NEUROBIOLOGICAL TECHNOLOGIES INC /CA/
Form 10-Q
November 13, 2002
Table of Contents

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 September 30, 2002

OR

o **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 o

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: 17,762,571 shares outstanding as of October 25, 2002

Table of Contents

NEUROBIOLOGICAL TECHNOLOGIES, INC.

FORM 10-Q

TABLE OF CONTENTS

Table of Contents

PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NEUROBIOLOGICAL TECHNOLOGIES, INC.
(A development stage company)

CONDENSED BALANCE SHEETS

	September 30, 2002	June 30, 2002
	(unaudited)	*(Note 1)*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,199,687	$ 277,062
Short-term investments	6,009,167	5,417,434
Interest receivable	63,706	155,896
Prepaid expenses and other	190,451	244,534
Total current assets	7,463,011	6,094,926
Long-term investments	310,878	1,564,598
Property and equipment, net	2,673	5,456
	$ 7,776,562	$ 7,664,980
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,142,944	$ 1,052,277
Total current liabilities	1,142,944	1,052,277
Stockholders equity:		
Convertible preferred stock, $.001 par value, 5,000,000 shares authorized, 1,372,000 Series A shares issued and outstanding at September 30, 2002 and June 30, 2002	686,000	686,000
Common stock, $.001 par value, 35,000,000 shares authorized, 17,771,071 and 17,783,571 outstanding at September 30, 2002 and June 30, 2002, respectively	43,821,582	43,876,705
Deferred compensation	(123,188)	(136,876)
Deficit accumulated during development stage	(37,773,953)	(37,830,056)
Accumulated other comprehensive income	23,177	16,930
Total stockholders equity	6,633,618	6,612,703
	$ 7,776,562	$ 7,664,980

See accompanying notes.

Table of Contents

NEUROBIOLOGICAL TECHNOLOGIES, INC.
(A development stage company)

CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three months ended September 30,		Period from August 27, 1987 (inception) through September 30, 2002
	2002	2001	
Revenues			
License	$ 1,406,230	$	$ 8,287,480
Grant			149,444
Total revenues	1,406,230		8,436,924
Expenses			
Research and development	906,759	255,561	31,078,602
General and administrative	488,611	499,690	18,458,495
Total expenses	1,395,370	755,251	49,537,097
Operating income (loss)	10,860	(755,251)	(41,100,173)
Interest income	45,243	116,697	3,326,220
Net income (loss)	$ 56,103	$ (638,554)	$ (37,773,953)
Basic net income (loss) per share	$ 0.00	$ (0.04)	
Weighted average shares used in basic net income (loss) per share calculation	17,782,288	17,503,699	
Diluted net income (loss) per share	$ 0.00	$ (0.04)	
Weighted average shares used in diluted net income (loss) per share calculation	19,848,357	17,503,699	

See accompanying notes.

Table of Contents

NEUROBIOLOGICAL TECHNOLOGIES, INC.
(A development stage company)

CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

	Three months ended September 30,		Period from August 27, 1987 (inception) through September 30, 2002
	2002	2001	
OPERATING ACTIVITIES:			
Net income (loss)	$ 56,103	$ (638,554)	$ (37,773,953)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	2,783	5,841	692,852
Gain on sale of property and equipment			(1,500)
Amortization of deferred stock compensation	13,688	13,688	150,562
Issuance of common stock, options and warrants for license rights and services			209,975
Changes in assets and liabilities:			
Interest receivable	92,190	15,420	(63,706)
Prepaid expenses and other current assets	54,084	71,104	(190,451)
Accounts payable and accrued expenses	90,667	(233,202)	1,142,944
Net cash provided by (used in) operating activities	309,514	(765,703)	(35,833,277)
INVESTING ACTIVITIES:			
Purchase of investments	(6,631,766)	(5,421,046)	(54,687,420)
Maturity of investments	7,300,000	4,927,360	48,390,552
Purchases of property and equipment, net			(412,463)
Proceeds from sale of property & equipment			1,500
Additions to patents and licenses			(283,062)
Net cash provided by (used in) investing activities	668,234	(493,686)	(6,990,893)
FINANCING ACTIVITIES:			
Payment of note payable			(200,000)
Proceeds from short-term borrowings			435,000
Issuance of common stock, net	10,502		35,696,400
Repurchase of common stock	(65,625)		(65,625)
Issuance of preferred stock, net			8,158,082
Net cash provided by (used in) financing activities	(55,123)		44,023,857
Increase (decrease) in cash and cash equivalents	922,625	(1,259,389)	1,199,687
Cash and equivalents at beginning of period	277,062	3,626,700	
Cash and equivalents at end of period	$ 1,199,687	$ 2,367,311	$ 1,199,687
SUPPLEMENTAL DISCLOSURES:			
Conversion of short-term borrowings to Series A preferred stock	$	$	$ 235,000
Conversion of preferred stock to common stock	$	$	$ 7,707,082

Deferred stock compensation related to options granted	$	$	$ 273,750

See accompanying notes.

