

March 15, 2013



Neuralstem Announces 2012 Financial Results, Provides Clinical Trials Update

ROCKVILLE, Md., March 15, 2013 /PRNewswire/ -- Neuralstem, Inc. (NYSE MKT: CUR) today provided an update on its clinical trial programs and reported its 2012 financial results for the year ended December 31, 2012.

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"2012 saw the company achieve success in all of its Phase I clinical trial objectives," said Karl Johe, Ph.D., Neuralstem's Chairman of the Board and Chief Scientific Officer. "We have been able to demonstrate the safety and tolerability of Neuralstem's novel core technologies, from intraspinal transplantation procedures, to the cells themselves in ALS patients, as well as our NSI-189 neurogenic small molecule drug in healthy volunteers. Additionally, we believe we have seen evidence of a treatment effect in some NSI-566 cell therapy patients over a sustained period of time, as measured by levels of functional recovery and a slowdown in the progression of ALS. In spinal cord injury, a leading peer-reviewed scientific journal, 'CELL,' published compelling evidence that NSI-566 cells can 'bridge the gap' in a severed spinal cord animal model and return functionality. We have recently been approved by the FDA to commence a trial treating chronic spinal cord injury patients.

A highlight of 2012 was the completion of our ground-breaking ALS Phase I trial. Following the last treatment of the final cervical cohort of return patients in August, our collaborators, University of Michigan's Dr. Eva Feldman and Emory University's Dr. Jonathan Glass, presented trial data that showed promise of a treatment effect for ambulatory ALS patients as well as definitive DNA-fingerprint evidence of long-term NSI-566 cell survival," continued Dr. Johe. "These positive data support our plan to accelerate the ALS trial in Phase II, by increasing both the number of NSI-566 cells and number of injections delivered to the cervical spinal cord, where we believe we can most positively affect patients' lives by sustaining their breathing capacity. Our proposed Phase II trial protocol, which would be simultaneously conducted at Emory University Hospital and University of Michigan, is currently in review at the FDA. The National Institutes of Health and ALSA have committed to generous grants totaling nearly \$3,000,000 in funding for this next phase of the study, pending FDA approval. We join with our esteemed collaborators in being eager to move forward to future trial phases to examine therapeutic efficacy of NSI-566. We hope to commence the ALS Phase II trial in the second quarter."

Dr. Johe continued, "2013 promises to be a transformative year for the company, with five NSI-566 cell therapy trials planned. The two new U.S. trials will be the ALS Phase II, and the recently FDA-approved Phase I in chronic spinal cord injury. We hope to have agreements with multiple sites for the Phase I chronic spinal cord injury trial in place by the end of the 2nd Quarter and then begin the transplantations. Internationally, our

ischemic stroke trial is expected to commence in Beijing at world-class BaYi Brain Hospital in the coming weeks, through our subsidiary, Neuralstem China. A planned ALS combined Phase I/II is expected to take place in Mexico City, pending finalization of a partnership agreement. Later this month, we expect to file an IND for an acute spinal cord injury trial in Seoul, South Korea, which we anticipate conducting with our partner, CJ CheilJedang.

"2012 also saw advances through the clinic for NSI-189, the company's lead compound in our first-in-class neurogenic small molecule drug," Dr. Johe commented further. "The FDA approved dosing the second cohort of eight depression patients in our ongoing NSI-189/major depressive disorder (MDD) Phase Ib trial. Dosing has now increased from 40 mg. q.d.(once/day) for 28 days, which had been shown to be well-tolerated and safe in the first cohort, to 40 mg. b.i.d.(twice/day) for 28 days. Dosing of all patients in the second cohort will be completed this month and, pending FDA approval, we will commence dosing the final cohort."

Neuralstem's President and CEO Richard Garr added, "Neuralstem continued to strengthen its patent estate in 2012. Among the highlights, U.S. Patent number 8,236,299 includes claims covering processes for dissociating our neural stem cells from CNS tissue; culturing the cells; expanding the cells in vitro, and transplanting the cells into the spinal cord of a patient to treat a wide array of neurodegenerative conditions, including ALS, chronic and acute spinal cord injury, and stroke. Both the substance and life of this patent (into 2030) are reflective of the Intellectual Property value we are creating in our cell therapy programs. Additionally, during the past 12 months we have executed the first two out-licenses of our spinal platform cell therapy technology."

