NEUROBIOLOGICAL TECHNOLOGIES INC /CA/
Form 10-K
September 28, 2001

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, 2001

OR

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

For the transition period from to

Commission file number: 0-23280

NEUROBIOLOGICAL TECHNOLOGIES, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	94-3049219
(State of Incorporation)	(I.R.S. Employer Identification No.)

3260 Blume Drive, Suite 500, Richmond, California 94806
(Address of Principal Executive Offices)

(510) 262-1730
(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
(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 [X] No [_]

Indicate by check mark if disclosure of delinquent filers pursuant to Item

405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [_]

As of August 31, 2001, the issuer had outstanding 17,503,699 shares of common stock and the aggregate market value of the shares of common stock held by non-affiliates on that date was $71,000,819 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 Item 10 and Items 11 and 12 of Part III incorporate by reference information from the issuer's Proxy Statement for the Annual Meeting of Stockholders to be held on November 15, 2001 (the "Proxy Statement").

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PART I

ITEM 1. BUSINESS

This report contains forward-looking statements. These forward-looking statements are based on our current expectations about our business and industry, and include, but are not limited to, statements and concerns about plans to: continue development of our current product candidates; conduct clinical trials with respect to product candidates; seek regulatory approvals; address certain markets; engage third party manufacturers to supply our commercial requirements; market, sell and distribute our products; and evaluate additional product candidates for subsequent clinical and commercial development. In some cases, these statements may be identified by terminology such as "may", "will", "should", "expects", "plans", "anticipates", "believes", "estimates", "predicts", "potential", or "continue" or the negative of such terms and other comparable terminology. These statements involve known and unknown risk and uncertainties that may cause our or our industry's 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 under the captions "Business", "Risks Associated with Our Business" and "Management's Discussion and Analysis of Financial Conditions and Results of Operations". Except as 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 as "NTI," "we," "us," "our," or the "Company") is an emerging drug development company focused on the clinical development and regulatory approval of neuroscience drugs. We develop neuroprotective and neuromodulatory agents to treat progressive neurological impairments characteristic of various nervous system disorders, including diabetic neuropathy, brain cancer and AIDS-related dementia.

Our strategy is to in-license and develop early 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 seeks partnerships with pharmaceutical and biotechnology companies for late-stage development and marketing of our product candidates. We currently have two product candidates that have completed or are in Phase II or Phase III human clinical testing. These candidates, Memantine and Xerecept, are described below.

MEMANTINE

Memantine is an orally-dosed compound that appears to restore the function of impaired neurons by modulation of the N-methyl-D-aspartate (NMDA) receptor, integral to the membranes of these cells. Restoration of this function inhibits injured or damaged neurons from firing abnormally, a pathological process associated with many neurological conditions, including dementia, Alzheimer's disease, neuropathic pain (persistent pain resulting from abnormal signals to the brain) and AIDS-related dementia.

In April 1998, we entered into a strategic research and marketing cooperation agreement with Merz + Co. ("Merz") 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 to facilitate regulatory review and marketing approval by the Food and Drug Administration ("FDA") and foreign

regulatory authorities. Pursuant to this agreement, we will share in future revenues from sales, if any, of Memantine for all indications. Memantine has been marketed by Merz in Germany since 1989 with the labeling "dementia syndrome."

In June 2000, Merz entered into an agreement with Forest Laboratories, Inc. ("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 ("Lundbeck") 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, 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 Suntory Ltd., respectively. In October 2000, we received $2.5 million and in April 2001 we received $2.3 million from Merz under our 1998 strategic research and marketing cooperation agreement, representing our portion of the payments received by Merz pursuant to Merz's agreements with Forest and Lundbeck.

In January 2001, Forest announced the outcome of its meeting with the FDA to review a summary of the clinical study results for Memantine in treating moderately severe to severe Alzheimer's disease. The FDA agreed that the summary data of the Phase III study conducted in the United States, if confirmed in a full submission, provided evidence of efficacy in treating moderately severe to severe Alzheimer's disease. The FDA indicated that a second study performed in Europe would likely need to be reviewed by an advisory committee to determine whether the specific endpoints utilized were adequate to qualify it as a second study required to demonstrate efficacy. As a result, Forest is preparing a New Drug Application ("NDA") that it expects to file with the FDA in late 2001 or early 2002. Forest initiated an additional Phase III study in the United States of Memantine for moderately severe to severe Alzheimer's disease in July 2001. We anticipate that this study will be completed in the second half of 2002 and will be used as additional evidence of efficacy as needed.

The AIDS-related dementia clinical trial was completed in May 2001 and we observed consistent, though statistically insignificant, trends of improvement for both neuropsychological performance and neuropathy.

In August 2001, we announced that Forest would be conducting the second of two trials necessary for registration of an NDA to the FDA for diabetic neuropathy. This will be a large-scale, multi-center, double-blind placebo controlled trial to assess the safety and efficacy of Memantine in the treatment of diabetic neuropathy and is expected to be completed in 2002. We conducted the first such trial with an enrollment of over 400 patients and reported positive results in January 2000.

XERECEPT (TM)

We are also developing XERECEPT, a synthetic preparation of the natural human peptide Corticotropin-Releasing Factor, as a treatment for brain swelling due to brain tumors (peritumoral brain edema). XERECEPT received orphan drug designation for this indication by the FDA. Orphan drug designation provides NTI with seven years market exclusivity and makes NTI eligible to receive Orphan Drug Grants to fund clinical research. We are currently planning a second Phase II trial of XERECEPT for peritumoral brain edema.

In August 2000, we announced that we had signed an option with the University of California, Berkeley to license its patents on corticotropin-releasing hormone (CRH) analogues. The option agreement includes a work plan that will encompass in vivo models of the hormones to screen CRH-analogues to arrive at the optimum CRH-analogue for clinical purposes.

PRODUCT CANDIDATES

Product/Indication	Development Status	Primary Benefit Sou
MEMANTINE		
Diabetic 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. NTI's collaborative partner Forest Laboratories initiated a year-long Phase III trial in July 2001.	Treatment of chronic pa associated with diabeti neuropathy.
Mild to Moderate Vascular Dementia.....	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 cognitiv improvement.
Moderate to Severe Dementia and Alzheimer's Disease.....	Phase III trial completed by Merz in the United States showing improvement in functional independence and reduction in required level of care. Forest initiated an additional Phase III trial in July 2001 to confirm these initial results.	Functional and cognitiv improvement.
AIDS-Related Dementia and Neuropathic Pain.....	Phase II trial completed. Consistent but statistically insignificant trends of improvement observed for both neuropsychological performance and neuropathy. Further studies to validate initial data are under consideration.	Improvement in neuropsychological func peripheral neuropathy.
XERECEPT(TM) (CORTICOTROPIN-RELEASING FACTOR)		
Peritumoral Brain Edema.....	Phase II trial completed. Results confirmatory but not definitive. Further study in planning.	Stabilization or improv neurological function.

SCIENTIFIC BACKGROUND

Our therapeutic focus is neuroprotection and neuromodulation: 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, brain cancer, and AIDS-related dementia.

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 IN DEVELOPMENT

Memantine

Memantine is an orally-available neuromodulatory agent that has been marketed in Germany by Merz since 1989 with the labeling "dementia syndrome." It 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 overstimulation 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. There are currently no approved neuroprotective treatments for any of the pathologies associated with NMDA-receptor overstimulation.

We have been developing Memantine both as a treatment for neuropathic pain as well as for neurological deficits associated with AIDS. Estimates are that approximately 1,000,000 patients in the United States suffer from intractable neuropathic pain. In addition, as many as one-third of AIDS patients eventually develop neurological problems, such as loss of cognition and coordination.

Nerve cells in the brain communicate by sending signals to excite or inhibit each other. These signals are initiated by compounds known as neurotransmitters. 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 overstimulation 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.

