NEUROBIOLOGICAL TECHNOLOGIES INC /CA/
Form 10-Q
November 06, 2008

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2008
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)	**(IRS Employer Identification No.)**

2000 Powell Street, Suite 800, Emeryville, California 94608
(Address of principal executive offices)
(510) 595-6000
(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 þ No o
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, non-accelerated filer or a smaller reporting company. See definition of accelerated filer , large accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act):

Large Accelerated Filer o	Accelerated Filer o	Non-Accelerated Filer o	Smaller Reporting Company þ

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes o No þ
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, $0.001 par value: 26,924,124 shares outstanding as of October 31, 2008.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

NEUROBIOLOGICAL TECHNOLOGIES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except per share amounts)

	September 30, 2008 *(Unaudited)*	June 30, 2008 *(Note 1)*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 26,122	$ 27,941
Short-term investments	2,059	2,039
Accounts receivable	184	599
Prepaid expenses and other current assets	268	280
Total current assets	28,633	30,859
Deposits	85	85
Long-term investments	10,274	11,850
Property and equipment, net	346	393
	$ 39,338	$ 43,187
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 517	$ 588
Accrued clinical trial expenses	2,187	1,075
Accrued manufacturing and related expenses	492	581
Accrued external research expenses, professional expenses and other liabilities	1,368	1,258
Deferred revenue	5,500	5,500
Warrant liability	3	40
Total current liabilities	10,067	9,042
Accrued clinical trial expenses and other liabilities	117	567
Deferred revenue, net of current portion	11,917	13,292
Total liabilities	22,101	22,901

Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.001 par value, 5,000 shares authorized; 3,000 authorized shares designated as Series A convertible preferred stock, 2,332 shares issued and 494 outstanding, with aggregate liquidation preference of $247	247	247
Common stock, $0.001 par value, 50,000 shares authorized, 26,924 shares issued and outstanding	27	27
Additional paid-in capital	145,357	145,113
Accumulated deficit	(128,353)	(125,591)
Accumulated other comprehensive (loss) income	(41)	490
Total stockholders equity	17,237	20,286
	$ 39,338	$ 43,187

See accompanying notes.

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NEUROBIOLOGICAL TECHNOLOGIES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited in thousands, except per share amounts)

	Three months ended September 30,	
	2008	**2007**
REVENUES		
Royalty	$ 2,078	$ 1,981
Technology sale and collaboration services	1,487	1,919
Total revenues	3,565	3,900
EXPENSES		
Research and development	5,452	5,460
General and administrative	1,331	1,659
Total expenses	6,783	7,119
Operating loss	(3,218)	(3,219)
Interest income	249	28
Gain on sale of long-term investments	170	
Interest expense, including non-cash amortization of $588 discount on notes for the three months ended September 30, 2007		(633)
Non-cash gain on decrease in fair value of warrants	37	2,902
NET LOSS	$ (2,762)	$ (922)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.10)	$ (0.19)
Shares used in basic and diluted net loss per share calculation	26,924	4,772

See accompanying notes.

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NEUROBIOLOGICAL TECHNOLOGIES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited in thousands)

	Three months ended September 30,	
	2008	**2007**
OPERATING ACTIVITIES:		
Net loss	$ (2,762)	$ (922)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	49	54
Stock-based compensation	244	241
Gain on sale of long-term investments	(170)	
Non-cash gain on decrease in fair value of warrants	(37)	(2,902)
Amortization of note discount		588
Changes in assets and liabilities:		
Accounts receivable	415	(383)
Prepaid expenses and other current assets	12	(23)
Accounts payable and accrued liabilities	612	(1,235)
Deferred revenue	(1,375)	(1,375)
Net cash used in operating activities	(3,012)	(5,957)
INVESTING ACTIVITIES:		
Purchase of investments		(400)
Maturity and sale of investments	1,195	1,318
Purchases of property and equipment	(2)	(1)
Net cash provided by investing activities	1,193	917
FINANCING ACTIVITIES:		
Proceeds from issuance of notes and common stock, net of issuance costs		5,990
Deferred offering costs paid		(554)
Net cash provided by financing activities		5,436
(Decrease) increase in cash and cash equivalents	(1,819)	396
Cash and equivalents at beginning of period	27,941	5,538
Cash and equivalents at end of period	$ 26,122	$ 5,934

See accompanying notes.

