

NEUROBIOLOGICAL TECHNOLOGIES INC /CA/

Form 10-K

September 29, 2003

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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, 2003

OR

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

For the transition period from _____ to _____

Commission file number: 0-23280

NEUROBIOLOGICAL TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State of Incorporation)

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

3260 Blume Drive Suite 500, Richmond, California 94806

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(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 No

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

Indicate by check mark whether the registrant is an accelerator filer (as defined in Exchange Act Rule 12b-2). Yes No

As of September 24, 2003, the issuer had outstanding 19,183,945 shares of common stock.

The aggregate market value of the shares of common stock held by non-affiliates as of December 31, 2002, the registrant's most recently completed second fiscal quarter, was approximately \$92,346,000 based upon the last sale price of the issuer's common stock reported on The NASDAQ SmallCap Market on that date.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2003 Annual Meeting of Stockholders, which will be held November 13, 2003, are incorporated by reference into Part III of this report.

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PART I

ITEM 1. BUSINESS

This report contains forward-looking statements. These forward-looking statements are based on our current expectations about our business and industry. In some cases, these statements may be identified by terminology such as 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 risks and uncertainties that may cause our results, levels of activity, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Factors that may cause or contribute to such differences include, among others, those discussed in this report under the caption Other Factors that May Affect Future Results. Except as may be required by law, we undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

OVERVIEW

Neurobiological Technologies, Inc., alternatively referred to in this report as NTI, we, us, our, or the Company, is 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 and brain cancer.

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 III human clinical testing, Memantine and XERECEPT.

MEMANTINE

Memantine is an orally dosed compound that appears to restore the function of impaired neurons by modulation of the N-methyl-D-aspartate or NMDA receptor, which is 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 and neuropathic pain (persistent pain resulting from abnormal signals to the brain).

In April 1998, we entered into a strategic research and marketing cooperation agreement with Merz Pharmaceuticals GmbH, or Merz and Children's Medical Center Corporation 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, or FDA, and foreign regulatory authorities. Pursuant to this agreement, we will share in future revenues from sales of Memantine for all indications. Memantine has been marketed by Merz in Germany since 1989 with the labeling dementia syndrome.

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

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In July 2001, Forest initiated the second of two trials necessary for registration of a new drug application, or NDA, to the FDA for diabetic neuropathy. This was a large-scale, multi-center, double-blind placebo controlled trial to assess the safety and efficacy of Memantine in the treatment of diabetic neuropathy. In May 2003, Forest announced that Memantine had failed to demonstrate a statistically significant difference versus placebo with regards to the primary endpoint of this trial. Forest has announced that it is in the process of analyzing the data in greater depth to determine its future course of action. NTI conducted the first such trial with an enrollment of 400 patients and reported positive results in January 2000.

In September 2002, Forest completed a placebo-controlled Phase III study in which a significant benefit was observed when Memantine was combined with donepezil in patients with moderately-severe to severe Alzheimer's disease. In December 2002, Forest submitted an NDA to the FDA seeking approval of Memantine for the treatment of moderate-to severe Alzheimer's disease. In January 2003, Forest announced that the FDA had accepted its NDA for filing.

In May 2002, Merz announced that Memantine (Ebixa®) was approved by the regulatory authorities in the European Union for the treatment of Alzheimer's disease. In July 2002, Merz received a payment from Lundbeck relating to this approval. This triggered a \$1.4 million payment to NTI in August 2002 from Merz under our 1998 strategic research and marketing cooperation agreement. We also received payments of \$281,000 in January 2003 and \$281,000 in May 2003 from Merz, which represent a portion of the payments received by Merz pursuant to Merz's agreement with H. Lundbeck A/S for the approval of Memantine for the treatment of Alzheimer's disease. NTI expects to receive royalty payments from Merz on sales in certain European countries and the United States, when these sales commence. In May 2003, we received our first royalty payment of \$11,000 on Memantine sales.

Forest is presently conducting three additional placebo-controlled studies in either mild-to-moderate or moderate-to-severe Alzheimer's disease. In June 2003, Forest announced that one of these trials did not demonstrate statistically significant effects on cognitive or global outcomes compared to placebo. This trial combined Memantine with Acetyl cholinesterase inhibitors for mild-to-moderate Alzheimer's disease. Forest representatives have stated that they do not believe that these results should affect their current NDA for moderate-to severe Alzheimer's disease.

XERECEPT

We are 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). In April 1998, XERECEPT received orphan drug designation for this indication from 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 discussing with the FDA two pivotal trials for the treatment of peritumoral brain edema for XERECEPT and completing the FDA required long-term animal toxicity studies. We expect to commence two Phase III clinical trials before the end of 2003.

In July 2003, we terminated our option agreement with the University of California, Berkeley to license its patents on corticotropin-releasing hormone analogues after further screening tests failed to show the desired efficacy for continued development.

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PRODUCT CANDIDATES

<u>Product/Indication</u>	<u>Development Status</u>	<u>Primary Benefit Sought</u>
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. In May 2003, Forest announced that primary endpoint results in the second pivotal trial did not demonstrate a statistically significant difference versus placebo. Forest has announced that it is in the process of analyzing the data in greater depth.	Treatment of chronic pain associated with diabetic 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 cognitive 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 program in July 2001. In one such trial, significant benefit was demonstrated for Memantine when combined with donepezil in patients with moderately severe to severe Alzheimer s Disease. A second trial combining Memantine and approved Acetyl cholinesterase inhibitors in patients with mild to moderate Alzheimer s Disease did not demonstrate comparable benefit.	Functional and cognitive improvement.
	Merz and Lundbeck obtained drug approval in Europe in May 2002. Forest submitted an NDA to FDA in December 2002.	
XERECEPT (CORTICOTROPIN-RELEASING FACTOR)		
Peritumoral Brain Edema	Two pivotal Phase III trials are anticipated to start prior to the end of calendar 2003.	Stabilization or improvement of neurological function with substantial dexamethasone sparing.

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SCIENTIFIC BACKGROUND

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

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

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

PRODUCTS 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 over stimulation of NMDA receptors contributes to the impairment and death of neurons. This occurs in a variety of chronic neurodegenerative diseases, including neuropathic pain, dementia, Alzheimer's disease, and Huntington's disease. There are currently no approved neuroprotective treatments for any of the pathologies associated with NMDA receptor over stimulation.

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

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.

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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 over activation of NMDA receptors in the CNS plays an important role.

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

Based on the results from our Phase IIA trial of Memantine in patients with neuropathic pain, we initiated a Phase IIB trial of Memantine in the second quarter of fiscal 1999, exclusively in patients with PDN. In May 2000, we presented results of our placebo-controlled Phase IIB dose ranging human clinical trial of Memantine. Results of this 421 patient Phase IIB clinical trial of Memantine as a treatment for painful diabetic

neuropathy showed that 44% of the patients receiving 40 mg dosages experienced a 50% or greater pain reduction, compared to 29% in the placebo group at the end of eight weeks. Although positive trends were seen in the groups treated with 20 mg of Memantine compared to placebo, no statistical significance were observed.

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In July 2001, Forest initiated an additional year-long, large-scale, multi-center, double-blind placebo controlled trial to assess the safety and efficacy of Memantine in the treatment of diabetic neuropathy. In May 2003, Forest announced that Memantine had failed to demonstrate a statistically significant difference versus placebo with regards to the primary endpoint of this trial. Forest has announced that it is in the process of analyzing the data in greater depth to determine its future course of action.

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 our existing license 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, or hCRF that 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 our pre-clinical studies and pilot human clinical trials have demonstrated the compound's potential to reduce swelling in brain tissue and to be well-tolerated 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 primary brain tumors, and 120,000 with metastatic brain tumors. Patients with this condition are in need of a safe alternative to corticosteroids, which have serious adverse effects at the high, chronic doses required for efficacy.