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.

The profound psychotic side effects associated with other NMDA receptor antagonists previously evaluated in human clinical trials were virtually absent with Memantine. Merz has carefully documented Memantine's history of safe clinical use in Germany over years of post-launch clinical experience and active surveillance. In a post-marketing surveillance study sponsored by Merz with 1,420 dementia outpatients treated for up to more than one year, Memantine was rated as having very good to good tolerability in 93.8% of the cases at the end of the observation period.

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 treatments 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 overactivation 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 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.

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 was observed.

In August 2001, we announced that Forest would be conducting an additional large-scale, multi-center, double-blind placebo controlled trial to assess the safety and efficacy of Memantine in the treatment of diabetic neuropathy.

AIDS-Related Dementia and Neuropathic Pain

Recent research indicates that infection of the CNS with HIV, the virus associated with AIDS, also leads to neuronal impairment. Such impairment may result in neurological complications, including loss of cognition, movement, and sensation, referred to as AIDS-related dementia Complex. Approximately one-half of children and one-third of adults with AIDS are expected to develop these symptoms. There are currently no therapies specifically directed towards HIV-associated neuronal impairment. Current AIDS therapies, even if effective at reducing the circulating virus level, do not appear to be effective at eliminating AIDS-induced impairment to the CNS.

Besides the AIDS-related cognitive impairments, many AIDS patients experience painful peripheral neuropathies due to overstimulation of NMDA receptors. This often occurs in the later stages of AIDS and results in a burning pain of the feet as well as pain from anything that touches the skin. Walking in particular may become extremely difficult. Effective treatments are still unavailable for this incapacitating condition and certain AIDS therapies may aggravate this type of neuropathic pain.

Memantine has been shown to reduce NMDA receptor-mediated neuronal

impairment in both in vitro (outside the body) experiments and in vivo (inside the body) animal models. Neuronal dysfunction due to HIV infection has been shown to be mitigated by antagonists of the NMDA receptor, including Memantine.

In December 1996, we announced the initiation of a Phase II clinical trial of Memantine as a treatment for AIDS-related dementia and neuropathic pain. This study was funded by the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health and was being conducted by the AIDS Clinical Trials Group (ACTG), a clinical trials consortium funded by the NIAID. In December 1999, enrollment was completed at 140 AIDS patients. The results of the blinded portion of this trial indicate consistent trends of improvement for both neuropsychological performance and neuropathy. However, because these results cannot be considered statistically significant, further studies are necessary. The ACTG also implemented a protocol extension permitting open-label dosing for up to 60 weeks following the blinded phase of the trial. This open-label phase will provide data on the long-term safety of Memantine. NTI will have the right to use the resulting data to further the commercial development of Memantine for that indication.

Agreement with Merz and Additional Indications

In April 1998, we entered into a strategic research and marketing cooperation agreement with Merz and a new revenue sharing partnership with Children's Medical Center Corporation to further the clinical development and commercialization of Memantine. Pursuant to this agreement, Children's Medical Center Corporation terminated its existing license to NTI for AIDS-related dementia and neuropathic pain and granted exclusive rights to Merz. NTI and Merz share scientific, clinical and regulatory information about Memantine, particularly safety data, to facilitate regulatory review and marketing approval by the FDA and foreign regulatory authorities. Pursuant to the agreement with Merz, NTI will share in future revenues from sales of Memantine for all indications.

XERECEPT (Human Corticotropin-Releasing Factor)

XERECEPT is our synthetic preparation of the human peptide Corticotropin-Releasing Factor (hCRF) which we are developing as a 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 preclinical studies and pilot human clinical trials previously sponsored by the Company have demonstrated the compound's potential to reduce swelling in brain tissue and to be well-tolerated and apparently safe. Thus, XERECEPT has 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 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 approved our application for orphan drug designation for XERECEPT to treat this unmet medical need. Orphan drug designation provides us with seven years market exclusivity and makes us eligible to receive federal monies for clinical research under the Orphan Drug Grant Program.

hCRF is a natural neuroendocrine peptide hormone found in humans both centrally (within the brain) and peripherally (outside the brain). Researchers

discovered anti-edema affects of hCRF through systemic administration. 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 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. Preclinical studies sponsored by us 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 initially 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 result 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.

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 the adverse side effects associated with current therapies. 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.

Results from pilot human clinical trials previously sponsored by us demonstrated the potential of XERECEPT to reduce swelling of brain tissue and to be well-tolerated and apparently safe. Based on these

results, we initiated a Phase II human clinical trial in 1997 to evaluate the efficacy of XERECEPT to stabilize or improve neurological symptoms caused by peritumoral brain edema. Patients enrolled in this randomized, double-blind, positive-controlled trial had neurological symptoms requiring stable dosing of synthetic corticosteroids, the current standard treatment. We closed enrollment for this trial at 33 patients (one third of projected enrollment) in order to provide expedited but abbreviated analysis of the data. All responders, as defined by the trial protocol, were in the XERECEPT treatment groups. However, rigorous statistical analysis of the data was not meaningful due to the small numbers enrolled. The clinical study should be regarded as confirmatory but not definitive with regard to neurologic improvements that may be attained with XERECEPT in symptomatic brain tumor patients. We are currently planning a second Phase II trial of XERECEPT for peritumoral brain edema.

COMPETITION

Competition in the biopharmaceutical industry is intense and is expected to increase. There are other therapies under development for each of these therapeutic targets and the development and sale of drugs for the treatment of the therapeutic targets we are pursuing is highly competitive. We may not be able to develop products that will be as efficacious or as cost-effective as currently-marketed products. We have both exclusive and non-exclusive licenses to patent rights covering certain uses of XERECEPT(TM). Consequently, others may develop, manufacture and market products that could compete with those that we are developing.

We 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.

We believe that our ability to compete successfully will depend on our ability to obtain funding, create and maintain scientifically advanced technology, develop proprietary products, attract and retain scientific personnel, obtain patent or other protection for our products, obtain required regulatory approvals and manufacture and successfully market products either alone or through other parties. Most of our competitors have substantially greater financial, marketing and human resources than us. Therefore, we expect to encounter significant competition.

SUPPLIERS

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

XERECEPT has been manufactured by established methods using chemical synthesis to our specifications. We performed audits on our contractors who supplied XERECEPT to assess compliance with the current Good Manufacturing Practice ("cGMP") regulations. Fresh materials produced under a new process have been supplies to the company. Alternative cGMP suppliers of the bulk drugs and of finished dosage form 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 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 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 TECHNOLOGY

In April 1998, in connection with our agreement with Merz, our exclusive license from Children's Medical Center Corporation to a series of patents and patent applications relating to certain non-ophthalmic uses of Memantine was terminated.

We hold non-exclusive worldwide licenses to four issued U.S. patents covering the composition of matter of XERECEPT and various analogues, together with certain foreign patents and patent applications. Because of the non-exclusivity of the four issued U.S. patents, others may develop, manufacture and market products that could compete with those we develop. However, we also have exclusive rights to four issued patents and one patent application covering uses of XERECEPT and analogues. We are responsible for the costs of prosecuting the patent applications related to XERECEPT for which we have exclusive rights. In addition to the patents and pending applications we have licensed from others, we hold U.S. Patent No. 5,870,430 which covers certain liquid formulations of hCRF and hCRF-related peptides.

In August 2000, we announced that we had signed an option with the University of California, Berkeley for Berkeley's patents on corticotropin-releasing hormone analogues. The option agreement includes a work plan that will encompass in vivo models of the hormones to screen CRH-analogues to arrive at the optimum CRH-analogue for clinical purposes.

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.

