

NEUROBIOLOGICAL TECHNOLOGIES INC /CA/

Form 10-Q

February 09, 2005

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## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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### FORM 10-Q

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(Mark One)

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

For the quarterly period ended December 31, 2004

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

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## NEUROBIOLOGICAL TECHNOLOGIES, INC.

(Exact name of Registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**94-304929**  
(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)

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act): 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: 27,053,695 shares outstanding as of January 27, 2005.

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**NEUROBIOLOGICAL TECHNOLOGIES, INC.**

**FORM 10-Q**

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**Table of Contents****PART 1. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****NEUROBIOLOGICAL TECHNOLOGIES, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

	<b>December 31,</b>	<b>June 30,</b>
	<b>2004</b>	<b>2004</b>
	<i>(unaudited)</i>	<i>(Note 1)</i>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 47,880	\$ 2,012,452
Short-term investments	6,381,917	11,849,763
Interest receivable	66,038	103,259
Prepaid expenses and other	531,388	277,027
	<hr/>	<hr/>
Total current assets	7,027,223	14,242,501
Long-term investments	8,697,413	6,871,344
Property and equipment, net	341,601	6,209
Other tangible assets, net	893,302	
Intangible assets, net	7,150,056	
Deferred acquisition costs		263,544
	<hr/>	<hr/>
<b>TOTAL ASSETS</b>	<b>\$ 24,109,595</b>	<b>\$ 21,383,598</b>
	<hr/>	<hr/>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 741,695	\$ 258,855
Accrued professional fees	159,893	210,025
Accrued clinical trial expenses	159,392	42,550
Accrued toxicology and manufacturing expenses	275,427	42,284
Accrued compensation	150,125	
Accrued liabilities	95,939	106,835
	<hr/>	<hr/>
Total current liabilities	1,582,471	660,549
Stockholders equity:		
Convertible Series A Preferred stock, \$.001 par value, 5,000,000 shares authorized, 2,332,000 issued in series, 524,000 and 534,000 outstanding at December 31, 2004 and June 30, 2004, respectively	262,000	267,000
Common stock, \$.001 par value, 35,000,000 shares authorized, 27,053,695 and 23,993,938 outstanding at December 31, 2004 and June 30, 2004, respectively	73,032,378	62,880,926
Deferred compensation		(27,376)

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Accumulated deficit	(50,752,074)	(42,324,627)
Accumulated other comprehensive loss	(15,178)	(72,874)
Total stockholders' equity	22,527,124	20,723,049
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 24,109,595</b>	<b>\$ 21,383,598</b>

See accompanying notes.

**Table of Contents****NEUROBIOLOGICAL TECHNOLOGIES, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(Unaudited)

	Three months ended		Six months ended	
	December 31,		December 31,	
	2004	2003	2004	2003
<b>REVENUES</b>				
License	\$	\$ 281,230	\$	\$ 281,230
Royalty		694,338		18,659
			1,211,190	28,443
Total revenue		694,338	299,889	1,211,190
				309,673
<b>EXPENSES</b>				
Research and development		2,268,907	513,365	3,432,667
Acquired in-process research and development				841,290
General and administrative		1,090,422	854,842	4,251,335
				1,431,080
Total expenses		3,359,328	1,368,207	9,705,804
				2,272,370
Operating loss		(2,664,990)	(1,068,318)	(8,494,613)
Investment income (loss)		(10,182)	9,270	67,166
				30,533
<b>NET LOSS</b>	\$	\$ (2,675,172)	\$ (1,059,048)	\$ (8,427,447)
				\$ (1,932,164)
<b>BASIC AND DILUTED NET LOSS PER SHARE</b>				
	\$	(0.10)	(0.06)	(0.32)
				(0.10)
Shares used in basic and diluted net loss per share calculation		26,846,878	19,206,054	26,008,306
				19,019,739

See accompanying notes.

**Table of Contents****NEUROBIOLOGICAL TECHNOLOGIES, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS***(Unaudited)*

	Six months ended	
	December 31,	
	2004	2003
<b>OPERATING ACTIVITIES:</b>		
Net loss	\$ (8,427,447)	\$ (1,932,164)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	362,094	3,272
Acquired in-process research and development	4,251,335	
Loss on sale of property and equipment		2,849
Amortization of deferred stock compensation	27,376	27,375
Issuance of common stock, options and warrants for license rights and services		28,200
Changes in assets and liabilities:		
Interest receivable	37,221	31,561
Prepaid expenses and other current assets	(254,361)	206,498
Accounts payable and accrued liabilities	921,923	(198,126)
Net cash used in operating activities	(3,081,859)	(1,830,535)
<b>INVESTING ACTIVITIES:</b>		
Acquisition, net of cash acquired	(2,950,690)	
Purchase of investments	(57,274,046)	(2,919,837)
Maturity and sale of investments	60,973,519	5,434,507
Purchases of property and equipment	(325,246)	(2,383)
Net cash provided by (used in) investing activities	423,537	2,512,287
<b>FINANCING ACTIVITIES:</b>		
Issuance of common stock	693,750	58,913
Net cash provided by financing activities	693,750	58,913
Increase (decrease) in cash and cash equivalents	(1,964,572)	740,665
Cash and equivalents at beginning of period	2,012,452	66,138
Cash and equivalents at end of period	\$ 47,880	\$ 806,803
<b>Supplemental disclosure of non-cash investing activities:</b>		
Issuance of common stock for acquisition of Empire	\$ 9,452,702	\$
Conversion of preferred stock to common stock	\$ 5,000	\$ 200,000

See accompanying notes.



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**NEUROBIOLOGICAL TECHNOLOGIES, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

*(Unaudited)*

**December 31, 2004**

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

**BASIS OF PRESENTATION**

The accompanying unaudited condensed consolidated financial statements of Neurobiological Technologies, Inc. and its subsidiary ( NTI or the Company ) have been prepared in accordance with accounting principles generally accepted for reporting on interim periods and pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC ) contained in the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, the enclosed condensed consolidated financial statements do not include all of the information and footnote disclosures required by generally accepted accounting principles for reporting on other than interim periods. These condensed consolidated financial statements should be read in conjunction with the financial statements and notes in the Company s Annual Report on Form 10-K for the year ended June 30, 2004.

The notes and accompanying condensed consolidated financial statements are unaudited and reflect all adjustments, which, in the opinion of management, are necessary for a fair presentation of results for the interim periods presented. Such adjustments consist only of normally recurring items. Operating results for the three and six-month periods ending December 31, 2004 are not necessarily indicative of the results that may be expected for the fiscal year ended June 30, 2005, or any future period. The preparation of these condensed consolidated financial statements in conformity with accounting principles generally accepted for reporting on interim periods in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reported periods. Actual results could differ from these estimates.

The condensed consolidated balance sheet at June 30, 2004 has been derived from the audited financial statements at that date but does not include all the information and notes required by generally accepted accounting principles for financial statements prepared for other than interim periods.