The FDA has 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 funds 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 effects of hCRF through systemic administration. Additionally XERECEPT has been shown to have anti-neoplastic properties. Research by our scientific collaborators has revealed that XERECEPT significantly reduces edema, or swelling of damaged tissue, in animal models. Edema is a condition characterized by swelling after tissue injury when fluid, plasma proteins, and white blood cells flow from small blood vessels into the surrounding tissues, further contributing to the destruction of these tissues. Our pre-clinical studies have shown that XERECEPT reduces the flow of fluid through blood vessels at sites of traumatic tissue injury. Specifically, these studies have shown that XERECEPT injected systemically into animals can reduce brain edema after injury, brain edema associated with cancer tumors, and swelling in muscle tissue following surgical trauma.

Product Development Status

Peritumoral Brain Edema

We have been evaluating XERECEPT for the treatment of cerebral edema caused by brain tumors. In these patients, the tumor promotes increased permeability of the small blood vessels in the brain, which results in the excess flow of fluids into the brain, swelling of brain tissue, and a consequent impairment of neurological function. Current treatment of peritumoral brain edema, primarily corticosteroids, results in serious adverse side

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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.

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

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

Based on the pharmacologic profile of XERECEPT, there is evidence that the compound may be efficacious without the adverse side effects associated with current therapies. There is also evidence that XERECEPT may enhance radiation therapy, whereas cortisols appear to interfere with this conventional brain tumor therapy. 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. We expect to initiate two pivotal Phase III trials of XERECEPT for peritumoral brain edema before the end of 2003.

COMPETITION

Competition in the biopharmaceutical industry is intense and is expected to increase. There are other therapies under development for each of our therapeutic targets and the development and sale of drugs for the treatment of the therapeutic targets that we and our collaborative partners are pursuing is highly competitive. We may not be able to develop products that will be as efficacious or as cost-effective as currently-marketed products and, because our license to certain XERECEPT patent rights is non-exclusive, others may develop competing products using the same compound. Consequently, others may develop, manufacture and market products that could compete with those that we are developing.

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

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

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Manufacturing Practice, or cGMP, regulations. 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 pre-clinical 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. Merz holds rights to those uses from Children's Medical Center Corporation under the research and marketing cooperation agreement among the Company, Merz and Children's Medical Center.

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. We also have exclusive rights to four issued patents and one patent application covering certain 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.

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

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others may independently develop similar products, duplicate any of our potential products, or design around the claims of any of our potential patented products.

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

As a result of all of these factors, there can be no assurance that patent applications relating to our potential products or processes will result in patents being issued, or that patents, if issued, will provide protection against competitors who successfully challenge our patents, obtain patents that may have an adverse effect on our ability to conduct business, or be able to circumvent our patent position.

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

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In addition to patent protection, we rely upon trade secret protection for our confidential and proprietary information. It is our policy that each employee enter into a confidentiality agreement which contains provisions generally prohibiting the disclosure of confidential information to anyone outside NTI and requiring disclosure to us of ideas, developments, discoveries or inventions conceived during employment and assignment to us of proprietary rights to such matters related to our business and technology. However, it is possible that these agreements could be breached. In addition, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology.

GOVERNMENT REGULATION

In order to clinically test, produce, and market products for therapeutic use, a company must comply with mandatory procedures and safety standards established by the FDA and comparable agencies in foreign countries.

A company generally must conduct pre-clinical testing on laboratory animals of new pharmaceutical products prior to commencement of clinical studies involving humans. These studies evaluate the potential efficacy and safety of the product. The company then submits the results of these studies to the FDA as part of an investigational new drug application, or IND, which must become effective before clinical testing in humans can begin.

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

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

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

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

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

The results of the pre-clinical and clinical testing are submitted to the FDA in the form of an NDA for approval prior to commercialization. In responding to an NDA, the FDA may grant marketing approval, request additional information, or deny the application. Failure to receive approval for any of our potential products would have a material adverse effect on us. Among the requirements for product approval is the requirement that each domestic manufacturer of the product conform to the FDA's cGMP regulations, which must be followed at all times. Compliance with the cGMP regulations requires that manufacturers continue to expend time, money and effort in the area of production and quality control to ensure full technical compliance.

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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.

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

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

impose costly procedures upon our activities.

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

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

In addition, success in pre-clinical or early stage clinical trials does not assure success in later-stage clinical trials. For example, although our Phase II clinical trials for Memantine for the treatment of diabetic neuropathy produced positive results, subsequent clinical trials conducted by Forest did not replicate these results. 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, 2003, we employed eleven people, six of whom are full-time employees. Additionally, 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.

WEBSITE ADDRESS

Our website address is www.nti.com. We make available free of charge through our website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to these reports as soon as reasonably practicable after filing, by providing a hyperlink to the SEC's website directly to our reports.

ITEM 2. PROPERTIES

Our executive offices occupy approximately 4,333 square feet in Richmond, California, pursuant to a lease that expires in July 2004 and that is renewable for an additional one-year term. We believe that our facilities are adequate to meet our needs for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

Not applicable.

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, 2003.

Table of Contents**PART II.****ITEM 5. MARKET FOR REGISTRANTS COMMON EQUITY AND RELATED STOCKHOLDER MATTERS**

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

As of June 30, 2003, there were approximately 222 holders of record of our common stock and 18,755,553 shares of common stock outstanding. No dividends have been paid on our common stock to date, and we do not anticipate paying any dividends in the foreseeable future.

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

Fiscal 2002	High	Low
First Quarter	\$ 4.53	\$ 2.57
Second Quarter	\$ 5.32	\$ 2.90
Third Quarter	\$ 5.14	\$ 3.74
Fourth Quarter	\$ 5.00	\$ 2.10
Fiscal 2003	High	Low
First Quarter	\$ 3.54	\$ 1.90
Second Quarter	\$ 6.80	\$ 2.40
Third Quarter	\$ 7.79	\$ 5.46
Fourth Quarter	\$ 8.35	\$ 3.49

In August 2002, NTI's board of directors authorized a stock repurchase program of up to 500,000 shares of its common stock. Depending on market conditions and other factors, repurchases will be made from time to time in the open market and in negotiated transactions, including block transactions and may be discontinued at any time. As of June 30, 2003, NTI had repurchased 32,000 shares of common stock for a total cost of \$86,950, or at an average per share cost of \$2.72.

Table of Contents**ITEM 6. SELECTED FINANCIAL DATA**

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

	Year Ended June 30,					Period from
	2003	2002	2001	2000	1999	August 27, 1987 (inception) through June 30, 2003
	(in thousands, except per share data)					
Statement of Operations Data:						
Total revenue	\$ 1,980	\$	\$ 4,781	\$	\$ 100	\$ 9,010
Expenses:						
Research and development	2,317	2,013	1,194	1,896	2,780	32,489
General and administrative	2,493	2,637	2,556	1,380	1,059	20,463
Total expenses	4,810	4,650	3,750	3,276	3,839	52,952
Operating income (loss)	(2,830)	(4,650)	1,031	(3,276)	(3,739)	(43,942)
Interest income, net	144	342	599	161	47	3,425
Income (loss) before income tax	(2,686)	(4,308)	1,630	(3,115)	(3,692)	(40,517)
Income tax benefit (provision)		42	(42)			
Net income (loss)	\$ (2,686)	\$ (4,266)	\$ 1,588	\$ (3,115)	\$ (3,692)	\$ (40,517)
Basic net income (loss) per share	\$ (0.15)	\$ (0.24)	\$ 0.10	\$ (0.27)	\$ (0.49)	
Diluted net income (loss) per share	\$ (0.15)	\$ (0.24)	\$ 0.08	\$ (0.27)	\$ (0.49)	
Weighted average shares of common stock outstanding - basic	18,016	17,570	16,532	11,461	7,555	
Weighted average shares of common stock outstanding - diluted	18,016	17,570	21,071	11,461	7,555	

June 30,

2003	2002	2001	2000	1999
(in thousands)				

Balance Sheet Data:

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Cash, cash equivalents and short-term investments	\$ 4,402	\$ 5,694	\$ 10,182	\$ 8,554	\$ 201
Working capital (deficit)	4,238	5,043	9,806	7,886	(890)
Total assets	4,813	7,665	11,458	8,683	249
Total current liabilities	566	1,052	762	769	1,135
Deficit accumulated during development stage	(40,517)	(37,830)	(33,564)	(35,152)	(32,037)
Stockholders' equity (deficit)	4,248	6,613	10,696	7,913	(886)