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NEUROBIOLOGICAL TECHNOLOGIES, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2008
(Unaudited)
(Tabular amounts in thousands, except per share amounts, percentages and years)

1. Basis of Presentation and Summary of Significant Accounting Policies

Business Description

Neurobiological Technologies (NTI or the Company) is a biopharmaceutical company focused on developing novel, first-in-class treatments for central nervous system conditions and other serious unmet medical needs. The Company s most advanced product candidate, Viprinex , is in Phase 3 clinical testing as a novel investigational drug for the treatment of acute ischemic stroke. Stroke is one of the most prevalent, debilitating and costly diseases in the world, and there are few acceptable treatment options. Viprinex is a fibrinogen-reducing agent that is designed to expand the treatment window from three hours to six hours. The Company has the right to receive royalty payments from the sales of Namenda® (memantine HCL), an approved drug marketed for Alzheimer s disease and potential milestone and royalty payments from the development of XERECEPT, an investigational drug which is in Phase 3 clinical trials for the treatment of swelling associated with cerebral tumors. Additionally, NTI s earlier stage pipeline includes rights to two proteins in preclinical development for the treatment of Alzheimer s disease and Huntington s disease.

Basis of Presentation

The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, NTI-Empire, Inc. All intercompany accounts and transactions have been eliminated. NTI operates in one business segment, the development of pharmaceutical products.

These financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information 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 GAAP for reporting on complete financial statements. 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, 2008. The condensed consolidated financial statements 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 months ended September 30, 2008 are not necessarily indicative of the results that may be expected for the fiscal year ending June 30, 2009.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the balances and disclosures. Actual results could differ from these estimates.

The consolidated balance sheet as of June 30, 2008 has been derived from the audited financial statements at that date but as noted above does not include all disclosures required for complete financial statements.

Revenue Recognition

Revenues are recognized according to the terms of contractual agreements to which NTI is a party, when the Company s performance requirements have been fulfilled, the amount is fixed and determinable, and collection is reasonably assured. Revenue from license fees with non-cancelable, non-refundable terms and no future performance obligations is recognized when collection is assured. Milestone payments are recognized when the Company has fulfilled development milestones and collection is assured. Revenue from services performed for other parties is recorded during the period in which the expenses are incurred.

Royalty revenue is generally recorded when payments are received.

Revenue arrangements with multiple components are divided into separate units of accounting if certain criteria are met, including whether the delivered component has stand-alone value to the customer, and whether there is objective reliable evidence of the fair value of the undelivered items. Consideration received is allocated among the separate units of accounting based on their relative fair values, and the applicable revenue recognition criteria are identified and applied to each of the units.

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2. Investments

Available-for-sale securities were as follows:

	As of September 30, 2008		As of June 30, 2008	
	Cost	Estimated Fair Value	Cost	Estimated Fair Value
Type of security and term				
Auction rate securities (ARS)				
Maturing in 22 to 37 years	$ 10,352*	$ 10,274	$ 11,372*	$ 11,850
Corporate debt obligations				
Maturing within one year	2,022	2,059	2,027	2,039
Total investments	$ 12,374	$ 12,333	$ 13,399	$ 13,889
Classification				
Short-term		$ 2,059		$ 2,039
Long-term		10,274		11,850
Total investments		$ 12,333		$ 13,889

* Cost represents purchase price less impairment charge of $1,598 and $1,768 on securities still held at September 30, 2008 and June 30, 2008, respectively.

The Company s investments in auction rate securities (ARS) were structured to provide liquidity via an auction process that resets the applicable interest rate at predetermined calendar intervals. Beginning in February 2008, failed auctions occurred throughout the ARS market, and since then all auctions for NTI s ARS have been unsuccessful. While the credit rating of these securities remains high and the ARS are paying interest according to their terms, as a result of the potentially long maturity and lack of liquidity for ARS, the Company believes the value of the ARS in NTI s portfolio has been impaired. During the fiscal year ended June 30, 2008, the Company recorded an impairment charge to reduce the carrying value of the ARS. The impairment charge was based on a model of discounted future cash flows and assumptions regarding interest rates. The Company has recorded an unrealized loss of $78,000 on its ARS at September 30, 2008 based on a decrease in the estimated fair value since the impairment charge was initially recorded. All other unrealized gains and losses were immaterial. The Company has classified its ARS as long-term at September 30, 2008, and all other investments are classified as short-term. The following table shows additional information regarding the individual ARS held by the Company:

