NEUROBIOLOGICAL TECHNOLOGIES INC /CA/
Form 10-Q
November 09, 2005
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2005

OR

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

For the transition period from _____ to _____

Commission file number 0-23280

NEUROBIOLOGICAL TECHNOLOGIES, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**94-3049219**
(State or other jurisdiction of incorporation)	**(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 x No ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act) Yes ¨ No x

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

Indicate the number of shares outstanding of each of the issuer s classes of the common stock, as of the latest practical date. Common Stock, $.001 Par Value: 27,083,335 shares outstanding as of November 2, 2005.

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NEUROBIOLOGICAL TECHNOLOGIES, INC.

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PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NEUROBIOLOGICAL TECHNOLOGIES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2005	June 30, 2005
	(Unaudited)	*(Note 1)*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,200,874	$ 828,416
Investment securities	2,579,677	7,677,818
Interest receivable	29,022	52,648
Prepaid expenses and other current assets	598,957	546,796
Total current assets	4,408,530	9,105,678
Restricted cash	31,082	30,933
Deposits	75,475	82,117
Property and equipment, net	756,461	596,021
Acquisition-related tangible and intangible assets	7,461,407	7,655,391
TOTAL ASSETS	$ 12,732,955	$ 17,470,140
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 536,125	$ 579,647
Accrued clinical trial expenses	470,350	573,520
Accrued professional expenses	544,944	503,068
Accrued toxicology and manufacturing expenses	1,067,871	1,551,049
Other accrued liabilities	566,185	608,751
Total current liabilities	3,185,475	3,816,034
Stockholders equity:		
Convertible Series A Preferred stock, $.001 par value, 5,000,000 shares authorized, 2,332,000 issued in series, 504,000 outstanding at September 30, and June 30, 2005 (aggregate liquidation preference of $252,000 at September 30, and June 30, 2005)	252,000	252,000
Common stock, $.001 par value, 50,000,000 shares authorized at September 30, and June 30, 2005, 27,083,335 outstanding at September 30, and 27,077,418 outstanding at June 30, 2005	73,312,918	73,051,935
Accumulated deficit	(63,973,857)	(59,646,803)
Accumulated other comprehensive loss	(43,581)	(3,026)

Total stockholders equity	9,547,480	13,654,106
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 12,732,955	$ 17,470,140

See accompanying notes.

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NEUROBIOLOGICAL TECHNOLOGIES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Quarter ended September 30,	
	2005	**2004**
Royalty revenue	$ 1,052,448	$ 516,852
EXPENSES		
Research and development	3,595,962	1,163,760
Acquired in-process research and development		4,251,335
General and administrative	1,800,462	931,380
Total expenses	5,396,424	6,346,475
Operating income (loss)	(4,343,976)	(5,829,623)
Investment income	16,922	77,348
NET LOSS	$ (4,327,054)	$ (5,752,275)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.16)	$ (0.23)
Shares used in basic and diluted loss per share calculation	27,077,933	25,169,734

See accompanying notes.

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NEUROBIOLOGICAL TECHNOLOGIES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Quarter ended September 30,	
	2005	**2004**
OPERATING ACTIVITIES:		
Net loss	$ (4,327,054)	$ (5,752,275)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	231,775	163,794
Stock-based compensation	244,316	13,688
Acquired in-process research & development		4,251,336
Changes in assets and liabilities:		
Interest receivable	23,626	(22,040)
Prepaid expenses and other current assets	(52,161)	(306,753)
Restricted cash	(149)	
Deposits	6,642	
Accounts payable and accrued expenses	(630,559)	652,714
Net cash used in operating activities	(4,503,564)	(999,536)
INVESTING ACTIVITIES:		
Acquisition of Empire, net of cash acquired		(2,950,690)
Purchase of investments	(2,397,454)	(2,897,268)
Maturity and sale of investments	7,455,040	6,147,530
Purchases of property and equipment	(198,231)	(261,401)
Net cash provided by investing activities	4,859,355	38,171
FINANCING ACTIVITIES:		
Issuance of common stock	16,667	41,790
Net cash provided by financing activities	16,667	41,790
Increase (decrease) in cash and cash equivalents	372,458	(919,575)
Cash and cash equivalents at beginning of period	828,416	2,012,452
Cash and cash equivalents at end of period	$ 1,200,874	$ 1,092,877
Supplemental disclosure of non-cash investing activities:		
Issuance of common stock for acquisition of Empire	$	$ 9,452,702

See accompanying notes.

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NEUROBIOLOGICAL TECHNOLOGIES, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

September 30, 2005

(Unaudited)

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, 2005.

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 quarter ended September 30, 2005 are not necessarily indicative of the results that may be expected for the fiscal year ending June 30, 2006, 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 accompanying condensed consolidated financial statements included in this report include information for NTI-Empire, Inc., a wholly-owned subsidiary of the Company. In July 2004, NTI acquired Empire Pharmaceuticals, Inc. (Empire), a privately held corporation, through the merger of Empire into NTI-Empire, Inc. The acquisition of Empire is accounted for as a purchase of assets in accordance with Statement of Financial Accounting Standards (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 from the date of the acquisition. All intercompany balances at September 30, and June 30, 2005, have been eliminated in consolidation. The Company operates in one segment, therapeutic drug development.

