

# Neuralstem Reports Third Quarter 2016 Results

## **Provides Business and Clinical Updates**

GERMANTOWN, Md., Nov. 08, 2016 (GLOBE NEWSWIRE) -- Neuralstem, Inc. (Nasdaq:CUR), a biopharmaceutical company focused on the development of central nervous system therapies based on its neural stem cell technology, reported its financial results and provided business and clinical updates for the three and nine month periods ended September 30, 2016.

"This is an exciting time for Neuralstem, as we successfully continue to execute the new operational and clinical development strategy that was implemented in the beginning of the year," commented Rich Daly, Chief Executive Officer. "The recent announcement of the \$20 million strategic investment from Tianjin Pharmaceutical Holdings Co., Ltd. provides credibility for our technology and a healthy financial runway through 2017. Furthermore, we reached 50% enrollment for our NSI-189 Phase 2 study in major depressive disorder ahead of schedule, maintaining expected data results in the second half of 2017."

#### **Recent Business and Clinical Highlights**

- In May 2016, we enrolled the first subject in our NSI-189 Phase 2 clinical trial for the treatment of major depressive disorder (MDD).
- In June 2016, we announced new NSI-189 preclinical data showing enhancement of mouse long term potentiation (LTP), an in vitro biomarker of memory by NSI-189 in a concentration-dependent and time-dependent manner. We believe that this study not only suggests the cognition enhancing potential of NSI-189, but also contributes toward the understanding of its mechanism of action.
- In September 2016, we entered into a definitive agreement with Tianjin Pharmaceutical Holdings Co., Ltd. for a private placement of common stock and convertible preferred stock for gross proceeds of \$20 million. This agreement is expected to close in the fourth quarter of 2016.
- In September 2016, we achieved 50% enrollment in our Phase 2 clinical trial evaluating NSI-189 for the treatment of major depressive disorder (MDD).
- In September 2016, we presented preclinical data which showed that NSI-189 was effective in the prevention and reversal of diabetic neuropathies in Type 1 and Type 2 diabetic mouse models.

• In October 2016, we presented preclinical data which showed NSI-189's ability to ameliorate radiation-induced cognitive impairment and to protect hippocampal neurogenesis in a mouse model of brain injury due to radiation therapy of brain cancers.

#### **Results of Operations for the Third Quarter 2016**

Research and Development expenses increased approximately \$198,000 or 6% for the three months ended September 30, 2016 compared to the comparable period of 2015. This was primarily attributable to increased spending on clinical trials associated with our on-going Phase 2 MDD study, partially offset by salary and benefits saving associated with our reduction-in-force in May and reduced manufacturing expenses.

General and Administrative expenses decreased approximately \$478,000 or 26% for the three months ended September 30, 2016 compared to the comparable period of 2015. This was primarily due to a reduction in salaries, benefits and consulting expenses as a result of our May 2016 reduction-in-force.

Other expenses, net totaled approximately \$303,000 and \$440,000 for the three months ended September 30, 2016 and 2015, respectively. Other expense, net in 2016 consisted of approximately \$538,000 of losses related to the fair value adjustment of our derivative instruments and \$240,000 of interest expense primarily related to our long-term debt, partially offset by a gain of approximately \$459,000 related to our entering into a reimbursement agreement with a former executive officer.

Other expenses, net in 2015 consisted primarily of approximately \$464,000 of interest expense principally related to our long-term debt partially offset by approximately \$24,000 in interest income.

#### **Results of Operations for the Nine Months Ended September 30, 2016**

Research and Development expenses decreased approximately \$758,000 or 8% for the nine months ended September 30, 2016 compared to the comparable period of 2015. This was primarily attributable to a decrease in manufacturing costs associated with producing clinical supplies of NSI-189 partially offset by an increase in pre-clinical and clinical trial expenses related to the initiation of our Phase 2 MDD study.

General and Administrative expenses increased approximately \$937,000 or 19% for the nine months ended September 30, 2016 compared to the comparable period of 2015. This was primarily due to a severance accrual and increased non-cash stock based compensation resulting from the accelerated vesting of options, both related to the resignation of our former Chief Executive Officer coupled with non-cash stock based compensation expense resulting from grants to our new Chief Executive Officer which were partially offset by a decrease in our employee bonus expense.

Other expenses, net totaled approximately \$694,000 and \$1,334,000 for the nine months ended September 30, 2016 and 2015, respectively. Other expense, net in 2016 consisted of approximately \$949,000 of interest expense primarily related to our long-term debt and

\$464,000 of fees related to the issuance of our derivative instruments, partially offset by a gain of approximately \$459,000 related to our entering into a reimbursement agreement with a former executive officer of the Company and \$219,000 of gain related to the change in the fair value adjustment of our derivative instruments.

Other expenses, net in the nine months ended September 30, 2015 consisted primarily of approximately \$1,377,000 of interest expense principally related to our long-term debt partially offset by approximately \$54,000 in interest income.

