NEUROBIOLOGICAL TECHNOLOGIES INC /CA/
Form 10-Q
February 17, 2004
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended December 31, 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	**94-3049219**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**

3260 Blume Drive, Suite 500

Richmond, California 94806

(Address of principal executive offices)

(510) 262-1730

(Registrant s telephone number, including area code)

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

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

Indicate the number of shares outstanding of each of the issuer s classes of the common stock, as of the latest practical date:

Common Stock, $.001 Par Value: 19,250,117 shares outstanding as of January 31, 2004.

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NEUROBIOLOGICAL TECHNOLOGIES, INC.

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PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NEUROBIOLOGICAL TECHNOLOGIES, INC.

(A development stage company)

CONDENSED BALANCE SHEETS

	December 31, 2003	June 30, 2003
	(unaudited)	*(Note 1)*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 806,803	$ 66,138
Short-term investments	1,811,532	4,336,127
Interest receivable	18,778	50,339
Prepaid expenses and other	144,035	350,533
Total current assets	2,781,148	4,803,137
Property and equipment, net	6,335	10,073
TOTAL ASSETS	$ 2,787,483	$ 4,813,210
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 367,469	$ 565,595
Total current liabilities	367,469	565,595
Stockholders equity:		
Convertible Series A Preferred stock, $.001 par value, 5,000,000 shares authorized, 2,332,000 issued in series, 754,000 and 1,154,000 outstanding at December 31, 2003 and June 30, 2003, respectively	377,000	577,000
Common stock, $.001 par value, 35,000,000 shares authorized, 19,230,117 and 18,755,553 outstanding at December 31, 2003 and June 30, 2003, respectively	44,546,646	44,259,534
Deferred compensation	(54,751)	(82,126)
Deficit accumulated during development stage	(42,448,688)	(40,516,524)
Accumulated other comprehensive income	(193)	9,731
Total stockholders equity	2,420,014	4,247,615
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 2,787,483	$ 4,813,210

See accompanying notes.

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NEUROBIOLOGICAL TECHNOLOGIES, INC.

(A development stage company)

CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

	Three months ended December 31,		Six months ended December 31,		Period from August 27, 1987 (inception) through December 31,
	2003	2002	2003	2002	2003
REVENUES					
License	$ 281,230	$	$ 281,230	$ 1,406,230	$ 9,131,170
Royalty	18,659		28,443		39,392
Grant					149,444
Total revenue	299,889		309,673	1,406,230	9,320,006
EXPENSES					
Research and development	513,365	678,765	841,290	1,585,524	33,330,111
General and administrative	854,842	687,604	1,431,080	1,176,215	21,893,935
Total expenses	1,368,207	1,366,369	2,272,370	2,761,739	55,224,046
Operating loss	(1,068,318)	(1,366,369)	(1,962,697)	(1,355,509)	(45,904,040)
Interest income	9,270	40,991	30,533	86,234	3,455,351
NET LOSS	$ (1,059,048)	$ (1,325,378)	$ (1,932,164)	$ (1,269,275)	$ (42,448,689)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.06)	$ (0.07)	$ (0.10)	$ (0.07)	
Shares used in basic and diluted net loss per share calculation	19,206,054	17,772,633	19,019,739	17,777,460	

See accompanying notes.

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NEUROBIOLOGICAL TECHNOLOGIES, INC.

(A development stage company)

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

	Six months ended December 31,		Period from August 27, 1987 (inception) through
	2003	2002	December 31, 2003
OPERATING ACTIVITIES:			
Net loss	$ (1,932,164)	$ (1,269,275)	$ (42,448,688)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,272	4,931	702,056
(Gain) loss on sale of property and equipment	2,849		1,349
Amortization of deferred stock compensation	27,375	27,375	218,999
Issuance of common stock, options and warrants for license rights and services	28,200		238,175
Changes in assets and liabilities:			
Interest receivable	31,561	81,427	(18,778)
Prepaid expenses and other current assets	206,498	104,588	(144,035)
Accounts payable and accrued expenses	(198,126)	(339,586)	367,469
Net cash used in operating activities	(1,830,535)	(1,390,540)	(41,083,453)
INVESTING ACTIVITIES:			
Purchase of investments	(2,919,837)	(3,599,081)	(57,695,322)
Maturity of investments	5,434,507	5,517,733	55,883,596
Purchases of property and equipment, net	(2,383)	(6,217)	(428,178)
Proceeds from sale of property & equipment			1,500
Additions to patents and licenses			(283,062)
Net cash provided by (used in) investing activities	2,512,287	1,912,435	(2,521,466)
FINANCING ACTIVITIES:			
Payment of note payable			(200,000)
Proceeds from short-term borrowings			435,000
Issuance of common stock, net	58,913	81,760	36,105,590
Repurchase of common stock		(86,950)	(86,950)
Issuance of preferred stock, net			8,158,082
Net cash (used in) provided by financing activities	58,913	(5,190)	44,411,722
Increase (decrease) in cash and cash equivalents	740,665	516,705	806,803
Cash and equivalents at beginning of period	66,138	277,062	
Cash and equivalents at end of period	$ 806,803	$ 793,767	$ 806,803