**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 of 807,755 and 2,791,981, which consist of options, warrants, and convertible preferred stock, have been excluded from the computation of diluted net loss per share for the three months ended December 31, 2004 and 2003, respectively, as their effect is antidilutive. Potentially dilutive securities of 510,044 and 2,757,244, which consist of options, warrants, and convertible preferred stock, have been excluded from the computation of diluted net loss per share for the six months ended December 31, 2004 and 2003, respectively, 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. Revenues associated with milestones are recognized as earned, based on completion of development milestones, either upon receipt, or when collection is assured. Revenues associated with royalty agreements on sales of products by our marketing partners are recognized when the proceeds are received due to the limited sales history of the product and our inability to estimate such sales.

**Table of Contents****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 25, Accounting for Stock Issued to Employees ( APB 25 ) and related Interpretations because the alternative fair value accounting provided under Statement of Financial Accounting Standards ( SFAS ) 123, Accounting for Stock-Based Compensation SFAS 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 SFAS 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 SFAS 123, and as amended by SFAS 148, Accounting for Stock-Based Compensation Transition and Disclosure, the Company elected to continue to apply the provisions of 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 equal to or greater than fair value at the date of grant.

Pro forma information regarding net loss and net loss per share is required by SFAS 148 and has been determined as if the Company had accounted for its employee stock options under the fair value method prescribed by the SFAS 123. There were new grants for a total of 255,500 shares during the three months ended December 30, 2004. There were new grants for a total of 34,000 shares during the three months ended December 30, 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, except for per share data).

	Three months ended December 31,		Six months ended December 31,	
	2004	2003	2004	2003
Net loss as reported	\$ (2,675)	\$ (1,059)	\$ (8,427)	\$ (1,932)
Add back:				
Stock-based employee compensation expense included in net loss as reported		14	27	27
Deduct:				
Stock-based employee expense determined under SFAS 123	(249)	(137)	(448)	(254)
Pro forma net loss	<u>\$ (2,924)</u>	<u>\$ (1,182)</u>	<u>\$ (8,848)</u>	<u>\$ (2,159)</u>
Basic and diluted net loss per share as reported	<u>\$ (0.10)</u>	<u>\$ (0.06)</u>	<u>\$ (0.32)</u>	<u>\$ (0.10)</u>
Basic and diluted pro forma net loss per share	<u>\$ (0.11)</u>	<u>\$ (0.06)</u>	<u>\$ (0.34)</u>	<u>\$ (0.11)</u>

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions, are fully transferable and are actively traded. 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.

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In December 2004, the FASB issued Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment ( SFAS 123(R) ) which requires all share-based payments to employees, including grants of stock options, to be recognized in the financial statements based on their fair values. As a result, the cost of employee services received in exchange for a grant of an equity instrument will be measured at fair value on the grant-date of the award and recorded as expense over the period during which the employee is required to provide service in exchange for the award. Pro forma disclosure of such cost is no longer an alternative for disclosing the cost share-based payments to employees.

SFAS 123(R) is effective at the beginning of the first interim or annual period beginning after June 15, 2005 and may be adopted using either the *Modified-Prospective Transition* method or the *Modified-Retrospective Transition* method of application. Using the *Modified-Prospective Transition* method, the Company would recognize the cost of share-based payments based on their grant-date fair value from the beginning of the fiscal period in which the provisions of SFAS 123(R) are first adopted. Measurement and assignment of compensation cost for share-based payments granted prior to, but not vested as of the date of adopting SFAS 123(R), would be based upon the same estimate of grant-date fair value used previously under SFAS 123, whether the estimate was recognized in the financial statements or disclosed only in a pro forma manner. Recognizing a liability for share-based payments made prior to, but not vested as of the date of adopting SFAS 123(R), would be recognized as the cumulative effect of a change in accounting principle. Using the *Modified-Retrospective Transition* method of application, the Company would be allowed to restate previously reported periods by recognizing compensation expense in the amounts previously reported as pro forma disclosure under the earlier provisions of SFAS 123. New awards and vested awards would be accounted for in the same manner as the *Modified-Prospective Transition* method.

We will adopt SFAS 123(R) effective July 1, 2005, and are currently evaluating the impact that this will have on our operating results.

**NOTE 2 - ACQUISITION OF EMPIRE PHARMACEUTICALS, INC.**

In July 2004, NTI acquired the assets of Empire Pharmaceuticals, Inc. ( Empire ), a privately held corporation, through the merger of Empire into Empire Acquisition Corp., a wholly-owned subsidiary of NTI. Pursuant to the transaction, NTI acquired worldwide rights to Viprinex™ (ancrod), a late-stage reperfusion therapy for use in treatment of ischemic stroke. The acquisition of Empire is accounted for as a purchase of assets in accordance with SFAS 141, Business Combinations and under SFAS 142, Goodwill and Other Intangible Assets. Accordingly, the results of operations of Empire have been included in the accompanying condensed consolidated financial statements of operations from the date of the acquisition. All intercompany balances at December 31, 2004 have been eliminated in consolidation.

As a result of the acquisition, all of Empire's issued and outstanding capital stock immediately prior to the acquisition was automatically converted into the right to receive an aggregate of 2,399,163 shares of NTI's common stock and \$1,500,000 in cash. Additionally, NTI paid \$500,000 to Empire's principal stockholder to partially reimburse advances made by the stockholder to Empire. If pivotal Phase III trials for Viprinex are commenced as currently planned, NTI will issue an additional 2,375,170 shares and pay an additional \$1,515,675 to the selling stockholders of Empire and will pay Empire's principal stockholder an additional \$484,325 for advances he made to Empire. Excluding the contingent consideration that will be paid if and when pivotal Phase III trials for Viprinex are commenced, the aggregate purchase price was \$12,669,184, which consists of common stock valued at \$9,452,702, cash of \$2,000,020, including \$20 for fractional shares, and acquisition-related costs of \$1,216,462. The additional amounts payable upon commencement of the Phase III trials are being treated as contingent consideration. In accordance with SFAS 141, the total purchase price has been allocated to the tangible and intangible assets acquired and liabilities assumed based upon management's estimates of current fair values and may change as additional information becomes available. Intangible assets resulting from the acquisition will be accounted for according to SFAS 142, Goodwill and Other Intangible Assets.

*IN-PROCESS RESEARCH AND DEVELOPMENT*

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As part of the purchase price allocation, all intangible assets were identified and valued. It was determined that certain development technology, which was in-process, had value. As a result of this identification and valuation process, the Company allocated \$4,251,335 of the purchase price to in-process

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research and development. This allocation represents the estimated fair value based upon risk-adjusted cash flows related to incomplete research and development activities associated with Viprinex and preparation for Phase III clinical trials. At the date of the acquisition, the development of Viprinex had not yet reached technological feasibility and the research and development in progress had no alternative future uses. Accordingly, the acquired in-process research and development was charged to expense as of the date of the acquisition, in accordance with accounting principles generally accepted in the United States.

*PURCHASE PRICE ALLOCATION*

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed, at the date of acquisition for an aggregate purchase price of \$12,669,184, including acquisition costs.

	<b>Amount</b>
Current assets	\$ 2,900
Property and equipment, net	16,604
Patents	78,245
Other tangible assets	965,027
License agreement	7,355,073
In-process research and development	4,251,335
<b>Total assets acquired</b>	<b>\$ 12,669,184</b>

License agreements and patents, in the table above, are included in Intangible assets in the accompanying condensed consolidated balance sheet, net of accumulated amortization. Other tangible assets in the table above, which consist primarily of snake venom and snake venom compound from which Viprinex is derived, are included in Other tangible assets in the accompanying condensed consolidated balance sheet, net of accumulated depreciation.