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Selected quarterly financial information is summarized below:

	Fiscal 2003				Total
	September 30	December 31	March 31	June 30	
	(in thousands, except per share data) (Unaudited)				
Quarterly Results of Operations					
Total revenue	\$ 1,407	\$	\$ 281	\$ 292	\$ 1,980
Research and development	(907)	(679)	(435)	(296)	(2,317)
General and administrative	(489)	(687)	(623)	(694)	(2,493)
Interest income	45	41	30	28	144
Net income (loss)	\$ 56	\$ (1,325)	\$ (747)	\$ (670)	\$ (2,686)
Basic net income (loss) per share	\$ 0.00	\$ (0.07)	\$ (0.04)	\$ (0.04)	\$ (0.15)
Weighted average shares used in basic net income (loss) per share calculation	17,782	17,773	17,985	18,524	18,016
Diluted net income (loss) per share	\$ 0.00	\$ (0.07)	\$ (0.04)	\$ (0.04)	\$ (0.15)
Weighted average shares used in diluted net income (loss) per share calculation	19,848	17,773	17,985	18,524	18,016

	Fiscal 2002				Total
	September 30	December 31	March 31	June 30	
	(in thousands, except per share data) (Unaudited)				
Quarterly Results of Operations					
Total revenue	\$	\$	\$	\$	\$
Research and development	(256)	(361)	(504)	(892)	(2,013)
General and administrative	(500)	(529)	(657)	(951)	(2,637)
Interest income	117	93	72	60	342
Loss before income taxes	(639)	(797)	(1,089)	(1,783)	(4,308)
Income tax benefit			42		42
Net loss	\$ (639)	\$ (797)	\$ (1,047)	\$ (1,783)	\$ (4,266)
Basic and diluted net loss per share	\$ (0.04)	\$ (0.05)	\$ (0.06)	\$ (0.10)	\$ (0.24)
Weighted average shares of common stock outstanding basic and diluted	17,504	17,508	17,565	17,691	17,570

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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 those discussed below under the caption "Other Factors that May Affect Future Results" and elsewhere in this Annual Report on Form 10-K. Actual results may differ materially from those projected. Except as may be required by law, we undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

OVERVIEW

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 and brain cancer. 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 fiscal 2001, we have incurred significant losses each year since our inception. As of June 30, 2003, our deficit accumulated during the development stage was \$40.5 million and total stockholders' equity was \$4.2 million. We expect to incur additional operating losses over at least the next year as we continue our research and development efforts.

CRITICAL ACCOUNTING POLICIES

We consider certain accounting policies related to revenue recognition and use of estimates to be critical.

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. Revenues associated with milestones are recognized as earned, based on completion of development milestones, either upon receipt, or when collection is assured.

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. Estimates in the financial statements include, but are not limited to, accrued but unbilled expenses in clinical trials,

pre-clinical studies, outside experts and consultants and useful lives of property and equipment for depreciation calculations.

RESULTS OF OPERATIONS

REVENUES. In fiscal 2003, we had revenue of \$1,969,000 from license fee payments and \$11,000 from royalty income. In fiscal 2002, we had no revenue. In fiscal 2001, we had revenue of \$4,781,000 from license fee payments.

Our fiscal 2003 revenue related to the approval of Memantine in the European Union for the treatment of Alzheimer's disease, which occurred in May 2002. In July 2002, Merz received a payment from H. Lundbeck A/S relating to this approval. This triggered a \$1.4 million payment to NTI in August 2002 from Merz under our

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1998 strategic research and marketing cooperation agreement. We also received payments of \$281,000 in January 2003 and \$281,000 in May 2003 from Merz, which represent a portion of the payments that Merz received pursuant to its agreement with Lundbeck for the approval of Memantine for the treatment of Alzheimer's disease. In May 2003, we received our first royalty payment of \$11,000 on sales of Memantine.

NTI expects to receive royalty payments from Merz on sales in certain European countries and the United States. We expect near-term total revenues to fluctuate depending upon the ability of Merz and its marketing partners to gain regulatory approval for and market Memantine and the timing and amounts of payments related to these activities.

RESEARCH AND DEVELOPMENT EXPENSES. Research and development expenses were \$2,317,000 in fiscal 2003, compared to \$2,013,000 in fiscal 2002 and \$1,194,000 in fiscal 2001. The increases were primarily due to costs associated with the manufacture of clinical supplies and the initiation of long-term toxicology studies of XERECEPT.

The table captioned "Product Candidates" in Item 1 of this report sets forth the regulatory approval and clinical trial status for Memantine and XERECEPT. XERECEPT cost were approximately \$2,292,000, \$1,981,000, and \$848,000 for the years ended June 30, 2003, 2002, and 2001, respectively. To date, we have incurred costs of approximately \$8.9 million in the development of Memantine and \$16.1 million in the development of XERECEPT. All future costs for the development and commercialization of Memantine will be borne by Merz and its marketing partners, Forest and Lundbeck. We are currently unable to estimate the costs of completing human clinical trials for XERECEPT due to the uncertainties inherent in conducting clinical trials and seeking regulatory approval for a drug candidate.

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.

GENERAL AND ADMINISTRATIVE EXPENSES. General and administrative expenses were \$2,493,000 in fiscal 2003, compared to \$2,637,000 in fiscal 2002, and \$2,556,000 in fiscal 2001. The decrease from fiscal 2002 to fiscal 2003 was primarily due to decreased expenditures in activities related to seeking financing and strategic partnerships. The increase from fiscal 2001 to fiscal 2002 was primarily due to an increase in employee costs and professional services expenses.

INTEREST INCOME. Interest income was \$144,000 in fiscal 2003, compared to \$343,000 in fiscal 2002 and \$599,000 in fiscal 2001. The decreases were primarily due to lower average interest rates and lower average invested cash balances.

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 fiscal 2001, we have incurred losses in each year since our inception and we expect to continue to incur losses in the future due to ongoing research and development efforts.

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We believe that our available cash, cash equivalents and investments of \$4,402,000 as of June 30, 2003 are adequate to fund our operations through at least the next twelve months. We expect to incur ongoing costs in fiscal 2004 primarily for Phase III clinical trials of XERECEPT and related administrative support. Merz and Merz's marketing partners will pay all future development costs of Memantine.

Our operating activities provided cash of \$1,372,000 in fiscal 2001, and used cash of \$3,913,000 and \$3,110,000 in fiscal 2002 and 2003, respectively. Sources and uses of cash in operating activities were primarily derived from net income (loss) for each fiscal period.

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Net cash used in investing activities was \$6,213,000 in fiscal 2001, and net cash provided by investing activities was \$452,000 and \$2,625,000 in fiscal 2002 and 2003, respectively. The cash used in 2001 primarily represented purchases of investments of \$11,742,000 less maturities of investments of \$5,551,000. The cash provided in fiscal 2002 primarily represented maturities of investments of \$1,700,000, less purchases of investments of \$1,248,000. The cash used in 2003 primarily represented maturities of investments of \$9,359,000, less purchases of investments of \$6,720,000.

Financing activities provided cash of \$1,140,000 in fiscal 2001, \$111,000 in fiscal 2002 and \$274,000 in fiscal 2003. The amounts primarily consist of the net proceeds we received from the sale of common stock and issuances of common stock upon exercise of stock options and warrants. In fiscal 2003, \$87,000 was used to repurchase shares of our common stock under our buyback program.

We may seek to raise additional funds when market conditions permit. However, there can be no assurance that funding will be available or that, if available, will be on acceptable terms. Our future capital requirements will depend on a number of factors, including:

the amount of payments received from marketing agreements for Memantine;

the amount of royalties received from Merz for future sales of Memantine;

the progress of our clinical development programs;

the time and cost involved in obtaining regulatory approvals;

the cost of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights;

the acquisition or licensing of new drug candidates;

competing technological and market developments;

our ability to establish collaborative relationships; and

the development of commercialization activities and arrangements.

Our future contractual obligations are related to the lease for our physical facility. The minimum payment is approximately \$91,000 for the one-year term of the lease, which expires July 2004.