	As of September 30, 2008	
	Par Value	Estimated Fair Value
ARS		
Brazos Texas Higher Ed. Authority	$ 1,200	$ 1,107
Kentucky Higher Ed. Student Loan Corporation	1,000	877
Mississippi Higher Ed. Assistance Corporation	1,800	1,606
Pennsylvania St. Higher Ed. Assistance Agency	2,000	1,707
Panhandle Plains Student Fin. Corporation	1,500	1,310
Vermont Student Assistant Loan Corporation	2,000	1,581
Others, none individually over $600 in estimated fair value	2,450	2,086
Total	$ 11,950	$ 10,274

Custody of the Company s investments is held by Fidelity Investments. The majority of the Company s cash and cash equivalents consist of commercial paper which is also held in custody at Fidelity Investments. Par value does not reflect the impairment charge.

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3. Fair Value of Financial Instruments

Effective July 1, 2008, the Company adopted the provisions of Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (SFAS 157), for financial assets and liabilities and any other assets and liabilities carried at fair value. SFAS 157 establishes a valuation hierarchy for measurement of fair value. This hierarchy prioritizes the inputs into levels of objectivity as follows:

Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument.

Level 3 inputs are unobservable inputs based on management s own assumptions used to measure assets and liabilities at fair value, which are supported by little or no market activity.

A financial asset or liability s classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. The inputs or methodology used for valuing securities are not necessarily an indication of credit risk associated with investing in those securities. The following table provides the fair value measurements of our financial assets according to the fair value levels defined by SFAS 157 as of September 30, 2008:

		Fair Value Measurements at September 30, 2008 Using		
	Total Carrying Value as of September 30, 2008	Level 1 Quoted prices in active markets	Level 2 Significant other observable inputs	Level 3 Significant unobservable inputs
Short-term investments	$ 2,059	$ 2,059	$	$
Long-term investments	10,274			10,274
Total	$ 12,333	$ 2,059	$	$ 10,274

Short-term investments include cash and cash equivalents and available-for-sale securities and are measured at fair value using quoted market prices and are classified within Level 1 of the valuation hierarchy. Long-term investments consisting of ARS holdings have been valued using level 3 inputs. The Company s investments in auction rate securities are classified within Level 3 because there are no active markets for the auction rate securities and therefore the Company is unable to obtain independent valuations from market sources. Therefore, the auction rate securities were valued using a discounted cash flow model. Some of the inputs to the cash flow model are unobservable in the market. The adoption of SFAS 157 did not have any impact on the Company s results of operations or financial position.

4. Warrant Liability

The fair value of warrants issued by the Company in connection with an April 2007 sale of common stock has been recorded as a liability on the consolidated balance sheet based on a Black-Scholes option pricing model, and is marked to market on each financial reporting date. The change in fair value of the warrants is recorded in the consolidated statements of operations as a non-cash gain or loss. The key assumptions used to value the warrants at September 30, 2008 were a volatility factor of 0.70, a risk-free interest rate of 2.4% and no dividend yield for the remaining 3 1/2 years until maturity.

5. Stock-based Compensation

The Company recognizes stock-based compensation expense in its statement of operations based on estimates of the fair value of employee stock option and stock grant awards as measured on the grant date and uses the Black-Scholes option pricing model to determine the value of the awards granted. The Company amortizes the estimated value of the options over their vesting period, which generally ranges from one to four years. The option pricing model requires various input assumptions, which are noted in the tables below.

For the Three Months Ended September 30, 2008:	**4 year vesting 10 year term**
Expected volatility	0.67
Expected term (in years)	6.25
Risk free interest rate	2.8%

For the Three Months Ended September 30, 2007:	**4 year vesting 7 year term**
Expected volatility	0.80
Expected term (in years)	4.75
Risk free interest rate	4.2%

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Expected volatilities are based on historical volatilities of the Company s stock. The expected term of options represents the period that the Company s stock-based awards are expected to be outstanding based on the simplified method, which is the mid-point between the weighted-average vesting period and the contractual life of the option. The Company has used the simplified method for estimating the terms of options granted between July 1, 2008 and September 30, 2008 because its management believes the magnitude of the November 2007 underwritten public offering qualifies as a recapitalization of the Company, which is a significant structural change rendering historical option exercise data potentially unreasonable for estimating the expected term of options granted subsequently. Nevertheless, an expected-term analysis based on historical stock option grants for the Company s outstanding stock options at September 30, 2008 approximates the expected term under the simplified method. The risk free interest rate for periods related to the expected life of the options is based on the U.S. Treasury yield curve in effect at the time of grant. The expected dividend yield assumed for all options granted is zero, as the Company does not anticipate paying dividends in the near future. Stock-based compensation expense has been recorded in the condensed consolidated statement of operations as follows:

	Three months ended September 30,	
	2008	2007
General and administrative	$ 139	$ 159
Research and development	105	82
Total stock-based compensation expense	$ 244	$ 241

During the three months ended September 30, 2008, the Company granted options to purchase a total of 111,000 shares of common stock for which the aggregate grant-date fair value was $77,000. During the three months ended September 30, 2007, the Company granted options to purchase a total of 1,000 shares of common stock for which the aggregate grant-date fair value was $8,000. As of September 30, 2008, there was $1,724,000 of total unrecognized compensation cost related to unvested stock-based compensation awards which is expected to be recognized over the weighted average vesting period of 3.2 years.

6. Net Loss per Share

Basic and diluted net loss per share is based on the weighted average number of shares of common stock issued and outstanding during the period. If the Company had reported net income, the dilutive effect of additional equity instruments totaling 2,994,000 and 1,005,000 shares for the three months ended September 30, 2008 and 2007, respectively, would need to be considered.

7. Comprehensive Loss

The Company s comprehensive loss was $3,293,000 and $919,000 for the three months ended September 30, 2008 and 2007, respectively. The comprehensive loss is comprised of the net loss and certain changes in equity that are excluded from the Company s net loss, which are the unrealized holding gains or loss on available-for-sale investments.

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 referred to 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. The Company s Annual Report on Form 10-K also contains risk factors that provide examples of risks, uncertainties, and events that may cause our actual results to differ materially from those implied or projected. For example, there can be no assurance that:

the interim analysis for Viprinex will be successful;

there will be positive results from the on-going trials for Viprinex;

the FDA will approve Viprinex;

we will be able to comply with Nasdaq s continued listing standards; and

we will receive sufficient liquidity for our ARS.

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.

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Overview

We are a biopharmaceutical company focused on developing novel, first-in-class treatments for central nervous system conditions and other serious unmet medical needs. Our most advanced product candidate, Viprinex (ancrod), is in Phase 3 clinical testing as a novel investigational drug for the treatment of acute ischemic stroke. Stroke is one of the most prevalent, debilitating and costly diseases in the world, and there are few acceptable treatment options. Viprinex is a fibrinogen-reducing agent that is designed to expand the treatment window from three hours to six hours. We have rights to receive royalty payments from the sales of Namenda® (memantine HCL), an approved drug marketed for Alzheimer s disease and potential milestone and royalty payments from the development of XERECEPT an investigational drug which is in Phase 3 clinical trials for the treatment of swelling associated with cerebral tumors. Our earlier stage pipeline also includes rights to two proteins in preclinical development for the treatment of Alzheimer s disease and Huntington s disease.

Below is an overview of key developments affecting our business to date in fiscal 2009.

Viprinex , our Phase 3 investigational drug for acute ischemic stroke

We are currently conducting two Phase 3 clinical trials of Viprinex (ancrod) for acute ischemic stroke and expect to complete an interim futility analysis of merged data from the studies by January 2009. Following a meeting with the U.S. Food and Drug Administration, or FDA, in October 2008, we announced that we would combine the two concurrently running clinical trials and analyze the results as a single Phase 3 pivotal trial once a total of 650 patients have been treated. We plan to complete an interim futility analysis of the combined trials, based on the first 500 treated patients, no later than January 2009. Passing the futility analysis would indicate that the drug has met predetermined interim efficacy criteria. This futility review will constitute a go/no-go decision for the Viprinex program, and will be the first efficacy review since we started our clinical trials in 2005. The interim analysis will be conducted by an independent Data Safety Monitoring Board, or DSMB, which will also conduct a review of the safety of the drug. If the trial continues beyond the futility review, we expect final trial results from the combined trials to be available approximately mid-2009.

XERECEPT®, a Phase 3 investigational drug for which we have rights to receive milestone and royalty/profit-sharing payments

Celtic Pharmaceuticals, to whom we sold rights to XERECEPT in 2005, continues to develop XERECEPT (corticorelin acetate) for the treatment of brain edema associated with cerebral tumors. Celtic has informed us that it expects to report results of a Phase 3 clinical trial during the fourth quarter of 2008.