Depreciation and amortization expense related to the acquired tangible and intangible assets that will continue to be depreciated and amortized in the future was \$39,880 and \$154,861, respectively, during the quarter, and \$73,114 and \$283,912, respectively, during the six months ended December 31, 2004. Acquired tangible and intangible assets are depreciated and amortized using the straight-line method over the anticipated useful lives of: twelve years for the license agreement with Abbott Laboratories; four to eight years for snake venom compound and snake venom; and twelve years for certain patents. The estimated depreciation and amortization expense related to acquired tangible and intangible assets is summarized in the following table.

	<b>Amount</b>
Six months ending June 30, 2005	\$ 388,763
Year ending June 30, 2006	778,006
Year ending June 30, 2007	778,006
Year ending June 30, 2008	778,006
Year ending June 30, 2009	709,269
Year ending June 30, 2010	706,281

Total	\$ 4,138,331
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*PRO FORMA RESULTS*

The following unaudited pro forma financial information presents the combined results of operations of NTI and Empire as if the acquisition had occurred as of the beginning of the periods presented. The pro forma results for the six months ended December 31, 2004 include \$281,782 of transaction fees and expenses incurred by Empire related to the acquisition during the period and were recorded in the quarter ended September 30, 2004, but exclude \$4,251,335 of research and development expenses recorded during the quarter ended September 30, 2004. The unaudited pro forma financial information is based upon available information and certain assumptions that management believes are reasonable. The unaudited pro forma financial information is not intended to represent or be indicative of the consolidated results of operations or financial condition of the Company that would have been reported



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had the acquisition been completed as of the dates presented and should not be taken as representative of the future consolidated results of operations or financial condition of the Company.

	Quarter ended		Six months ended	
	December 31,		December 31,	
	2004	2003	2004	2003
Total revenues	\$ 694,338	\$ 299,889	\$ 1,211,190	\$ 309,763
Net loss	2,675,172	1,702,751	8,779,146	2,602,827
Basic and diluted net loss per share	\$ (0.10)	\$ (0.08)	\$ (0.34)	\$ (0.12)

**NOTE 3 - INVESTMENTS**

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

**December 31, 2004**

	Amortized Cost	Market Value	Gross Unrealized (Losses)	Gross Unrealized Gains
<b>Securities maturing within 1 year</b>				
Corporate securities	\$ 71	\$ 70	\$ (1)	
Municipal securities	200	200		
U.S. Government securities	6,109	6,112		3
	<u>6,380</u>	<u>6,382</u>	<u>(1)</u>	<u>3</u>
<b>Securities maturing between 1 and 5 years</b>				
Securities issued by foreign governments and agencies	20	20		
Mortgage and asset-backed securities	200	183	(17)	
Corporate securities	2,995	2,980	(15)	
	<u>3,215</u>	<u>3,183</u>	<u>(32)</u>	
<b>Securities maturing after 5 years</b>				
Securities issued by foreign governments and agencies	80	80		
Corporate securities	1,693	1,694		1
Mortgage and asset-backed securities	3,726	3,740		14
	<u>5,499</u>	<u>5,514</u>		<u>15</u>
	<u>\$ 15,094</u>	<u>\$ 15,079</u>	<u>(33)</u>	<u>18</u>

**June 30, 2004**

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	<u>Amortized Cost</u>	<u>Market Value</u>	<u>Gross Unrealized (Losses)</u>
<b>Securities maturing within 1 year</b>			
Corporate securities	\$ 7,772	\$ 7,766	\$ (6)
U.S. Government securities	4,097	4,084	(13)
	<u>11,869</u>	<u>11,850</u>	<u>(19)</u>
<b>Securities maturing between 1 and 5 years</b>			
Corporate securities	2,623	2,598	(25)
U.S. Government securities	4,302	4,273	(29)
	<u>6,925</u>	<u>6,871</u>	<u>(54)</u>
<b>Total investments</b>	<b>\$ 18,794</b>	<b>\$ 18,721</b>	<b>\$ (73)</b>

**Table of Contents****NOTE 4 - EQUITY TRANSACTIONS**

During the quarter ended December 31, 2004, warrants were exercised through a cashless exercise in accordance with the terms of the warrants and 245,265 shares of common stock were issued to the warrant holders. Additionally, warrants were exercised during the quarter ended December 31, 2004, and 319,000 shares of common stock were issued to the warrant holders for a purchase price of \$558,250; options for 33,458 common shares were exercised for proceeds of \$89,014; 1,485 common shares were issued to the Company's Employee Stock Purchase Plan for proceeds of \$4,696; and 10,000 shares of the Company's Convertible Series A Preferred stock were exchanged for 10,000 of the Company's common stock for which no additional proceeds were received by the Company.

During the quarter ended September 30, 2004, one warrant was exercised through a cashless exercise in accordance with the terms of the warrant and 27,506 shares of common stock were issued to the warrant holder. Additionally, one warrant was exercised during the quarter ended September 30, 2004, and 23,880 shares of common stock were issued to the warrant holder for a purchase price of \$41,790.

In July 2004, we acquired Empire Pharmaceuticals. Under the terms of the merger agreement, NTI initially issued 2,399,163 shares of common stock and paid \$2,000,000 to Empire stockholders. If pivotal Phase III trials for Viprinex are commenced as currently planned, NTI will issue an additional 2,375,170 shares of common stock and pay an additional \$2 million to Empire stockholders, as discussed above in Note 2.

**NOTE 5 - COMPREHENSIVE LOSS**

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

	Quarter ended		Six months ended	
	December 31,		December 31,	
	2004	2003	2004	2003
Net loss	\$ (2,675,172)	\$ (1,059,048)	\$ (8,427,447)	\$ (1,932,164)
Other comprehensive (loss)	(40,843)	(94)	(57,696)	(9,924)
<b>Comprehensive loss</b>	<b>\$ (2,716,015)</b>	<b>\$ (1,059,142)</b>	<b>\$ (8,485,143)</b>	<b>\$ (1,942,088)</b>

**Note 5 SUBSEQUENT EVENT**

In January 2005, the Company received a royalty payment in the amount of \$765,425 from Merz Pharmaceuticals GmbH ( Merz ) for sales of Memantine during the quarter ended September 30, 2004. Merz informed the Company that a reduction of \$107,574 had been made from this payment to reflect the correction for an over-payment of royalties for certain sales in foreign countries during earlier quarterly periods.

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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. Except as may be required by law, we undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

#### **OVERVIEW**

Neurobiological Technologies, Inc. is a biotechnology company engaged in the business of acquiring and developing central nervous system (CNS) related drug candidates. The Company is focused on therapies for neurological conditions that occur in connection with dementia, Alzheimer's disease, ischemic stroke, neuropathic pain, and brain cancer.