"Dr. Johe and I would like to extend our continued deep appreciation to our patients, their families and caregivers, our world-class clinical collaborators, and the Neuralstem team for enabling positive, ground-breaking clinical work which has now positioned us to move forward," added Garr.

Business Highlights for 2012

Cellular Therapy: NSI-566 Phase I Clinical Trial in ALS (amyotrophic lateral sclerosis, or Lou Gehrig's disease) at Emory University Hospital

- Neuralstem completed the final surgery of its Phase I NSI-566/ALS trial in August. The trial proved the safety of the company's proprietary technology, the cells and proprietary intraspinal surgical procedure. Data presented at the International Symposium on ALS/MND in December (2012) showed evidence of long-term NSI-566 cell survival in patients, through DNA fingerprinting. It was further announced that the study team has received a grant from the National Institutes of Health (NIH) to cover a majority of the cost of an upcoming NSI-566/ALS Phase II trial. In October, Eva Feldman, M.D., Ph.D., the trial's principal investigator and Director of the A. Alfred Taubman Medical Research Institute and Director of Research of the ALS Clinic at the University of Michigan Health System, presented updated data at the American Neurological Association (ANA) annual meeting. Dr. Feldman, who is president of the ANA, presented interim results on all 18 procedures in 15 patients, and said, "...we are exploring a paradigm shift in the treatment of ALS. ...Although this phase of the trial was not powered to demonstrate efficacy, we appear to have

interrupted the progression of the disease in one subgroup of patients." The Phase I NSI-566/ALS safety trial consisted of 18 treatments in 15 patients, at Emory University Hospital. All injections delivered 100,000 cells, for a dosing range of up to 1.5 million cells. In February, Patient 14 was the second patient to be dosed in the cervical (upper back) region where the cells could support breathing, the key function that is lost as ALS progresses. In May, the FDA approved additional NSI-566 dosing of patients who had previously received lumbar injections, to return for cervical injections as the trial's final cohort; the FDA-approved trial amendment was subsequently approved by the Emory University Institutional Review Board in June. Additionally, Neuralstem had submitted a trial amendment to the FDA to increase both the number of patients treated as well as the dose in future cohorts, which was then withdrawn and modified to become the Phase II protocol. The entire Phase I ALS trial officially concluded in February 2013, six months after the final surgery.

Neurogenic Small Molecule NSI-189: Phase I Clinical Trial in Major Depressive Disorder (MDD)

- The company's lead neurogenic small molecule compound, NSI-189, advanced with FDA approval to treat the second cohort of eight depression patients in the ongoing NSI-189/major depressive disorder (MDD) Phase Ib clinical trial, in October. NSI-189 was shown to be well-tolerated and safe during the 28-day dosing of the first cohort, in the randomized, double-blind, placebo-controlled, multiple-dose escalating trial. The 24-patient Phase Ib commencement was announced in June, with efficacy data blinded for all cohorts until the end of the trial. Neuralstem is expected to complete the entire NSI-189/MDD Phase I trial in the third quarter of 2013. This proprietary new chemical entity increases hippocampal volume and stimulates new neuron growth in the hippocampus, a region of the brain believed to be implicated in MDD, as well as other cognitive and psychological diseases and conditions such as chronic traumatic encephalopathy (CTE), Alzheimer's disease, and post-traumatic stress disorder (PTSD). Data collection includes post-dosing MRIs at both four and eight weeks after completion of the 28-day dosing.
- In February, the company raised approximately \$5.2 million in gross proceeds through an offering of its common stock to fund its ongoing clinical trials and working capital for general corporate purposes.
- In March, the science journal, "STEM CELLS," published early Neuralstem NSI-566/ALS Phase I interim results, entitled, "Lumbar Intraspinal Injection of Neural Stem Cells in Patients with ALS: Results of a Phase I Trial in 12 Patients." "STEM CELLS" reported that one patient had shown dramatic improvement in his clinical status, and that there was no evidence of accelerated disease progression due to the intervention in any of the 12 patients (who were followed from 6-18 months after injections at this point), nor any long-term complications related to either the surgery or the cells.
- In July, Neuralstem received a notice of issuance for patent application number 12/710,097 (subsequently issued patent number 8,236,299) titled: "Transplantation of Human Neural Cells for Treatment of Neurodegenerative Conditions." This patent,

which will expire in the first quarter of 2030, covers both the culturing of central nervous system (CNS) cells as well as their transplantation into spinal cord tissue to treat neurodegenerative conditions, including ALS, ischemic stroke, and chronic and acute spinal cord injury.