RECENT ACCOUNTING PRONOUNCEMENTS

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In June 2002, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 146, Accounting for Costs Associated with Exit or Disposal Activities. SFAS No. 146 provides guidance related to accounting for costs associated with disposal activities covered by SFAS No. 144 or with exit or restructuring activities previously covered by Emerging Issues Task Force (EITF) Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring). SFAS No. 146 supercedes EITF Issue No. 94-3 in its entirety. SFAS No. 146 requires that costs related to exiting an activity or to a restructuring not be recognized until the liability is incurred. SFAS No. 146 will be applied prospectively to any exit or disposal activities that are initiated after December 31, 2002.

In November 2002, the FASB issued FASB Interpretation No. 45 (FIN 45), Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others. FIN 45 requires that a liability be recorded in the guarantor s balance sheet upon issuance of a guarantee. In addition, FIN 45 requires disclosures about the guarantees that an entity has issued. The recognition provisions of FIN 45 will be applied prospectively to any guarantees issued after December 31, 2002. The Company adopted the disclosure provisions of FIN 45 during fiscal 2003. The adoption of FIN 45 did not have an impact on the Company s results of operations or financial position.

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In November 2002, the EITF reached a consensus on Issue No. 00-21, Revenue Arrangements with Multiple Deliverables. EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The Company does not expect the adoption of EITF Issue No. 00-21 to have a material effect on its results of operations or financial position.

In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation, Transition and Disclosure. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires that disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation be displayed more prominently and in a tabular format. Additionally, SFAS No. 148 requires disclosure of the pro forma effect in interim financial statements. The Company adopted the disclosure requirements of SFAS No. 148 in fiscal year 2003.

In January 2003, the FASB issued FASB Interpretation No. 46 (FIN 46), Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. The adoption of FIN 46 in fiscal year 2003 did not have an impact on the Company's results of operations or financial position.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity. SFAS No. 150 requires that certain financial instruments, which under previous guidance were accounted for as equity, to be accounted for as liabilities. The financial instruments affected include mandatorily redeemable stock, certain financial instruments that require or may require the issuer to buy back some of its shares in exchange for cash or other assets and certain obligations that can be settled with shares of stock. SFAS No. 150 is effective for all financial instruments entered into or modified after May 31, 2003 and must be applied to Company's existing financial instruments effective July 1, 2003, the beginning of the first interim period beginning after June 15, 2003. The Company does not expect the adoption of SFAS No. 150 to have a material effect on its results of operations or financial position.

OTHER FACTORS THAT MAY AFFECT FUTURE RESULTS

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

Our product candidates are based on new and relatively unproven technologies. As a result, these candidates face numerous risks of failure, including the possibility that these candidates 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 be uneconomical to market;

be precluded from marketing by us or our marketing partners 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. Although Merz has received approval to market Memantine for the treatment of Alzheimer's disease in Europe, Merz and its

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marketing partners may not receive approval to market Memantine for Alzheimer's disease in the United States or elsewhere, or to market Memantine for neuropathic pain or other indications. The failure of Merz or its marketing partners to receive approval to market Memantine for neuropathic pain or indications other than Alzheimer's disease could adversely affect our rights under our research and marketing cooperation agreement with Merz and Children's Medical Center.

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

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

Under certain circumstances, Merz or Children's Medical Center can terminate our research and marketing cooperation agreement upon six months' notice. The termination of this agreement, or any failure by Merz or its partners to successfully commercialize Memantine, could reduce or terminate our future royalties under the research and marketing cooperation agreement and would have a material adverse effect on our business, financial conditions and results of operations.

Other than Memantine, we have one potential product that is in clinical development and we may not develop another candidate product that will receive required regulatory approval or be successfully commercialized.

We are still a development-stage company and, except for Memantine, we have only one product, XERECEPT, in clinical development. The results of our pre-clinical 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. For example, although our Phase II clinical trials for Memantine for the treatment of neuropathic pain yielded positive results, subsequent clinical trials conducted by Forest did not replicate these results. Similar variations -in later-stage clinical trial results may also be seen in XERECEPT as longer trials and larger patient populations are used. Further, although we expect to launch Phase III clinical trials of XERECEPT before the end of 2003, patient enrollment in these trials may be slow, as it was in our clinical trials of XERECEPT for peritumoral brain edema. Any delays in patient enrollment could delay the development of XERECEPT. It is also possible that either or both of Memantine or XERECEPT will not be further developed or successfully commercialized if later stage trials do not validate earlier results.

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 (which are generally non-exclusive) with consultants, academic collaborators, licensors, licensees and others, and we are dependent upon the level of commitment and subsequent success of these outside parties in performing their responsibilities. Certain of these agreements place significant responsibility for pre-clinical testing and human clinical trials and for preparing and submitting submissions for regulatory approval for potential products on the collaborator, licensor or contractor. 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 our view of the future likelihood of FDA approval or commercial viability of these potential products.

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We have agreements and licenses with third parties that require us to meet certain due diligence obligations, provide regular reports and make royalty and other payments to such parties. Our failure to satisfy these obligations 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 under a policy that only covers 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 the commercial sales of products. We cannot 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.

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 six persons full-time and five persons part-time. Any reduction in our staff 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 has historically been low, even when compared to that of other biopharmaceutical companies. Because of our relatively low trading volume, our stock price can be highly volatile.

Factors that may affect the volatility of our stock price include:

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

other evidence of the safety or efficacy of our products, 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, 2003, the fair value of our investments was \$4.3 million and 100% of our total portfolio will mature in one year or less. 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. We do not use or hold derivative financial instruments.

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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, 2003 and 2002, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended June 30, 2003, and for the period from August 27, 1987 (inception) through June 30, 2003. 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, 2003 and 2002, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2003, and for the period from August 27, 1987 (inception) through June 30, 2003, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Palo Alto, California

August 7, 2003

Table of Contents**NEUROBIOLOGICAL TECHNOLOGIES, INC.****(a development stage company)****BALANCE SHEETS**

	June 30,	
	2003	2002
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 66,138	\$ 277,062
Short-term investments	4,336,127	5,417,434
Interest receivable	50,339	155,896
Prepaid expenses and other current assets	350,533	244,534
	<u>4,803,137</u>	<u>6,094,926</u>
Total current assets	4,803,137	6,094,926
Long-term investments		1,564,598
Property and equipment, net	10,073	5,456
	<u>\$ 4,813,210</u>	<u>\$ 7,664,980</u>
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 309,558	\$ 611,021
Accrued expenses	256,037	441,256
	<u>565,595</u>	<u>1,052,277</u>
Total current liabilities	565,595	1,052,277
Commitments		
Stockholders' equity:		
Convertible Series A Preferred stock, \$.001 par value, 5,000,000 shares authorized, 2,332,000 issued in series, 1,154,000 and 1,372,000 outstanding at June 30, 2003 and 2002, respectively (aggregate liquidation preference of \$577,000 at June 30, 2003)	577,000	686,000
Common stock, \$.001 par value, 35,000,000 shares authorized, 18,755,553 and 17,783,571 outstanding at June 30, 2003 and 2002, respectively	44,259,534	43,876,705
Deferred stock compensation	(82,126)	(136,876)
Deficit accumulated during development stage	(40,516,524)	(37,830,056)
Accumulated other comprehensive income	9,731	16,930
	<u>4,247,615</u>	<u>6,612,703</u>
Total stockholders' equity	4,247,615	6,612,703
	<u>\$ 4,813,210</u>	<u>\$ 7,664,980</u>

See accompanying notes.

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NEUROBIOLOGICAL TECHNOLOGIES, INC.

