

November 12, 2013



NEURALSTEM INC.

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

ROCKVILLE, Md., Nov. 12, 2013 /PRNewswire/ -- Neuralstem, Inc. (NYSE MKT: CUR) today reported financial results for the three months and nine months ended September 30, 2013 and provided a business and clinical update.

(Logo: <https://photos.prnewswire.com/prnh/20061221/DCTH007LOGO> )

"The Company reached several major milestones in the third quarter. We completed patient dosing in our Phase Ib trial to treat major depressive disorder with NSI-189, our lead small molecule compound. We also commenced a multicenter Phase II cell therapy trial with NSI-566 to treat ALS, and completed dosing of all patients in the first cohort," said Karl Johe, PhD, Neuralstem's Chairman of the Board and Chief Scientific Officer. "The dose escalation trial for NSI-189 advanced through three cohorts of eight depression patients each, with the final cohort receiving three daily doses of 40 mg for 28 days. During the coming months we will be compiling the data from this Phase I study.

"We are particularly excited to have begun our Phase II ALS dose escalation trial, treating the first cohort of three patients in the cervical region of the spinal cord. We are currently treating the second of five cohorts and hope to transplant all 15 patients by the completion of the second quarter of 2014," continued Dr. Johe. "We are pleased that principal investigator Dr. Eva Feldman, added the University of Michigan Health System, where she is Director of Research of the ALS Clinic and Director of the A. Alfred Taubman Medical Research Institute, as a second trial center. We are working towards adding a third site, Massachusetts General, in the coming months. The Phase II trial protocol calls for increased dosing and a maximum of 40 injections and up to 400,000 cells per injection, with a one-month observation period between each cohort.

"Dr. Feldman, who is also the president of the American Neurological Association, recently presented complete Phase I NSI-566/ALS trial data at the annual ANA meeting, which showed a clear slowing of disease progression or actual improvement for more than 700-to-approximately-850 days post-surgery, in six non-bulbar ALS patients who were treated early in the course of their disease. All patients in Phase II are also ambulatory and within approximately two years of the onset of symptoms of the disease," said Dr. Johe. "The results from the complete Phase I data will be made public after they are published in a peer-reviewed scientific journal anticipated later this year.

"Looking ahead, our NSI-566/stroke Phase I/II trial at BaYi Brain Hospital, in Beijing, is expected to be underway later in the fourth quarter. This trial will treat with one-time intracerebral injections of cells directly into the ischemic stroke area," continued Dr. Johe. "The first phase will determine the maximum safe dose in up to 18 patients, and is expected to be completed in seven or eight months. Phase II will advance to a multicenter, randomized, controlled single-blind study with up to 100 patients, and is designed to evaluate efficacy and safety for clinical proof-of-concept. Also, of note, we continue to make progress towards commencement of the FDA-approved NSI-566/chronic spinal cord injury Phase I trial in the first quarter of 2014. This trial, which will treat eight patients with T2-T12 complete paralysis, uses the same cells and methodology as our ALS trial.

"The recent publication of an animal study by our collaborators at the University of California, Irvine, provided proof of principle for NSI-566 in the amelioration of cognitive dysfunction induced by brain irradiation, a common treatment for brain cancer in humans. In the study, rats injected with the cells two days after brain irradiation demonstrated a reduction in radiation-induced cognitive dysfunction. This is an important validation for the ongoing NSI-566 preclinical program in multiple indications where loss of cognitive function is prevalent."

"We thank our shareholders for their continued support; we begin the fourth quarter on solid financial footing, with cash on-hand to cover our corporate and clinical budgets for the next two years," said Richard Garr, Neuralstem's President and CEO. "Dr. Johe and I extend our deep appreciation to our patients, and their families and caregivers, for their continued support and dedication to our work in ALS and other debilitating diseases and conditions of the central nervous system. We thank our team of world-class clinical collaborators and investigators around the globe, innovators all, who we are proud to call our partners."

### Third Quarter Clinical Program and Business Highlights

In August, the company completed dosing of the NSI-189/major depressive disorder (MDD) Phase Ib trial. The trial of Neuralstem's lead neurogenic small molecule drug was designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics effect of escalating doses of NSI-189 for 28 daily administrations in 24 depressed patients in three cohorts. Data is being compiled.

In August, University of California, Irvine researchers published a paper in the scientific journal, CELL TRANSPLANTATION – THE REGENERATIVE MEDICINE JOURNAL, which reported that NSI-566 reversed cognitive defect and improved cognitive function in rats that had received radiation to the brain. "Transplantation of Human Fetal-Derived Neural Stem Cells Improves Cognitive Function Following Cranial Irradiation" used an animal model of radiation treatment for brain cancer and showed that brain-irradiated rats that received NSI-566 transplants had improved cognitive function, including improved hippocampal spatial memory, as assessed by two separate cognitive tasks.