The consolidated balance sheet at June 30, 2005 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. For the quarter ended September 30, 2005, basic net loss per share is based on the weighted average shares of common stock issued and outstanding, and diluted net loss per share gives appropriate effect to all dilutive common equivalent shares consisting of stock options, warrants, and the assumed conversion of convertible preferred stock. Basic net loss per share is computed based on the weighted average shares of common stock issued and outstanding and excludes the effect of options, warrants, and convertible securities because they are antidilutive. Potentially dilutive securities of 777,823, which consist of options and convertible preferred stock for the quarter ended September 30, 2005, and 846,654, which consist of options, warrants, and convertible stock for the quarter ended September 30, 2004, have been excluded from the computation of diluted net loss per share as their effect is antidilutive.

REVENUE RECOGNITION

Revenue related to license fees with non-cancelable, non-refundable terms and no future performance obligations are recorded 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.

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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. Royalty revenue received pursuant to the agreement with Merz Pharmaceuticals GmbH (Merz) is recorded when received, which occurs in the second quarter following the quarter in which the revenues are earned by Merz s marketing partners.

STOCK-BASED COMPENSATION

We have adopted the requirements of SFAS 123(R) effective July 1, 2005, utilizing the Modified-Prospective Transition method, by which the Company has recognized 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. Measuring and assigning of compensation cost for share-based grants made prior to, but not vested as of the date of adopting SFAS 123(R), have been based upon the same estimate of grant-date fair value previously disclosed under SFAS 123 in a pro forma manner.

The Company has two share-based compensation plans. In September 2003, the Board of Directors adopted the 2003 Equity Incentive Plan (the 2003 Equity Plan), which was approved by the stockholders in December 2003. The 2003 Equity Plan provides for the issuance of options and stock awards and reserves up to 1,000,000 shares of common stock for issuance under the plan. In general, options are granted at fair market value on the date of the grant, have a term of 10 years and become exercisable over the vesting period of either one year or four years.

In September 2003, the Board of Directors adopted the 2003 Employee Stock Purchase Plan (the 2003 ESPP Plan), which was approved by stockholders in December 2003. The 2003 ESPP Plan has reserved 500,000 shares of common stock for sale. The 2003 ESPP Plan permits eligible employees to purchase common stock at a discount through payroll deductions during defined accumulation periods. The price at which the stock is purchased is equal to the lower of 85% of the fair value of the stock on the last trading day before the commencement of the applicable offering period or 85% of the fair value of the common stock on the last trading day of the accumulation period. During the quarter ended September 30, 2005, no shares were issued under the 2003 ESPP Plan, and no compensation expense was recorded for this Plan.

The amount of compensation expense recognized during the quarter ended September 30, 2005 under these plans was $244,316. No income tax benefit was recognized in the income statement for share-based compensation arrangements for the quarter ended September 30, 2005, as the Company reported an operating loss. As of September 30, 2005, there was $1,746,000 of total unrecognized compensation cost related to non-vested share based compensation arrangements granted under the 2003 Equity Plan.

The fair value of each option award is estimated on the date of grant using the Black Scholes option valuation model which uses the assumptions noted in the following table. Because option valuation models incorporate ranges of assumptions for inputs, those ranges are disclosed. Expected volatilities are based on historical volatilities of the Company s stock. The Company uses historical data to estimate option exercise and employee termination within the valuation model. The expected term of options is derived from the output of the option valuation model and represents the period of time that options granted are expected to be outstanding. The risk free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The Company grants options under the 2003 Equity Plan to both employees and non-employee directors, for whom the vesting period of the grants is four years and one year, respectively. The following assumptions are used for these two types of grants to determine stock-based compensation:

	4 year	**1 year**

	vesting	vesting
Weighted average volatility	1.14	0.89
Expected dividends	0	0
Expected term (in years)	5	3
Risk free rate	3.88%	4.13%

Prior to the adoption of SFAS123 (R), the Company accounted for stock option grants in accordance with Accounting Principals Board (APB) Opinion 25, *Accounting for Stock Issued to Employees* (APB 25) and related Interpretations. Under APB 25, when the exercise price of employee stock options equals the market price of the underlying stock on the date of the grant, no compensation expense is recognized. The Company grants stock

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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.

As permitted by SFAS 123, and as amended by SFAS 148, *Accounting for Stock-Based Compensation Transition and Disclosure*, SFAS 148, 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.

Disclosures of 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 using the Black-Scholes option valuation model.

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 previously reported during periods prior to the adoption of FAS123R was as follows (in thousands, except for per share data).

	For the Quarter ended September 30, 2004
Net loss as reported	$ (5,752)
Add back:	
Stock-based employee compensation expense included in net loss as reported	14
Deduct:	
Stock-based employee expense determined under SFAS 123	(200)
Pro forma net loss	$ (5,983)
Basic and diluted net loss per share as reported	$ (0.23)
Basic and diluted pro forma net loss per share	$ (0.24)

The assumptions used to determine the pro forma expenses under the Black Scholes option valuation model for the quarter ended September 30, 2004 under FAS148 include the following: Expected Dividend: 0; Volatility: 0.65, Expected Term (in years): 5, Risk Free Rate: 3.52%.