(a development stage company)

STATEMENTS OF OPERATIONS

	Year ended June 30,			Period from August 27, 1987 (inception) through June 30, 2003
	2003	2002	2001	
REVENUES:				
License	\$ 1,968,690	\$	\$ 4,781,250	\$ 8,849,940
Royalty	10,949			10,949
Grant				149,444
Total revenues	1,979,639		4,781,250	9,010,333
EXPENSES:				
Research and development	2,316,978	2,013,403	1,193,731	32,488,821
General and administrative	2,492,971	2,637,332	2,556,272	20,462,855
Total expenses	4,809,949	4,650,735	3,750,003	52,951,676
Operating income (loss)	(2,830,310)	(4,650,735)	1,031,247	(43,941,343)
Interest income, net	143,842	342,549	598,975	3,424,819
Income (loss) before income tax (expense) benefit	(2,686,468)	(4,308,186)	1,630,222	(40,516,524)
Income tax (expense) benefit		41,831	(41,831)	
NET INCOME (LOSS)	\$ (2,686,468)	\$ (4,266,355)	\$ 1,588,391	\$ (40,516,524)
BASIC NET INCOME (LOSS) PER SHARE	\$ (0.15)	\$ (0.24)	\$ 0.10	
Shares used in basic net income (loss) per share calculation	18,015,644	17,569,923	16,531,649	
DILUTED NET INCOME (LOSS) PER SHARE	\$ (0.15)	\$ (0.24)	\$ 0.08	
Shares used in diluted net income (loss) per share calculation	18,015,644	17,569,923	21,070,598	

See accompanying notes.

Table of Contents**NEUROBIOLOGICAL TECHNOLOGIES, INC.****(a development stage company)****STATEMENTS OF STOCKHOLDERS EQUITY**

	Convertible Preferred Stock		Common Stock		Deferred Stock Compensation	Deficit	Accumulated	Accumulated	Total Stockholders
	Shares	Amount	Shares	Amount		During Development Stage	Other Comprehensive Income	Equity	
Period from August 27, 1987 (inception) through June 30, 2000									
Issuance of common stock		\$	740,863	\$ 1,616,706	\$	\$	\$	\$ 1,616,706	
Issuance of common stock at \$5.30 per unit, net of issuance costs			1,200,000	5,727,400				5,727,400	
Issuance of warrants to purchase 304,786 shares of common stock				43,290				43,290	
Issuance of common stock and warrants at \$0.55 per unit			1,010,410	555,725				555,725	
Issuance of common stock and warrants at \$4.00 per unit, net of issuance costs			5,434,700	4,051,898				4,051,898	
Issuance of common stock for services and license rights			88,248	120,875				120,875	
Issuance of common stock upon exercise of options and warrants			1,589,397	2,314,056				2,314,056	
Issuance of common stock under employee stock purchase plan			116,867	184,557				184,557	
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						1,166,000	
Issuance of 5,691,000 shares of Series A preferred stock, net of issuance costs	5,691,000	5,573,194						5,573,194	
Issuance of 2,657,881 shares of Series B preferred stock, net of issuance costs	2,657,881	1,653,888						1,653,888	
Conversion of preferred stock in connection with the initial public offering	(8,348,881)	(7,227,082)	1,046,912	7,227,082					
Conversion of preferred stock to common stock	(50,000)	(25,000)	50,000	25,000					
Issuance of common stock at \$8.00 per share in connection with initial public offering net of issuance costs			1,840,000	12,817,000				12,817,000	
Issuance of common stock at \$3.25 per share in connection with public offering net of issuance costs			2,530,000	7,143,279				7,143,279	
Options granted to consultants for services rendered				70,200				70,200	
Deferred stock compensation				273,750	(273,750)				
Amortization of deferred stock compensation					27,374			27,374	
Net loss and comprehensive loss						(35,152,092)		(35,152,092)	
Balances at June 30, 2000	2,282,000	1,141,000	15,647,397	42,170,818	(246,376)	(35,152,092)		7,913,350	

(continued on following page)

Table of Contents**NEUROBIOLOGICAL TECHNOLOGIES, INC.****(a development stage company)****STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)**

	<u>Convertible Preferred Stock</u>		<u>Common Stock</u>		<u>Deferred Stock Compensation</u>	<u>Deficit Accumulated During Development Stage</u>	<u>Accumulated Other Comprehensive Income</u>	<u>Total Stockholders Equity</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>				
Issuance of common stock upon exercise of options and warrants			1,129,925	1,115,945				1,115,945
Amortization of deferred stock compensation					54,750			54,750
Conversion of preferred stock to common stock	(700,000)	(350,000)	700,000	350,000				
Issuance of common stock under employee stock purchase plan			26,377	23,794				23,794
Net income and comprehensive income						1,588,391		1,588,391
Balances at June 30, 2001	1,582,000	791,000	17,503,699	43,660,557	(191,626)	(33,563,701)		10,696,230
Issuance of common stock upon exercise of warrants			58,000	80,500				80,500
Amortization of deferred stock compensation					54,750			54,750
Conversion of preferred stock to common stock	(210,000)	(105,000)	210,000	105,000				
Issuance of common stock under employee stock purchase plan			11,872	30,648				30,648
Comprehensive loss:								
Net loss						(4,266,355)		(4,266,355)
Unrealized gain on securities							16,930	16,930
Total comprehensive loss								(4,249,425)
Balances at June 30, 2002	1,372,000	686,000	17,783,571	43,876,705	(136,876)	(37,830,056)	16,930	6,612,703
Issuance of common stock upon exercise of options and warrants			769,955	320,422				320,422
Repurchase of common stock			(32,000)	(86,950)				(86,950)
Amortization of deferred stock compensation					54,750			54,750
Conversion of preferred stock to common stock	(218,000)	(109,000)	218,000	109,000				
Issuance of common stock under employee stock purchase plan			16,027	40,357				40,357
Comprehensive loss:								
Net loss						(2,686,468)		(2,686,468)
Unrealized loss on securities							(7,199)	(7,199)
Total comprehensive loss								(2,693,667)
Balances at June 30, 2003	1,154,000	\$ 577,000	18,755,553	\$ 44,259,534	\$ (82,126)	\$ (40,516,524)	\$ 9,731	\$ 4,247,615

See accompanying notes.

Table of Contents**NEUROBIOLOGICAL TECHNOLOGIES, INC.****(a development stage company)****STATEMENTS OF CASH FLOWS**

	Year ended June 30,			Period from August 27, 1987 (inception) through June 30, 2003
	2003	2002	2001	
Operating Activities				
Net income (loss)	\$ (2,686,468)	\$ (4,266,355)	\$ 1,588,391	\$ (40,516,524)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:				
Depreciation and amortization	8,715	23,364	22,481	698,784
Gain on sale of property and equipment			(1,500)	(1,500)
Amortization of deferred stock compensation	54,750	54,750	54,750	191,624
Issuance of common stock, options and warrants for license rights and services				209,975
Changes in assets and liabilities:				
Interest receivable	105,557	(23,852)	(73,424)	(50,339)
Prepaid expenses and other current assets	(105,999)	9,293	(211,530)	(350,533)
Accounts payable and accrued expenses	(486,682)	290,228	7,344	565,595
Net cash provided by (used in) operating activities	(3,110,127)	(3,912,572)	1,371,824	(39,252,918)
Investing Activities				
Purchase of investments	(6,719,831)	(1,248,214)	(11,742,170)	(54,775,485)
Maturities of investments	9,358,537	1,700,000	5,550,874	50,449,089
Purchases of property and equipment	(13,332)		(23,523)	(425,795)
Proceeds from sale of property and equipment			1,500	1,500
Additions to patents and licenses				(283,062)
Net cash provided by (used in) investing activities	2,625,374	451,786	(6,213,319)	(5,033,753)
Financing Activities				
Payment of note payable				(200,000)
Proceeds of short-term borrowings				435,000
Issuance of common stock, net	360,779	111,148	1,139,739	36,046,677
Repurchase of common stock	(86,950)			(86,950)
Issuance of preferred stock, net				8,158,082
Net cash provided by financing activities	273,829	111,148	1,139,739	44,352,809
Increase (decrease) in cash and cash equivalents	(210,924)	(3,349,638)	(3,701,756)	66,138
Cash and cash equivalents at beginning of period	277,062	3,626,700	7,328,456	
Cash and cash equivalents at end of period	\$ 66,138	\$ 277,062	\$ 3,626,700	\$ 66,138

Supplemental Disclosures:

Conversion of short-term-borrowings to Series A preferred stock	\$	\$	\$	\$ 235,000
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Conversion of preferred stock to common stock	\$ 109,000	\$ 105,000	\$ 350,000	\$ 7,816,082
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Deferred stock compensation related to options granted	\$	\$	\$	\$ 273,750
	<u> </u>	<u> </u>	<u> </u>	<u> </u>

See accompanying notes.

