

Neuralstem Reports Third Quarter Financial Results And Provides Business And Clinical Update

GERMANTOWN, Md., Nov. 7, 2014 /PRNewswire/ -- Neuralstem, Inc. (NYSE MKT: CUR) today reported its financial results for the three months and nine months ended September 30, 2014 and provided a business and clinical update.

"The third quarter of 2014 marked several important clinical milestones for Neuralstem," said Dr. Karl Johe, Chairman and CSO. "Using our lead NSI-566 cell therapy, we completed transplantation of the final cohort in our Phase II ALS trial and the first patient in our Phase I chronic spinal cord injury trial. Additionally, patient enrollment in our Beijing stroke trial remains on track. These clinical advancements utilizing Neuralstem's lead product for three different indications continues to demonstrate the breadth of our cell therapy platform."

"With the recent refinance of our SBIR loan the Company's cash position remains strong in excess of \$30 million to support the ongoing product development of NSI-566 and NSI-189. Additionally, we continued to strengthen our global IP portfolio for both our cell therapy and small molecule drug platforms," said Richard Garr, Neuralstem's President and CEO. "Lastly on behalf of Dr. Johe and myself, we would like to acknowledge the brave patients and caregivers who participate and support Neuralstem's clinical initiatives. We also thank our exceptional collaborators: NSI-566 ALS principal investigator, Eva L. Feldman, MD, PhD; site principal investigator, Jonathan D. Glass, MD; and site investigator, Merit Cudkowicz, MD; NSI-566 chronic spinal cord injury lead collaborator, Martin Marsala, MD, PhD; and principal investigator and neurosurgeon, Joseph Ciacci, MD; and NSI-189 small molecule trial consultant, Maurizio Fava, MD."

Third Quarter Clinical Program and Business Highlights

NSI-566 spinal cord-derived stem cell therapy for the treatment of ALS

Neuralstem announced the last patient was treated in the current multicenter Phase II ALS clinical trial. This dose escalating trial treated 15 ambulatory patients in five different cohorts. Each of the three patients in the final cohort received a total of 40 injections of 400,000 cells in both the cervical and lumbar regions. The six-month observation period and data lock is scheduled to conclude in late January 2015 at which time the company anticipates providing its Phase II ALS results.

In September, Jonathan D. Glass, MD, NSI-566 ALS site principal investigator at Emory University, presented long-term follow-up data of approximately 1,200 days on the Phase I trial, at the Annual Symposium on ALS of the Foundation Andre-Delambre, in Montreal. Dr. Glass reported that patients in the final safety cohort received a total of 15 injections of 100,000 cells treatments in both the lumbar and cervical regions of the spinal cord showed significant slowing of the progression of the symptoms of the disease as measured by the ALSFR-S scores. One patient showed functional improvement from pre-treatment baseline, which is maintained to present day. The other two patients are maintaining the same level of functionality as they had at the baseline.

NSI-566 spinal cord derived cell therapy for the treatment of chronic spinal cord injury (cSCI)

In September, the first patient was treated in Neuralstem's US NSI-566 chronic spinal cord injury (cSCI) Phase I trial at the University of California, San Diego School of Medicine. UCSD reported in *Science Daily* that the patient is "recovering without complication or adverse effects at home." The NSI-566 cSCI Phase I trial, will treat four patients with stem cell transplants directly into the region of the injury. Patient inclusion criteria includes thoracic spinal cord injuries (T2-T12) between one and two years post-injury and have an American Spinal Injury Association (AIS) grade A level of impairment which is complete paralysis with no motor or sensory function in the relevant segments at and below the injury. The NSI-566 cSCI trial uses the same spinal cord-derived stem cells and similar procedure as the company's NSI-566/ALS trials which have treated 30 ALS patients safely. In addition to the early neurotrophic factor expression of the cells shown in published Phase I ALS data, the NSI-566 mechanism of action in cSCI patients includes rebuilding neural circuitry for structural repair to "bridge the gap."