Our strategy is to in-license and develop later stage drug candidates that target major medical needs and that can be rapidly commercialized. Our experienced management team oversees the human clinical trials necessary to establish preliminary evidence of efficacy and then seeks partnerships with pharmaceutical and biotechnology companies for late-stage development and marketing of our product candidates. Currently, we receive revenues on the sales of one approved product and have two product candidates in clinical development. The approved product, Memantine, is an orally dosed compound that is approved for the treatment of moderate to severe Alzheimer's disease and is marketed in the United States and Europe by our marketing partners. Memantine is also being developed for the treatment of neuropathic pain. Our current product candidates are XERECEPT®, a compound being developed for the treatment of peritumoral brain edema, or swelling around brain tumors, and Viprinex®, a compound being developed for the treatment of acute ischemic stroke.

#### **MEMANTINE**

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, we share in revenues from sales of Memantine for all indications.

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

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 October 2003, Forest announced that Memantine (Namenda®) was approved by the FDA for the treatment of moderate-to-severe Alzheimer's disease. Memantine became commercially available in the United States in January 2004.

Forest has announced results of three additional placebo-controlled trials in either mild-to-moderate or moderate-to-severe Alzheimer's disease. In June 2003, Forest announced that one of these trials did not demonstrate statistically significant effects on cognitive or global outcomes compared to the control group. This trial combined Memantine with Acetyl cholinesterase inhibitors for mild-to-moderate Alzheimer's disease. In an additional trial, patients with moderate-to-severe Alzheimer's disease who received the combined therapy of Memantine with the Acetyl cholinesterase inhibitor donepezil showed greater cognitive, functional, global and behavioral benefits over those with donepezil alone. These results were published in the Journal of the American Medical Association, or JAMA, a peer review journal, in January 2004. In January 2004, Forest announced positive results of a Phase III study using Memantine as a monotherapy in mild-to-moderate Alzheimer's disease. Forest has announced that it plans to seek approval for Memantine for a mild-to-moderate indication.

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In July 2001, Forest initiated the second of two trials necessary for submission of a new drug application, or NDA, for Memantine for the treatment of diabetic neuropathy. In May 2003, Forest announced that Memantine had failed to demonstrate a statistically significant difference versus the control group with regards to the primary endpoint of this trial. In October 2003, Forest announced the resumption of its clinical development of Memantine for the neuropathic pain indication with an expanded clinical program to examine various neuropathic pain conditions at different dosages. Forest anticipates that the earliest submission of an NDA would be 2006. NTI conducted the first pivotal trial of Memantine for the treatment of neuropathic pain with an enrollment of 400 patients and reported positive results in January 2000.

### **XERECEPT**

We are developing XERECEPT™ (corticotropin human acetate), a synthetic preparation of the natural human peptide, Corticotropin-Releasing Factor, as a treatment for brain swelling due to brain tumors (peritumoral brain edema). In April 1998, XERECEPT received orphan drug designation for this indication from the FDA. Orphan drug designation provides NTI with seven years market exclusivity and makes NTI eligible to receive Orphan Drug Grants to fund clinical research. In fiscal 2004, we completed animal toxicology studies, and the FDA undertook extensive review of the clinical trial designs for two pivotal trials for the treatment of peritumoral brain edema. In April 2004, enrollment began in one trial, which has a target enrollment of 200 patients. Enrollment in the second pivotal trial, which is expected to enroll 120 patients, has been delayed due to delays in obtaining the necessary supply of XERECEPT for the trial. This trial is currently scheduled to start during the quarter ending March 31, 2005.

### **VIPRINEX**

In July 2004, we acquired the assets of Empire Pharmaceuticals, Inc. ( Empire ), a privately held corporation, through the merger of Empire into Empire Acquisition Corp., a wholly-owned subsidiary of NTI. Pursuant to the transaction, we acquired worldwide rights to Viprinex (ancrod), a late-stage reperfusion therapy for use in treatment of ischemic stroke. Empire acquired the exclusive worldwide rights to Viprinex in a royalty-bearing license from Abbott Laboratories in March 2002. Viprinex was being developed by Knoll AG, prior to its acquisition by Abbott in 2001. In January 2005, Viprinex received fast-track status from the FDA for investigation of intended use in patients suffering from ischemic stroke. The fast-track designation provides for expedited regulatory reviews for new drug candidates demonstrating the potential to address current medical needs for the treatment of serious or life-threatening conditions.

The acquisition of Empire is accounted for as a purchase of assets in accordance with accounting principles generally accepted in the United States, and, accordingly, the results of operations of Empire have been included in the accompanying condensed consolidated financial statements of operations from the date of the acquisition.

Except for fiscal 2001, we have incurred significant losses each year since our inception. As of December 31, 2004, our accumulated deficit was \$50.8 million and total stockholders' equity was \$22.5 million. We expect to incur additional operating losses over at least the next year as we continue our research and development efforts.

### **CRITICAL ACCOUNTING POLICIES**

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements

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requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities, if any, at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We consider our accounting policies related to revenue recognition and use of estimates to be critical.



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### ***Revenue recognition***

Revenue related to license fees with non-cancelable, non-refundable terms and no future performance obligations are recognized when collection is assured. Revenues are deferred and recognized over the performance period in the event that future performance obligations exist. Non-refundable up-front payments received in connection with research and development activities are deferred and recognized on a straight-line basis over the relevant periods specified in the agreement, generally the research term. Revenues associated with milestones are recognized as earned, based on completion of development milestones, either upon receipt, or when collection is assured. Revenues associated with royalty agreements on sales of products are recognized when the proceeds are received due to the limited sales history of the product and our inability to estimate such sales.

### ***Research and development expenses***

Our research and development expenses include certain expenses that are incurred over multiple reporting periods, such as fees for contractors and consultants, fees to collaborators for pre-clinical research studies, patient treatment costs related to clinical trials and related clinical manufacturing costs, and license fees for use of third-party intellectual property rights. Management assesses how much of these multi-period costs should be charged to research and development expense in each reporting period. In determining whether clinical trial activities and preclinical animal studies performed by third parties should be recognized in a specific reporting period, management considers:

estimates of the percentage of work completed over the life of the individual study in accordance with agreements established with the third-party service providers; and

estimates of the percentage of work completed over the life of the individual study in accordance with discussions with internal clinical and preclinical personnel and independent service providers as to the progress or stage of completion of trials or services and the agreed upon fee to be paid for such services.

The assessment of the percentage of work completed that determines the amount of research and development expense that should be recognized in a given period requires significant judgment, and could have a material impact on our balance sheet and results of operations. These estimates may or may not match the actual services performed by the service providers as determined by patient enrollment levels, pre-clinical animal study schedules, and related activities. We monitor service provider activities to the extent possible; however, if we underestimated activity levels associated with various studies at a given point in time, we could record significant research and development expenses in future periods.

### ***Valuation of Long-Lived and Intangible Assets***

Intangible assets acquired in a business combination, including acquired in-process research and development, are recorded under the purchase method of accounting at their estimated fair values at the date of acquisition. The fair values of acquired intangible assets are determined by management using relevant information and assumptions, which process is assisted by an independent, professional appraiser. Fair value is generally calculated as the present value of estimated future cash flows using a risk-adjusted discount rate, which requires significant judgment with respect to revenue and expense growth rates, and the selection and use of an appropriate discount rate. Amortization of intangibles with defined lives is calculated using the straight-line method.