RESULTS OF OPERATIONS

Revenues

The major components of our revenue are as follows (in thousands):

	Three Months Ended September 30,		Variance From Period in Prior Year
	2008	2007	2008/2007
Royalty	$ 2,078	$ 1,981	$ 97
XERECEPT® sale	1,375	1,375	
Collaboration services	112	544	(432)
Technology sale and collaboration services	1,487	1,919	(432)
Total revenues	$ 3,565	$ 3,900	$ (335)

Total revenues of $3,565,000 for the three months ended September 30, 2008, decreased by $335,000 from revenues of $3,900,000 in the same period of fiscal 2008. Our first quarter fiscal 2009 revenues consisted of $2,078,000 from royalties on the commercial sales of memantine by Merz and its marketing partners in the United States, $1,375,000 from the sale of our rights and interests in XERECEPT to Celtic and $112,000 from the reimbursement of the direct expenses incurred for services provided to Celtic for development of XERECEPT. Royalties were higher for the three months ended September 30, 2008 than the three months ended September 30, 2007 because of higher sales of memantine by Merz s marketing partner in the United States, Forest Laboratories, Inc., more than offsetting discontinuation of royalty payments for sales in Europe and lower royalty rates that resulted from the amendment of our agreement with Merz in February 2008. Revenues from the sale of XERECEPT were the same for the three months ended September 30, 2008 and for the three months ended September 30, 2007 because we are recognizing the up-front payment of $33 million we received in November 2005 on a straight-line basis over the estimated term of our obligations, which extends to November 2011. Revenues from collaboration services declined by $432,000, or 79%, to $112,000 for the three months ended September 30, 2008 compared to the three months ended September 30, 2007 because we have transitioned most of the XERECEPT drug development work to Celtic and are no longer incurring or being reimbursed for higher levels of costs.

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RESEARCH AND DEVELOPMENT EXPENSES

Because we are in the business of drug development and our current drug candidates have not been approved for sale, the majority of our costs are related to the research and development of these drug candidates and are expensed as incurred. Research and development costs include clinical trial costs, drug supply and manufacturing costs, salaries and related personnel costs for employees involved in the development of our products, and other costs related to developing investigational drugs, including outside consultants. The following table shows our research and development expenses by product under development (in thousands):

	Three months ended September 30,		Variance From Period in Prior Year
	2008	2007	2008/2007
Viprinex for acute ischemic stroke	$ 4,908	$ 4,900	$ 8
XERECEPT	76	560	(484)
Preclinical treatments for Alzheimer s and Huntington s Diseases	468		468
Total	$ 5,452	$ 5,460	$ (8)

Total research and development expenses were $5,452,000 for the three months ended September 30, 2008, which represented a decrease of $8,000 compared to the same period in fiscal 2008. For the three months ended September 30, 2008, our spending on Viprinex aggregated $4,908,000, an increase of $8,000 from spending of $4,900,000 for the three months ended September 30, 2007. The majority of our research and development efforts are focused on Viprinex, a phase 3 investigational drug for the treatment of acute ischemic stroke which we acquired rights to in July 2004. Since acquiring these rights, we have established GMP manufacturing capability and initiated pivotal Phase 3 trials. In the first quarter of fiscal 2009, our expenditures on the Viprinex program were similar to the levels in the first quarter of fiscal 2008, as higher expenses on our clinical trial were largely offset by lower expenses on drug manufacturing. To date, we have spent approximately $71 million in direct costs on the development of Viprinex.

For the three months ended September 30, 2008, our spending on XERECEPT decreased to $76,000 from $560,000 for the comparable period in fiscal 2008. During fiscal 2008 we transitioned substantially all drug development activities to Celtic and are no longer incurring these costs. The decrease in our research and development costs for XERECEPT is comparable to the decrease in revenue for reimbursement of these costs by Celtic. In future periods, we expect research and development costs to increase for the Viprinex program as additional patients are enrolled into our clinical trial.

In fiscal 2008 we entered into two collaboration and license agreements with the Buck Institute for Age Research, or Buck, for the development of proteins in preclinical development for the treatment of Alzheimer s and Huntington s diseases. Under the agreements, we fund specified preclinical research work as performed by Buck in return for the development rights to the proteins that are the subject of their research. There were no comparable costs for the period in fiscal 2008.