NSI-566 spinal cord derived stem cell therapy for the treatment in stroke

Our collaborative Phase I/II ischemic stroke trial with BaYi Brain Hospital in Beijing commenced in December 2013. The two part trial in which NSI-566 cells are injected directly into the brain near stroke lesions is designed

to enroll up to 118 patients. The Phase I open label, dose-escalation trial is designed to enroll 18 patients to determine the maximum safe dose. The second part, Phase II proof of concept study, will be a multi-site, randomized, controlled, single-blind study with enrollment of up to 100 patients.

NSI-189 oral hippocampal small molecule for the treatment of major depressive disorder (MDD)

Positive Phase Ia / Ib data results were released in June 2014. Subsequently, the Company reiterated its plans to commence a multi-site Phase II clinical trial which it expects to start in the second guarter of 2015.

NSI-532.IGF preclinical hippocampal stem cell therapy expands product pipeline

In October, the first data in a study transplanting Neuralstem's cells in an animal model of Alzheimer's disease was presented at the Congress of Neurological Surgeons Annual Meeting. The science oral presentation entitled, "Peri-hippocampal stem cell transplantation rescues cognitive decline in Alzheimer's disease," was presented by Osama N. Kashlan, MD, of the departments of Neurology and Neurosurgery at the University of Michigan Medical School. The researchers concluded that Neuralstem's NSI-532.IGF cells rescued spatial learning and memory deficits in mice with an animal model of Alzheimer's disease. NSI-532.IGF cells, Neuralstem's second stem cell product, are a cortical neural stem cell line engineered to deliver an extra therapeutic benefit. In this cell line, the benefit is provided by human insulin-like growth factor 1 (IGF-1). Many studies provide evidence that IGF-1 has been shown to have wide-ranging neuroprotective properties, in addition to those of the stem cells. The researchers reported that the cells injected in the peri-hippocampal region survived for up to ten weeks. Fourteen weeks post-surgery, the NSI-532.IGF injected mice performed significantly better than the control mice. The hippocampus plays an important role in memory encoding and retrieval. It is also one of the first regions of the brain to be affected in Alzheimer's disease. The researchers concluded that this approach could provide a viable approach to treat Alzheimer's disease in humans in the future. The NSI-532.IGF product pipeline expansion into a different neural stem cell line highlights the platform nature of Neuralstem's technology that enables the company to isolate develop stem cells from different regions of the central nervous system (CNS). This is also the first instance in which the company is demonstrating the ability of the cells, which integrate in the CNS under the blood brain barrier, acting as a stable delivery vehicle for gene therapy. Although the focus of this study is on the hippocampus, the cells and the therapeutic protein distribute widely and provide global therapeutic effects throughout the brain.

Business Highlights

In September, Neuralstem's President and CEO, Richard Garr presented an overview of the company's cell therapy and neurogenic small molecule clinical trials at the 2014 Rodman & Renshaw Annual Global Investment Conference.

The company also was notified of the issuance of U.S. issued patent 8,846,914 for "Compositions and Methods of Use." In August and September, Indonesia, Mexico, and New Zealand issued patents (108142605, 323079, 59889) for "Synthesis of a Neurostimulative Piperazine." In August, South Korea issued patent 10-14929284 for "Methods of Treating Spinal Cord Injury."

Third Quarter Financial Results

Cash equivalents and short-term investments on hand was approximately \$26,953,000 at September 30, 2014, compared to \$16,846,000 at December 31, 2013. The \$10,107,000 increase resulted from our raising \$18.7 million through our January 2014 registered direct offering along with approximately \$1.8 million from the exercise of certain common stock purchase warrants and options, partially offset by cash used in our operations.