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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", 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 over at least the next fiscal year ending June 30, 2004. The Company may seek to raise additional funds whenever market conditions permit. However, there can be no assurance that funding will be available, or, if available, that it will be available on acceptable terms. If the Company is not able to raise adequate funds, it may be required to delay, scale back, or terminate its clinical trials or to obtain funds through entering into arrangements with collaborative partners or others.

Revenue Recognition

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. Revenues associated with milestones are recognized as earned, based on completion of development milestones, either upon receipt, or when collection is assured.

Research and Development

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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.

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. Available-for-sale securities are carried at estimated fair value, based on available market information, with unrealized

Table of Contents**NEUROBIOLOGICAL TECHNOLOGIES, INC.****(a development stage company)****NOTES TO FINANCIAL STATEMENTS (Continued)**

gains and losses reported as a component of stockholders' equity. Realized gains or losses, amortization of premiums, accretion of discounts and earned interest are included in investment income. The cost of securities when sold is based upon specific identification.

Property and Equipment

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

Net Income (Loss) 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, 2003 and 2002, 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, 2003 and 2002.

The computation of diluted net loss per share for the year ended June 30, 2003 excludes the impact of options to purchase 788,221 shares of common stock, warrants to purchase 1,511,824 shares of common stock, and the conversion of convertible preferred stock into 1,295,462 shares of common stock. The computation of diluted net loss per share for the year ended June 30, 2002 excludes the impact of options to purchase 628,449 shares of common stock, warrants to purchase 1,369,263 shares of common stock, and the conversion of convertible preferred stock into 1,543,841 shares of common stock.

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

	Year ended June 30,		
	2003	2002	2001
Net income (loss)	\$ (2,686)	\$ (4,266)	\$ 1,588

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Weighted-average shares outstanding:			
Denominator for basic earnings per share	18,016	17,570	16,532
Common stock equivalents:			
stock options			779
warrants			1,682
convertible preferred stock			2,078
Denominator for diluted earnings per share	18,016	17,570	21,071
Net income (loss) per share:			
Basic	\$ (0.15)	\$ (0.24)	\$ 0.10
Diluted	\$ (0.15)	\$ (0.24)	\$ 0.08

Stock-Based Compensation

The Company grants stock options for a fixed number of shares to employees with an exercise price equal to the fair value of the shares at the date of the grant. The Company accounts for stock option grants in accordance

Table of Contents**NEUROBIOLOGICAL TECHNOLOGIES, INC.****(a development stage company)****NOTES TO FINANCIAL STATEMENTS (Continued)**

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 accounted 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.

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

Pro forma information regarding net loss and net loss per share is required by SFAS 148 and has been determined as if the Company had accounted for its employee stock options under the fair value method prescribed by the SFAS 123. The fair value for these options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions: Expected volatility calculations based on historical data (.846), expected option lives of five years, and no dividend yield. Risk free interest rates assumptions were based on U.S. government bonds with maturities equal to the expected option lives of 5.32%, 4.08% and 1.27% for 2001, 2002 and 2003, respectively.

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

	Year ended June 30,		
	2003	2002	2001
Net income (loss) as reported	\$ (2,686)	\$ (4,266)	\$ 1,588
Add back:			
Deferred compensation expense	55	55	55
Deduct:			
Stock-based employee expense determined under SFAS 123	(491)	(518)	(523)

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Pro forma net income (loss)	\$ (3,122)	\$ (4,729)	\$ 1,120
Basic net income (loss) per share as reported	\$ (0.15)	\$ (0.24)	\$ 0.10
Diluted net income (loss) per share as reported	\$ (0.15)	\$ (0.24)	\$ 0.08
Basic pro forma net income (loss) per share	\$ (0.17)	\$ (0.27)	\$ 0.07
Diluted pro forma net income (loss) per share	\$ (0.17)	\$ (0.27)	\$ 0.05

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NEUROBIOLOGICAL TECHNOLOGIES, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS (Continued)

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's employee stock options and employee stock purchase plans have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair market value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options, nor do they necessarily represent the effects of employee stock options on reported net income (loss) for future years.

Comprehensive Income (Loss)

In accordance with Financial Accounting Standards Board Statement No. 130, Reporting Comprehensive Income (FAS 130), we are required to display comprehensive income (loss) and its components as part of our complete set of financial statements. Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) includes certain changes in equity that are excluded from our net income (loss), specifically, the unrealized gains and losses on available-for-sale securities. For the year ended June 30, 2001, our comprehensive income (loss) was the same as net income (loss) as there were no adjustments reported in stockholders' equity that were included in the computation. For the years ended June 30, 2003 and 2002, the components of comprehensive income (loss) have been included in the Statement of Stockholders' Equity.

Impairment of Long-Lived Assets

The Company reviews 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. 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, 2003, there have been no such losses.

Recent Accounting Pronouncements

In June 2002, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 146, Accounting for Costs Associated with Exit or Disposal Activities. SFAS No. 146 provides guidance related to accounting for costs associated with disposal activities covered by SFAS No. 144 or with exit or restructuring activities previously covered by Emerging Issues Task Force (EITF) Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring). SFAS No. 146 supercedes EITF Issue No. 94-3 in its entirety. SFAS No. 146 requires that costs related to exiting an activity or to a restructuring not be recognized until the liability is incurred. SFAS No. 146 will be applied prospectively to any exit or disposal activities that are initiated after December 31, 2002.

In November 2002, the FASB issued FASB Interpretation No. 45 (FIN 45), Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others. FIN 45 requires that a liability be recorded in the guarantor s balance sheet upon issuance of a guarantee. In addition, FIN 45 requires disclosures about the guarantees that an entity has issued. The recognition provisions of FIN 45 will be applied prospectively to any guarantees issued after December 31, 2002. The Company adopted the disclosure provisions of FIN 45 during fiscal 2003. The adoption of FIN 45 did not have an impact on the Company s results of operations or financial position.

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NEUROBIOLOGICAL TECHNOLOGIES, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS (Continued)

In November 2002, the EITF reached a consensus on Issue No. 00-21, Revenue Arrangements with Multiple Deliverables. EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The Company does not expect the adoption of EITF Issue No. 00-21 to have a material effect on its results of operations or financial position.

In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation, Transition and Disclosure. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires that disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation be displayed more prominently and in a tabular format. Additionally, SFAS No. 148 requires disclosure of the pro forma effect in interim financial statements. The Company adopted the disclosure requirements of SFAS No. 148 in fiscal year 2003.

In January 2003, the FASB issued FASB Interpretation No. 46 (FIN 46), Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. The adoption of FIN 46 in fiscal year 2003 did not have an impact on the Company's results of operations or financial position.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity. SFAS No. 150 requires that certain financial instruments, which under previous guidance were accounted for as equity, to be accounted for as liabilities. The financial instruments affected include mandatorily redeemable stock, certain financial instruments that require or may require the issuer to buy back some of its shares in exchange for cash or other assets and certain obligations that can be settled with shares of stock. SFAS No. 150 is effective for all financial instruments entered into or modified after May 31, 2003 and must be applied to Company's existing financial instruments effective July 1, 2003, the beginning of the first interim period beginning after June 15, 2003. The Company does not expect the adoption of SFAS No. 150 to have a material effect on its results of operations or financial position.

Table of Contents**NEUROBIOLOGICAL TECHNOLOGIES, INC.****(a development stage company)****NOTES TO FINANCIAL STATEMENTS (Continued)****Note 2. Investments**

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

	<u>Cost</u>	<u>Gross Unrealized Gains</u>	<u>Market Value</u>
June 30, 2003			
Corporate debt obligations:			
Maturing within 1 year	\$ 2,826	\$ 9	\$ 2,835
U.S. Government obligations:			
Maturing within 1 year	1,500	1	1,501
	<u>4,326</u>	<u>10</u>	<u>4,336</u>
Total investments	\$ 4,326	\$ 10	\$ 4,336
June 30, 2002			
Corporate debt obligations:			
Maturing within 1 year	\$ 4,895	\$ 2	\$ 4,897
Maturing between 1-2 years	1,550	15	1,565
U.S. Government obligations:			
Maturing within 1 year	520		520
	<u>6,965</u>	<u>17</u>	<u>6,982</u>
Total investments	\$ 6,965	\$ 17	\$ 6,982

Estimated fair value is based upon quoted market prices for these or similar instruments. There were no realized gains or losses during the years ended June 30, 2003, 2002 and 2001.