CASH EQUIVALENTS AND INVESTMENTS

The Company s investments include securities of the U.S. government and its agencies, municipalities, corporations and mortgage-backed securities. All securities which are highly liquid and purchased with original maturities of 90 days or less are recorded as cash equivalents. The Company has classified its cash equivalent and investment securities as available for sale securities as it does not intend to hold securities with stated maturities greater than twelve months until maturity. The Company manages its investment securities to maintain a duration of approximately two years and, in response to liquidity requirements and changes in the market value of securities, will sell investment securities

prior to their stated maturities. Available-for-sale securities are carried at estimated fair value, based on available market information, with unrealized gains and losses reported as a component of Accumulated Other Comprehensive Income (Loss) in Stockholders Equity. Realized gains or losses, amortization of premiums, accretion of discounts and earned interest are included in investment income. The cost of securities when sold is based upon specific identification.

RECLASSIFICATION

Certain balances reported in the prior period reflect the reclassification of long-term investments to short-term investments to conform with the presentation of the reported current period as we may not hold investment securities with stated maturities greater than twelve months to such stated maturity.

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NOTE 2 - SALE OF RIGHTS TO AND INTERESTS IN XERECEPT

In September 2005, we entered into a binding agreement to sell all our rights and assets related to XERECEPT to two subsidiaries of Celtic Pharma Holdings, L.P. (Celtic). Under the terms of the agreement, the Company will receive $20 million upon closing and will receive the total of an additional $13 million in non-contingent installment payments in January and June 2006, and January 2007. The Company is also eligible to receive up to an additional $15 million upon the achievement of certain regulatory objectives. The Company is eligible to receive profit-sharing payments on sales of XERECEPT in the United States and royalties on any sales elsewhere in the world, if the product receives regulatory approval for commercial sale. The Company will provide services relating to the current clinical trials of XERECEPT, and the buyers will assume responsibility for product development and will reimburse all direct product development expenses.

Pursuant to the terms of the agreement, we are required to provide Celtic with the assignment of our license rights in XERECEPT and provide confirmation by the FDA regarding certain elements of the protocol for the Phase III trials of XERECEPT. Obtaining the assignments has required the coordination among the several parties to the license assignments and has taken longer than initially anticipated when we signed the agreement. We have obtained the required confirmation from the FDA and one of the two necessary license assignments, and we anticipate obtaining the remaining license assignment by November 11, 2005. We anticipate closing the transaction with Celtic immediately following the receipt of the final assignment and receiving the $20 million in cash payment from Celtic during the week of November 14, 2005.

NOTE 3 - INVESTMENTS

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

September 30, 2005

	Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	Market Value
Corporate debt obligations:				
Maturing within 1 year	$ 116		$ (1)	$ 115
Maturing after 1 through 5 years	1,229		(25)	1,204
Maturing after 5 years	740		(14)	726
U.S. Government obligations:				
Maturing after 1 through 5 years	20			20
Municipal Securities				
Maturing within 1 year	15			$ 15
Mortgage and asset-backed securities				
Maturing after 5 years	503		(4)	$ 499
Total investments	$ 2,623		$ (44)	$ 2,580

June 30, 2005

	Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	Market Value
Corporate debt obligations:				
Maturing within 1 year	$ 113	$	$ (1)	$ 112
Maturing after 1 through 5 years	2,304		(23)	2,281
Maturing after 5 years	1,263	4		1,267
U.S. Government obligations:				
Maturing after 1 through 5 years	297			297
Maturing after 5 years	272	4		276
Municipal Securities				
Maturing within 1 year	329			329
Mortgage and asset-backed securities				
Maturing after 5 years	3,088	13		3,101
Securities issued by foreign governments and agencies denominated in $US				
Maturing after 5 years	15			15
Total investments	$ 7,681	$ 21	$ (24)	$ 7,678

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NOTE 4 - EQUITY TRANSACTIONS

During the quarter ended September 30, 2005, the Company issued 5,917 shares upon the exercise of common stock options for proceeds of $16,667.

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 in whole 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 $2.0 million to Empire stockholders. When the first patient is enrolled in the pivotal Phase III trials for Viprinex, NTI will issue an additional 2,375,170 shares of common stock and pay an additional $2.0 million to Empire stockholders, which we anticipate will occur in the quarter ending December 31, 2005.

NOTE 5 - COMPREHENSIVE LOSS

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

	Quarter ended September 30,	
	2005	**2004**
Net loss	$ (4,327,054)	$ (5,752,275)
Other comprehensive income (loss)	(43,581)	16,853
Comprehensive loss	$ (4,370,635)	$ (5,735,422)

NOTE 6 - SUBSEQUENT EVENTS

In October 2005, the Company received a royalty payment in the amount of $1,268,271 from Merz Pharmaceuticals GmbH (Merz) for sales of Memantine during the quarter ended June 30, 2005. Royalty revenue received pursuant to the agreement with Merz is recorded when received, which occurs in the second quarter following the quarter in which the revenues are earned by Merz s marketing partners.