#### Neuralstem, Inc.

	Three Months Ended September 30,			Nine Months Ended September 30,				
		2016		2015		2016		2015
Revenues	\$	2,500	\$	2,500	\$	7,500	\$	7,917
Operating expenses: Research and development expenses General and administrative		3,589,793			9,130,012			9,887,750
expenses		1,329,712 1,807,934		5,862,374			4,925,389	
Total operating expenses		4,919,505		5,200,020		14,992,386		14,813,139
Operating loss		(4,917,005)		(5,197,520)		(14,984,886)		(14,805,222)
Other income (expense): Interest income Interest expense Change in fair value of derivative instruments Gain on related party settlement Fees related to issuance of derivative instrument and other expenses Total other income (expense)		17,293 (240,462) (538,261) 458,608 (456) (303,278)		24,149 (464,197 ) - - - (440,048 )		41,862 (949,375) 219,014 458,608 (463,798) (693,689)		53,802 (1,377,004 ) - - (10,326 ) (1,333,528 )
Net loss	\$	(5,220,283)	\$	(5,637,568)	\$	(15,678,575)	\$	(16,138,750)
Net loss per share - basic and diluted	\$	(0.05)	\$	(0.06)	\$	(0.15)	\$	(0.18)
Weighted average common shares outstanding - basic and diluted		114,855,581		91,569,826		104,248,993		90,532,073

#### Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss

Comprehensive loss:

Net loss Foreign currency translation adjustment	\$ (5,220,283)	\$ (5,637,568)	\$ (15,678,575)	\$ (16,138,750 )
	 21	(2,275)	1,516	(2,280)
Comprehensive loss	\$ (5,220,262)	\$ (5,639,843 )	\$ (15,677,059)	\$ (16,141,030 )

#### Neuralstem, Inc.

#### **Unaudited Condensed Consolidated Balance Sheets**

	September 30, 2016		December 31, 2015	
ASSETS				
CURRENT ASSETS				
Cash and cash equivalents	\$	5,676,129	\$	4,716,533
Short-term investments		-		7,517,453
Trade and other receivables		12,685		37,316
Current portion of related party receivable, net of discount		51,733		-
Prepaid expenses		946,943		1,159,782
Total current assets		6,687,490		13,431,084
Property and equipment, net		315,543		343,200
Patents, net		984,125		1,103,467
Related party receivable, net of discount and current portion		413,466		-
Other assets		49,984		71,797
Total assets	\$	8,450,608	\$	14,949,548
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY CURRENT LIABILITIES				
Accounts payable and accrued expenses	\$	2,484,335	\$	1,455,826
Accrued bonuses		-		161,362
Current portion of long-term debt, net of fees and discount		4,829,428		4,545,180
Other current liabilities		538,350		263,104
Total current liabilities		7,852,113		6,425,472
Long-term debt, net of fees, discount and current portion Derivative instruments		- 4,363,156		3,382,654
Other long-term liabilities		4,303,150		- 174,144
Total liabilities		12,235,559		9,982,270
		12,200,000		0,002,210

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### STOCKHOLDERS' (DEFICIT) EQUITY

Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding

Common stock, \$0.01 par value; 300 million shares authorized, 114,823,460 and 92,005,705 shares outstanding in 2016 and 2015, respectively	1,148,235	920,057
Additional paid-in capital	182,699,484	176,002,832
Accumulated other comprehensive income	4,587	3,071
Accumulated deficit	(187,637,257)	(171,958,682)
Total stockholders' (deficit) equity	(3,784,951)	4,967,278
Total liabilities and stockholders' (deficit) equity	\$ 8,450,608	\$ 14,949,548

#### About Neuralstem

Neuralstem's patented technology enables the commercial-scale production of multiple types of central nervous system stem cells, which are being developed as potential therapies for multiple central nervous system diseases and conditions.

Neuralstem's technology enables the generation of small molecule compounds by screening hippocampal stem cell lines with its proprietary systematic chemical screening process. The screening process has led to the discovery and patenting of molecules that Neuralstem believes may stimulate the brain's capacity to generate new neurons, potentially reversing pathophysiologies associated with certain central nervous system (CNS) conditions.

The company has completed Phase 1a and 1b trials evaluating NSI-189, a novel neurogenic small molecule product candidate, for the treatment of major depressive disorder or MDD, and is currently conducting a Phase 2 efficacy study for MDD.

Neuralstem's stem cell therapy product candidate, NSI-566, is a spinal cord-derived neural stem cell line. Neuralstem is currently evaluating NSI-566 in three indications: stroke, chronic spinal cord injury (cSCI), and Amyotrophic Lateral Sclerosis (ALS).

Neuralstem is conducting a Phase 1 safety study for the treatment of paralysis from chronic motor stroke at the BaYi Brain Hospital in Beijing, China. In addition, NSI-566 was evaluated in a Phase 1 safety study to treat paralysis due to chronic spinal cord injury, as well as, a Phase 1 and Phase 2a risk escalation, safety trials for ALS. Patients from all three indications are currently in long-term observational follow-up periods to continue to monitor safety and possible therapeutic benefits.

#### Cautionary Statement Regarding Forward Looking Information:

This news release contains "forward-looking statements" made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements relate to future, not past, events and may often be identified by words such as "expect," "anticipate," "intend," "plan," "believe," "seek" or "will." Forward-looking statements by their nature address matters that are, to different degrees, uncertain.

Specific risks and uncertainties that could cause our actual results to differ materially from those expressed in our forward-looking statements include risks inherent in the development and commercialization of potential products, uncertainty of clinical trial

results or regulatory approvals or clearances, need for future capital, dependence upon collaborators and maintenance of our intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements. Additional information on potential factors that could affect our results and other risks and uncertainties are detailed from time to time in Neuralstem's periodic reports, including the Annual Report on Form 10-K for the year ended December 31, 2015, and filed with the Securities and Exchange Commission (SEC) on March 14, 2016, Form 10-Q for the period ended September 30, 2016, and in other reports filed with the SEC.

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Source: Neuralstem, Inc.