For the three months ended September 30, 2014, the Company reported a net loss of approximately \$4,455,000 or \$0.05 per share, compared with a net loss of approximately \$6,687,000 or \$0.09 per share, for the comparable 2013 period. The decrease in net loss was primarily due to the prior year period including non-cash expenses of \$1,945,000 related to modifications of certain stock purchase warrants and \$678,000 related to the change in fair value of our warrant liability.

Our operating loss increased by \$473,000 primarily due to a \$262,000 increase in consulting and professional fees related to patent, litigation and other corporate matters and a \$211,000 increase in research and development efforts.

For the nine months ended September 30, 2014, the Company reported a net loss of approximately \$17,126,000 or \$0.20 per share, compared with a net loss of approximately \$16,529,000 or \$0.23 per share, for the comparable 2013 period. The increase in our net loss was due to a \$3,034,000 increase in our operating loss

largely offset by a \$2,437,000 decrease in other expenses.

The increase in operating loss was due primarily due to a \$2,786,000 increase in our general and administrative expenses, comprised primarily of a \$1,525,000 increase in non-cash stock based compensation cost along with a \$1,035,000 increase in legal, consulting and professional fees related to patent, litigation and other corporate matters. In addition, in the 2013 period we recognized \$108,000 of revenue primarily related to upfront licensing fees compared to \$14,000 in licensing fees in the 2014 period.

The decrease in other expenses was primarily due to a \$1,907,000 decrease non-cash expense related to modifications of certain stock purchase warrants coupled with a \$525,000 decrease in non-cash expense for the change in fair value of our warrant liability.

September 30, December 31,

2013

2014

Neuralstem, Inc.

Unaudited Condensed Consolidated Balance Sheets

ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 11,945,2	16,846,052
Short-term investments	15,007,478	-
Billed and unbilled receivables	32,761	10,000
Deferred financing fees, current portion	339,752	507,334
Prepaid expenses	409,140	255,733
Total current assets	27,734,384	17,619,119
Property and equipment, net	301,282	230,971
Patents, net	1,245,502	1,137,701
Deferred financing fees, net of current portion	104,407	360,848
Other assets	57,720	64,897
Total assets	\$ 29,443,295	\$ 19,413,536

LIABILITIES AND STOCKHOLDERS' EQUITY

CURRENT LIABILITIES

Accounts payable and accrued expenses	\$ 2,444,03		39\$	1,662,058
Current portion of long term debt, net of discount	3,058,4	195	2,763,12	21
Derivative instruments	-	- 1,417,527		27
Other current liabilities	202,383 93,426			
Total current liabilities	5,704,9	917	5,936,132	
Long term debt, net of discount and current portion	2,611,4	1 21	4,934,21	10
Other long term liabilities	222,970			
Total liabilities	abilities 8,539,308			
STOCKHOLDERS' EQUITY				
Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding	-		-	
Common stock, \$0.01 par value; 300 million shares authorized, 87,155,672 and 77,886,031 shares outstanding in 2014 and 2013, respectively	871,55	7	778,860	
Additional paid-in capital	165,57	7,933	136,058	,135
Accumulated other comprehensive income	6,110	6,110 7,241		
Accumulated deficit	I deficit (145,551,613) (128,426,037)			
Total stockholders' equity	20,903	,987	8,418,19	99
Total liabilities and stockholders' equity	\$ 29,443	,295	\$ 19,413,5	536

Neuralstem, Inc.

Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss

Three Months Ended Se	ptember 30.Nine Montl	ns Ended September 30.