In September 2005, we entered into a binding agreement to sell all our rights and assets related to XERECEPT to two subsidiaries of Celtic Pharma Holdings, L.P. (Celtic). Under the terms of the agreement, the Company will receive $20 million upon closing and will receive the total of an additional $13 million in non-contingent installment payments in January and June 2006, and January 2007. The Company is also eligible to receive up to an additional $15 million upon the achievement of certain regulatory objectives. The Company is eligible to receive profit-sharing payments on sales of XERECEPT in the United States and royalties on any sales elsewhere in the world, if the product receives regulatory approval for commercial sale. The Company will provide services relating to the current clinical trials of XERECEPT, and the buyers will assume responsibility for product development and will reimburse all direct product development expenses. Pursuant to the terms of the agreement, we are required to provide Celtic with the assignment of our license rights in XERECEPT and provide confirmation by the FDA regarding certain elements of the protocol for the Phase III trials of XERECEPT. Obtaining the assignments has required the coordination among the several parties to the license assignments and has taken longer than initially anticipated when we signed the agreement. We have obtained the required confirmation from the FDA and one of the two necessary license assignments, and we anticipate obtaining the remaining license assignment by November 11, 2005. We anticipate closing the transaction with Celtic immediately following the receipt of the final assignment and receiving the $20 million in cash payment from Celtic during the week of November 14, 2005.

In October 2005, we announced that we had received regulatory approval to commence the first of two planned pivotal Phase III trials of Viprinex for the treatment of acute ischemic stroke. We anticipate enrolling our first patient in this trial during November 2005, which will trigger the payment obligations to the former stockholders of Empire Pharmaceuticals as described above under Note 4. In satisfaction of these payment obligations, the Company will issue a total of 2,375,170 additional shares of common stock and make additional cash payments of $2.0 million.

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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 has been 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 we have sought partnerships with pharmaceutical and biotechnology companies for late-stage development and marketing of our product candidates. We anticipate that we will continue to acquire and develop multiple late-stage neuropathic products and will develop the resources to market these products in selected world regions.

Currently, we receive revenues on the sales of one approved product, Memantine, and have two product candidates in clinical development, Viprinex® and XERECEPT®. 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. As of September 30, 2005, Memantine was also being developed for the treatment of neuropathic pain.

We are currently developing Viprinex for the treatment of acute ischemic stroke. In September 2005, we received regulatory approval to commence the first of two planned Phase III clinical trials for Viprinex and we expect to enroll the first patient in this trial during the quarter ending December 31, 2005. We plan to build a sales organization to market and sell Viprinex in United States and may seek marketing partnerships in other regions of the world.

We have been developing XERECEPT for the treatment of peritumoral brain edema, or swelling around brain tumors. In September 2005, we entered into a definitive agreement for the sale of our rights and assets related to XERECEPT to two subsidiaries of Celtic Pharma Holdings, L.P., (Celtic). Under this agreement we will receive total upfront payments of $33 million, plus up to an additional $15 million if and when certain development milestones are met. If XERECEPT is approved for commercialization, we will receive royalties on sales outside the United States and will be eligible to receive profit-sharing payments on sales in the United States. Following the closing of this transaction, which is expected to occur in the quarter ending December 31, 2005, the Celtic entities will assume responsibility for the clinical development of XERECEPT. Pursuant to the terms of the agreement, we are required to provide Celtic with the assignment of our license rights in XERECEPT and provide confirmation by the FDA regarding certain elements of the protocol for the Phase III trials of XERECEPT. Obtaining the assignments has required the coordination among the several parties to the license assignments and has taken longer than initially anticipated when we signed the agreement. By November 9, 2005, we have obtained the confirmation from the FDA and one of the license assignments, and we anticipate obtaining the remaining license assignment by November 11, 2005. We anticipate to close the transaction with Celtic immediately following the receipt of the final assignment during the week of November 14, 2005, at which time we will receive $20 million.

Our general and administrative expenses have increased as a result of our acquisition of Empire Pharmaceuticals in July 2004, pursuant to which we acquired the rights to Viprinex. As a result of this acquisition, we have leased an additional office facility in New Jersey in order to support the development activities for Viprinex. Our general and administrative expenses have also increased as we have added management and operating staff to support these activities and independent consultants to assist with documenting and assessment of our internal controls. Except for fiscal 2001, we have incurred significant losses each year since our inception.

We expect to incur additional operating losses through at least fiscal 2007 as we continue our drug development efforts. Our development expenses were higher in the first quarter of fiscal 2006 as a result of the commencement of the clinical trials for XERECEPT and preparation for clinical trials of Viprinex. However, following the sale of our rights to Xerecept, we will be reimbursed for the development costs incurred for this drug candidate, resulting in an estimated annual savings of approximately $6 million. The closing the Xerecept sale will provide us with $20 million at closing and three non-contingent payments due in January and June 2006 and January 2007, totaling $13 million. Although this transaction is expected to provide sufficient cash to fund our ongoing operations, including the first Phase III clinical trial for Viprinex, we may seek to raise additional capital as market conditions permit.

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 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

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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, research and development expenses, and valuation of long-lived and intangible assets to be critical.