In September, Neuralstem's NSI-566/ALS Phase II dose escalation and safety trial commenced, with the first patient treated at Emory University Hospital and the second patient treated at University of Michigan Health System. The multicenter trial is designed to treat up to 15 ambulatory ALS patients in five different dosing cohorts. Patients in the first cohort received 10 injections of 200,000 cells per injection. In subsequent cohorts, the dose will increase in both number of injections and cells per injection, advancing up to a maximum of 40 injections and up to 400,000 cells per injection in the fifth cohort. The first 12 patients will receive injections in the cervical region of the spinal cord only, where the stem cells could help preserve breathing function. The final three patients will receive both cervical and lumbar injections.

#### Corporate News:

This quarter, Neuralstem increased its global IP portfolio to 49 issued and 59 pending patents. The company received issuance of Japan Patent # 5266297, and filed a new patent application in South Korea, 10-2013-7020263, both related to the company's existing stem cell technology. The company also filed a new U.S. patent application 61/844,165, which covers methods of treating cognitive defects with spinal cord neural stem cells.

In September, the company raised aggregate gross proceeds of \$4,556,000 in a registered direct offering.

In September, President and CEO Richard Garr presented at the Stem Cells & Regenerative Medicine Congress. NSI-566/ALS Phase I patient, Ted Harada, also spoke about his experience with ALS and treatments at the congress.

#### Subsequent News:

In October, University of Michigan Health System, the second center for the NSI-566/ALS Phase II dose escalation trial, treated its second patient. With one patient already treated at Emory University Hospital, this represented the completion of the first of the trial's five cohorts in less than a month's time.

In October, Dr. Eva Feldman, MD, PhD, gave an update on the NSI-566/ALS trial at the annual American Neurological Association Meeting. Dr. Feldman is principal investigator for Neuralstem's NSI-566/ALS trial, Director of the A. Alfred Taubman Medical Research Institute, Director of Research of the ALS Clinic at the University of Michigan Health System, President of the American Neurological Association, and an unpaid consultant to Neuralstem.

### **Third Quarter Financial Results**

For the third quarter of 2013, the Company reported a net loss of approximately \$6,687,000 or \$0.09 per share, compared with a net loss of approximately \$2,577,000 or \$0.04 per share, for the comparable 2012 period. The increase in net loss was primarily due to non-cash charges of approximately \$1,945,000 related to the modification of certain stock purchase warrants, \$678,000 related to the change in fair value of the Company's derivative instruments and a \$520,000 increase in share-based compensation coupled with a \$377,000 increase in project and lab related expenses due to the ramping up of our clinical trial and research efforts and \$449,000 of interest expense related to the Company's long term debt.

For the nine months ended September 30, 2013 the Company reported a net loss of approximately \$16,529,000 or \$0.23 per share, compared with a net loss of approximately \$7,407,000, or \$0.14 per share for the comparable 2012 period. The increase in net loss was primarily due to non-cash charges of approximately \$5,017,000 related to the modification of certain stock purchase warrants, \$860,000 related to the change in fair value of the Company's derivative instruments and a \$893,000 increase in share-based compensation coupled with a \$868,000 increase in research and development expenses due to an increase in headcount and the ramping up of our clinical

trial and research efforts and \$936,000 of interest expense related to the Company's long term debt. In addition, the Company recognized approximately \$108,000 in revenue from third party licensing of certain intellectual properties in the first nine months of 2013.

Cash and cash equivalents on hand was approximately \$16,402,000 at September 30, 2013, compared with approximately \$9,873,000 at September 30, 2012. The increase in our cash and cash equivalents of approximately \$6,528,000, was primarily due to our raising approximately \$17.6 million through our March 2013 issuance of debt (\$7.6 million), issuance of stock from exercise of investor warrants (\$5.8 million) and issuance of stock and warrants from our September equity offering (\$4.2 million), partially offset by cash used in operations

#### About Neuralstem

Neuralstem's patented technology enables the ability to produce neural stem cells of the human brain and spinal cord in commercial quantities, and the ability to control the differentiation of these cells constitutively into mature, physiologically relevant human neurons and glia. Neuralstem's NSI-566 spinal cord-derived stem cell therapy is in an FDA-approved Phase II clinical trial for amyotrophic lateral sclerosis (ALS), often referred to as Lou Gehrig's disease. Neuralstem has been awarded orphan status designation by the FDA for its ALS cell therapy.