A number of pharmaceutical and biotechnology companies and research and academic institutions have developed technologies, filed patent applications or received patents on various technologies that may be related to our business. Some of these technologies, applications or patents may conflict with our or any of our licensors' technologies or patent applications. Such conflict could limit the scope of the patents, if any, that we may be able to obtain or to which we have a license or result in the denial of our patent applications or the patent applications for which we have licenses. In addition, if patents that cover our activities have been or are issued to other companies, there can be no assurance that we would be able to obtain licenses to these patents at a reasonable cost, or be able to develop an alternative technology.

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 preclinical 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.

- 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 preclinical 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 current Good Manufacturing Practice or 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 preclinical or early stage clinical trials does not assure success in later stage 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

As of June 30, 2001, we employed 10 people, 5 of whom are full-time employees.

We use consultants to complement our staffing. Our employees are not subject to any collective bargaining agreements, and we regard our relations with employees to be good.

ITEM 2. PROPERTIES

Our executive offices are located in Richmond, California. On April 1, 2001, we entered into an assignment and assumption of lease to sublease approximately 4,333 square feet of space. The master lease under which we sublease these

facilities expires in July 2002. Rental payments are approximately $7,600 per month over the term of the sublease.

We believe that our facilities are adequate for our current needs and that, if required, we will be able to lease suitable alternative or additional space on commercially acceptable terms.

ITEM 3. LEGAL PROCEEDINGS

Currently we are not a party to 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, 2001.

PART II

ITEM 5. MARKET FOR COMMON STOCK AND RELATED SHAREHOLDER MATTERS

From February 1998 to July 2000, our common stock was traded on the Nasdaq Stock Market's Over-the-Counter (OTC) Bulletin Board. Since July 2000, our common stock has been quoted on The Nasdaq SmallCap Market under the symbol NTII.

High and low closing sales prices shown below through July 2000 refer to the high and low bid quoted on the OTC Bulletin Board. These quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions. High and low closing sales prices shown after July 2000 refer to the high and low trading prices during that period as reported on The Nasdaq SmallCap Market.

Fiscal 2000	High	Low
First Quarter	$ 1.53	$0.84
Second Quarter	$ 3.75	$0.84
Third Quarter	$ 9.28	$2.81
Fourth Quarter	$ 8.50	$3.88

Fiscal 2001	High	Low
First Quarter	$11.00	$5.94
Second Quarter	$ 7.88	$3.47
Third Quarter	$ 5.00	$1.84
Fourth Quarter	$ 3.44	$1.56

As of June 30, 2001 there were approximately 264 holders of record of our common stock and 17,503,699 shares of common stock outstanding. No dividends have been paid on the common stock since our inception, and we do not anticipate paying any dividends in the foreseeable future.

ITEM 6. SELECTED FINANCIAL DATA

The following selected financial information has been derived from audited consolidated financial statements. 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,					Period August 27 (incept throu
	2001	2000	1999	1998	1997	June 30,
	(in thousands, except per share data)					
Statement of Operations Data:						
Total revenue	$ 4,781	$ --	$ 100	$ 2,100	$ --	$ 7,0
Expenses:						
Research and development	1,194	1,896	2,780	2,026	5,478	28,1
General and administrative	2,556	1,380	1,059	2,347	2,298	15,3
Total expenses	3,750	3,276	3,839	4,373	7,776	43,4
Operating income (loss)	1,031	(3,276)	(3,739)	(2,273)	(7,776)	(36,4
Interest income	599	161	47	100	407	2,9
Income (loss) before income tax	1,630	(3,115)	(3,692)	(2,173)	(7,369)	(33,5
Provision for income tax	42	--	--	--	--	
Net income (loss)	$ 1,588	$ (3,115)	$ (3,692)	$ (2,173)	$ (7,369)	$(33,5
Basic net income (loss) per share	$ .10	$ (.27)	$ (.49)	$ (.32)	$ (1.13)	
Diluted net income (loss) per share	$ .08	$ (.27)	$ (.49)	$ (.32)	$ (1.13)	
Weight1ed average shares of common stockoutstanding--basic	16,532	11,461	7,555	6,862	6,527	
Weighted average shares of common stockoutstanding--diluted	21,071	11,461	7,555	6,862	6,527	

	June 30,				
	2001	2000	1999	1998	1997
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 10,182	$ 8,554	$ 201	$ 2,021	$ 3,838
Working capital (deficit)	9,806	7,886	(890)	1,582	3,013
Total assets	11,458	8,683	249	2,133	4,207
Total current liabilities	762	769	1,135	498	997

Deficit accumulated during development stage	(33,564)	(35,152)	(32,037)	(28,345)	(26,172)
Stockholders' equity (deficit)	10,696	7,913	(886)	1,636	3,211

	2001				
-	September 30	December 31	March 31	June 30	Tot
	(in thousands, except per share amounts) (Unaudited)				
Quarterly Results of Operations:					
Total revenue	$ --	$ 2,531	$ --	$ 2,250	$ 4,
Research and development	(236)	(318)	(451)	(189)	(1,
General and administrative	(529)	(591)	(808)	(628)	(2,
Interest income	147	166	152	134	
Income (loss) before income taxes	(618)	1,788	(1,107)	1,567	1,
Income tax expense	--	--	--	42	
Net income (loss)	$ (618)	$ 1,788	$(1,107)	$ 1,525	$ 1,
Basic net income (loss) per share	$ (0.04)	$ 0.11	$ (0.07)	$ 0.09	$ 0
Diluted net income (loss) per share	$ (0.04)	$ 0.08	$ (0.07)	$ 0.08	$ 0
Weighted average shares of common stock outstanding--basic	16,104	16,104	16,506	17,328	16,
Weighted average shares of common stock outstanding--diluted	16,104	21,649	16,506	20,108	21,

	2000				
	September 30	December 31	March 31	June 30	Tot
	(in thousands, except per share amounts) (Unaudited)				
Quarterly Results of Operations:					
Total revenue	$ --	$ --	$ --	$ --	$
Research and development	(536)	(625)	(402)	(333)	(1,
General and administrative	(247)	(245)	(328)	(560)	(1,
Interest income	2	21	37	101	
Loss before income taxes	(781)	(849)	(693)	(792)	(3,
Income tax expense	--	--	--	--	
Net loss	$ (781)	$ (849)	$ (693)	$ (792)	$(3,
Basic and diluted net loss per common share	$ (0.10)	$ (0.07)	$ (0.05)	$ (0.05)	$ (0

Weighted average shares of common stock outstanding--basic and diluted.....	7,690	11,519	13,563	14,924	11,

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 are forward-looking statements that involve risks and uncertainties, including our dependence on Merz and its marketing partners for the successful development of Memantine, our ability to properly design, implement and complete planned trials, meet regulatory requirements, demonstrate safety and efficacy for products, manage third party contractors, and avoid infringement of third-party proprietary rights, as well as other risks detailed from time to time in our Securities and Exchange Commission filings. Actual results may differ materially from those projected. These forward-looking statements represent our judgment as of the date of the release. We disclaim, however, any intent or obligation to update these forward-looking statements.

OVERVIEW

We are an emerging drug development company focused on the clinical development and regulatory approval of neuroscience drugs. We are developing neuroprotective and neuromodulatory agents to treat progressive neurological impairments characteristic of various nervous system disorders, including diabetic neuropathy, brain cancer and AIDS-related dementia. Our strategy is to in-license and develop early-stage drug candidates that target major medical needs and that may be rapidly commercialized.

Except for the current year, we have incurred significant losses since our inception. As of June 30, 2001, our accumulated deficit was $34 million and total stockholders' equity was $11 million. We expect to incur additional operating losses over at least the next year as we continue to expand our research and development efforts. Operating expenses decreased from $3.8 million in 1999 to $3.3 million in 2000 and increased to $3.8 million for 2001.

RESULTS OF OPERATIONS

TOTAL REVENUES. In April 1998, we entered into a strategic research and marketing cooperation agreement with Merz + Co. (Merz) 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 FDA and foreign regulatory authorities. Pursuant to this agreement, we will share in future revenues from sales of Memantine for all indications.