Revenue recognition

Revenues are recorded according to the terms of formal agreements to which we are a party, when our performance requirements have been fulfilled, the fee is determinable and when collection of the fee is probable or reasonably assured. Revenue related to license fees with non-cancelable, non-refundable terms and no future performance obligations are recognized when collection is assured. Revenues associated with milestone payments, pursuant to the non-cancelable and non-refundable terms of agreements to which we are a party, are recognized when we have fulfilled development milestones and when collection of the fee is assured. Revenues resulting from royalty fees earned from the sale of the product are based upon the sales reported by our licensees and determined in accordance with the specific terms of the license agreements. We record royalty revenue when it is received because we are unable to estimate and accrue royalty revenue due to the limited sales history of the product. We have made no material adjustments to date for revenue recorded from royalty fees.

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, 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 by assessing the level and related costs of the services provided during each reporting period. In determining whether clinical trial activities performed by third parties should be recognized in a specific reporting period, management considers:

- estimates of the percentage of work completed through the applicable reporting period in accordance with agreements established with the third-party service providers; and

- estimates of the percentage of work completed through the applicable reporting period 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. Management applies judgment and bases its estimates with the benefit of historical experience with the development of similar drugs and with third party contracts structured with similar performance and payment terms. While our historic estimates have been materially accurate, we recognize that estimates of expense incurred during current and future periods are determined greatly by patient enrollment levels and related activities, which may vary from historic patterns . We monitor service providers activities to the extent possible in order to assess current enrollment levels and related activities; however, if we under- or overestimate activity levels associated with various studies at a given point in time, we could materially under- or overestimate research and development expenses in future periods.

Valuation of Long-Lived and Intangible Assets

Intangible assets acquired, including acquired in-process research and development, are recorded 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 over the period that we estimate to be the economic useful life of the related asset.

We assess the impairment of 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 September 30, 2005, we had $6.7 million and $776,000 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.

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RESULTS OF OPERATIONS

REVENUES

Quarter Ended September 30,		Increase From Period in Prior Year
2005	2004	2005/2004
$1,052,000	$ 517,000	$ 535,000

Revenues of $1,052,000 in the quarter ended September 30, 2005 increased by $535,000 compared to revenues of $517,000 in the same quarter of 2004. Revenues in the quarter ended September 30, 2004 and 2005 consist of royalty fees from the sale of Memantine in the U.S. and in certain European countries.

Royalty revenues result from sales of Memantine by our marketing partners who do not make anticipated future sales volumes available to us. Because we do not have this data, and because of the limited history of Memantine sales, we are currently unable to estimate future royalty revenues.

RESEARCH AND DEVELOPMENT EXPENSES

Quarter Ended September 30,		Increase From Period in Prior Year
2005	2004	2005/2004
$ 3,596,000	$ 1,164,000	$ 2,432,000

Research and development expenses of $3,596,000 in the quarter ended September 30, 2005 increased by $2,432,000 compared to expenses of $1,164,000 in the same quarter of 2004. The incremental research and development expenses of $2,432,000 in the current quarter over the same quarter of the prior year include an additional $1,806,000 of expenses incurred to prepare for Phase III clinical trials of Viprinex and $626,000 of expenses for the continuing Phase III clinical trials for XERECEPT, which were initiated during April 2004. The incremental $1,806,000 research and development expenses incurred for Viprinex consist primarily of approximately $859,000 of expenses for the manufacture of Viprinex clinical materials, $490,000 for clinical trial preparation expenses, $405,000 of compensation-related expenses, and $55,000 for amortization of the intangible marketing license for Viprinex and depreciation and maintenance of venom concentrate, raw venom and the related snake-farm facilities utilized in the development of Viprinex. The additional $626,000 of research and development expenses related to XERECPT consist principally of approximately $331,000 for manufacturing of clinical drug materials, and $185,000 of compensation related

expenses Included in the additional compensation-related expenses during the quarter ended September 30, 2005 is $84,000 of stock-based compensation related to the adoption of FAS123R.

We anticipate that the level of Viprinex-related expenditures for research and development expenses will increase in the future as we enroll patients in the clinical Phase III trials of Viprinex, but that this increase will be partially offset by the savings we will realize from the reimbursement of our Xerecept-related development costs we will receive from Celtic following the closing of the transaction.

ACQUIRED 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. When pivotal

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Phase III trials for Viprinex are commenced, 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 former principal stockholder, who is currently an officer of NTI, $484,325 for the remainder of advances that he previously made to Empire. Upon enrollment of the first patient in the Phase III trials and payment of the proceeds to the selling stockholders of Empire, we expect that approximately $3,750,000 of the contingent consideration will be identified as in-process research and development based on its pro-rata allocation of the total consideration for the acquisition, assuming a per-share valuation of $3.85 for the issued shares. The acquired in-process research and development will be recorded as expense in the period during which the contingent payment is made, which we expect to occur during the quarter ending December 31, 2005.

