

NEUROBIOLOGICAL TECHNOLOGIES INC /CA/
Form 10-Q
May 14, 2002

UNITED STATES
SECURITY 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 March 31, 2002

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 or other jurisdiction of incorporation
or organization)

94-3049219
(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 ☒ 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 17,570,609 shares outstanding as of May 1, 2002

NEUROBIOLOGICAL TECHNOLOGIES, INC.

FORM 10-Q

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PART 1. FINANCIAL INFORMATION**ITEM 1. FINANCIAL STATEMENTS****NEUROBIOLOGICAL TECHNOLOGIES, INC.**
(A development stage company)**CONDENSED BALANCE SHEETS**

	March 31, 2002	June 30, 2001
	(Unaudited)	(Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,086,973	\$ 3,626,700
Short-term investments	6,613,976	6,555,575
Interest receivable	114,149	132,044
Prepaid expenses and other	179,333	253,827
	<u> </u>	<u> </u>
Total current assets	7,994,431	10,568,146
Long-term investments	1,042,450	861,313
Property and equipment, net	11,297	28,820
	<u> </u>	<u> </u>
	<u>\$ 9,048,178</u>	<u>\$ 11,458,279</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 702,617	\$ 762,049
	<u> </u>	<u> </u>
Total current liabilities	702,617	762,049
Stockholders' equity:		
Convertible preferred stock, \$.001 par value, 5,000,000 shares authorized, 2,332,000 issued in series, 1,572,000 and 1,582,000 outstanding at March 31, 2002 and June 30, 2001, respectively	786,000	791,000
Common stock, \$.001 par value, 35,000,000 shares authorized, 17,570,609 and 17,503,699 outstanding at March 31, 2002 and June 30, 2001, respectively	43,756,557	43,660,557
Deferred compensation	(150,563)	(191,626)
Deficit accumulated during development stage	(36,046,433)	(33,563,701)
	<u> </u>	<u> </u>
Total stockholders' equity	8,345,561	10,696,230
	<u> </u>	<u> </u>
	<u>\$ 9,048,178</u>	<u>\$ 11,458,279</u>

See accompanying notes.

NEUROBIOLOGICAL TECHNOLOGIES, INC.
(A development stage company)

CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three months ended March 31,		Nine months ended March 31,		Period from August 27, 1987 (inception) through March 31, 2002
	2002	2001	2002	2001	
Revenues:					
License income	\$	\$	\$	\$ 2,531,250	\$ 6,881,250
Grant					149,444
Total revenue				2,531,250	7,030,694
Expenses:					
Research and development	504,153	450,584	1,120,347	1,004,261	29,278,787
General and administrative	657,028	808,293	1,685,962	1,927,581	17,018,514
Total expenses	1,161,181	1,258,877	2,806,309	2,931,842	46,297,301
Operating loss	(1,161,181)	(1,258,877)	(2,806,309)	(400,592)	(39,266,607)
Interest income	72,011	152,338	281,746	463,938	3,220,174
Income (loss) before income tax benefit	(1,089,170)	(1,106,539)	(2,524,563)	63,346	(36,046,433)
Income tax benefit	(41,831)		(41,831)		
Net income (loss)	\$ (1,047,339)	\$ (1,106,539)	\$ (2,482,732)	\$ 63,346	\$ (36,046,433)
Basic net income (loss) per share	\$ (0.06)	\$ (0.07)	\$ (0.14)	\$ 0.00	
Shares used in basic net income (loss) per share calculation	17,565,498	16,506,132	17,529,837	16,315,101	
Diluted net income (loss) per share	\$ (0.06)	\$ (0.07)	\$ (0.14)	\$ 0.00	
Shares used in diluted net income (loss) per share calculation	17,565,498	16,506,132	17,529,837	21,306,719	

See accompanying notes.