SUPPLEMENTAL DISCLOSURES:			
Conversion of short-term borrowings to Series A preferred stock	$	$	$ 235,000
Conversion of preferred stock to common stock	$ 200,000	$	$ 8,016,082
Deferred stock compensation related to options granted	$	$	$ 273,750

See accompanying notes.

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NEUROBIOLOGICAL TECHNOLOGIES, INC.

(A development stage company)

NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

December 31, 2003

NOTE 1-BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

BASIS OF PRESENTATION

The accompanying unaudited condensed financial statements have been prepared in accordance with generally accepted accounting principles for interim financial reporting and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnote disclosures required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three- and six-month periods ended December 31, 2003 are not necessarily indicative of the results that may be expected for the fiscal year ended June 30, 2004.

The balance sheet at June 30, 2003 has been derived from the audited financials at that date but does not include all the information and notes required by generally accepted accounting principles for complete financial statements. For further information, refer to the financial statements and notes included in our Annual Report on Form 10-K for the fiscal year ended June 30, 2003.

BASIC AND DILUTED NET LOSS PER SHARE

Net loss per share is presented under the requirements of Financial Accounting Standards Board (FAS) No. 128, Earnings per Share. Basic net loss per share is computed based on the weighted average shares of common stock outstanding and excludes any options, warrants, and convertible securities. Potentially dilutive securities, such as options, warrants, and convertible preferred stock, have been excluded from the computation of diluted net loss per share for the three- and six-month periods ended December 31, 2003 and 2002 as their effect is antidilutive.

REVENUE RECOGNITION

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

STOCK-BASED COMPENSATION

The Company grants stock options for a fixed number of shares to employees with an exercise price equal to the fair value of the shares at the date of the grant. The Company accounts for stock option grants in accordance with APB Opinion No. 25, Accounting for Stock Issued to Employees (APB 25) and related Interpretations 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

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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 common 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: risk-free interest rates ranging from 3.27% to 3.29% for the three months ended December 31, 2003. There were new grants for a total of 34,000 shares during the three months ended December 31, 2003.

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

	Three months ended December 31,		Six months ended December 31,	
	2003	2002	2003	2002
Net loss as reported	$ (1,059)	$ (1,325)	$ (1,932)	$ (1,269)
Add back:				
Stock-based employee compensation expense included in net loss as reported	14	14	14	14
Deduct:				
Stock-based employee expense determined under SFAS 123	(137)	(122)	(254)	(246)
Pro forma net loss	$ (1,182)	$ (1,433)	$ (2,172)	$ (1,501)
Basic and diluted net loss per share as reported	$ (0.06)	$ (0.07)	$ (0.10)	$ (0.07)
Basic and diluted pro forma net loss per share	$ (0.06)	$ (0.08)	$ (0.11)	$ (0.08)

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.

NOTE 2-INVESTMENTS

The following is a summary of available-for-sale investments (in thousands).

December 31, 2003

	Cost	Gross Unrealized Losses	Market Value
Corporate debt obligations	$ 1,676	$	$ 1,676
U.S. Government obligations	901		901
Total investments	$ 2,577	$	$ 2,577

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June 30, 2003

	Cost	Gross Unrealized Gains	Market Value
Corporate debt obligations	$ 2,826	$ 9	$ 2,835
U.S. Government obligations	1,500	1	1,501
Total investments	$ 4,326	$ 10	$ 4,336

At December 31, 2003 approximately $765,000 of investments are included in cash equivalents.

NOTE 3-EQUITY TRANSACTIONS

A warrant was exercised through a cashless exercise in accordance with the terms of the warrant and shares of common stock was issued to the warrant holder as follows; 28,392 shares in the quarter ended September 30, 2003 and 18,225 shares in the quarter ended December 31, 2003.