GENERAL AND ADMINISTRATIVE EXPENSES

Quarter Ended September 30,		Increase From Period in Prior Year
2005	**2004**	**2005/2004**
$1,800,000	$ 931,000	$ 869,000

General and administrative expenses of $1,800,000 in the quarter ended September 30, 2005 increased compared to $931,000 for the same quarter in 2004. The increase of $869,000 during 2005 resulted primarily from additional expenses of $268,000 for compensation for additional administrative personnel related to public reporting and compliance with the Sarbanes-Oxley Act of 2002 and assisting with the financial management of the Company. In addition, there was an increase of $180,000 in legal fees during the quarter ended September 30, 2005 due to financing activities related to the sale of rights to Xerecept and an increase of $160,000 related to stock-based compensation expense related to the adoption of FAS123R. We also had additional expenses of $71,000 during the quarter ended September 30, 2005 related to the administrative operations of our New Jersey office that was established in September 2004.

INVESTMENT INCOME.

Quarter Ended September 30,		Decrease From Period in Prior Year
2005	**2004**	**2005/2004**
$17,000	$ 77,000	$ (60,000)

Investment income of $17,000 in the quarter ended September 30, 2005, decreased by $60,000 compared to investment income of $77,000 in the same quarter of 2004. The decrease in investment income resulted from a greater average balance of invested funds throughout the quarter ended September 30, 2004 compared to the same quarter in 2005 as we continued to use our available cash for our operations.

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LIQUIDITY AND CAPITAL RESOURCES

	September 30, 2005	June 30, 2005
Cash and cash equivalents, and investments	$ 3,781,000	$ 8,506,000
Working capital	1,223,000	5,290,000

	Quarter Ended September 30,	
	2005	2004
Cash provided by (used in):		
Operating activities	$ (4,504,000)	$ (1,000,000)
Investing activities	4,859,000	38,000
Financing activities	17,000	42,000

Since our founding in 1987, we have applied the 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 resulting from our ongoing research and development efforts.

As of September 30, 2005, we had cash, cash equivalents and total investment securities available for sale of $3,781,000. The balance of cash and cash equivalents of $3,781,000 at September 30, 2005 declined by $4,725,000 from cash and cash equivalents of $8,506,000 as of June 30, 2005 resulting from our operating, investing and financing activities during the three months ended September 30, 2005.

In August 2005, the Company established a $10 million line of credit with a national commercial bank. The line of credit is a revolving credit facility which is secured by the Company s assets (excluding intellectual property but including the right to receive payments pursuant to intellectual property agreements), matures in two years, bears interest at the bank s annual prime rate plus 1.00%, provides that the Company maintain one of several alternative liquidity covenants and requires payment of an annual commitment fee of 0.15% on the committed balance. As of September 30, 2005, no advances had been made on the line of credit, and the Company did not meet a required covenant for advances to have been made.

Cash Flows from Operating Activities

We used cash of $4,504,000 for operating activities during the quarter ended September 30, 2005, resulting primarily from our operating loss of $(4,327,000), which includes the non-cash expenses of $476,000 for depreciation, amortization, and stock-based compensation expense. Cash flows from operating activities benefited from sources of cash represented by a decrease in interest receivable of $24,000, and a decrease of $7,000 in deposits, which were exceeded by uses of cash to reduce accounts payable and accrued liabilities of $631,000 and an increase in prepaid and other current assets by $52,000. The decrease in accounts payable and accrued liabilities resulted primarily from the payment of liabilities previously accrued for the manufacture of clinical trial materials for Viprinex The increase in prepaid and other expenses of $52,000 reflect prepayments and deposits made for the continued clinical trials of XERECEPT and the preparation for clinical trials of Viprinex.

Cash Flows from Investing Activities

Investing activities provided $4,859,000 of cash in the quarter ended September 30, 2005 resulting primarily from the net proceeds from the sale and maturity of our investments, which was partially offset by our purchases of investments and purchases of property and equipment primarily for our new office facilities in Emeryville, California and Edgewater, New Jersey.

Cash Flows from Financing Activities

Financing activities provided cash of $17,000 in the quarter ended September 30, 2005, and consisted of the value of the common stock we issued for the exercise of options for our common stock during the period.

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At September 30, 2005 our balance of available cash, cash equivalents and investment securities is $3,781,000. As described above, we expect to incur increased costs in 2006 and subsequent fiscal years primarily for Phase III clinical trials for Viprinex, along with related administrative support costs. Additionally, when the first patient is enrolled in the Phase III clinical trials for Viprinex, which we anticipate will occur in November 2005, we will pay the former Empire stockholders an additional $2.0 million in cash and issue an additional 2,375,170 shares of common stock. All future development costs for Memantine will be paid by Merz, together with its marketing partners.