NEUROBIOLOGICAL TECHNOLOGIES, INC.
(A development stage company)

CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine months ended March 31,		Period from August 27, 1987 (inception) through March 31, 2002
	2002	2001	
OPERATING ACTIVITIES:			
Net income (loss)	\$ (2,482,732)	\$ 63,346	\$ (36,046,433)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	17,523	16,641	684,228
Gain on sale of property and equipment			(1,500)
Amortization of deferred stock compensation	41,063	41,063	123,187
Issuance of common stock, options and warrants for license rights and services			209,975
Changes in assets and liabilities:			
Interest receivable	17,895		(114,149)
Prepaid expenses and other current assets	74,494	(254,654)	(179,333)
Accounts payable and accrued expenses	(59,432)	192,770	702,617
Net cash (used in) provided by operating activities	(2,391,189)	59,166	(34,621,408)
INVESTING ACTIVITIES:			
Purchase of investments	(1,939,538)	(5,147,194)	(48,746,978)
Maturity of investments	1,700,000	2,905,574	41,090,552
Purchases of property and equipment, net		(23,524)	(412,463)
Proceeds from sale of property & equipment			1,500
Additions to patents and licenses			(283,062)
Net cash used in investing activities	(239,538)	(2,265,144)	(8,350,451)
FINANCING ACTIVITIES:			
Payment of note payable			(200,000)
Proceeds from short-term borrowings			435,000
Issuance of common stock, net	91,000	1,085,423	35,665,750
Issuance of preferred stock, net			8,158,082
Net cash provided by financing activities	91,000	1,085,423	44,058,832
(Decrease) increase in cash and cash equivalents	(2,539,727)	(1,120,555)	1,086,973
Cash and cash equivalents at beginning of period	3,626,700	7,387,076	
Cash and cash equivalents at end of period	\$ 1,086,973	\$ 6,266,521	\$ 1,086,973
SUPPLEMENTAL DISCLOSURES:			
Conversion of short-term borrowings to Series A preferred stock	\$	\$	\$ 235,000
Conversion of preferred stock to common stock	\$ 5,000	\$ 50,000	\$ 7,607,082
Deferred stock compensation related to options granted	\$	\$	\$ 273,750

See accompanying notes.

NEUROBIOLOGICAL TECHNOLOGIES, INC.
(A development stage company)

NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

March 31, 2002

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 nine month periods ended March 31, 2002 are not necessarily indicative of the results that may be expected for the fiscal year ended June 30, 2002.

The balance sheet at June 30, 2001 has been derived from the audited financial statements at that date but does not include all the information and footnotes required by generally accepted accounting principles for complete financial statements.

For further information, refer to the financial statements and footnotes included in our annual report on Form 10-K/A for the fiscal year ended June 30, 2001.

BASIC AND DILUTED NET INCOME (LOSS) PER SHARE

Net income (loss) per share is presented under the requirements of Financial Accounting Standards Board (FAS) No. 128, Earnings per Share. Basic income (loss) per share is computed based on the weighted average shares of common stock outstanding and excludes any options, warrants, and convertible securities. For the three and nine month periods ended March 31, 2002, and for the three month period ended March 31, 2001, potentially dilutive securities, such as options, warrants, and convertible preferred stock, have also been excluded from the computation of diluted net loss per share as their effect is antidilutive. For the nine month period ended March 31, 2001, diluted earnings per share is computed in the same manner and also gives effect to all dilutive common equivalent shares consisting of employee stock options, warrants, and the assumed conversion of convertible preferred stock. The following table sets forth the computation of basic and diluted earnings per share.

NEUROBIOLOGICAL TECHNOLOGIES, INC.
(A development stage company)

NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)
(Unaudited)

March 31, 2002

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2002	2001	2002	2001
Numerator for basic and diluted earnings per share net income (loss)	\$ (1,047,339)	\$ (1,106,539)	\$ (2,482,732)	\$ 63,346
Weighted average shares outstanding:				
Denominator for basic EPS	17,565,498	16,506,132	17,529,6837	16,315,101
Common stock equivalents:				
stock options				870,974
warrants				1,931,318
convertible preferred stock				2,189,326
Denominator for diluted EPS	17,565,498	16,506,132	17,529,837	21,306,719
Net income (loss) per share:				
Basic	\$ (0.06)	\$ (0.07)	\$ (0.14)	\$ 0.00
Diluted	\$ (0.06)	\$ (0.07)	\$ (0.14)	\$ 0.00

COMPREHENSIVE INCOME (LOSS)

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

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.