Note 3. Property and Equipment

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

	<u>2003</u>	<u>2002</u>
Machinery and equipment	\$ 200,679	\$ 187,347
Furniture and fixtures	145,426	145,426
	<u>346,105</u>	<u>332,773</u>
Less accumulated depreciation	(336,032)	(327,317)
	<u>\$ 10,073</u>	<u>\$ 5,456</u>

Note 4. Operating Lease Commitments

On April 1, 2001 the Company entered into an assignment and assumption of lease of its executive offices in Richmond, California. The master lease commenced in July 1997 and expired in July 2002. The lease has since been renewed twice for a one-year term, with the current term expiring in July 2004 and with rental payments of approximately \$7,600 per month. The lease is renewable for one additional one-year period. Rent expense for the years ending June 30, 2003, 2002 and 2001 was \$89,000, \$91,000 and \$92,000 respectively.

Table of Contents**NEUROBIOLOGICAL TECHNOLOGIES, INC.****(a development stage company)****NOTES TO FINANCIAL STATEMENTS (Continued)****Note 5. Stockholders Equity***Convertible Preferred Stock*

At June 30, 2003, the Company has 1,154,000 shares of Series A convertible preferred stock outstanding. The holders of the Series A convertible preferred stock are entitled to receive annual noncumulative dividends of 8% per share per annum, when and if declared by the Board of Directors. These dividends are in preference to any declaration or payment of any dividend on the common stock of the Company. As of June 30, 2003, 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, 2003, the Company had outstanding warrants to purchase shares of common stock as follows:

<u>Number of Shares</u>	<u>Exercise Price</u>	<u>Issue Date</u>	<u>Expiration Date</u>
519,200	\$1.00	April 1999	April 2004
1,012,380	\$1.75	November 1999	November 2004
431,000	\$4.40	November 1999	November 2004

1,962,580

Stock Option Plan

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, November 1999 and November 2001 and will expire in November 2003. Under the 1993 Stock Plan, 2,700,000 shares of common stock were authorized 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.

Table of Contents**NEUROBIOLOGICAL TECHNOLOGIES, INC.****(a development stage company)****NOTES TO FINANCIAL STATEMENTS (Continued)**

A summary of the Company's stock option activity, and related information for the three years ended June 30, 2003 follows:

	Options Available for Grant	Options Outstanding	
		Number of Shares	Weighted Average Exercise Price
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
Options granted	(111,500)	111,500	3.08
Options canceled	1,071	(1,071)	3.73
Options authorized	200,000		
Balance at June 30, 2002	163,936	1,789,387	2.49
Options granted	(4,000)	4,000	3.82
Options canceled	72,250	(72,250)	4.17
Options exercised		(70,108)	1.51
Balance at June 30, 2003	232,186	1,651,029	\$ 2.46

At June 30, 2003 and 2002, options to purchase 232,186 and 163,936 shares of common stock remained available for grant, respectively, and options to purchase 1,269,988 and 1,158,285 shares of common stock were exercisable, respectively. The weighted-average exercise price of options exercisable at June 30, 2003 was \$2.46. The weighted-average fair value of options granted during 2003, 2002 and 2001 was \$3.17, \$4.65, and \$2.10, respectively.

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

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Shares Outstanding	Weighted Average	Weighted Average	Shares Exercisable	Weighted Average

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			<u>Remaining Contractual Life (years)</u>	<u>Exercise Price</u>		<u>Exercise Price</u>
\$0.01	1.99	820,198	5.26	\$0.84	637,072	\$0.86
2.00	3.99	532,803	5.46	2.87	400,259	2.86
4.00	5.99	8,928	4.06	4.81	8,928	4.81
6.00	8.00	289,100	6.86	6.22	223,729	6.22
		<u>1,651,029</u>	5.59	\$2.46	<u>1,269,988</u>	\$2.46

In connection with the grant of certain stock options to senior management, we recorded deferred compensation of \$274,000 in fiscal 2000. Deferred compensation represents the difference in the market value of the stock on the date granted and the exercise price of these options. Deferred compensation is presented as a reduction of stockholders' equity and is amortized over the vesting period of the option using a straight-line method. We recognized amortization of deferred stock compensation expense of \$55,000 each fiscal year ended June 30, 2003, 2002, and 2001.

Table of Contents**NEUROBIOLOGICAL TECHNOLOGIES, INC.****(a development stage company)****NOTES TO FINANCIAL STATEMENTS (Continued)***Employee 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 authorized for issuance under the plan was increased by 50,000 to 100,000. In November 1999 the shares authorized were increased by an additional 50,000 shares to 150,000. In November 2000 the shares authorized were increased by 150,000 shares to 300,000. The employee stock purchase plan will expire in February 2004. Under the plan, 128,863 shares remain available for issuance at June 30, 2003.

Stock Repurchase Program

In August 2002, the Board of Directors authorized a stock repurchase program of up to 500,000 shares of the Company's common stock. Depending on market conditions and other factors, repurchases will be made from time to time in the open market and in negotiated transactions, including block transactions, and may be discontinued at any time. In the year ended June 30, 2003, the Company repurchased 32,000 shares of its common stock for \$87,000. All shares repurchased have been retired.

Common Stock Reserved for Future Issuance

At June 30, 2003, the Company has reserved shares of common stock for future issuance as follows:

Conversion of preferred stock into common stock	1,154,000
1993 Stock Plan	1,883,215
Warrants	1,962,580
Employee stock purchase plan	128,863
	<hr/>
	7,820,658
	<hr/>

Note 6. Income Taxes

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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. Valuation allowances are established, when necessary, to reduce differed tax assets to the amounts expected to be realized.

There was no provision (benefit) for income taxes for the year ended June 30, 2003. The provision (benefit) for income taxes for the years ended June 30, 2002 and 2001 consists of the following (in thousands):

	<u>2002</u>	<u>2001</u>
Current:		
Federal	\$ (40)	\$ 40
State	(2)	2
	<u> </u>	<u> </u>
Total	\$ (42)	\$ 42
	<u> </u>	<u> </u>

The income tax provision (benefit) for 2002 and 2001 is a result of the federal alternative minimum tax. The benefit in 2002 is primarily due to a change in federal tax law. There was no deferred income tax expense for the years ended June 30, 2003, 2002, and 2001.

Table of Contents**NEUROBIOLOGICAL TECHNOLOGIES, INC.****(a development stage company)****NOTES TO FINANCIAL STATEMENTS (Continued)**

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):

	Year Ended June 30,	
	2002	2001
Provision (benefit) at U.S. statutory rate	\$ (1,508)	\$ 571
Unbenefited loss (utilization of net operating loss)	1,508	(591)
Alternative minimum tax	(42)	42
Other		20
Total	\$ (42)	\$ 42

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

	June 30,	
	2003	2002
Deferred Tax Assets:		
Net Operating Losses	\$ 6,230	\$ 5,100
Research credits	430	430
Other	360	340
Total deferred tax assets	7,020	5,870
Valuation allowance	(7,020)	(5,870)
Net deferred tax assets	\$	\$

Realization of the deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The net valuation allowance increased by \$1,150,000 and decreased by \$8,557,000 during 2003 and 2002, respectively.

As of June 30, 2003, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$15,000,000 which expire in the years 2006 through 2023, and federal research and development tax credits of approximately \$200,000 which will expire in the years 2007 through 2023.

As of June 30, 2003, the Company had net operating loss carryforwards for state income tax purposes of approximately \$18,000,000 which expire in the years 2005 through 2014, and state research and development tax credits of approximately \$300,000 which do not expire.