In fiscal 2001, we had revenue of $4,781,000, which consisted of license fee payments from Merz, which represents our portion of the payments received by Merz pursuant to Merz's agreements with Forest and Lundbeck. In fiscal 2000, we had no revenue. In fiscal 1999, we had revenue of $100,000 from a Small Business Innovative Research grant awarded by the National Institutes of Health.

RESEARCH AND DEVELOPMENT EXPENSES. Research and development expenses were

$1,194,000 in fiscal 2001, compared to $1,896,000 in fiscal 2000 and $2,780,000 in fiscal 1999. The decrease in fiscal 2001 was primarily due to the absence of any ongoing clinical costs other than the remaining cost for patient data analysis. The decrease in fiscal 2000 was primarily due to the completion of our Phase IIB human clinical trial to evaluate Memantine as a treatment for peripheral diabetic neuropathy. We expect that our research and development expenditures will increase in future years to support additional product development activities and clinical trials. The rate of increase depends on a number of factors, including progress in research and development and clinical trials.

GENERAL AND ADMINISTRATIVE EXPENSES. General and administrative expenses were $2,556,000 in fiscal 2001, compared to $1,380,000 in fiscal 2000 and $1,059,000 in fiscal 1999. The increase in fiscal 2001 was

primarily due to an increase in rent expense, employee bonuses, and activities relating to seeking financing and corporate partnerships. The increase in fiscal 2000 reflected expenditures in activities relating to seeking financing and corporate partnerships and relisting our common stock on The Nasdaq SmallCap Market.

INTEREST INCOME. Interest income was $599,000 in fiscal 2001 compared to $161,000 in fiscal 2000 and $47,000 in fiscal 1999. The increases were primarily due to increases in average cash balances as a result of a private financing in 2000 and revenue payments received in 2001.

INCOME TAXES. The income tax provision in fiscal 2001 is a result of the federal alternative minimum tax. Due to our loss position, there was no income tax provision in fiscal 2000 and fiscal 1999.

LIQUIDITY AND CAPITAL RESOURCES

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 the current year, 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.

We believe that our available cash and cash equivalents and investments of $11,044,000 as of June 30, 2001 are adequate to fund our operations through at least the next twelve months. In the course of our development activities, we have incurred significant losses, although we were profitable in the year ended June 30, 2001, and expect additional losses in the year ending June 30, 2002. We expect to incur ongoing costs in fiscal 2002 primarily for Phase II and Phase III clinical trials of XERECEPT(TM) and CRH-analogues and related administrative support. Merz and Merz's marketing partners will pay all future development costs of Memantine.

Our operating activities (used) provided cash of $(3,198,000) in 1999, $(3,234,000) in 2000 and $1,372,000 in 2001. Sources and uses of cash in operating activities were primarily derived from net operating income (losses).

Net cash provided by (used in) investing activities was $8,000 in 1999, $(1,256,000) in 2000 and $(6,213,000) in 2001. The cash used in 2001 primarily represented purchases of investments of $11,742,000, less maturities of investments of $5,551,000.

Financing activities provided cash of $1,370,000 in 1999, $11,617,000 in

2000 and $1,140,000 in 2001. The 2000 amount primarily consists of the net proceeds we received from the sale of common stock. The 2001 amount primarily consists of the net proceeds we received from the issuance of common stock upon exercise of stock options and warrants.

We may seek to raise additional funds whenever market conditions permit. 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 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;
- competing technological and market developments;
- our ability to establish collaborative relationships; and
- the development of commercialization activities and arrangements.

RISKS ASSOCIATED WITH OUR BUSINESS

You should consider carefully the following risk factors, along with the other information contained or incorporated by reference in this Annual Report on Form 10-K. These factors, among others, may cause actual results, events or performance to differ materially from those expressed in any forward-looking statements we make in this Annual Report or our other reports and prospectuses filed with the Securities and Exchange Commission.

Because all our potential products are in clinical development, we may not develop a candidate product that will receive required regulatory approval or be successfully commercialized.

We are still in the development stage and have no marketable products. As a result, we have no revenues from product sales, and most of our resources are dedicated to the development of selected candidate pharmaceutical products. The results of our preclinical studies and early stage clinical trials are not necessarily indicative of those that will be obtained upon further clinical testing in later stage clinical trials. It is possible that none of our candidate products will receive regulatory approval or be successfully commercialized.

Our potential products are subject to the risks of failure inherent in the development of products based on new technologies.

Our potential products are subject to the risks of failure inherent in the development of products based on new technologies. These risks include the possibility that the potential products may:

- be found to be unsafe, ineffective or toxic;
- fail to receive necessary regulatory clearances;

- if approved, be difficult to manufacture on a large scale or uneconomical to market;
- be precluded from marketing by us due to the proprietary rights of third parties; and
- not be successful because third parties market or may market superior or equivalent products.

Further, our development activities may not result in any commercially viable products. We do not expect to be able to commercialize any products for a number of years, if at all.

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

All of our revenues in fiscal 2001 were license fee payments from Merz related to our portion of payments received by Merz pursuant to Merz's agreements with its partners. The only revenues that we will receive in the foreseeable future for Memantine are royalties on product sales by Merz or its marketing partners and our share of payments received by Merz from its partners. Under certain circumstances, Merz can terminate our agreement upon six months notice. The termination of our agreement with Merz or any failure by Merz or its partners to successfully commercialize Memantine after its development would have a material adverse effect on our business, financial conditions and results of operations.

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

We have entered into various contractual arrangements (many of which are 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 place significant responsibility for preclinical testing and human clinical trials and for preparing and submitting submissions for regulatory approval for potential products on the collaborator, licensor or contractor. If the

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 to our view of the future likelihood of FDA approval or commercial viability of these potential products.

We have agreements and licenses with third parties that require us to pay royalties and make other payments to such parties. Our failure to make such payments could cause us to lose rights to technology or data under these agreements.

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 only to cover liabilities arising from clinical trials. It is possible that our current insurance may not be adequate to cover liabilities arising from our clinical trials.

Our current product liability insurance does not cover commercial sales of products. We can not be sure that we will be able to obtain product liability insurance covering commercial sales or, if such insurance is obtained, that sufficient coverage can be acquired at a reasonable cost. An inability to obtain insurance at acceptable cost or otherwise protect against potential product liability claims could prevent or inhibit commercialization of any products we develop.

Further reductions in our staff might delay the achievement of planned development objectives.

Each person currently employed by us serves an essential function. We currently employ five persons full-time and five persons part-time. Any further reduction in force could impair our ability to manage ongoing clinical trials and may have a material adverse effect on our operations.

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 during fiscal 2001 has been low compared to that of other biopharmaceutical companies. Our common stock was delisted from The Nasdaq Stock Market in February 1998 because we failed to meet the financial conditions necessary to remain listed. In July 2000, we were approved for listing on The Nasdaq SmallCap Market. However, we may not continue to qualify for listing on that market.

Factors that may cause volatility in our stock price include:

- the results of preclinical studies and clinical trials by us, Merz or its marketing partners or our competitors;
- other evidence of the safety or efficacy of our products of the Company, or those of Merz or its marketing partners 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, 2001, approximately 92% of our total portfolio will mature in one year or less, with the remainder maturing in less than two 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.

ITEM 8. FINANCIAL STATEMENTS

REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Stockholders
Neurobiological Technologies, Inc.