GENERAL AND ADMINISTRATIVE EXPENSES

The following table shows our general and administrative expenses (in thousands):

Three months ended September 30,		Decrease From Period in Prior Year
2008	2007	2008/2007

$	1,331	$ 1,659	$ (328)

General and administrative expenses were $1,331,000 for the three months ended September 30, 2008, a 20% decrease from the expenses of $1,659,000 for the same period in fiscal 2008. The decrease of $328,000 for the three months ended September 30, 2008 is due primarily to cost savings measures implemented in the fourth quarter of fiscal 2008 and include a reduction in use of various consulting services.

We continually review our general and administrative expenses, and will further evaluate all expenses following the interim and final analyses of the current clinical trial.

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INTEREST INCOME

Interest income for the three month period ended September 30, 2008 was $249,000, compared to $28,000 for the same period in fiscal 2008. The increase over the same period in the prior year is primarily due to higher cash and investment balances following our underwritten sale of common stock in November 2007.

INTEREST EXPENSE

Interest expense for the three months ended September 30, 2007 was related to short-term notes issued in September 2007 and repaid in November 2007, and accordingly, there was no comparable expense for the three months ended September 30, 2008.

NON-CASH GAIN ON DECREASE IN FAIR VALUE OF WARRANTS

In April 2007, we issued warrants to purchase 435,000 shares of common stock in connection with a concurrent sale of common stock. The warrants are exercisable through April 2012 at a price of $16.80 per share. Although the terms of the warrants do not provide for net-cash settlement, in certain circumstances, physical or net-share settlement of the warrants is deemed not to be within our control and, accordingly, we are required to account for these warrants as a derivative financial instrument liability. The warrant liability is re-valued on each reporting date with changes in the fair value from prior periods reported as non-cash charges or credits to earnings. For warrant-based derivative financial instruments, the Black-Scholes option valuation model is used to value the warrant liability. The classification of derivative instruments, including whether these instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period. The non-cash gain on the decrease in fair value of warrants represents changes in the Black-Scholes value of the warrants we issued, which has occurred primarily as a result of the decrease in the price of our common stock.

LIQUIDITY AND CAPITAL RESOURCES

We assess liquidity primarily by the cash and investments available to fund our operations, which are primarily the continuation of the development of Viprinex for acute ischemic stroke and the administrative expenses of operating as a public company. We also assess liquidity by our working capital, modified to exclude deferred revenue and the warrant liability, available to fund operations. We exclude deferred revenue and the warrant liability from our working capital as we do not believe these items will ever require payments from our funds. The following table shows our cash and short-term investments and working capital (in thousands).

	September 30, 2008	June 30, 2008
Cash, cash equivalents, and short-term investments	$ 28,181	$ 29,980
Cash, cash equivalents, short-term and long-term investments	38,455	41,830
Working capital (excluding deferred revenue and the warrant liability)	24,069	27,357

Since our inception in 1987, we have applied the majority of our resources to our research and development programs and have generated only limited operating revenue. We have experienced operating losses in nearly every year since inception as we have funded the development and clinical testing of our drug candidates. We expect to continue to incur losses for the foreseeable future.

As of September 30, 2008, our combined balance of cash, cash equivalents and short-term investments decreased by $1.8 million from the balance at the end of our most recent fiscal year, June 30, 2008. The decrease was a result of the operating activities of conducting our clinical trials and other operations of the Company, which used approximately $3.0 million in cash and short-term investments. The use of cash and short-term investments for the first quarter would have been higher by an additional $1.5 million if our accounts receivable balance did not decrease and our accrued clinical trial expenses did not increase during the period. In addition, during the three months ended September 30, 2008, $1.2 million in par value of our investments in ARS were called at their par value.

We believe that our cash and investments (long and short-term combined) as of September 30, 2008 will be sufficient to fund our planned operations through at least the next twelve months. Estimates of our future liquidity thereafter will

be materially impacted by future business decisions regarding the development of Viprinex, which we plan to make following the interim and final analyses of the combined clinical trials. 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, it will be on acceptable terms.

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

- the results of the combined analysis of our Viprinex trials;
- the time and cost involved in completing the clinical trials and obtaining regulatory approval for Viprinex if the interim analysis is incomplete;
- the value we are able to receive upon our disposition of the ARS we hold as long-term investments;
- the royalties received from Merz on future sales of memantine;
- the cost of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights;
- competing technological and market developments;
- our ability to establish collaborative relationships;
- the development of commercialization activities and arrangements;
- the cost of our research collaborations with the Buck Institute for Age Research; and
- the receipt of milestone, royalty and profit-sharing payments pursuant to our agreements with Celtic.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our consolidated financial condition, changes in our consolidated financial condition, revenues or expenses, consolidated results of operations, liquidity, capital expenditures or capital resources.