Warrants were exercised in accordance with the terms of the warrants and 16,500 shares of common stock were issued to the warrant holders for an aggregate purchase price of $25,875 in the quarter ended December 31, 2003.

A warrant to purchase 10,000 shares of common stock at $5.14 per share was issued in the quarter ended December 31, 2003 for consulting services and will expire December 22, 2006. The warrant valuation of $28,200 is reflected in general and administrative expense for the quarter ended December 31, 2003.

Options were exercised in accordance with the terms of the options and 5,455 shares of common stock were issued to the option holders for an aggregate purchase price of $18,067 in the quarter ended December 31, 2003.

400,000 shares of convertible Series A preferred stock were converted to common stock on a one-for-one basis in the quarter ended September 30, 2003.

Employees purchased 5,992 shares of common stock in the quarter ended December 31, 2003 in accordance with the Employee Stock Purchase Plan for an aggregate purchase price of $14,970.

NOTE 4-COMPREHENSIVE INCOME (LOSS)

Comprehensive income (loss) is comprised of net loss and unrealized holding gains and losses on available-for-sale investments.

	Three Months Ended December 31,		Six Months Ended December 31,	
	2003	2002	2003	2002
Net loss	$ (1,059,048)	$ (1,325,378)	$ (1,932,164)	$ (1,269,275)
Other comprehensive income	(94)		(9,924)	6,247
Comprehensive loss	$ (1,059,142)	$ (1,325,378)	$ (1,942,088)	$ (1,263,028)

NOTE 5-SUBSEQUENT EVENTS

In January 2004, we received a $2.25 million payment from Merz Pharmaceuticals GmbH under our 1998 strategic research and marketing cooperation agreement. This payment represents a portion of the payment received by Merz pursuant to Merz s agreement with Forest Laboratories, Inc., for the approval of Memantine (Namenda) for the treatment of Alzheimer s disease the United States.

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In January 2004, we received a $51,700 payment from Merz under our 1998 strategic research and marketing cooperation agreement. This payment represents a portion of the royalties received by Merz on sales of Memantine (Ebixa) by Lundbeck during the quarter ended December 31, 2003.

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

OVERVIEW

Neurobiological Technologies, Inc. (NTI® , we , us , our or the Company) is an emerging drug development company focused on the clinical evaluation 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- and later-stage drug candidates that target major medical needs and which can be rapidly commercialized.

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 in certain geographic markets.

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, where Forest has development rights, and Japan, where Merz has granted development rights to Daiichi Suntory Pharma Co., Ltd.

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. We received a payment of $281,000 in October 2003 from Merz, which represented a portion of the payments received by Merz pursuant to Merz s agreement with Lundbeck for the approval of Memantine for the treatment of Alzheimer s disease.

In October 2003, Forest announced that it received FDA approval of Memantine (Namenda) for the treatment of moderate-to-severe Alzheimer s disease. Namenda became available for patients starting in January 2004. Under our strategic research and marketing cooperation agreement with Merz, the approval of Namenda triggered a payment of $2.25 million from Merz, which we received in January 2004, and is expected to result in royalty payments from sales of Namenda in the United States beginning in the third or fourth quarter of fiscal 2004.

In October 2003, based on the completed analysis of its Phase II trial, Forest announced that it had decided to proceed with an expanded clinical program, with the objective of obtaining approval of Memantine for neuropathic pain. The expanded clinical program will include a new Phase

II trial that will examine various neuropathic pain conditions at different dosages. Based on the outcome of this Phase II trial, Forest may initiate additional placebo-controlled Phase III trials, with the goal of generating sufficient clinical data for submission of a New Drug Application, or NDA, for the treatment of neuropathic pain. We conducted the first Phase II trial of Memantine for neuropathic pain with an enrollment of over 400 patients and reported positive results in January 2000. In May 2003, Forest announced that Memantine had failed to demonstrate a statistically significant difference versus placebo with regards to the primary endpoint of its Phase II clinical trial for neuropathic pain.

We are also developing XERECEPT, a synthetic preparation of the natural human peptide, Corticorelin Human Acetate, as a treatment for brain swelling due to brain tumors (peritumoral brain edema). In April 1998,

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XERECEPT received orphan drug designation for this indication from the FDA. Orphan drug designation provides us with seven years market exclusivity and makes us eligible to receive Orphan Drug Grants to fund clinical research. XERECEPT has undergone a special protocol assessment with the FDA. We expect to start enrolling patients in February 2004 for the first trial, which is expected to last 18 months. The second trial is expected to start in the Spring 2004 and is expected to last 12 months.