	2014		2013		2014		2013	
Revenues	\$	5,000	\$	2,500	\$	14,167	\$	107,500
Operating expenses:								
Research and development expenses	2,058,865		1,847,403		5,577,644	ļ	5,502,137	
General and administrative expenses	1,969,879		1,707,690		6,971,186	5	4,184,740	
Depreciation and amortization	83,001		81,393		260,221		181,991	
Total operating expenses	4,111,745		3,636,486		12,809,05	51	9,868,868	
Operating loss	(4,106,745)		(3,633,986)		(12,794,8	84)	(9,761,368	3)
Other income (expense):								
Interest income	13,127		18,776		55,267		45,336	
Interest expense	(361,619)		(448,943)		(1,191,97	6)	(936,471)	
Warrant modification expense	-		(1,945,214)		(3,109,85	0)	(5,017,156	6)
Gain (loss) from change in fair value of derivative instruments	f -		(677,883)		(334,133)		(859,682)	
Other income	-		293		250,000		667	
Total other income (expense)	(348,492)		(3,052,971)		(4,330,69	2)	(6,767,306	6)
N	Φ /4.4		\$		0 (47)	05 570	\d	. 500 074

Net loss \$ (4,455,237)\$ \$ (17,125,576)\$ (16,528,674)

Net loss per share - basic and diluted	\$ (0.0	5) \$ (0.0	9)\$ ((0.20)\$	(0.23)
Weighted average common shares outstanding - basic and diluted	87,366,234	72,986,698	86,777,197	70,533,035	
Comprehensive loss:					
Net loss	\$ (4,455,2	37)\$ (6,686,95	57) ^{\$} (17,125,576	\$ 6) (16,528,674)
Foreign currency translation adjustme	ent3	6,101	(1,131)	6,101	
Comprehensive loss	\$ (4,455,234)	\$ (6,680,856)	\$ (17,126,70)	\$ 7) (16,522,573)

About Neuralstem

Neuralstem's patented technology enables the production of multiple types of brain and spinal cord neural stem cells in commercial quantities for the potential treatment of central nervous system diseases and conditions. Neuralstem's first stem cell product, NSI-566, a spinal cord-derived neural stem cell line, is in an ongoing Phase II clinical trial to treat amyotrophic lateral sclerosis (ALS, or Lou Gehrig's disease). A later stage trial is anticipated to commence in 2015 at multiple centers. Neuralstem received orphan status designation by the FDA for NSI-566 in ALS. In addition, NSI-566 is also in a Phase I trial for the treatment of chronic spinal cord injury at UC San Diego School of Medicine. NSI-566 is also in clinical development to treat neurological diseases such as ischemic stroke and acute spinal cord injury.

Neuralstem's second stem cell product, NSI-532.IGF, consists of human cortex-derived neural stem cells that have been engineered to deliver human insulin-like growth factor 1 (IGF-1). In animal data presented at the Congress of Neurological Surgeons 2014 Annual Meeting, the cells rescued spatial learning and memory deficits in an animal model of Alzheimer's disease.

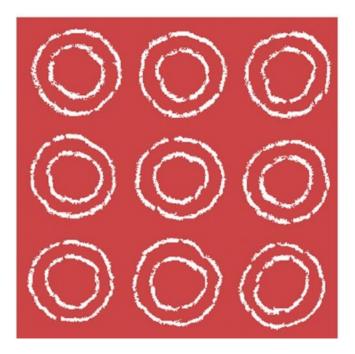
Additionally, Neuralstem's ability to generate human neural stem cell lines for chemical screening has led to the discovery and patenting of compounds that may stimulate the brain's capacity to generate neurons, possibly reversing pathologies associated with certain central nervous system (CNS) conditions. The company has completed Phase Ia and Ib trials evaluating NSI-189, its first neurogenic small molecule product candidate, for the treatment of major depressive disorder (MDD). The MDD Phase II clinical trial is expected to launch in 2015. Additional indications might include traumatic brain injury (TBI), Alzheimer's disease, and post-traumatic stress disorder (PTSD).

For more information, please visit www.neuralstem.com or connect with us on Twitter, Facebook and LinkedIn

Cautionary Statement Regarding Forward Looking Information:

This news release may contain forward-looking statements made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that such forward-looking statements in this press release regarding potential applications of Neuralstem's technologies constitute forward-looking statements that involve risks and uncertainties, including, without limitation, 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, 2013 and Form 10Q, for the period ended September 30, 2014.



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