Table of Contents

NOTES TO CONDENSED FINANCIAL STATEMENTS

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-month period ended September 30, 2002 are not necessarily indicative of the results that may be expected for the fiscal year ended June 30, 2003.

The balance sheet at June 30, 2002 has been derived from the audited financials 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 for the fiscal year ended June 30, 2002.

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 net 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 months ended September 30, 2002, 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. Potentially dilutive securities, such as options, warrants, and convertible preferred stock, have also been excluded from the computation of diluted net loss per share for the three months ended September 30, 2001 as their effect is antidilutive. The following table sets for the computation of basic and diluted earnings per share.

	Three Months Ended September 30,	
	2002	2001
Numerator for basic and diluted earnings per share net income (loss)	$ 56,103	$ (638,554)
Denominator for basic earnings per share weighted average shares Effect of dilutive securities:	17,782,288	17,503,699
Employee stock options	61,506	
Warrants	632,563	
Assumed conversion of convertible preferred stock	1,372,000	
Denominator for diluted earnings per share	19,848,357	17,503,699
Basic net income (loss) per share	$ 0.00	$ (0.04)
Diluted net income (loss) per share	$ 0.00	$ (0.04)

Table of Contents

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.

NOTE 2-INVESTMENTS

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

September 30, 2002

	Cost	Gross Unrealized Gains	Market Value
Corporate debt obligations	$ 5,283	$ 22	$ 5,305
U.S. Government obligations	1,014	1	1,015
Total investments	$ 6,297	$ 23	$ 6,320

June 30, 2002

	Cost	Gross Unrealized Gains	Market Value
Corporate debt obligations	$ 6,445	$ 17	$ 6,462
U.S. Government obligations	520		520
Total investments	$ 6,965	$ 17	$ 6,982

NOTE 3-STOCK REPURCHASE

In August 2002, our board of directors authorized the repurchase of up to 500,000 shares of our 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 September 30, 2002, we had repurchased 23,500 shares of common stock under this program at an aggregate purchase price of $65,625.

Table of Contents

NOTE 4-COMPREHENSIVE INCOME (LOSS)

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

	Three Months Ended September 30	
	2002	**2001**
Net income (loss)	$ 56,103	$ (638,554)
Other comprehensive income	6,247	
Comprehensive income (loss)	$ 62,350	$ (638,554)

Table of Contents

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. 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 evaluation 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- 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 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. 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 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 Suntory Ltd.

In July 2001, Forest initiated the second of two trials necessary for the submission of a New Drug Application, or NDA, with the FDA for diabetic neuropathy. This is a large-scale, multi-center, double-blind placebo controlled trial to assess the safety and efficacy of Memantine in the treatment of diabetic neuropathy and is expected to have results in the first half of 2003. We conducted the first such trial with an enrollment of over 400 patients and reported positive results in January 2000.

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 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 September 2002, Forest voluntarily withdrew its previously filed NDA and announced that it expected to file a new NDA incorporating the results of the Phase III study by the end of 2002.

Forest is presently conducting three additional placebo-controlled studies in either mild-to-moderate or moderate-to-severe Alzheimer s disease. The results are expected no earlier than 2003, and are expected to be used as additional evidence of efficacy.

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 September 30, 2002, our deficit accumulated during the development stage was $37.8 million.

Table of Contents

RESULTS OF OPERATIONS

Our revenues are $1.4 million for the three months ended September 30, 2002. In July 2002, Merz received a payment from Lundbeck relating to Memantine s approval in Europe for the treatment of Alzheimer s disease. This triggered a $1.4 million payment to NTI in August 2002 from Merz under our 1998 strategic research and marketing cooperation agreement. As there are no future obligations, the revenue was recognized when received. There was no revenue for the three months ended September 30, 2001.