We assess the impairment of identifiable intangible and long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If it is determined that the carrying value of intangible and long-lived assets might not be recoverable based upon the existence of one or more indicators of impairment, we would measure any impairment based on a projected discounted cash flow method if the undiscounted cash flows did not exceed the carrying value of such assets. No such impairment charges have been recorded to date. At December 31, 2004, we had \$7,150,056 and \$893,302 of net intangible and tangible long-lived assets, respectively. An impairment of our intangible or tangible long-lived assets could result in the recording of a material, non-cash expense in our consolidated statement of operations during the period in which such a charge could occur.

## RECENT ACCOUNTING PRONOUNCEMENTS

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment ( SFAS 123(R) ) which requires all share-based payments to employees, including grants of stock options, to be recognized in the financial statements based on their fair values. As a result, the cost of employee services received in exchange for a grant of an equity instrument will be measured at fair value on the grant-date of the award and recorded as expense over the period during which the employee is required to provide service in exchange for the award. Pro forma disclosure of such cost is no longer an alternative for disclosing the cost share-based payments to employees.

SFAS 123(R) is effective at the beginning of the first interim or annual period beginning after June 15, 2005 and may be adopted using either the *Modified-Prospective Transition* method or the *Modified-Retrospective Transition* method of application. Using the *Modified-Prospective Transition* method, the Company would recognize the cost of share-based payments based on their grant-date fair value from the beginning of the fiscal period in which the provisions of SFAS 123(R) are first adopted. Measurement and assignment of compensation cost for share-based payments granted prior to, but not vested as of the date of adopting SFAS 123(R), would be based upon the same estimate of grant-date fair value used previously under SFAS 123, whether the estimate was recognized in the financial statements or disclosed only in a pro forma manner. Recognizing a liability for share-based payments made prior to, but not vested as of the date of adopting SFAS 123(R), would be recognized as the cumulative effect of a change in accounting principle. Using the *Modified-Retrospective Transition* method of application, the Company would be allowed to restate previously reported periods by recognizing compensation expense in the amounts previously reported as pro forma disclosure under the earlier provisions of SFAS 123. New awards and vested awards would be accounted for in the same manner as the *Modified-Prospective Transition* method.

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We are currently evaluating the impact that the adoption of SFAS 123(R) will have on our operating results.

**RESULTS OF OPERATIONS***REVENUES*

Quarter Ended		Increase From	Six Months Ended		Increase From
December 31,		Period in Prior Year	December 31,		Period in Prior Year
2004	2003	2004/2003	2004	2003	2004/2003
\$694,000	\$ 300,000	\$ 394,000	\$ 1,211,000	\$ 310,000	\$ 901,000

Revenues of \$694,000 in the quarter ended December 31, 2004 increased by \$394,000 compared to revenues of \$300,000 in the same quarter of 2003. Revenues of \$694,000 in the quarter ended December 31, 2004 consist of royalty fees from the sale of Memantine in the U.S. and in certain European countries. Revenues of \$300,000 in the quarter ended December 30, 2003 consist of \$281,000 of license fees relating to the approval for sale of Memantine and \$19,000 of royalty fees from the sale of Memantine in certain European countries.

Revenues of \$1,211,000 in the six months ended December 31, 2004 increased by \$901,000 compared to revenues of \$310,000 for the same period in 2003. Revenues of \$1,211,000 in the six months ended December 31, 2004 results from the sale of Memantine in the U.S. and certain European countries. Revenues of \$310,000 in the six months ended December 31, 2003 consist of \$281,000 of license fees relating to the approval for sale of Memantine and \$29,000 of royalty fees from the sale of Memantine in certain European countries.

Royalty revenues result from sales of Memantine by Merz and its marketing partners who do not make anticipated future sales volumes available to us; nor, given the limited history of Memantine sales, are we able to estimate future royalty revenues.

*RESEARCH AND DEVELOPMENT EXPENSES*

Quarter Ended		Increase From	Six Months Ended		Increase From
December 31,		Period in Prior Year	December 31,		Period in Prior Year
2004	2003	2004/2003	2004	2003	2004/2003

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\$2,269,000	\$ 513,000	\$ 1,756,000	\$ 3,432,000	\$ 842,000	\$ 2,590,000
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Research and development expenses of \$2,269,000 in the quarter ended December 31, 2004 increased by \$1,756,000 compared to expenses of \$513,000 in the same quarter of 2003. The increase of \$1,756,000 consisted of \$1,413,000 of expenses incurred to prepare for Phase III clinical trials of Viprinex, which are anticipated to commence within the next nine months, and \$343,000 of additional expenses for continuing the Phase III clinical trials for XERECEPT, which were initiated during April 2004. The \$1,413,000 of research and development expenses incurred for Viprinex consist primarily of \$720,000 of expenses for the manufacture of Viprinex, approximately \$223,000 for consulting and travel expenses,

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\$155,000 for amortization of the intangible marketing license for Viprinex, \$147,000 of compensation related expenses, and \$62,000 of depreciation and maintenance of venom concentrate, raw venom and the related snake-farm facilities utilized in the development of Viprinex. The increase of \$343,000 of research and development expenses related to clinical Phase III trials of XERECPT consisted primarily of an increase of \$526,000 in expenses related to clinical activities, drug manufacturing and compensation, which were partially offset by decreases of \$155,000 and \$39,000 in expenses for consultants and toxicology.

Research and development expenses of \$3,432,000 in the six months ended December 31, 2004, increased by \$2,590,000 compared to expenses of \$842,000 in the same period in 2003. The increase of \$2,590,000 consisted of \$1,963,000 of expenses incurred to prepare for Phase III clinical trials of Viprinex and \$628,000 of additional expense for continuing Phase III trials for XERECPT, which were initiated in April 2004. The \$1,963,000 of research and development expense incurred for Viprinex consist primarily of \$820,000 of expenses for the manufacture of Viprinex, \$284,000 for amortization of the intangible marketing license for Viprinex, \$283,000 of consulting and travel expense, \$249,000 of compensation related expense, and \$108,000 of depreciation and maintenance of venom concentrate, raw venom and the snake farm facilities related to the development of Viprinex.

We anticipate that the level of expenditures for research and development expenses will increase in the future as we continue the clinical Phase III trials for XERECPT and prepare for clinical Phase III trials of Viprinex.

*IN-PROCESS RESEARCH AND DEVELOPMENT*

We acquired Empire in July 2004, in order to secure the worldwide rights to Viprinex, a late-stage perfusion therapy for use in ischemic stroke. The acquisition of Empire is recorded as a purchase of assets and, accordingly, the purchase price was assigned to all identified tangible and intangible assets. During the identification and valuation process, we determined that in-process research and development associated with Viprinex had a fair value of \$4,251,335. This valuation was determined using risk-adjusted valuation of the cash flows anticipated with completing the research and development of Viprinex. At the date of the acquisition, the development of Viprinex had not reached technological feasibility and the research and development in progress had no alternative future uses. Accordingly, the in-process research and development acquired with the acquisition of Empire was charged to expense at the date of the acquisition, in accordance with generally accepted accounting principles. If pivotal Phase III trials for Viprinex are commenced as currently planned, we will issue an additional 2,375,170 shares of our common stock and pay an additional \$1,515,675 to the selling stockholders of Empire and will pay Empire's principal stockholder the balance of \$484,325 for the remainder of advances previously made by the stockholder to the Empire. We anticipate that, in the event the pivotal Phase III trials for Viprinex are commenced and the additional proceeds are paid to the selling stockholders of Empire, approximately \$4,251,000 of the additional proceeds will be identified as in-process research and development, which will be recorded as expense in the period during which the additional payment is made. Otherwise, we currently do not expect to incur similar charges in future periods.