Item 3. Quantitative and Qualitative Disclosures 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 designed to help us protect against these and other exposures. We do not anticipate material potential losses in these areas, but no policies or business practices can protect against all risks, and there is always a chance that unanticipated risks could arise and create losses for us.

We invest funds not needed for near-term operating expenses in diversified short-term and long-term investments, consisting primarily of investment grade securities. We do not believe that changes in interest rates would result in a material decrease or increase in the fair value of our available-for-sale securities due to the general short-term nature of our investment portfolio, or the regular resetting of interest rates on the securities we own which have an overall maturity date of more than one year. We have no investments denominated in foreign country currencies and therefore our investments are not subject to foreign currency exchange risk.

We have two offices in the United States and no offices in foreign locations. However, the manufacturer of the Active Pharmaceutical Ingredient, or API, in our lead investigational drug, Viprinex, is based in Germany and our obligations to this manufacturer are denominated in Euros. In addition, we have entered into agreements with clinical trial sites and service providers throughout the world, and as a result have payment obligations denominated in various foreign currencies. Because we do not maintain any accounts in foreign currencies, decreases in the value of the United States dollar will increase our U.S. dollar costs as additional U.S. dollars would be necessary to pay the same costs denominated in the various foreign currencies.

As of September 30, 2008, we had $10.3 million invested in ARS, issued principally by student loan agencies and generally rated AAA by a major credit rating agency. Our original purchase price for these securities was approximately $12.0 million, which was subsequently written-down to a value of $10.4 million in fiscal 2008. ARS are structured to provide liquidity via an auction process that resets the applicable interest rate at predetermined calendar intervals, which are approximately once a month. Beginning in February 2008, auctions for the securities in

our portfolio began to fail, and none have been successful since that time. We have classified all of our ARS as long-term investments as of September 30, 2008 and have estimated the fair value of these investments based on a model of discounted future cash flows and assumptions regarding interest rates. If the auctions for these securities continue to fail, the ARS may not be readily convertible into cash, and we may be required to take losses on the sale of the securities. Based on our expected cash usage for the next twelve months, we do not anticipate the current illiquidity of these investments will affect our ability to operate our business as usual for this period.

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Item 4. Controls and Procedures.

Our Chief Executive Officer and Chief Financial Officer are responsible for establishing and maintaining disclosure controls and procedures (as defined in the rules promulgated under the Securities Exchange Act of 1934, as amended) for our company. Based on their evaluation of our disclosure controls and procedures (as defined in the rules promulgated under the Securities Exchange Act of 1934), our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2008, the end of the period covered by this report.

Changes in Internal Control over Financial Reporting.

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently party to any material legal proceedings, although from time to time we may be named as a party to lawsuits in the normal course of business.

Item 1A. Risk Factors.

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended June 30, 2008, filed with the SEC on September 16, 2008, and the following updates to these risk factors. Any of these risks could materially affect our business, financial condition and future results. The risks described below and in our Annual Report on Form 10-K are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and future results.

Viprinex has failed in one of two Phase 3 clinical trials previously conducted by another company for the treatment of acute ischemic stroke, and it may not prove to be safe and effective in our current Phase 3 trials. Because Viprinex is our only product candidate, the failure of the interim analysis or any negative or inconclusive results in the ongoing trials would significantly harm our prospects and depress our stock price.

Although it has shown success in one of the two Phase 3 studies conducted by another company before we acquired the rights to Viprinex, Viprinex has also previously failed in one of the two Phase 3 clinical trials. In the failed trial, an interim analysis concluded that Viprinex was unlikely to reach its primary efficacy endpoint. Further analysis of the trial data revealed that Viprinex-treated patients suffered from higher symptomatic intracranial hemorrhaging and higher mortality rates than patients receiving the placebo treatment. Although we believe we may be able to address these problems by using a significantly changed dosing regimen in our current clinical trials, we still may not be able to demonstrate that Viprinex is a safe and effective treatment for acute ischemic stroke to the satisfaction of the FDA or other regulatory agencies. There is only one approved treatment for acute ischemic stroke in the United States, and many other drug candidates for this indication have failed in late-stage clinical trials, even after successful earlier-stage trials. If we are unable to demonstrate that Viprinex is a safe and effective treatment for acute ischemic stroke to the satisfaction of the FDA or other regulatory agencies, we will not receive regulatory approval and our business would be materially harmed.