In September 2005, we signed a binding agreement for the sale of our rights in XERECEPT to two wholly-owned subsidiaries of Celtic Pharma Holdings, L.P. (Celtic). Under the terms of the agreement, we will receive $20 million in cash upon closing and a promissory note requiring the buyers to pay us an additional $13 million in non-contingent installment payments due in January and June 2006, and January 2007. We are also eligible to receive up to an additional $15 million upon the achievement of certain regulatory objectives and are eligible to receive profit-sharing payments on sales of XERECEPT in the United States and royalties on any sales elsewhere in the world, if the product receives regulatory approval. We will provide ongoing services relating to the current clinical trials of XERECEPT and the buyers will assume responsibility for product development and reimburse all direct product development expenses for XERECEPT which we incur. Pursuant to the terms of the agreement, we are required to provide Celtic with the assignment of our license rights in XERECEPT and provide confirmation by the FDA regarding certain elements of the protocol for the Phase III trials of XERECEPT. Obtaining the assignments has required the coordination among the several parties to the license assignments and has taken longer than initially anticipated when we signed the agreement. By November 9, 2005, we have obtained the confirmation from the FDA and one of the license assignments, and we anticipate obtaining the remaining license assignment by November 11, 2005. We anticipate to close the transaction with Celtic immediately following the receipt of the final assignment during the week of November 14, 2005, at which time we will receive $20 million.

We believe that our available cash, cash equivalents and investment balances of $3,781,000 as of September 30, 2005, our $10 million credit facility, which is expected to be available upon our receipt of the initial Celtic payment, the $20 million we expect to receive from our sale of rights to XERECEPT upon closing, which we anticipate during the week of November 14, 2005, the additional $13 million in non-contingent installment payments we will receive in January and June 2006, and January 2007, and the reimbursement of the ongoing direct development costs for XERECEPT, will provide adequate liquidity to fund our operations through at least the next twelve months. However, we may seek to raise additional liquidity to fund our operations in periods thereafter or to acquire development projects for our pipeline. Accordingly, we may seek to raise additional funds when market conditions permit, including through the sale of up to $25 million of common stock pursuant to our shelf registration statement. 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 receipts of payments pursuant to our agreements with Celtic;
- 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.

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RISK FACTORS

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 the Phase III clinical trial in Europe conducted by Knoll AG, where patients receiving Viprinex in the trial suffered from intercranial hemorrhaging and higher mortality rates than those patients receiving the placebo treatment. A Phase III clinical trial for Memantine for neuropathic pain failed to meet the primary endpoint. As evidenced by these trials, our product candidates face numerous risks of failure, including the possibility that these drug candidates may:

be found to be unsafe, ineffective or toxic; or

fail to receive necessary regulatory clearances.

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 2005, 2004 and 2003 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. We may be subject to such adjustments in the future.

Merz or Children s Medical Center can terminate our research and marketing cooperation agreement upon six months notice in the event that Merz does not meet certain conditions relating to the clinical development of Memantine. We believe these conditions are currently being met. However, 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.

When we complete the sale of our rights and assets related to XERECEPT as expected, we will be dependent upon these entities for the development and commercialization of XERECEPT.

In September 2005, we entered into an agreement to sell all our rights and assets related to XERECEPT to two newly-formed subsidiaries Celtic Pharma Holdings, L.P. Under the terms of the agreement, we are eligible to receive up to $15 million upon the achievement of certain regulatory objectives and are eligible to receive profit-sharing payments on sales of XERECEPT in the United States and royalties on any sales elsewhere in the world, if the product receives regulatory approval. However, because the buyers will assume responsibility for the clinical development of Xerecept throughout the world, our ability to receive these payments largely depends on the buyers. Although we will remain involved in the clinical development process, the buyers will ultimately control the design and execution of clinical trials and will oversee the final regulatory approval process and commercialization, if the product is approved. The clinical development and commercialization of a new drug candidate is complex and requires significant expertise and experience. If the buyers are unable to successfully develop and market Xerecept, we may not receive the potential development milestone payments and the value of our future royalty and profit-sharing rights could be greatly diminished.

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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 September 30, 2005, our accumulated deficit was approximately $64.0 million and we expect to continue to incur operating losses in the next several years as we continue our clinical trials for Viprinex and pursue potential acquisitions of complementary businesses, product candidates or technologies. 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 Viprinex is approved for commercialization, it may not be successfully commercialized.

If 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 HCI) Eisai Inc. and Pfizer Inc.

Exelon ® (rivastigmine tartrate) Novartis

Reminyl ® (galantamine HBr) Janssen Pharmaceutica

Neuropathic pain (Memantine)

Neurontin ® (gabapentin) Parke-Davis

Cymbalta ® (duloxetine HCI)	Lilly
Lyrica ® (pregabalin)	Pfizer Inc.

Peritumoral brain edema (XERECEPT)

Decadron ® (dexamenthasone)	Merck & Co. Inc.

Acute ischemic stroke (Viprinex)

Activase ® (alteplase, recombinat)	Genentech, Inc.

Our competitors are generally larger biotechnology or pharmaceutical companies with significantly greater financial resources and experience and have more internal development, sales and marketing personnel. Accordingly, 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, others may develop, manufacture and market products that could compete with those that we are developing.

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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 Viprinex for our clinical trials.

In March 2005, we executed an agreement with Nordmark Arzneimittel GmbH & Co. KG for supply of the active pharmaceutical ingredient of Viprinex that is manufactured in accordance with cGMP. The term of this supply agreement will expire in October 2019. In June 2005, we entered into a drug product development and clinical supply agreement with Baxter Pharmaceutical Solutions LLC for fill and finish of the Viprinex product for development and clinical use. This agreement will continue until such Viprinex product production is completed. In addition, we have taken steps to ensure an adequate supply of raw Malayan pit viper venom, from which the Viprinex active pharmaceutical ingredient is prepared (including steps towards the establishment of a colony of Malayan pit vipers in the United States). Any difficulties in obtaining raw Malayan pit viper venom in necessary quantities and potencies could adversely affect our ability to manufacture clinical and commercial supplies of Viprinex.