RECENT ACCOUNTING PRONOUNCEMENTS

In July 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 141, Business Combinations and SFAS No. 142, Goodwill and Other Intangible Assets. SFAS 141 requires that all business combinations be accounted for by the purchase method of accounting and changes the criteria for recognition of intangible assets acquired in a business combination. The provisions of SFAS 141 apply to all business combinations initiated after June 30, 2001. SFAS 142 requires that goodwill and intangible assets with indefinite useful lives no longer be amortized; however, these assets must be reviewed at least annually for impairment. Intangible assets with finite useful lives will continue to be amortized over their respective useful lives. The standard also establishes specific guidance for testing for impairment of goodwill and intangible assets with indefinite useful lives. The provisions of SFAS 142 will be effective for fiscal year 2003. The Company does not expect that the adoption of these statements will have a material impact on its financial position or results of operations.

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In October 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. SFAS 144 addresses financial accounting and reporting for the impairment of long-lived assets and for long-lived assets to be disposed of. The provisions of SFAS 144 will be effective for fiscal year 2003 and will be applied prospectively. The Company does not expect the adoption of this statement will have a material impact on its financial position or results of operations.

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 and our most recent Annual Report on Form 10-K, 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. We disclaim, however, any intent or obligation to update these forward-looking statements.

OVERVIEW

Neurobiological Technologies, Inc. (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 are developing neuroprotective and neuromodulatory agents to treat progressive neurological impairments characteristic of various nervous system disorders, including diabetic neuropathy, brain cancer and AIDS-related dementia. Our strategy is to in-license and develop early-stage drug candidates that target major medical needs and that may be rapidly commercialized.

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

In June 2000, Merz entered into an agreement with Forest Laboratories, Inc. (Forest) for the development and marketing of Memantine in the United States for the treatment of Alzheimer's disease, neuropathic pain and AIDS-related dementia. Forest is currently enrolling patients for the second pivotal Memantine clinical trial for the treatment of neuropathic pain. In August 2000, Merz entered into a strategic license and cooperation agreement with H. Lundbeck A/S (Lundbeck) of Copenhagen, Denmark for the further development and marketing of Memantine for the treatment of Alzheimer's disease, neuropathic pain and AIDS-related dementia. Lundbeck has acquired exclusive rights to Memantine in certain European markets, Canada, Australia and South Africa and semi-exclusive rights to co-market Memantine with Merz in other markets worldwide, excluding the United States, where Forest has development rights, and Japan, where Merz has granted development rights to Suntory Ltd. (Suntory). Memantine has been marketed by Merz in Germany since 1989 with the labeling dementia syndrome.

In February 2002, our strategic partner, Merz Pharma KGaA, was granted approvable status by the regulatory authorities in the European Union for Memantine as a treatment of Alzheimer's Disease. We expect the approvable status to be reviewed in June 2002 and anticipate that this review will lead to regulatory approval in Europe. In addition, Forest Laboratories, Inc. has stated that it will submit a New Drug Application in the United States by mid-year 2002 for Memantine as a treatment for Alzheimer's Disease.

If approved, Memantine will be the first in a new class of drugs called NMDA Receptor Inhibitors utilized for the treatment of this condition and we expect it will be the first drug ever approved for treatment of moderate to severe manifestations. Existing therapies belong to a group of drugs called acetylcholinesterase inhibitors and are used to treat mild to moderate manifestations of the disease.

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 in the future due to ongoing research and development efforts.

CRITICAL ACCOUNTING POLICIES

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

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.

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, outside experts and consultants and useful lives of property and equipment.

RESULTS OF OPERATIONS

All of our revenues in fiscal 2001 were license fee payments from Merz related to our portion of payments received by Merz pursuant to Merz's agreements with its partners. We received no such payments in the nine months ended March 31, 2002. Due to the nature of our agreement with Merz, the timing and amount of any future payments is uncertain and may vary significantly from quarter to quarter.

Our research and development expenses increased to approximately \$504,000 and \$1,120,000 in the three and nine months ended March 31, 2002 from approximately \$451,000 and \$1,004,000 in the three and nine months ended March 31, 2001. The increases were primarily due to costs associated with the initiation of long-term toxicology studies for the development of XERECEPT. General and administrative expenses decreased to approximately \$615,000 and \$1,644,000 in the three and nine months ended March 31, 2002 from \$808,000 and \$1,928,000 in the same periods of the prior year. The decreases were primarily due to decreased expenditures in activities relating to seeking financing and corporate partnerships. Interest income decreased to approximately \$72,000 and \$282,000 in the three and nine months ended March 31, 2002 from approximately \$152,000 and \$464,000 in the same periods of the prior year due to lower average interest rates and lower average invested cash balances.