- Also in July, the company extended the employment contracts of Dr. Karl Johe, Richard Garr, and Dr. Thomas Hazel for an additional 60 months.
- In September, Neuralstem received approval to commence a combined Phase I/II clinical trial to treat motor deficits due to ischemic stroke with direct injections into the brain of NSI-566 cells, at BaYi Brain Hospital, in Beijing, through its subsidiary, Neuralstem China (Suzhou Neuralstem Biopharmaceutical Company, Ltd.). The trial is designed to enroll up to 118 patients, and involve one-time intracerebral injections into the stroke area using well-accepted stereotactic injection procedures. Phase I will determine the maximum safe dose and the multi-site, randomized, controlled, single-blind Phase II/proof-of-concept study will evaluate efficacy, with 50 percent of the subjects receiving NSI-566 injections and physical therapy, and the other 50 percent receiving only the physical therapy. The combined trial, including patient monitoring and data collection, is expected to start in the first quarter and conclude in approximately two years following commencement.
- Also in September, "Long-Distance Growth and Connectivity of Neural Stem Cells After Severe Spinal Cord Injury: Cell-Intrinsic Mechanisms Overcome Spinal Inhibition" was published in a leading scientific journal, "CELL." The "CELL" study reported that NSI-566 cells induced significant functional improvement in permanent rat spinal cord injury, with the paralyzed rats regaining use of lower limbs. It was further reported that the transplanted neural stem cells turned into neurons which grew a "remarkable" number of axons that extended for "very long distances" over 17 spinal segments, making connections both above and below the point of severance.
- Also in September, Neuralstem granted the first licenses for use of its Spinal Cord Delivery Platform and Floating Cannula, used in the ALS Phase I trial for delivering therapeutic agents to the spinal cord.
- During the third quarter, the company raised approximately \$9.76 million in gross proceeds through offerings of its common stock to fund its ongoing clinical trials, research and development, and working capital.
- In October, Neuralstem engaged Locust Walk Partners, LLC, a life sciences' commercial licensing and partnering specialist advisory firm, to further explore partnership opportunities for a clinical-stage neurogenic small molecule program targeting a broad range of psychiatric and cognitive disorders.
- In October, research from two independent NSI-566/ischemic stroke animal studies were presented at Neuroscience 2012, the 42nd Annual Meeting for the Society for Neuroscience, along with three additional poster presentations on NSI-566 and

neurogenic small molecule compounds: NSI-144, NSI-150, NSI-158 and NSI-189. "Histopathological Assessment of Adult Ischemic Rat Brains after 4 Weeks of Intracerebral Transplantation of NSI-566RSC Cell Line," with study research led by Cesar V. Borlongan, Ph.D., the director at the Center of Excellence for Aging and Brain Repair at the University of South Florida College of Medicine, reported significant improvement in both motor and neurological functions in subacute ischemic stroke rats treated with NSI-566 cells seven days post-stroke with increasing intracerebral doses of NSI-566 into the stroke area. A separate research study, "Survival and Differentiation of Human Neural Stem Cells (NSI-566RSC) After Grafting into Ischemia-Injured Porcine Brain," led by Martin Marsala, M.D., professor and the head of the Neuroregeneration Laboratory at University of California, San Diego, demonstrated NSI-566 feasibility and safety in a chronic model of ischemic stroke in mini-pigs, a species that allowed for the use of human-scale transplantation tools and dosing, according to study authors.

- **Subsequent Events:**

In January 2013, Neuralstem received FDA approval to commence a Phase I safety trial of NSI-566 in chronic spinal cord injury (cSCI) patients. The open-label, multi-site study will enroll up to eight patients with thoracic spinal cord injuries (T2-T12), designated American Spinal Injury Association AIS-A level of impairment, between one and two years after injury. All patients will receive six injections in, or around, the injury site; the first four patients will receive 100,000 cells per injection, and the second four patients will receive 200,000 cells per injection. All patients will also receive physical therapy post-surgery, as well as immunosuppressive therapy, which will be for three months, as tolerated. The trial study period will end six months post-surgery for each patient, with a stated goal of trial completion within a one-year timeframe.