Pursuant to our agreement with Celtic, we will be required to supply XERECEPT for clinical trials. We have previously experienced delays obtaining the necessary clinical supplies of XERECEPT due to manufacturing difficulties. We may experience further delays in obtaining clinical supplies of XERECEPT, which could cause us to fail to meet our obligations to Celtic and delay the XERECEPT clinical trials.

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. The loss of our current supply arrangement could significantly delay our planned clinical trials for Viprinex and could impact the commercialization of the drug, if it is approved by the FDA.

As a result of our reliance on manufacturers, we face the following outsourcing risks:

- 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.

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.

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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 we cannot be certain that the Phase III clinical trials that we anticipate to commence in November 2005 or shortly thereafter, will not encounter similar difficulties. 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 and we have not yet commenced the second Phase III trial. Any further delays in patient enrollment could impede the development of XERECEPT and make it less likely that we or Celtic 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 may 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 financing transaction, it may adversely affect our stock price.

In order to maintain sufficient cash and investments to fund future operations, we may need to raise additional capital. Although we obtained a $10 million revolving credit facility in August 2005, and expect to receive aggregate payments of $33 million under our agreement with Celtic, which transaction we expect will close on November 14, 2005, we may seek to raise up to $25 million in additional capital over the next 12 to 24 months through various alternatives, including selling shares of our common stock.

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 relied and will continue to rely on others for research, development and commercialization of our potential products.

We have periodically 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 may place significant responsibility on the collaborator, licensor or contractor 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. In the quarter ended June 30, 2005, we entered into an agreement with SCIREX Corporation for the design and management of our anticipated Phase III clinical trials for Viprinex. We expect to rely substantially on SCIREX for these clinical trials. If this organization or any other 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.

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;

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- no consistent policy has emerged from the United States Patent and Trademark Office regarding the breadth of claims allowed or the degree of protection afforded under biotechnology patents; and

- others may independently develop similar products, duplicate any of our potential products, or design around the claims of any of our potential patented products.

In addition, because of the time delay in patent approval and the secrecy afforded United States patent applications, we do not know if other applications, which might have priority over our applications, have been filed.

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.

No infringement claims have been brought by third parties and we are not aware of any basis on which such claims could be made. Any infringement claims brought by a third party, even if these claims were ultimately found to be without merit, would be costly to defend against and would likely interfere with our operations while the claim was pending. If we were unsuccessful in defending against any such claims, it may be necessary for us to license certain additional rights. These licenses may be costly and may not be available on terms we find acceptable, if at all. Accordingly, the unfavorable resolution of any patent infringement claim could adversely affect our operations and prospects.

We have recently made several changes to the composition of our management team. If the members of our management team are unable to work together effectively, our ability to manage our business will suffer.

Following our acquisition of Empire Pharmaceuticals in July 2004, we have expanded our management team, adding Stephen J. Petti as Vice President, Product Development, David E. Levy as Vice President, Clinical Development, Jonathan R. Wolter as Vice President and Chief Financial Officer, and Karl G. Trass as Vice President, Regulatory Affairs. In October 2005, Mr. Petti has informed the Company of his intention to resign as an officer and employee of the Company for personal reasons after the end of calendar 2005. These changes in our management team can be disruptive to our business and, if our management team cannot work together effectively, 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.

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.

We issued 2,399,163 shares of common stock in connection with our acquisition of Empire Pharmaceuticals and will be required to issue an additional 2,375,170 shares following the enrollment of the first patient in the Phase III clinical trials for Viprinex. These shares have been registered for resale and are, or upon issuance will be, freely tradable. 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, Celtic 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, Celtic 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 September 30, 2005, the fair value of our investments was $2,580,000 and 5% 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 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 Chief Financial Officer concluded that the Company s disclosure controls and procedures were effective as of that date.

There has been no change in the Company s internal controls over financial reporting during the Company s most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company s internal controls over financial reporting.

PART II. OTHER INFORMATION

ITEM 5. OTHER INFORMATION

ITEM 6. EXHIBITS

10.1	Loan and Security Agreement, dated August 18, 2005, by and between Comerica and Neurobiological Technologies, Inc.
10.2	Amendment No. 1, dated September 20, 2005, to Loan and Security Agreement between Comerica and Neurobiological Technologies, Inc.
10.3	Asset Purchase Agreement, dated as of September 19, 2005, by and between Neurobiological Technologies, Inc., Neutron ROW Ltd. and Neutron Ltd.
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

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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 9, 2005

/s/ PAUL E. FREIMAN
Paul E. Freiman

President, Chief Executive Officer and Director

(Principal Executive Officer)

/s/ JONATHAN R. WOLTER
Jonathan R. Wolter

Vice President and Chief Financial Officer

(Principal Financial and Accounting Officer)