Registration No. 33-74118-LA) and is incorporated herein by reference.
- (2) This exhibit is filed as an exhibit to the Registrant's Annual Report on Form 10-KSB for the year ended June 30, 1998 and is incorporated herein by reference.
- (3) This exhibit is filed as an exhibit to the Registrant's Annual Report on Form 10-KSB for the year ended June 30, 1999 and is incorporated herein by reference.

Table of Contents

- (4) This exhibit is filed as an appendix to the Registrant's Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on October 9, 2001 and is incorporated herein by reference.
- (5) This exhibit is filed as an exhibit to the Registrant's Current Report on Form 8-K filed March 4, 2004 and is incorporated herein by reference.
- (6) This exhibit is filed as an exhibit to the Registrant's Annual Report on Form 10-K for the year ended June 30, 2003 and is incorporated herein by reference.
- (7) This exhibit is filed as an appendix to the Registrant's Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on October 9, 2003 and is incorporated herein by reference.
- (8) This exhibit is filed as an exhibit to the Registrant's Current Report on Form 8-K filed July 15, 2004 and is incorporated herein by reference.
- (9) This exhibit is filed as an exhibit to the Registrant's Current Report on Form 8-K and filed May 20, 2005 and is incorporated herein by reference.
- (10) This exhibit is filed as an exhibit to the Registrant's Registration Statement on Form S-3 filed February 25, 2005 and is incorporated herein by reference.
- (11) This exhibit is filed as an exhibit to the Registrant's Registration Statement on Form 10-K filed September 13, 2004.
- (12) This exhibit is filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q filed May 10, 2005 and is incorporated herein by reference.
- (13) This exhibit is filed as an exhibit to the Registrant's Registration Statement on Form 8-A filed May 20, 2005 and is incorporated herein by reference.
- + Confidential treatment has been granted or requested with respect to certain portions of these agreements.
- * This exhibit is a management contract or compensatory plan or arrangement.

Table of Contents

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

Dated: September 28, 2005

President, Chief Executive Officer

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 Jonathan Wolter, 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 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>
/s/ PAUL E. FREIMAN _____ Paul E. Freiman	Director, President and Chief Executive Officer (Principal Executive Officer)	September 28, 2005
/s/ JONATHAN R. WOLTER _____ Jonathan R. Wolter	Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	September 28, 2005
/s/ ABRAHAM E. COHEN _____ Abraham E. Cohen	Chairman of the Board	September 28, 2005
/s/ ENOCH CALLAWAY _____ Enoch Callaway	Director	September 28, 2005
/s/ THEODORE L. ELIOT, JR. _____ Theodore L. Eliot, Jr.	Director	September 28, 2005
	Director	September 28, 2005

Ronald E. Cape Ph.D.

/s/ ABRAHAM D. SOFAER

September 28, 2005

Abraham D. Sofaer

Director

/s/ JOHN B. STUPPIN

September 28, 2005

John B. Stuppin

Director

/s/ F. VAN KASPER

September 28, 2005

F. Van Kasper

Director