Since our founding in 1987, we have applied a majority of our resources to our 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 over at least the next twelve months due to ongoing research and development efforts. As of December 31, 2003, our deficit accumulated during the development stage was $42.4 million.

RESULTS OF OPERATIONS

We had $281,000 from license fee revenue for the three and six months ended December 31, 2003, and $19,000 and $28,000 of royalty revenue for the three and six months ended December 31, 2003. All of the license fee revenue and royalty revenue came from Merz under our 1998 strategic research and marketing cooperation agreement. We had no revenue in the three months ended December 31, 2002 and $1.4 million for the six months ended December 31, 2002 from Merz under our 1998 strategic research and marketing cooperation agreement, relating to Memantine s approval in Europe for the treatment of Alzheimer s disease.

Our research and development expenses decreased to approximately $513,000 and $841,000 for the three and six months ended December 31, 2003, down from approximately $679,000 and $1,586,000 for the three and six months ended December 31, 2002. The decrease was primarily due to the completion of long-term toxicology studies and manufacturing of initial clinical supplies of XERECEPT. General and administrative expenses increased to approximately $855,000 and $1,431,000 in the three and six months ended December 31, 2003, from $688,000 and $1,176,000 in the same periods of the prior year. The increases were primarily due to increased insurance costs, employee benefit costs and costs related to exploring strategic partnership activities. Interest income decreased to approximately $9,000 and $31,000 in the three and six months ended December 31, 2003, from approximately $41,000 and $86,000 in the same period of the prior year due to lower average interest rates and lower average invested cash balances.

Our two product candidates, Memantine and XERECEPT, have completed or are in Phase II or Phase III human clinical testing. To date, we have incurred costs of approximately $8.9 million in the development of Memantine and $17.0 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 expect to incur ongoing costs primarily for Phase III clinical trials for XERECEPT and related administrative support. We estimate the costs of completing our two planned Phase III human clinical trials for XERECEPT to be approximately $4 million.

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.

LIQUIDITY AND CAPITAL RESOURCES

From inception through December 31, 2003, we have raised a total of approximately $44 million in net proceeds from the sale of common and preferred stock.

We had available cash and cash equivalents and investments of approximately $2.6 million as of December 31, 2003, compared to approximately $4.4 million at June 30, 2003. We believe that our capital resources, including the $2.25 million payment received from Merz in January 2004, will be adequate to fund our planned operations through at least the next twelve months. In the course of our development activities, we have incurred significant losses, and, although we were profitable in the fiscal year ended June 30, 2001 and the quarter ended September 30, 2002, we expect fluctuations in our quarterly operating results to incur, which will result in some additional operating losses over the next twelve months as we continue to expand our research and development efforts. We expect to incur substantial 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.

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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 Merz for marketing approvals of 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; and
- our ability to establish collaborative relationships.

Our only long-term capital obligation relates to our leased facility in Richmond, California. The minimum payment is approximately $91,000 for the one-year term of the lease, which expires July 2004. We expect we will renew this lease on substantially similar terms or obtain another lease on comparable terms.

RISK FACTORS

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

All of our revenues to date have been license fees 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 sales of Memantine made by Merz or its marketing partners. This 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 many European countries and any commercialization efforts in these countries, or the importation of Memantine into the United States from these countries, would not directly benefit us. Although Forest has received marketing approval for Namenda for Alzheimer s disease in the United States, the launch could be delayed and revenue projections for Namenda may not be attained. If Merz or Forest 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 our research and marketing cooperation agreement with Merz, we are entitled to receive a substantially higher royalty rate on sales of Memantine for neuropathic pain and indications other than Alzheimer s disease. However, the agreement is not clear as to whether we will receive this higher royalty rate if such sales are a result of the off label usage of Memantine marketed for Alzheimer s disease. If there is significant off label usage of Memantine and, contrary to our position, it is determined that we are not entitled to the higher royalty rate on these sales, 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 condition and results of operations.

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;

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if approved, be difficult to manufacture on a large scale or 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, and Forest has recently received approval to market Namenda for the treatment of Alzheimer s disease in the United States, Merz and its marketing partners may not receive approval 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.

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 currently have only one product, XERECEPT, in clinical development. The results of our preclinical studies and early-stage clinical trials are not necessarily indicative of those that will be obtained upon further clinical testing in later-stage clinical trials. 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 the first Phase III clinical trial of XERECEPT in February 2004 and expect both Phase III trials to be completed by mid calendar year 2005, 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 XERECEPT will not be further developed or successfully commercialized.