Our research and development expenses increased to approximately $907,000 for the three months ended September 30, 2002, up from approximately $256,000 for the three months ended September 30, 2001. The increase was primarily due to costs associated with long-term toxicology studies and manufacturing XERECEPT . General and administrative expenses were approximately $489,000 for the three months ended September 30, 2002, compared to $500,000 for the same period of the prior year. Interest income decreased to approximately $45,000 for the three months ended September 30, 2002, down from approximately $117,000 for 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 $14.7 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 II and Phase III clinical trials for our development of XERECEPT and CRH-analogues and related administrative support. 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.

LIQUIDITY AND CAPITAL RESOURCES

From inception through September 30, 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 $7.5 million as of September 30, 2002, compared to approximately $7.3 million at June 30, 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 and the quarter ended September 30, 2002, we expect to incur additional operating losses over at least the next twelve months as we continue to expand our research and development efforts. We expect to incur substantial costs in fiscal 2003 primarily for Phase II and Phase III clinical trials of XERECEPT and CRH-analogues and related administrative support. 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;
- the acquisition or licensing of new drug candidates;
- competing technological and market developments;
- our ability to establish collaborative relationships; and
- the progress of commercialization activities and arrangements.

Our only long-term capital obligation relates to our leased facility in Richmond, California. Effective August 1, 2002, we entered into a lease agreement for our current premises. The minimum payment is

Table of Contents

approximately $89,000 for the one-year term of the lease, which will expire July 2003. The lease is renewable for two additional one-year periods.

RISK FACTORS

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

We had no revenues in fiscal 2002. All of our revenues in fiscal 2001 and to date in fiscal 2003 have been license fees 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. 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 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 can terminate our agreement upon six months notice. The termination of our agreement with Merz or any failure by Merz or its partners to successfully commercialize Memantine after its development would have a material adverse effect on our business, financial 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;
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, Merz and its marketing partners may not receive approval to market Memantine for Alzheimer s disease in the United States or elsewhere, or to market Memantine for other indications. Recently, Forest announced the voluntary withdrawal of its previously filed NDA for the use of Memantine in treating Alzheimer s disease. Although Forest stated that it expects to file a new NDA incorporating the results of an additional Phase III study by the end of 2002, further delays or the failure to obtain regulatory approvals would adversely affect our revenues.

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. Except for Memantine, which was recently approved for marketing in Europe for the treatment of Alzheimer s disease, we 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 of XERECEPT in later-stage clinical trials. It is possible that XERECEPT will not receive regulatory approval or will not be successfully commercialized.

Table of Contents

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, 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.

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. 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

Table of Contents

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

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

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. XERECEPT has been manufactured by established methods using chemical synthesis to our specifications. We performed audits on our contractors who supplied XERECEPT to assess compliance with the current Good Manufacturing Practice, 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.

Clinical trials or marketing of any of our potential products may expose us to liability claims from the use of such products which our insurance may not cover.

We currently have a limited amount of product liability insurance only to cover liabilities arising from clinical trials. It is possible that our current insurance may not be adequate to cover liabilities arising from our clinical trials.

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

Table of Contents

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 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. Because of our relatively low trading volume, our stock price can be highly volatile.

Factors that may cause volatility in our stock price include:

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 September 30, 2002, the fair value of our investments was $6.3 million and approximately 95% of our total portfolio will mature in one year or less, with the remainder maturing in less than two years. A hypothetical 50 basis point increase in interest rates would not result in a material decrease or increase in the fair value of our available-for-sale securities. We have no investments denominated in foreign country currencies and therefore our investments are not subject to foreign currency exchange risk. We do not use or hold derivative financial instruments.

ITEM 4. CONTROLS AND PROCEDURES

Within the 90 days prior to the date of this report, we carried out an evaluation, under the supervision and with the participation of our management, including our President and Chief Executive Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-14. Based upon that evaluation, our President and Chief Executive Officer concluded that our disclosure controls and procedures are effective in timely alerting him to material information relating to us that is required to be included in our periodic Securities and Exchange Commission filings. There have been no significant changes in our internal controls or in other factors that could significantly affect internal controls subsequent to the date we carried out its evaluation.

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.

Table of Contents

PART II. OTHER INFORMATION

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

	(a)	Exhibits:
99.1		Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
	(b)	Reports:

None.

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: November 12, 2002

/s/ PAUL E. FREIMAN

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

15

Table of Contents

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Paul E. Freiman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Neurobiological Technologies, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and I have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 12, 2002

/s/ PAUL E. FREIMAN

Paul E. Freiman
Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

Table of Contents

Exhibit Index

Exhibit	Description
99.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002