We have audited the accompanying balance sheets of Neurobiological Technologies, Inc. (a development stage company) as of June 30, 2001 and 2000, and the related statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended June 30, 2001, and for the period from August 27, 1987 (inception) through June 30, 2001. 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 auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Neurobiological Technologies, Inc. as of June 30, 2001 and 2000, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2001, and for the period from August 27, 1987 (inception) through June 30, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Palo Alto, California
August 10, 2001

(a development stage company)

BALANCE SHEETS

	June 30, 2001	
	2001	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,626,700	$ 7
Short-term investments	6,555,575	1
Interest receivable	132,044	
Prepaid expenses and other current assets	253,827	
Total current assets	10,568,146	8
Long-term investments	861,313	
Property and equipment, net	28,820	
	$ 11,458,279	$ 8
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 92,008	$
Accrued expenses	628,210	
Income taxes payable	41,831	
Total current liabilities	762,049	
Commitments		
Stockholders' equity:		
Convertible preferred stock, $.001 par value, 5,000,000 shares authorized, 2,332,000 issued in series, 1,582,000 and 2,282,000 outstanding at June 30, 2001 and 2000, respectively (aggregate liquidation preference of $791,000 at June 30, 2001)	791,000	1
Common stock, $.001 par value, 35,000,000 shares authorized, 17,503,699 and 15,647,397 outstanding at June 30, 2001 and 2000, respectively	43,660,557	42
Deferred stock compensation	(191,626)	
Deficit accumulated during development stage	(33,563,701)	(35
Total stockholders' equity	10,696,230	7
	$ 11,458,279	$ 8

See accompanying notes.

STATEMENTS OF OPERATIONS

	Year Ended June 30,			Period August 1987 (incept throu
	2001	2000	1999	June 30,
REVENUES				
License	$ 4,781,250	$ --	$ --	$ 6,881
Grant	--	--	99,544	149
Total revenue	4,781,250	--	99,544	7,030
EXPENSES				
Research and development	1,193,731	1,896,023	2,780,305	28,158
General and administrative	2,556,272	1,379,708	1,058,421	15,332
Total expenses	3,750,003	3,275,731	3,838,726	43,490
Operating income (loss)	1,031,247	(3,275,731)	(3,739,182)	(36,460
Interest income	598,975	160,999	46,949	2,938
Income (loss) before income tax expense	1,630,222	(3,114,732)	(3,692,233)	(33,521
Income tax expense	41,831	--	--	41
NET INCOME (LOSS)	$ 1,588,391	$(3,114,732)	$(3,692,233)	$(33,563
BASIC NET INCOME (LOSS) PER SHARE	$ 0.10	$ (0.27)	$ (0.49)	
Shares used in basic net income (loss) per share calculation	16,531,649	11,460,599	7,554,522	
DILUTED NET INCOME (LOSS) PER SHARE	$ 0.08	$ (0.27)	$ (0.49)	
Shares used in diluted net income (loss) per share calculation	21,070,598	11,460,599	7,554,522	

See accompanying notes.

NEUROBIOLOGICAL TECHNOLOGIES, INC.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Preferred Stock		Com
	Shares	Amount	Shares

Period from August 27, 1987 (inception) through June 30, 1998			
Issuance of common stock	--	$ --	740,8
Issuance of warrants to purchase 304,786 shares of common stock	--	--	
Issuance of common stock and warrants at $0.55 per unit	--	--	1,010,4
Issuance of common stock for services and license rights	--	--	88,2
Issuance of common stock upon exercise of options and warrants	--	--	232,1
Issuance of common stock under employee stock purchase plan	--	--	65,1
Issuance of 5,691,000 shares of Series A preferred stock, net of issuance costs	5,691,000	5,573,194	
Issuance of 2,657,881 shares of Series B preferred stock, net of issuance costs	2,657,881	1,653,888	
Conversion of preferred stock in connection with the initial public offering	(8,348,881)	(7,227,082)	1,046,9
Issuance of common stock at $8.00 per share in connection with initial public offering net of issuance costs	--	--	1,840,0
Issuance of common stock at $3.25 per share in connection with public offering net of issuance costs	--	--	2,530,0
Net loss and comprehensive loss	--	--	
Balances at June 30, 1998	--	--	7,553,6
Issuance of common stock under employee stock purchase plan	--	--	9,8
Issuance of 2,332,000 shares of Series A preferred stock and warrants at $2.50 per unit, net of issuance costs	2,332,000	1,166,000	
Net loss and comprehensive loss	--	--	
Balances at June 30, 1999	2,332,000	1,166,000	7,563,5

	Deficit Accumulated in Development Stage	Total Stockholders' Equity (Deficit)
Period from August 27, 1987 (inception) through June 30, 1998		
Issuance of common stock	$ --	$ 1,616,706
Issuance of warrants to purchase 304,786 shares of common stock	--	43,290
Issuance of common stock and warrants at $0.55 per unit	--	555,725
Issuance of common stock for services and license rights	--	120,875
Issuance of common stock upon exercise of options and warrants	--	296,421
Issuance of common stock under employee stock purchase plan	--	160,520
Issuance of 5,691,000 shares of Series A preferred stock, net of issuance costs	--	5,573,194
Issuance of 2,657,881 shares of Series B preferred stock, net of issuance costs	--	1,653,888
Conversion of preferred stock in connection with the initial public offering	--	--
Issuance of common stock at $8.00 per share in connection with initial public offering net of issuance costs	--	12,817,000
Issuance of common stock at $3.25 per share in connection with public offering net of issuance costs	--	7,143,279

Net loss and comprehensive loss	(28,345,127)	(28,345,127)
Balances at June 30, 1998	(28,345,127)	1,635,771
Issuance of common stock under employee stock purchase plan	--	4,454
Issuance of 2,332,000 shares of Series A preferred stock and warrants at $2.50 per unit, net of issuance costs	--	1,166,000
Net loss and comprehensive loss	(3,692,233)	(3,692,233)
Balances at June 30, 1999	(32,037,360)	(886,008)

(continued on following page)

NEUROBIOLOGICAL TECHNOLOGIES, INC.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)--(Continued)

	Preferred Stock		Com
	Shares	Amount	Shares
Balances at June 30, 1999	2,332,000	$1,166,000	7,563,5
Issuance of common stock and warrants at $4.00 per unit, net of issuance costs	--	--	5,434,7
Issuance of common stock at $5.30 per unit, net of issuance costs	--	--	1,200,0
Issuance of common stock upon exercise of options and warrants	--	--	1,357,2
Options granted to consultants for services rendered	--	--	
Deferred stock compensation	--	--	
Amortization of deferred stock compensation	--	--	
Conversion of preferred stock to common stock	(50,000)	(25,000)	50,0
Issuance of common stock under employee stock purchase plan	--	--	41,8
Net loss and comprehensive loss	--	--	
Balances at June 30, 2000	2,282,000	1,141,000	15,647,3
Issuance of common stock upon exercise of options and warrants	--	--	1,129,9
Amortization of deferred stock compensation	--	--	
Conversion of preferred stock to common stock	(700,000)	(350,000)	700,0
Issuance of common stock under employee stock purchase plan	--	--	26,3
Net income and comprehensive income	--	--	
Balances at June 30, 2001	1,582,000	$ 791,000	17,503,6

	Deficit Accumulated in	Total

	Development Stage	Stockholders' Equity (Deficit
Balances at June 30, 1999	$(32,037,360)	$ (886,008)
Issuance of common stock and warrants at $4.00 per unit, net of issuance costs	--	4,051,898
Issuance of common stock at $5.30 per unit, net of issuance costs	--	5,727,400
Issuance of common stock upon exercise of options and warrants	--	2,017,635
Options granted to consultants for services rendered	--	70,200
Deferred stock compensation	--	--
Amortization of deferred stock compensation	--	27,374
Conversion of preferred stock to common stock	--	--
Issuance of common stock under employee stock purchase plan	--	19,583
Net loss and comprehensive loss	(3,114,732)	(3,114,732)
Balances at June 30, 2000	(35,152,092)	7,913,350
Issuance of common stock upon exercise of options and warrants	--	1,115,945
Amortization of deferred stock compensation	--	54,750
Conversion of preferred stock to common stock	--	--
Issuance of common stock under employee stock purchase plan	--	23,794
Net income and comprehensive income	1,588,391	1,588,391
Balances at June 30, 2001	$(33,563,701)	$10,696,230

See accompanying notes.