The earlier failure of Viprinex illustrates the risks of clinical development of new drugs, including the possibility that drug candidates may be found to be unsafe and/or ineffective. If our trials do not have positive outcomes we may be forced to cease further development of Viprinex or to make additional significant expenditures for further clinical trials. Additionally, because Viprinex is the focus of nearly all of our current drug development efforts, the failure of Viprinex in the trials would greatly diminish our prospects and would likely cause our stock price to decline significantly.

We are scheduled to complete an interim analysis of the data gathered from the first 500 treated patients into our current Viprinex clinical trials no later than January 2009. Although the DSMB has reviewed the safety of Viprinex as studied in the current trials, they have never evaluated efficacy. New safety concerns could be identified during the analysis, or the DSMB could determine that we have not met the established efficacy hurdle to continue the study. Termination of the study following the interim analysis would likely result in our decision to terminate all future development of Viprinex, greatly diminishing our prospects and likely causing further declines in our stock price.

In September 2008, the results of a clinical trial evaluating rt-PA as a treatment for acute ischemic stroke when given between 3 and 4 1/2 hours after stroke onset were announced. The trial showed a response rate of approximately 52% for patients receiving rt-PA compared to approximately 45% for patients receiving placebo. If these results make rt-PA the standard of care for treatment of patients up to 4 1/2 hours after stroke onset, it could result in slower patient enrollment in our current clinical trials.

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In October 2008, we decided to combine the two concurrently running clinical trials and analyze the results as a single, pivotal Phase 3 clinical trial once enrollment reaches 650 treated patients. As a result, we expect to have final data on the merged clinical trial by mid-year 2009. Negative results of the combined clinical trial would greatly diminish our prospects and would likely cause our stock price to decline significantly.

The current volatility and disruption in the capital and credit markets may continue to exert downward pressure on our stock price and we may cease to be in compliance with the continued listing standards set forth by the Nasdaq Capital Market. If we cease to be in compliance with the continued listing standards, the Nasdaq Capital Market may commence delisting proceedings against us.

The capital and credit markets have been experiencing extreme volatility and disruption for more than twelve months. In recent weeks, the volatility and disruption have reached unprecedented levels. Stock markets in general, and our stock price in particular, have experienced significant price and volume volatility. Our stock is trading near historic lows and we could continue to experience further declines in stock price. Our stock is currently trading below $1.00 per share, which is in violation of Nasdaq s standard continued listing requirements. Although Nasdaq has suspended the enforcement of rules requiring a minimum $1.00 closing bid price, this suspension is currently only in effect through January 16, 2009. There is no guarantee that we will be in compliance with Nasdaq s continued listing requirements when this suspension is lifted. If our stock continues to trade below $1.00 when the temporary suspension is lifted, Nasdaq may commence delisting procedures against us. If we were to be delisted, the market liquidity of our common stock would likely be adversely affected and the market price of our common stock would likely decrease. Such a delisting could also adversely affect our ability to obtain financing for the continuation of our operations and could result in a loss of confidence by investors, suppliers and employees. In addition, our stockholders ability to trade or obtain quotations on our shares could be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask price for our common stock.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Submission of Matters to a Vote of Security Holders.

None.

Item 5. Other Information.

Effective November 4, 2008, the Company entered into an amendment (the Amendment) to its Rights Agreement, dated as of May 19, 2005 and amended on November 2, 2007 (collectively, the Rights Plan), between the Company and American Stock Transfer & Trust Company, as rights agent. The Amendment amends the definition of Acquiring Person to increase the percentage of permissible beneficial ownership without triggering the Rights Plan from 15% to 20%. All other terms of the Rights Plan remain unchanged.

Item 6. Exhibits

4.1	Amendment No. 2, effective November 4, 2008, to Rights Agreement dated as of May 19, 2005, as amended, by and between Neurobiological Technologies, Inc. and American Stock Transfer & Trust Company. (1)
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

(1) Previously filed with the Company s Registration

Statement on Form 8-A/A filed November 5, 2008 and incorporated herein by reference.	

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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: November 6, 2008

/s/ Paul E. Freiman

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

Dated: November 6, 2008

/s/ Matthew M. Loar

Matthew M. Loar
Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

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(1) Previously filed with the Company s Registration Statement on Form 8-A/A filed November 5, 2008 and incorporated herein by reference.