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

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NEUROBIOLOGICAL TECHNOLOGIES, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS (Continued)

Note 7. Collaboration Agreement

In April 1998, we entered into a strategic research and marketing cooperation agreement with Merz Pharmaceuticals GmbH and Children's Medical Center Corporation to further the clinical development and commercialization of Memantine. Pursuant to this agreement, NTI and Merz share scientific, clinical and regulatory information about Memantine, particularly safety data, to facilitate regulatory review and marketing approval by the Food and Drug Administration and foreign regulatory authorities. Pursuant to this agreement, we will share in future revenues from sales of Memantine for all indications. As of June 30, 2003 we have received \$10,949 in royalty payments for the sales of Memantine.

In June 2000, Merz entered into an agreement with Forest Laboratories, Inc. for the development and marketing of Memantine in the United States for the treatment of Alzheimer's disease, neuropathic pain and AIDS-related dementia. In August 2000, Merz entered into a strategic license and cooperation agreement with H. Lundbeck A/S of Copenhagen, Denmark for the further development and marketing of Memantine for the treatment of Alzheimer's disease, neuropathic pain and AIDS-related dementia. Lundbeck has acquired exclusive rights to Memantine in certain European markets, Canada, Australia and South Africa and semi-exclusive rights to co-market Memantine with Merz in other markets worldwide, excluding the United States, where Forest has development rights, and Japan, where Merz has granted development rights to Suntory/Dai-Ichi Ltd., respectively. Through June 30, 2003, we have received approximately \$8.8 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.

Note 8. Subsequent Event

On September 25, 2003, the Board of Directors adopted, subject to stockholder approval, the 2003 Equity Incentive Plan (the "2003 Plan") and the 2003 Employee Stock Purchase Plan (the "2003 ESPP"). The 2003 Plan provides for the issuance of options and stock awards and reserves up to 1,500,000 shares of common stock for issuance under the plan. The 2003 ESPP reserves up to 500,000 shares of common stock for sale under the ESPP. The 2003 Plan and 2003 ESPP will be presented at the Company's 2003 Annual Meeting of Stockholders for approval.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES.

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The Company's principal executive and financial officer carried out an evaluation of the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15(d)-15(e) under the Securities Exchange Act of 1934) as of the end of the period covered by this report. Based on that evaluation, this officer concluded that the Company's disclosure controls and procedures were adequate and designed to ensure that material information relating to the Company would be made known to him by others within the Company.

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

The directors and executive officers of the Company, their ages and positions as of September 29, 2003 are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Paul E. Freiman	69	President and Chief Executive Officer and Director
Lisa U. Carr, M.D., Ph.D.	48	Vice President, Medical Affairs
Abraham E. Cohen	67	Chairman of the Board of Directors
Enoch Callaway, M.D.	79	Director
Theodore L. Eliot, Jr.	75	Director
Abraham D. Sofaer	65	Director
John B. Stuppin	70	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. and serves on the boards of Penwest Pharmaceutical Co., Calypte Biomedical Corporation, 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, for which an IND and NDA were approved for solid organ transplantation. Dr. Carr holds a medical degree and a Ph.D. degree *magna cum laude* from the University of Munich in Germany.

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

Enoch Callaway, M.D. is a founder of the Company and has served as a director of the Company since September 1987. Dr. Callaway previously served as chairman of the Board of the Company from September 1987 to November 1990, as co-chairman of the Board of the Company from November 1990

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

Theodore L. Eliot, Jr. has served as a director of the Company since August 1992. Previously, he served as a director of the Company from September 1988 until April 1992, and as a Vice President of the Company from September 1988 until September 1991. Mr. Eliot retired from the United States Department of State in 1978, after a 30-year career in which he held senior posts in Washington and was Ambassador to Afghanistan. He was Dean of the Fletcher School of Law and Diplomacy from 1978 to 1985 and a director of Raytheon Co. from 1983 to 1998. He is currently a director of 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. From 1990 to 1994, Mr. Sofaer was a partner at the legal firm of Hughes, Hubbard & Reed in Washington, D.C., where he represented several major U.S. public companies. From 1985 to 1990, he served as the Legal Adviser to the United States Department of State, where he was principal negotiator on several international disputes. From 1979 to 1985, he served as a federal judge in the Southern District of New York. Mr. Sofaer is registered as a qualified arbitrator with the American Arbitration Association and is a member of the National Panel of the Center for Public Resolution of Disputes (CPR), a leading organization in the area of resolution of disputes outside litigation. He has mediated major commercial cases. Additionally, he acts regularly as an arbitrator in merger-acquisition disputes, commercial cases involving valuation of technology, and securities class action suits. Mr. Sofaer is on the board of Gen-Probe, Inc. and the International Advisory Board of Chugai Biopharmaceuticals, Inc., and serves as a director of American Friends of the Koret Israel Economic Development Fund and the Koret Foundation and as a Trustee of the National Museum of Jazz. Mr. Sofaer holds a B.A. degree from Yeshiva College and a L.L.B. degree from New York University.

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

Section 16(a) Beneficial Ownership Reporting Compliance

The information required by Item 405 of Regulation S-K is hereby incorporated by reference to the Section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" in our Proxy Statement for the Annual Meeting of Stockholders to be held November 13, 2003.

ITEM 11. EXECUTIVE COMPENSATION

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The information required by this item is hereby incorporated by reference to the section entitled "Executive Compensation" in our Proxy Statement for the Annual Meeting of Stockholders to be held November 13, 2003.

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

The information required by this item is hereby incorporated by reference to the section entitled Security Ownership of Certain Beneficial Owners and Management in our Proxy Statement for the Annual Meeting of Stockholders to be held November 13, 2003.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this item is hereby incorporated by reference to the section entitled Certain Relationships and Related Transactions in our Proxy Statement for the Annual Meeting of Stockholders to be held November 13, 2003.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information required by this item is hereby incorporated by reference to the section entitled Audit Fees in our Proxy Statement for the Annual Meeting of Stockholders to be held November 13, 2003.

Table of Contents**PART IV.****ITEM 15. 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, 2003 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:* On May 7, 2003, the registrant furnished the SEC with a Current Report on Form 8-K to report the issuance of a press release announcing the registrant's results of operations for the quarter ended March 31, 2003. In accordance with SEC Release No. 33-8216, such information, which was intended to be furnished under Item 12 of Form 8-K, Results of Operations and Financial Condition, was instead furnished under Item 9, Regulation FD Disclosure.

(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 Registrant. (5)
4.1	Form of Common Stock Certificate. (1)
4.2	Form of Warrant to Purchase Common Stock. (5)
10.1	1993 Stock Plan of Neurobiological Technologies, Inc. (7)*
10.2	Form of Indemnity Agreement between the Company and its directors and officers. (1)*
10.3	License Agreement between the Company and Research Corporation Technologies, Inc. dated May 30, 1990. (1)+
10.4	License Agreement between the Company and The Salk Institute for Biological Studies dated March 31, 1989, as amended. (1)+
10.5	License Agreement between the Company and the Regents of the University of California dated June 13, 1990, as amended. (1)+
10.6	Amended and Restated Neurobiological Technologies, Inc. Employee Stock Purchase Plan. (6)*
10.7	License and Cooperation Agreement among the Company, Merz + Co. GmbH & Co. and Children's Medical Center Corp., effective as of April 16, 1998. (4)+
10.8	Payment Agreement between the Company and Children's Medical Center Corp., effective as of April 16, 1998. (4)+
10.9	Employment Agreement between the Company and Paul E. Freiman dated April 1, 2003. *
10.10	First Amendment to Lease, dated June 2, 2003, by and between 3260 Blume Drive Associates and Neurobiological Technologies, Inc.

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23.1	Consent of Ernst & Young LLP, Independent Auditors.
24.1	Powers of Attorney. (Contained on Signature Page)
31.1	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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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.

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- (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 Appendix A to the Registrant's Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on October 16, 2000 and is incorporated herein by reference.
- (7) This exhibit is filed as Appendix A to Registrant's Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on October 9, 2001 and is incorporated herein by reference.
- + Confidential treatment has been granted with respect to certain portions of these agreements.
- * This exhibit is a management contract or compensatory plan or arrangement.

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/s/ ABRAHAM D. SOFAER

Director

September 29, 2003

Abraham D. Sofaer

/s/ JOHN B. STUPPIN

Director

September 29, 2003

John B. Stuppin