Our quarterly operating results may fluctuate significantly in future periods, and, as a result, our stock price may fluctuate or decline.

To date, our revenues have primarily come from licensing fee payments from Merz. Licensing fee payments and, therefore, our results of operations, may vary significantly from quarter to quarter. Accordingly, we believe that quarter-to-quarter comparisons of our historical results of operations are not indicative of our future performance.

We have relied and will continue to rely on others for research, development, 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 preclinical testing and human clinical trials and for preparing and submitting submissions for regulatory approval for potential products on the collaborator, licensor or contractor. If the collaborator, licensor or contractor fails to perform, our business, financial conditions and results may be adversely affected.

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

We have agreements and licenses with third parties that require us to 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.

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

Merz and Merz s marketing partners have the responsibility of supplying Memantine for their clinical trials. Our initial clinical supply of XERECEPT has been manufactured by established methods using chemical synthesis to

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our specifications. We will need additional supplies of XERECEPT to complete our clinical trials. We perform audits on our contractors who supply XERECEPT to assess compliance with the current Good 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 preclinical and human clinical testing if our contractors are unable to supply sufficient quantities of product candidates manufactured in accordance with cGMP on acceptable terms;
- the delay of market introduction and subsequent sales if we should encounter difficulties establishing relationships with manufacturers to produce, package and distribute products; and
- adverse effects on FDA pre-market approval of potential products 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.

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

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

- delay for a considerable period of time or prevent marketing of any product that we may develop; and/or
- impose costly procedures upon our activities.

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

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

In addition, success in preclinical 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 neurophathy produces 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.

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

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

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

In addition, because of the time delay in patent approval and the secrecy afforded United States patent applications, we do not know if other applications, which might have priority over our applications, have been filed. Further, because we have non-exclusive licenses to patent rights covering certain uses of XERECEPT, others may develop, manufacture and market products that could compete with those we develop.

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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.

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.

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 that only to 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 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. Any reductions 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 hostorically been low compared to that of other biopharmaceutical companies. Because of our relatively low trading volume, our stock price can be highly volatile.

Factors that may cause volatility in 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 3. 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 December 31, 2003, the fair value of our investments was

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$2.6 million and 100% of our 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.

ITEM 4. CONTROLS AND PROCEDURES

An evaluation was performed under the supervision and with the participation of President and Chief Executive Officer of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this quarterly report. Based on that evaluation, the Company and the President and Chief Executive Officer concluded that the Company s disclosure controls and procedures were effective.

We intend to review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis and to improve our controls and procedures over time and to correct any deficiencies that we may discover in the future. Our goal is to ensure that our senior management has timely access to all material financial and non-financial information concerning our business. While we believe the present design of our disclosure controls and procedures is effective to achieve our goal, future events affecting our business may cause us to modify our disclosure controls and procedures.

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PART II. OTHER INFORMATION

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

During the quarter ended December 31, 2003, the Company held its Annual Meeting of Stockholders. The following matters were voted on at the meeting, which was convened on November 13, 2003 and reconvened on December 11, 2003:

(1) The following six directors were elected:

	Votes For	Withheld
Paul E. Freiman	16,578,102	1,067,137
Abraham E. Cohen	17,585,219	60,020
Enoch Callaway, M.D.	16,643,241	1,001,998
Theodore L. Elliot, Jr.	16,457,043	1,188,196
Abraham D. Sofaer	17,342,893	302,346
John B. Stuppin	16,457,043	1,188,196

(2) The selection of Ernst & Young LLP as the independent auditors of the Company for the current year was ratified: For 17,607,899; Against 17,901; Abstain 19,439.

(3) The motion to approve the adoption of the Company s 2003 Equity Incentive Plan was approved: For 7,415,874; Against 1,698,500; Abstain 176,469.

(4) The motion to approve the adoption of the Company s 2003 Employee Stock Purchase Plan was approved: For 7,808,990; Against 1,351,941; Abstain 129,912.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits:

4.1 Common Stock Purchase Warrant, dated December 22, 2003

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

(b) Reports:

On November 12, 2003, we filed a Current Report on Form 8-K furnishing our press release announcing the results of operations for the quarter ended September 30, 2003.

SIGNATURE

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

NEUROBIOLOGICAL TECHNOLOGIES, INC.

Dated: February 16, 2003

/s/ Paul E. Freiman

Paul E. Freiman
President, Chief Executive Officer
(Principal Executive and Accounting Officer)

and Director