NEUROBIOLOGICAL TECHNOLOGIES, INC.
(a development stage company)

STATEMENTS OF CASH FLOWS

	2001	2000	1999	P Aug (Ju
Operating Activities:				
Net income (loss)	$ 1,588,391	$(3,114,732)	$(3,692,233)	$(
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:				
Depreciation and amortization	22,481	6,018	41,792	
Gain on sale of property and equipment	(1,500)	--	--	
Amortization of deferred stock compensation	54,750	27,374	--	
Issuance of common stock, options and warrants for license rights and services	--	70,200	--	
Changes in assets and liabilities:				
Interest receivable	(73,424)	(58,620)	--	

Prepaid expenses and other current assets.....	(211,530)	1,536	15,183	
Accounts payable and accrued expenses.....	(49,175)	(165,446)	437,261	
Income taxes payable.....	41,831	--	--	
Net cash provided by (used in) operating activities.....	1,371,824	(3,233,670)	(3,197,997)	(
Investing Activities:				
Purchase of investments.....	(11,742,170)	(1,225,592)	--	(
Maturities of investments.....	5,550,874	--	--	
Purchases of property and equipment, net.....	(23,523)	(30,000)	7,859	
Proceeds from sale of property and equipment.....	1,500	--	--	
Additions to patents and licenses.....	--	--	--	
Net cash (used in) provided by investing activities.....	(6,213,319)	(1,255,592)	7,859	
Financing Activities:				
Payment of note payable.....	--	(200,000)	--	
Proceeds of short-term borrowings.....	--	--	200,000	
Issuance of common stock, net.....	1,139,739	11,816,516	4,454	
Issuance of preferred stock, net.....	--	--	1,166,000	
Net cash provided by financing activities.....	1,139,739	11,616,516	1,370,454	
(Decrease) increase in cash and cash equivalents.....	(3,701,756)	7,127,254	(1,819,684)	
Cash and cash equivalents at beginning of period.....	7,328,456	201,202	2,020,886	
Cash and cash equivalents at end of period.....	$ 3,626,700	$ 7,328,456	$ 201,202	$
Supplemental Disclosures:				
Conversion of short-term-borrowings to Series A preferred stock.....	$ --	$ --	$ --	$
Conversion of preferred stock to common stock.....	$ 350,000	$ 25,000	$ --	$
Deferred stock compensation related to options granted.....	$ --	$ 273,750	$ --	$

See accompanying notes.

NEUROBIOLOGICAL TECHNOLOGIES, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS

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

Description of Business

Neurobiological Technologies, Inc. ("NTI(R)", "we", or the "Company") is an emerging drug development company focused on the clinical evaluation and regulatory approval of neuroscience drugs. The Company's strategy is to in-license and develop early-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 Company's principal activities to date involve research and development of drug delivery systems using proprietary technology, in-licensing of a product candidate, recruiting key personnel, establishing a manufacturing process and raising capital to finance its development operations. The Company is classified as a development stage company.

In the course of our development activities, we have incurred significant losses and, although the Company was profitable in the year ended June 30, 2001, it will likely incur additional losses in the year ending June 30, 2002. The Company may seek to raise additional funds whenever market conditions permit. However, there can be no assurance that funding will be available from any of these sources, 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

Revenue related to license fees with non-cancelable, non-refundable terms and no future performance obligations are recognized when collection is assured. Such revenues are deferred and recognized over the performance period if future performance obligations exist. Non-refundable up-front payments received in connection with research and development activities are deferred and recognized on a straight-line basis over the relevant periods specified in the agreement, generally the research term. Revenue associated with milestones are recognized as earned, based on completion of development milestones, either upon receipt, or when collection is assured.

Research and Development

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.

Reclassification

Certain prior year balances have been reclassified to conform to the current year presentation.

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. Actual results could differ from those estimates.

Cash Equivalents and Investments

The Company considers all highly liquid investments purchased with original maturities of 90 days or less to be cash equivalents. All of the Company's investment securities are classified as available for sale and are stated at amounts which approximate fair market value. The Company did not have any material realized or unrealized gains or losses on its investments. 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.

Net Income (Loss) per Share

Net loss per share is presented under the requirements of FAS No. 128, "Earnings per Share" ("FAS 128"), which requires disclosure of basic and diluted earnings per share. Basic and diluted earnings per share is calculated using the weighted average number of shares of common stock outstanding during the period, less shares subject to repurchase. Diluted earnings 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 for the years ended June 30, 2000 and 1999, they have been excluded from the computation of weighted-average shares used in computing diluted net loss per share for the years ended June 30, 2000 and 1999.

The following table presents the calculation of basic and diluted net loss per share (in thousands, except per share data):

	Year Ended December 31,		
	2001	2000	1999
Net income (loss) attributable to common stockholders	$ 1,588	$(3,115)	$(3,692)
Weighted-average shares outstanding:			
Denominator for basic earnings per share	16,532	11,461	7,555
Common stock equivalents:			
--stock options	779	--	--
--warrants	1,682	--	--
--convertible preferred stock	2,078	--	--
Denominator for diluted earnings per share	21,071	11,461	7,555
Net income (loss) per share:			
Basic	$ 0.10	$ (0.27)	$ (0.49)
Diluted	$ 0.08	$ (0.27)	$ (0.49)

Stock-Based Compensation

We grant 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. We account for stock option grants in accordance with APB Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and related Interpretations because the alternative fair value accounting provided under FASB Statement No. 123, "Accounting for Stock-Based Compensation" ("FAS 123") requires the use of option valuation models that were not developed for use in valuing employee stock options. 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 accounting for in accordance with FAS 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.

Comprehensive Income (Loss)

The Company has no items of other comprehensive income (loss), and, accordingly, its net income (loss) is equal to its comprehensive income (loss).

Impairment of Long-Lived Assets

In accordance with Statement of Financial Accounting Standards No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of" ("FAS 121"), we review long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Under FAS 121, an impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Impairment, if any, is assessed using discounted cash flows. Through June 30, 2001, there have been no such losses.

Accounting for Derivative Financial Instruments and for Hedging Activities

As of July 1, 2000 the Company adopted the Statement of Financial Accounting Standards No. 133 "Accounting for Derivative Instruments and Hedging Activities", as amended in June 2000 by Statement of Financial Accounting Standards No. 138 "Accounting for Certain Derivative Instruments and Certain Hedging Activities", which requires companies to recognize all derivatives as either assets or liabilities in the balance sheet and measure such instruments at fair value. As the Company does not hold any material derivatives or engage in hedging transactions, the adoption of these statements did not have a material impact on the Company's financial statements.

Note 2. Investments

The Company's investment portfolio is as follows (in thousands):

	June 30,	
	2001	2000
Corporate debt obligations	$4,596	$ 931
Commercial paper.....	--	295
US Government obligations.	2,821	--
Total investments.....	$7,417	$1,226

At June 30, 2001, the contractual maturities of investments were as follows (in thousands):

	Amortized Cost
Due within one year	$6,556
Due after one year.	861
	$7,417

All investments at June 30, 2000 were due within one year.

NEUROBIOLOGICAL TECHNOLOGIES, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS--(Continued)

Note 3. Property and Equipment

Property and equipment consisted of the following (in thousands):

	2001	2000
Machinery and equipment.....	$ 187,347	$ 176,756
Furniture and fixtures.....	145,426	145,426
	332,773	322,182
Less accumulated depreciation	(303,953)	(294,404)
	$ 28,820	$ 27,778

Note 4. Operating Lease Commitments

On April 1, 2001 the Company entered into an assignment and assumption of lease of the executive offices in Richmond, California. The master lease, which commenced in July 1997, will expire in July 2002. Rent expense for the years ending June 30, 2001, 2000 and 1999 was $92,000, $52,000 and $47,000 respectively. Future minimum annual payments are approximately $91,000 for the period ending June 30, 2002 and $7,600 for the period ending June 30, 2003. The Company received sublease income on its former premises of $0, $26,000, and $8,000 for the years ending June 30, 2001, 2000, and 1999, respectively.