*GENERAL AND ADMINISTRATIVE EXPENSES*

Quarter Ended		Increase From	Six Months Ended		Increase From
December 31,		Period in Prior Year	December 31,		Period in Prior Year
2004	2003	2004/2003	2004	2003	2004/2003

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\$1,090,000	\$ 855,000	\$ 235,000	\$ 2,022,000	\$ 1,431,000	\$ 591,000
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General and administrative expenses of \$1,090,000 in the quarter ended December 31, 2004 increased by \$235,000 compared to \$855,000 for the same quarter in 2003. The increase of \$235,000 during 2004 resulted primarily from \$80,000 of expense for the administrative operations of the New

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Jersey office established for the development of Viprinex subsequent to our acquisition of Empire in July 2004, together with increases of \$152,000 for professional fees related to public reporting and compliance with the Sarbanes-Oxley Act of 2002 and assisting with the financial management of the Company.

General and administrative expenses of \$2,022,000 in the six months ended December 31, 2004, increased by \$591,000 compared to expenses of \$1,431,000 for the same period in 2003. The increase of \$591,000 results primarily from \$119,000 for the administrative operations of the New Jersey office established for the development of Viprinex, together with increases of \$231,000 for professional fees related to public reporting and compliance with the Sarbanes-Oxley Act of 2002, and assisting with the financial management of the Company, an increase of \$160,000 for compensation related expenses, resulting from an increase in performance-based bonus compensation and the recruitment of a Chief Financial Officer, and \$54,000 for consulting services related to the Company's operations.

We anticipate that general and administrative expenses will increase in the future as we take necessary action to meet the additional reporting and compliance requirements of the Sarbanes-Oxley Act of 2002 and as we expand our New Jersey facilities.

*INVESTMENT INCOME.*

Quarter Ended		(Decrease) From Period in Prior Year	Six Months Ended		Increase From Period in Prior Year
December 31,			December 31,		
2004	2003	2004/2003	2004	2003	2004/2003
\$(10,000)	\$ 9,000	\$ (19,000)	\$ 67,000	\$ 31,000	\$ 36,000

Investment loss of \$(10,000) in the quarter ended December 31, 2004, represents a decline of \$(19,000) compared to investment income of \$9,000 in the same quarter of 2003. The loss is due to net realized losses on the sale of long-term securities, which was partially offset by interest income and accretion earned. We have evaluated our investment management strategy with our professional investment advisor and have modified our investment policy to minimize the recurrence of material losses in future periods. Investment income of \$67,000 in the six months ended December 31, 2004 increased by \$36,000 over the same period in 2003 resulting from the investment of funds which were available from our issuance of common stock in March 2004.

**LIQUIDITY AND CAPITAL RESOURCES**

	December 31,	June 30,
	2004	2004
Cash and cash equivalents, and investments	\$ 15,127,000	\$ 20,733,000
Working capital	5,445,000	13,582,000

Six Months Ended

December 31,

	2004	2003
Cash provided by (used in):		
Operating activities	\$ (3,082,000)	\$ (1,830,000)
Investing activities	424,000	2,512,000
Financing activities	694,000	59,000



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Since our founding in 1987, we have applied a majority of our resources to research and development programs and have generated only limited operating revenue. Except for fiscal 2001, we have incurred losses in each year since our inception and we expect to continue to incur losses in the future due to ongoing research and development efforts.

As of December 31, 2004, we had cash, cash equivalents and total investment securities available for sale of \$15,127,000. The balance of cash and cash equivalents of \$48,000 at December 31, 2004 declined by \$1,964,000 from cash and cash equivalents of \$2,102,000 as of June 30, 2003 resulting from our operating, investing and financing activities during the six-month period.

*Cash Flows from Operating Activities*

We used \$3,082,000 for operating activities during the six months ended December 31, 2004, resulting primarily from our operating loss of \$(8,427,000) but not including the non-cash expenses of \$4,641,000 for the charge-off of in-process research and development, depreciation and amortization, and deferred stock compensation. Cash flows from operating activities increased resulting from an increase in accounts payable and accrued liabilities of \$922,000 and a decrease in interest receivable of \$37,000, which were partially offset by an increase in prepaid expenses of \$254,000, of which the combined effect resulted in the cash use of \$3,082,000 for operations during the six months. Accounts payable and accrued liabilities increased from an increase in operations for continued clinical trials of XERECEPT and in anticipation of clinical trials for Viprinex; the increase in prepaid and other expenses reflect prepayments and deposits made for the continued clinical trials of XERECEPT and the preparation for clinical trials of Viprinex and establishing our new office facilities in New Jersey.

*Cash Flows from Investing Activities*

Investing activities provided \$424,000 of cash in the six months ended December 31, 2004 resulting primarily from the net proceeds from the sale and maturity of our investments which was partially offset by our purchase of Empire, purchases of investments and purchases of property and equipment.

*Cash Flows from Financing Activities*

Financing activities provided cash of \$694,000 in the six months ended December 31, 2004, and consisted of the value of the common stock we issued for the exercise of warrants and options for our common stock during the period.

Our contractual commitments as of December 31, 2004 are summarized below by category in the following table. As we move forward with the clinical development of XERECEPT and Viprinex, we will enter into contractual commitments for additional expenditures relating to these clinical trials; commitments for material additional expenditures, when contracted, will be reflected in the following table.

**Payments due by period**

Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
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Operating Lease Obligations	\$ 131,189	\$ 131,189			
Other Long-Term Liabilities *	2,000,000	2,000,000			
<b>Total</b>	<b>\$ 2,131,189</b>	<b>\$ 2,131,189</b>			

\* Includes contractual drug manufacturing commitment and additional contingent merger cash consideration payable to the selling stockholders of Empire Pharmaceuticals if and when Phase III clinical trials for Viprinex commence, but no earlier than July 14, 2005. We will also issue 2,375,170 additional shares to those selling stockholders if and when Phase III clinical trials for Viprinex commence, but no earlier than July 14, 2005.

Our available cash and cash equivalents of \$48,000, together with investments of \$15,079,000, were \$15,127,000 as of December 31, 2004. As described above, we expect to incur increased costs

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throughout fiscal 2005 primarily for Phase III clinical trials of XERECEPT and for the preparation of Phase III clinical trials for Viprinex, along with related administrative support costs. If and when Viprinex commences Phase III clinical trials, we will pay the former Empire stockholders up to an additional \$2,000,000 and issue up to an additional 2,375,170 shares of common stock. All future development costs for Memantine will be paid by Merz and its marketing partners. We believe that our available cash, cash equivalents and investment balances will be adequate to fund our operations through at least the next twelve months, although we expect that we may need to raise additional capital in the future to complete the clinical development of XERECEPT and Viprinex. Accordingly, we may seek to raise additional funds when market conditions permit. However, there can be no assurance that funding will be available or that, if available, will be on acceptable terms.