In addition to ALS, the company is also targeting major central nervous system conditions with its NSI-566 cell therapy platform, including spinal cord injury and ischemic stroke. The company has received FDA approval to commence a Phase I safety trial in chronic spinal cord injury.

Neuralstem also has the ability to generate stable human neural stem cell lines suitable for the systematic screening of large chemical libraries. Through this proprietary screening technology, Neuralstem has discovered and patented compounds that may stimulate the brain's capacity to generate new neurons, possibly reversing the pathologies of some central nervous system conditions. The company is conducting a Phase Ib safety trial evaluating NSI-189, its first neurogenic small molecule compound, for the treatment of major depressive disorder (MDD). Additional indications could include traumatic brain injury (TBI), Alzheimer's disease, and post-traumatic stress disorder (PTSD).

For more information, please visit [www.neuralstem.com](http://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, 2012 and the Form 10-Q for the period ended September 30, 2013.

#### **Neuralstem, Inc.**

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

<b>September 30,</b>	<b>December 31,</b>
<b>2013</b>	<b>2012</b>

#### **ASSETS**

## CURRENT ASSETS

Cash and cash equivalents	\$ 16,401,728	\$ 7,443,773
Billed and unbilled receivables	7,500	3,333
Deferred financing fees, current portion	575,377	-
Prepaid expenses	343,973	205,651
<b>Total current assets</b>	<b>17,328,578</b>	<b>7,652,757</b>
Property and equipment, net	253,562	230,397
Patent filing fees, net	1,047,940	807,357
Deferred financing fees, net of current portion	470,769	-
Other assets	64,862	59,568
<b>Total assets</b>	<b>\$ 19,165,711</b>	<b>\$ 8,750,079</b>

## LIABILITIES AND STOCKHOLDERS' EQUITY

### CURRENT LIABILITIES

Accounts payable and accrued expenses	\$ 1,212,578	\$ 1,199,662
Accrued bonus expense	462,882	465,865
Current portion of long term debt, net of discount	1,986,154	-
Derivative instruments	1,311,880	-
Other current liabilities	174,345	90,776
<b>Total current liabilities</b>	<b>5,147,839</b>	<b>1,756,303</b>
Long term debt, net of discount and current portion	5,661,336	-
Other long term liabilities	89,650	21,143

<b>Total liabilities</b>	10,898,825	1,777,446
<b>STOCKHOLDERS' EQUITY</b>		
Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding	-	-
Common stock, \$0.01 par value; 150 million shares authorized, 76,662,839 and 68,189,314 shares outstanding in 2013 and 2012, respectively	766,628	681,893
Additional paid-in capital	132,617,006	114,884,915
Accumulated other comprehensive income	6,101	-
Accumulated deficit	(125,122,849)	(108,594,175)
<b>Total stockholders' equity</b>	8,266,886	6,972,633
<b>Total liabilities and stockholders' equity</b>	\$ 19,165,711	\$ 8,750,079

**Neuralstem, Inc.**

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

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
Revenues	\$ 2,500	\$ 170,833	\$ 107,500	\$ 405,208
Operating expenses:				
Research and development costs	1,847,403	1,385,478	5,502,137	4,406,538
General and administrative expenses	1,707,690	1,280,606	4,184,740	3,264,146
Depreciation and amortization	81,393	87,908	181,991	164,154

Total operating expenses	3,636,486	2,753,992	9,868,868	7,834,838
Operating loss	(3,633,986)	(2,583,159)	(9,761,368)	(7,429,630)
Other income (expense):				
Interest income	18,776	5,411	45,336	21,601
Interest expense	(448,943)	(335)	(936,471)	(1,789)
Warrant modification expense	(1,945,214)	-	(5,017,156)	-
Loss from change in fair value of derivative instruments	(677,883)	-	(859,682)	-
Litigation settlement	293	692	667	3,265
Total other income (expense)	(3,052,971)	5,768	(6,767,306)	23,077
Net loss	\$ (6,686,957)	\$ (2,577,391)	\$ (16,528,674)	\$ (7,406,553)
Net loss per share - basic and diluted	\$ (0.09)	\$ (0.04)	\$ (0.23)	\$ (0.14)
Weighted average common shares outstanding - basic	72,986,698	58,363,721	70,533,035	54,751,377
and diluted				
Comprehensive loss:				
Net loss	\$ (6,686,957)	\$ (2,577,391)	\$ (16,528,674)	\$ (7,406,553)
Foreign currency translation adjustment	6,101	-	6,101	-
Comprehensive loss	\$ (6,680,856)	\$ (2,577,391)	\$ (16,522,573)	\$ (7,406,553)

SOURCE Neuralstem, Inc.