Note 5. Stockholders' Equity

Convertible Preferred Stock

At June 30, 2001, the Company has 1,582,000 shares of Series A convertible preferred stock issued and 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, 2001, 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 election of more than 50% of the Series A preferred stock to convert into common stock. The holders of preferred stock are entitled to the number of votes equal to the number of shares of common stock into which their preferred stock is convertible.

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.

Warrants to Purchase Common Stock

At June 30, 2001, the Company had outstanding warrants to purchase shares of common stock as follows:

Number of Shares	Exercise Price	Issue Date	Expiration Date
631,200	$1.00	April 1999	April 2004
1,814,880	$1.75	November 1999	November 2004
431,000	$4.40	November 1999	November 2004

2,877,080	$1.00-$4.40	April 2004-November 2004

The Company issued 1,044,015 and 752,321 shares of common stock upon exercise of warrants in fiscal years 2001 and 2000, respectively.

Stock Option Plan

The Company has elected to follow APB 25 and related interpretations in accounting for its employee stock option awards because, as discussed below, the alternative fair value accounting provided under SFAS 123 requires use of option valuation models that were not developed for use in valuing employee stock options. Under APB 25, when the exercise price of the Company's employee stock option equals the market price of the underlying stock on the date of grant, no compensation expense is recognized.

The Board of Directors adopted the Company's first stock option plans in 1989. In November 1993, the Board combined the plans and adopted the 1993 Stock Plan. The 1993 Stock Plan was subject to amendment and/or restatement in February 1994, November 1994, October 1996, November 1997 and November 1999. Under the 1993 Stock Plan, 2,500,000 shares of common stock have been reserved for issuance. 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 a 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, 2001 follows:

	Shares Authorized	Number of Shares Subject to Options	Weighted Average Exercise Price per Share
Balance at June 30, 1998.....	369,109	1,575,081	$2.42
Options granted.....	(488,500)	488,500	0.65
Options canceled.....	259,783	(259,783)	2.51
Balance at June 30, 1999.....	140,392	1,803,798	1.93
Options granted.....	(553,500)	553,500	3.96
Options canceled.....	36,349	(36,349)	2.66
Options exercised.....	--	(604,957)	2.51
Options authorized.....	500,000	--	--
Balance at June 30, 2000.....	123,241	1,715,992	2.38
Options granted.....	(111,500)	111,500	3.00
Options canceled.....	62,624	(62,624)	3.11
Options exercised.....	--	(85,910)	1.00
Balance at June 30, 2001.....	74,365	1,678,958	$2.52

(a development stage company)

NOTES TO FINANCIAL STATEMENTS--(Continued)

At June 30, 2001, options to purchase 74,365 shares of common stock remained available for grant, and options to purchase 966,272 shares of common stock were exercisable. The weighted average exercise price of options exercisable at June 30, 2001 was $2.15. The weighted average fair value of options granted during 2001, 2000, and 1999 were $1.97, $3.23, and $0.37, 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	878,483	7.22	$0.92	537,712	$0.90
2.00-3.99	472,647	6.09	2.95	312,647	2.84
4.00-5.99	11,228	5.10	4.70	5,928	4.08
6.00-8.00	316,600	8.86	6.22	109,985	6.23
	1,678,958	7.20	$2.52	966,272	$2.15

Pro forma information regarding net income (loss) and net income (loss) per share is required by SFAS 123, which requires that the information be determined as if the Company had accounted for its employee stock options granted subsequent to June 30, 1995 under the fair value method. The fair value of each option grant has been estimated as of the date of the grant using the Black-Scholes option pricing model with the following weighted average assumptions used for 1999, 2000 and 2001: Expected volatility calculations based on historical data (.846), expected option lives of five years, and no dividend yield. Risk free interest rate assumptions were based on U.S. government bonds with maturities equal to the expected option lives of 6.50%, 6.50%, and 5.32% for 1999, 2000, and 2001, respectively.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option pricing models require the input of highly subjective assumptions including the expected stock price volatility and expected life of the option. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of employee's options.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized over the options' vesting period. The Company's pro forma information follows (in thousands, except per share amounts):

	Year Ended June 30,		
	2001	2000	1999
Net income (loss)--as reported	$1,588	$(3,115)	$(3,692)
Net income (loss)--pro forma	1,065	(3,363)	(3,940)
Basic net income (loss) per share--as reported	0.10	(0.27)	(0.49)
Diluted net income (loss) per share--as reported	0.08	(0.27)	(0.49)
Basic net income (loss) per share--pro forma	0.06	(0.29)	(0.52)
Diluted net income (loss) per share--pro forma	0.05	(0.29)	(0.52)

In connection with the grant of certain stock options to senior management, we recorded deferred compensation of $274,000 in 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 deferred stock compensation expense of $55,000 in 2001 and $27,000 in 2000.

Stock Purchase Plan

Effective February 1994, the Company established an employee stock purchase plan under which the employees may purchase common stock at 85% of the lower of the share price at the beginning or end of a designated period. In November 1996, the amount of shares reserved for issuance under the plan was increased by 50,000 to 100,000. In November 1999 the amount of shares were increased an additional 50,000 to 150,000. In November 2000 the amount of shares were increased an additional 150,000 to 300,000. Under the plan, 156,756 shares remain available for issuance at June 30, 2001.

Common Stock Reserved for Future Issuance

At June 30, 2001, the Company has reserved shares of common stock for future issuance as follows:

Conversion of preferred stock into common stock	5,000,000
1993 Stock Plan	1,753,323
Warrants	2,877,080
Employee stock purchase plan	156,756
	9,787,159

Note 6. Income Taxes

The Company uses the liability method to account for income taxes as required by FASB Statement No. 109, "Accounting for Income Taxes." Under this

method, deferred tax assets and liabilities are determined based on the differences between financial reporting and tax bases of assets and liabilities and are measured using enacted tax rules and laws that will be in effect when the differences are expected to reverse.

The provision for income taxes for the year ended June 30, 2001 consists of the following (in thousands):

Current:	
Federal	$40
State	2
Total	$42

The current income tax provision for 2001 is a result of the federal alternative minimum tax. There was no current income tax expense for the years ended June 30, 2000 and 1999. There was no deferred income tax expense for the years ended June 30, 2001, 2000, and 1999.

A reconciliation of the income tax provision (benefit) at the federal statutory rate to the income tax provision (benefit) at the effective tax rate is as follows (in thousands):

	Years Ended June 30,		
	2001	2000	1999
Provision (benefit) at U.S. federal statutory rate..	$ 571	$(1,090)	$(1,292)
Unbenefited loss (utilization of net operating loss)	(591)	1,090	1,292
Alternative Minimum Tax	42	--	--
Other	20	--	--
Total	$ 42	$ --	$ --

Significant components of the Company's deferred tax assets (in thousands) are as follows:

	June 30,	
	2001	2000

Net operating loss carryforward	$ 13,044	$ 12,019
Research and development carryforward	955	2,275
Capitalized research and development	180	233
Other temporary differences	248	210
Gross deferred tax assets	14,427	14,737
Valuation allowance	(14,427)	(14,737)
Net deferred tax assets	$ --	$ --

Realization of the deferred tax assets is dependent upon future taxable income, if any, the amount and timing of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The net valuation allowance decreased by approximately $310,000, increased by $1,817,000 and increased by $1,320,000 during the years ended June 30, 2001, 2000 and 1999, respectively.