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

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

We do not have any off-balance sheet arrangements as defined by rules recently enacted by the Securities and Exchange Commission and Financial Accounting Standards Board, and accordingly, no such arrangements are likely to have a current or future effect on our financial position, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

## **RISK FACTORS**

You should carefully consider the following risks and uncertainties before you invest in our common stock. Investing in our common stock involves risk. If any of the following risks or uncertainties actually occurs, our business, financial condition or results of operations could be materially adversely affected. Additionally, risks and uncertainties of which we are unaware or that we currently believe are immaterial could

also materially adversely affect our business, financial condition or results of operations. In any case, the trading price of our common stock could decline, and you could lose all or part of your investment. Additionally, please refer to the cautionary statement regarding forward-looking language set forth above under the caption Management's Discussion and Analysis of 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. Viprinex has previously failed in one Phase III clinical trial and a recent Phase III clinical trial for Memantine for neuropathic pain failed to produce the desired results. As evidenced by these trials, our product candidates face numerous risks of failure, including the possibility that these candidates may:

be found to be unsafe, ineffective or toxic;

fail to receive necessary regulatory clearances;

if approved, be difficult to manufacture on a large scale or be uneconomical to market;

be precluded from marketing by us or our marketing partners due to the proprietary rights of third parties; and

not be successful because third parties market or may market superior or equivalent products.

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If any of these risks of failure should materialize, we may be forced to make additional significant expenditures for further clinical trials or cease further development of the drug candidate. In either case, our prospects would be harmed and our stock price could decline.

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

All of our revenues in fiscal 2003 and 2004 and in the first six months of fiscal 2005 were license fee and royalty payments from Merz related to our portion of payments received by Merz pursuant to its agreements with Forest and Lundbeck, its marketing partners. The only revenues that we expect to receive in the foreseeable future are our share of payments received by Merz from Forest and Lundbeck and royalties on Memantine sales made by Merz or its marketing partners, which depends, among other things, on the continuation of our research and marketing cooperation agreement with Merz and Children's Medical Center. Although Merz has received approval to market Memantine for Alzheimer's disease in Europe, we are not entitled to receive royalty payments for Memantine sales for Alzheimer's disease in certain European countries and any commercialization efforts in these markets would not directly benefit us. If Merz is unable to successfully commercialize Memantine, or if Memantine is not commercialized for indications or in markets where we are entitled to royalty payments, our revenues would be adversely affected.

In February 2005, Merz made a royalty payment to us in the amount of \$765,000 for sales of Memantine during the quarter ended September 30, 2004, for the treatment of moderate-to-severe Alzheimer's disease. Merz informed us that the payment reflected a one-time reduction of \$108,000 to correct an apparent over-payment on royalties on certain sales outside of the U.S. in earlier quarters.

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

*We expect that we will need to raise additional capital to fund ongoing operations. If we are unable to raise additional capital, we may be forced to curtail operations. If we succeed in raising additional capital through a licensing or financing transaction, it may affect our stock price and future revenues.*

In order to maintain sufficient cash and investments to fund future operations, we will need to raise additional capital. We expect to seek to raise additional capital over the next 12 to 24 months through various alternatives, including licensing or sales of our technologies and drug candidates and selling shares of our common stock.

If we raise capital through licensing or sales of one or more of our technologies or drug candidates, then we may not realize revenues from product sales for products that are successfully developed, approved by the FDA and marketed. If we license any of our technologies or drug candidates, then the development of these products or technologies may no longer be in our control. A licensee might not ever reach any of the milestones in a license agreement and we would not earn any additional payments in such an event. Further, if we sell any of our technologies or drug candidates, the sales price may not fully cover our investment in such technology or drug candidate.

If we raise capital by issuing additional shares of common stock at a price per share less than the then-current market price per share, the value of the shares of our common stock then outstanding may be reduced. Further, even if we were to sell shares of common stock at prices

equal to or higher than the current market price, the issuance of additional shares may depress the market price of our common stock and dilute voting rights.

We may not be able to raise capital on terms that we find acceptable, or at all. If we are unable to raise additional capital to fund future operations, then we might have to reduce operations or defer or abandon one or more of our clinical or preclinical research programs. Any of these actions could be expected to have an adverse effect on our stock price.

*We have a history of losses and we may never achieve or maintain profitability.*

Except for fiscal 2001, we have experienced operating losses every year since inception in funding the research, development and clinical testing of our drug candidates. As of December 31, 2004, our

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accumulated deficit was approximately \$50.8 million and we expect to continue to incur operating losses in the future as we continue our clinical trials for XERECEPT and commence our planned clinical trials for Viprinex. To achieve profitability, we would need to generate significant additional revenue with positive gross margins. Although we expect that our royalty revenues from the sales of Memantine will increase in future periods, these increases may not occur and, even if they do increase in line with our expectations, we do not expect that these increases will be sufficient to allow us to operate profitably at any time in the foreseeable future.

*Even if our other product candidates are approved for commercialization, these candidates may not be successfully commercialized.*

If either XERECEPT or Viprinex is approved for commercialization, we will be required either to market the drug directly, which would require the recruitment and training of a direct sales force, or license the drug to a larger biotechnology or pharmaceutical company with an existing sales force. The building of a direct sales force is costly and we may not succeed in directly marketing any approved drug. If we elected to license the approved drug to a larger company with an existing sales force, we would be required to share the revenues from commercialization and would lose a significant degree of control over the commercialization of the drug.

### ***Our Industry is Highly Competitive***

Competition in the biopharmaceutical industry is intense and is expected to increase. There are other therapies under development for each of our therapeutic targets and the development and sale of drugs for the treatment of the therapeutic targets that we and our collaborative partners are pursuing is highly competitive. Specifically, we face known competition from the following companies for each of the indications listed below.

Indication / Principal known competing products and competitors

Alzheimer's disease (Memantine)

ARICEPT® (donepezil HCl) Eisai Inc. and Pfizer Inc.

Exelon® (rivastigmine tartrate) Novartis

Reminyl® (galantamine HBr) Janssen Pharmaceutica

Neuropathic pain (Memantine)

Neurontin® (gabapentin) Parke-Davis

Peritumoral brain edema (XERECEPT)

Decadron® (dexamethasone) Merck & Co. Inc.

Acute ischemic stroke (Virpinex)

Activase® (alteplase, recombinat) Genentech, Inc.

We may not be able to develop products that will be as efficacious or as cost-effective as currently-marketed products or those products being developed by our competitors. In addition, because our license to certain XERECEPT patent rights is non-exclusive, others may develop competing products using the same compound. Consequently, others may develop, manufacture and market products that could compete with those that we are developing.



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*It is difficult to integrate acquired companies, products, technologies and personnel into our operations and our inability to do so could greatly lessen the value of any such acquisitions.*

In July 2004, we acquired Empire Pharmaceuticals in a merger transaction and we may make additional strategic acquisitions of companies, products or technologies in the future in order to complement our product pipeline or to implement our business strategy. In connection with the Empire acquisition, we added two new members to our senior management team and we established offices in New Jersey. This is the first time that we will be managing two facilities and the distance between the facilities may make integration more difficult. If we are unable to successfully integrate acquired businesses, products, technologies or personnel with our existing operations, we may not receive the intended benefits of such acquisitions.

Additionally, disputes may arise following the consummation of an acquisition regarding representations and warranties, indemnity, earn-out and other provisions in the acquisition agreement. For these reasons, acquisitions may subject us to unanticipated liabilities or risks, disrupt our operations or divert management's attention from day-to-day operations.