LIQUIDITY AND CAPITAL RESOURCES

From inception through March 31, 2002, 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 \$8.7 million as of March 31, 2002. We believe that our capital resources will be adequate to fund our 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, we expect to incur additional losses in the fiscal year ending June 30, 2002. Merz and Merz's marketing partners will pay all future development costs of Memantine.

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

- the amount of payments received from marketing agreements for Memantine;
- the amount of royalties received from Merz for future sales of Memantine;
- the progress of our clinical development programs;
- the time and cost involved in obtaining regulatory approvals;
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- competing technological and market developments;
- our ability to establish collaborative relationships;
- and
- the development of commercialization activities and arrangements.

RISK FACTORS

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

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

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

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

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

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

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

All of our revenues in fiscal 2001 were license fee payments from Merz related to our portion of payments received by Merz pursuant to Merz's agreements with its partners. We received no such payments in the nine-month period ended March 31, 2002 and there can be no assurance that we will receive any payments from Merz in fiscal 2002. The only revenues that we will receive in the foreseeable future for Memantine are royalties on product sales by Merz or its marketing partners and our share of payments received by Merz from its partners. Under certain circumstances, Merz can terminate its agreement with us upon six months notice. The termination of our agreement with Merz or any failure by Merz or its partners to successfully commercialize Memantine after its development would have a material adverse effect on our business, financial condition and results of operations.

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, manufacture and commercialization of our potential products.

We have entered into various contractual arrangements (many of which are non-exclusive) with consultants, academic collaborators, licensors, licensees and others, and we are dependent upon the level of commitment and subsequent success of these outside parties in performing their responsibilities. Certain of these agreements place significant responsibility for preclinical testing and human clinical trials and for preparing and submitting submissions for regulatory approval for potential products on the collaborator, licensor or contractor. If the collaborator, licensor or contractor fails to perform, our business, financial conditions and results may be adversely affected.

We have also relied on scientific, technical, 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 pay royalties and make other payments to such parties. Our failure to make such payments could cause us to lose rights to technology or data under these agreements.

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:

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

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. 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.

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

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

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. We rely on third-party contract manufacturers to provide us with XERECEPT which is manufactured to our specifications using established chemical synthesis methods. We have performed audits on these third-party manufacturers to ensure compliance with the current Good Manufacturing Practice (cGMP) regulations. We currently have no plans to build or develop an in-house manufacturing capability for XERECEPT. We believe that alternative cGMP suppliers of the bulk drug and finished dosage forms of the product will be available to meet our needs. However, 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 our products; and
- adverse effects on FDA pre-market approval of potential products and contract manufacturers if they do not adhere to cGMP regulations.

Therefore, 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.

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 have a limited amount of product liability insurance to cover liabilities arising from 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.

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

Each person currently employed by NTI serves an essential function. Any reductions in work force could impair our ability to manage ongoing clinical trials and may have a material adverse effect on our operations.

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

The average daily trading volume of our common stock has been low compared to that of other biopharmaceutical companies. Our common stock was delisted from The Nasdaq Stock Market in February 1998 because we failed to meet the financial conditions necessary to remain listed. In July 2000, we were approved for listing on The Nasdaq SmallCap Market. In light of the historic volatility of our stock price, it is possible that we may not continue to qualify for listing on that market. Our stock price has varied between \$3.92 and \$5.09 for the quarter ending March 31, 2002.

Factors that may cause volatility in our stock price include:

- the results of preclinical studies and clinical trials by the Company, Merz or its marketing partners or our competitors;
- other evidence of the safety or efficacy of products of the Company, Merz or its marketing partners or our competitors;
- announcements of technological innovations or new therapeutic products by the Company or our competitors;
- developments in patent or other proprietary rights of the Company 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 investments, consisting primarily of investment grade securities. As of March 31, 2002, 88% 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 or revenues denominated in foreign country currencies and therefore are not subject to foreign currency exchange risk.

PART II. OTHER INFORMATION

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits:

None.

(b) Reports:

The Company did not file a report on Form 8-K during the three months ended March 31, 2002.

SIGNATURES

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.

/s/ PAUL E.
FREIMAN

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

Dated: May 14, 2002