As of June 30, 2001, the Company had federal operating loss carryforwards of approximately $34,000,000. The Company also had federal research and development tax credit carryforwards of approximately $700,000. The net operating loss and tax credit carryforwards will expire at various dates beginning in 2007, if not utilized.

Utilization of the net operating loss carryforwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

Note 7. Collaboration Agreement

In April 1998, we entered into a strategic research and marketing cooperation agreement with Merz + Co. (Merz) 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 share in future revenues from sales of Memantine for all indications.

In June 2000, Merz entered into an agreement with Forest Laboratories, Inc. ("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 ("Lundbeck") 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 Suntory Ltd. In October 2000, we received $2.5 million and in April 2001 we received $2.3 million from Merz under our 1998 strategic research and marketing cooperation agreement, representing our portion of the payments received by Merz pursuant to Merz's agreements with Forest and Lundbeck.

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

Not applicable.

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 10, 2001 are as follows:

Name	Age	Position
Paul E. Freiman	67	President and Chief Executive Officer and Director
Lisa U. Carr, M.D., Ph.D.	46	Vice President, Medical Affairs
Abraham E. Cohen	65	Chairman of the Board of Directors
Enoch Callaway, M.D.	77	Director
Theodore L. Eliot, Jr.	73	Director
Abraham D. Sofaer	63	Director
John B. Stuppin	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 boards of Digital GeneTechnologies, Inc., a private genomics company, and SciGen Pte. Ltd. Mr. Freiman currently serves on the boards of Penwest Pharmaceutical Co., Calypte Biomedical Corporation, Omware, Inc., PHYTOS Inc., and Otsuka America Pharmaceuticals, Inc. 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. 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 (IND and NDA approved for solid organ transplantation). Dr. Carr holds a medical degree and a Ph.D. magna cum laude from the University of Munich in Germany.

Abraham E. Cohen has been a director of the Company since March 1993 and has been Chairman of the Board of Directors 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 a director of seven other public companies: Akzo Nobel N.V., Axonyx, Inc., Chugai Pharmaceutical Co., Pharmaceutical Product Development, Inc., Smith Barney Mutual Funds, Teva Pharmaceutical Industries, Ltd. and Vasomedical, Inc. Additionally, he serves as a Trustee on The Population Council.

Enoch Callaway, M.D. is a founder and former employee 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 Directors 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 IRB for SAM Technologies, Inc. and Abratek, Inc. Dr. Callaway is a Director of Phytos, Inc. 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 Fiberstars, Inc. and 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 since 1997. From 1990 to 1994, Mr. Sofaer was a partner at the legal firm of Hughes, Hubbard and 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. Sofaer is on the International Advisory Board of Chugai Biopharmaceuticals, Inc., a director of Koret Israel Economic Development Fund and a Trustee of the National Museum of Jazz. Mr. Sofaer holds a B.A. degree from Yeshiva College and a L.L.B. from New York University.

John B. Stuppin is a founder and employee of the Company and has served as a director of the Company since September 1988. From September 1987 until October 1990, Mr. Stuppin served as President of the Company, from November 1990 to August 1993 as Co-Chairman of the Board of Directors, 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. Mr. Stuppin 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. Stuppin holds an A.B. degree from Columbia College.

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 of the Securities and Exchange Act of 1934" in our Proxy Statement for the Annual Meeting of Stockholders to be held November 15, 2001.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is hereby incorporated by reference to the section entitled "Executive Compensation" in our Proxy Statement for the Annual Meeting of Stockholders to be held November 15, 2001.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by this item is hereby incorporated by reference to the section entitled "Security Ownership of Certain Beneficial Owners and Management" in our Proxy Statement for the Annual Meeting of Stockholders to be held November 15, 2001.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

None.

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENTS, FINANCIAL STATEMENTS SCHEDULES AND REPORTS ON FORM 8-K

(a) Financial Statements and Schedules: Financial Statements for the three years ended June 30, 2001 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) Reports on Form 8-K: None

(c) Exhibits:

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

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of Registrant.(1)
3.2	Bylaws of Registrant.(1)
3.3	Certificate of Designations, Preferences and Rights of Series A Preferred Stock of Regist
4.1	Form of Common Stock Certificate.(1)
4.2	Form of Warrant issued to Van Kasper & Co.(1)
4.3	Form of Warrant issued to Van Kasper & Co. and Gerard Klauer Mattison & Co., LLC.(1)
4.4	Form of Class A Warrant to Purchase Common Stock.(4)
4.5	Form of Class B Warrant to Purchase Common Stock.(4)
4.6	Form of Warrant to Purchase 25,000 Shares of Common Stock.(4)
4.7	Form of Warrant to Purchase 100,000 Shares of Common Stock.(4)
4.8	Form of Warrant to Purchase Common Stock.(5)
10.1	1993 Stock Plan of Neurobiological Technologies, Inc.(6)*
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 among the Company, Dynorphin Partnership, Nancy M. Lee and Horace C. Lo dated April 1, 1989, as amended.(1)+
10.5	License Agreement between the Company and Immuno-Dynorphin Partnership dated October 1, 1990.(1)+
10.6	License Agreement between the Company and des-Tyr Dynorphin Partnership dated December 20 1992.(1)+
10.7	License Agreement between the Company and DUZ Partnership dated December 20, 1992.(1)+
10.8	License Agreement between the Company and The Salk Institute for Biological Studies dated March 31, 1989, as amended.(1)+

10.9 License Agreement between the Company and the Regents of the University of California dat June 13, 1990, as amended.(1)+

10.10 Option Agreement between the Company and the Regents of the University of California date December 1, 1992.(1)+

10.11 Amended and Restated Neurobiological Technologies, Inc. Employee Stock Purchase Plan.(6)*

10.12 Cooperative Agreement among Company, Merz + Co. GmbH & Co. and Children's Medical Center Corp., effective as of April 16, 1998.(4)+

Exhibit Number	Description

10.13 Payment Agreement between the Company and Children's Medical Center Corp., effective as o April 16, 1998.(4)+

10.14 Retention Agreement between the Company and Dr. Lisa Carr dated February 1, 1999.(5)*

10.15 Sublease Agreement between the Company and Ladbroke Racing Corp. dated May 1, 2000.(7)

23.1 Consent of Ernst & Young LLP, Independent Auditors.

24.1 Powers of Attorney. (Contained on Signature Page)

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(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, 1995 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, 1996 and is incorporated herein by reference.
(4) 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.
(5) 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.
(6) This exhibit is filed as an exhibit to Registrant's Registration Statement on Form S-8 (Registration Number 333-92425) filed December 9, 1999 and is incorporated herein by reference.
(7) This exhibit is filed as an exhibit to the Registrant's Annual Report on Form 10-KSB for the year ended June 30, 2000 and is incorporated herein by reference.
+ Confidential treatment has been granted with respect to certain portions of these agreements.
* This exhibit is a management contract or compensatory plan or arrangement.

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.

/s/ PAUL E. FREIMAN

Dated: September 27, 2001

By: _____
Paul E. Freiman
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 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 attorney-in-fact and agent 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 attorney-in-fact and agent or his substitute 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.

Signature	Title	Date
/s/ PAUL E. FREIMAN Paul E. Freiman	President, Chief Executive Officer (Principal Executive Officer and Principal Financial Officer and Principal Accounting Officer) and Director	September 27, 2001
/s/ ABRAHAM E. COHEN Abraham E. Cohen	Chairman of the Board	September 27, 2001
/s/ ENOCH CALLAWAY Enoch Callaway	Director	September 27, 2001
/s/ THEODORE L. ELIOT, JR. Theodore L. Eliot, Jr.	Director	September 27, 2001
/s/ ABRAHAM D. SOFAER Abraham D. Sofaer	Director	September 27, 2001
/s/ JOHN B. STUPPIN	Director	September 27, 2001

John B. Stuppin