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

Although Merz and its marketing partners have the responsibility of supplying Memantine for the clinical trials and commercialization of the drug, we must procure our own supplies of XERECEPT and Viprinex for our clinical trials of these compounds. Our clinical supply of XERECEPT has been manufactured by established methods using chemical synthesis to our specifications, and we are currently making arrangements for an initial clinical supply of Viprinex to be produced to our specifications. We have recently experienced delays obtaining the necessary clinical supplies of XERECEPT, and this has delayed our clinical program and may do so in the future. Further, although we perform audits on our contractors who supply our drug candidates to assess compliance with their current Good Manufacturing Practice, or cGMP, regulations, there can be no assurance that our suppliers will meet cGMP standards or be able to synthesize and deliver our drug compounds in a timely fashion. Although alternative cGMP suppliers of the bulk drugs and of finished dosage form products are available to us, Viprinex is difficult and costly to produce and we believe that there is only a limited number of manufacturers who are capable of producing the compound.

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 if contract manufacturers do not adhere to cGMP regulations.

Because of these risks, our dependence on third parties for the manufacture of products may adversely affect our ability to develop and deliver products on a timely and competitive basis and our results of operations.

*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.

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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 us 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 pre-clinical or early stage clinical trials does not assure success in later-stage clinical trials. For example, although our Phase II clinical trials for Memantine for the treatment of diabetic neuropathy produced positive results, a subsequent clinical trial conducted by Forest did not replicate these results. Similarly, the results of Knoll AG's Phase III clinical trials for Viprinex in the United States were not replicated in the subsequent European clinical trial, and this may impair our ability to obtain FDA and foreign regulatory approval to commence our planned Phase III clinical trials for Viprinex. Similar variations in later-stage clinical trial results may also occur in XERECEPT, as longer trials and larger patient populations are used. Further, since we began the first Phase III clinical trial of XERECEPT in April 2004, patient enrollment has been slow. Any further delays in patient enrollment could impede the development of XERECEPT and make it less likely that we will be able to further develop or successfully commercialize the drug.

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.

***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 pre-clinical testing and human clinical trials and for preparing and submitting submissions for regulatory approval for potential products on the collaborator, licensor or contractor. If the collaborator, licensor or contractor fails to perform, our business, financial conditions and results may be adversely affected.

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

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.

***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.

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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.

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 our company 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.

*If the members of our expanded management team are unable to work together effectively, our ability to manage our business will suffer.*

Since our acquisition of Empire Pharmaceuticals in July 2004, we have expanded our management team. Stephen J. Petti joined us as Vice President, Product Development in July 2004, David E. Levy joined us as Vice President, Clinical Development in September 2004 and Jonathan R. Wolter joined us as Vice President and Chief Financial Officer in December 2004. In addition, we are also seeking to hire other executive officers in the near future. If these employees cannot work together effectively with our existing management team, our ability to manage our business will suffer.

*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 for our clinical trials, with coverage limits of \$5 million per incident and \$5 million in the aggregate. It is possible that our current insurance may not be adequate to cover liabilities arising from our clinical trials.

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

*We must report on the adequacy of our internal controls starting in fiscal 2005 and our auditors must attest to our report. Any delays or difficulties in doing so could result in a loss of public confidence in our internal controls and/or financial disclosure.*

## Edgar Filing: NEUROBIOLOGICAL TECHNOLOGIES INC /CA/ - Form 10-Q

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we will be required, beginning with our fiscal year ending June 30, 2005, to include in our annual report our assessment of the effectiveness of our internal controls over financial reporting and our audited financial statements for that fiscal year. Furthermore, our independent registered public accounting firm will be required to attest to whether our assessment of the effectiveness of our internal controls over financial reporting is fairly stated in all material respects and separately report on whether it believes we maintained, in all material respects, effective internal controls over financial reporting as of June 30, 2005. Although we currently believe that we will satisfy these requirements in a timely fashion, we have not yet completed our assessment of the effectiveness of our internal controls. If we fail to timely complete this assessment, or if our independent registered public accounting firm cannot timely attest to our assessment, we could receive an adverse report, which may result in a loss of public confidence in our internal controls and/or the accuracy of our financial disclosure. In addition, any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to timely meet our regulatory reporting obligations.

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

The average daily trading volume of our common stock has historically been low, even when compared to that of other biopharmaceutical companies. Because of our relatively low trading volume, our stock price can be highly volatile.

Additionally, in July 2004, we issued 2,399,163 shares of common stock in connection with our acquisition of Empire Pharmaceuticals and, if we commence Phase III clinical trials for Viprinex, we will be required to issue an additional 2,375,170 shares. These shares have been registered for resale and the selling stockholders of Empire will be able to begin selling their NTI common stock on the earlier of the commencement of Phase III clinical trials of Viprinex or July 14, 2005. The issuance of these additional shares and any large sales that may be made by former stockholders of Empire or otherwise could have a negative effect on the price and volatility of our stock price.

Additional factors that may affect the volatility of our stock price include:

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

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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 and long-term investments, consisting primarily of investment grade securities. As of December 31, 2004, the fair value of our investments was \$15.1 million and 42% of our total portfolio will mature in one year or less. A hypothetical 50 basis point increase in interest rates would not result in a material decrease or increase in the fair value of our available-for-sale securities. We have no investments denominated in foreign country currencies and therefore our investments are not subject to foreign currency exchange risk.

**ITEM 4. CONTROLS AND PROCEDURES**

An evaluation was performed under the supervision and with the participation of President and Chief Executive Officer and Vice President and Chief Financial 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 and Vice President and Chief Financial 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.

**PART II. OTHER INFORMATION**

**ITEM 5. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

During the quarter ended December 31, 2004, the Company held its Annual Meeting of Stockholders. The following matters were voted on at the meeting, which was convened on November 18, 2004:

- (1) The following eight directors were elected:

	<u>Votes For</u>	<u>Withheld</u>
Paul E. Freiman	20,156,664	1,307,857
Abraham E. Cohen	20,196,656	1,267,865
Enoch Callaway, M.D.	20,125,375	1,339,146
Ronald E. Cape, Ph.D.	21,360,481	104,040
Theodore L. Eliot, Jr.	20,124,400	1,340,121
Abraham D. Sofaer	21,368,981	95,540
F. Van Kasper	21,369,481	95,040
John B. Stupp	20,156,564	1,307,957



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- (2) The motion to increase the number of authorized shares of common stock was approved: For 20,761,632; Against 611,064; Abstain 91,825.
  
- (3) The motion to approve the amendment of the Company's 2003 Equity Incentive Plan was approved: For 9,992,865; Against 577,513; Abstain 101,791.
  
- (4) The selection of Ernst & Young LLP as the independent auditors of the Company for the current year was ratified: For 21,306,381; Against 86,730; Abstain 71,410.

**ITEM 6. EXHIBITS**

- 31.1 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 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
- 32.2 Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 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.

Dated: February 9, 2005

/s/ PAUL E. FREIMAN

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

/s/ JONATHAN R. WOLTER

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Jonathan R. Wolter  
Vice President and Chief Financial Officer  
(Principal Financial and Accounting Officer)