In February 2013, the company granted licenses to intellectual property surrounding its spinal cord delivery platform, floating cannula, and method for delivering therapeutic agents to the spinal cord to Cedars-Sinai Medical Center, a nonprofit academic medical center located in Los Angeles, CA. The license agreements grant Cedars-Sinai Medical Center the non-exclusive right to use the licensed intellectual property in academic research. This is the second group of licenses announced by Neuralstem for these technologies and medical devices.

Results of Operations for the Year Ended December 31, 2012:

- In the year ended December 31, 2012, the Company reported a net loss of approximately \$10,122,000 or \$0.17 per share, compared to a loss of approximately 12,519,000 or \$0.26 per share for the year ended December 31, 2011. The decrease in net loss was primarily due to a decrease in non-cash stock based compensation expense of approximately \$1,723,000 coupled with a decrease of approximately \$450,000 in project related expenses related to studies which ended in 2011 and an approximately \$790,000 reduction in legal expenses partially offset by gains related to a legal settlement and changes in the fair value of certain warrant obligations in 2011.

- In 2012, the Company recognized revenue of approximately \$234,000 related to its DOD contract which was completed in the second quarter of 2012 compared to revenue of approximately \$391,000 in 2011. The Company also recognized revenue of approximately \$173,000 related to the licensing of certain intellectual property to third parties in 2012.
- Total cash and cash equivalents was approximately \$7,444,000 at December 31, 2012, compared with approximately \$2,352,000 at December 31, 2011. The increase in our cash and cash equivalents of approximately \$5,092,000 was primarily due to proceeds from our capital market activities during 2012 partially offset by cash used to fund our operations.

Neuralstem, Inc.

Balance Sheets

	December 31,	
	2012	2011
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 7,443,773	\$ 2,352,013
Prepaid expenses	205,651	430,356
Billed and unbilled receivables	3,333	234,375
	7,652,757	3,016,744
Total current assets		
Property and equipment, net	230,397	292,193
Patent filing fees, net	807,357	701,846
Other assets	59,568	75,394
	8,750,079	4,086,177
Total assets		
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	\$ 1,199,662	\$ 1,843,684
Accrued bonus expense	465,865	582,675
Other current liabilities	90,776	-
	1,756,303	2,426,359
Total current liabilities		
Deferred rent, net of current portion	21,143	-
	21,143	-

Total liabilities	<u>1,777,446</u>	<u>2,426,359</u>
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STOCKHOLDERS' EQUITY

Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding	-	-
Common stock, \$0.01 par value; 150 million shares authorized, 68,189,314 and 48,682,118 shares outstanding in 2012 and 2011, respectively	681,893	486,821
Additional paid-in capital	114,884,915	99,645,655
Accumulated deficit	<u>(108,594,175)</u>	<u>(98,472,658)</u>
Total stockholders' equity	<u>6,972,633</u>	<u>1,659,818</u>
Total liabilities and stockholders' equity	<u>\$ 8,750,079</u>	<u>\$ 4,086,177</u>

Neuralstem, Inc.

Statements of Operations

	Year Ended December 31,	
	<u>2012</u>	<u>2011</u>
Revenues	<u>\$ 407,708</u>	<u>\$ 390,625</u>
Operating expenses:		
Research and development costs	6,105,984	7,354,857
General and administrative expenses	4,247,037	5,839,188
Depreciation and amortization	<u>211,143</u>	<u>187,050</u>
Total operating expenses	<u>10,564,164</u>	<u>13,381,095</u>
Operating loss	<u>(10,156,456)</u>	<u>(12,990,470)</u>
Other income (expense):		
Litigation settlement	3,484	250,000
Interest income	34,154	60,955
Interest expense	(2,699)	(821)
Gain from change in fair value of warrant obligations	<u>-</u>	<u>161,809</u>
Total other income (expense)	<u>34,939</u>	<u>471,943</u>
Net loss	<u>\$ (10,121,517)</u>	<u>\$ (12,518,527)</u>
Net loss per share - basic and diluted	<u>\$ (0.17)</u>	<u>\$ (0.26)</u>
Weighted average common shares outstanding - basic and diluted	<u>58,153,929</u>	<u>48,340,557</u>

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 completed an FDA-approved Phase I safety clinical trial for amyotrophic lateral sclerosis (ALS), often referred to as Lou Gehrig's disease, in February 2013, and has submitted recommended Phase II trial protocol to the FDA. 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, ischemic stroke and glioblastoma (brain cancer). The company received approval to commence a Phase I safety trial in chronic spinal cord injury in January 2013.

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 in 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 chronic traumatic encephalopathy (CTE), 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, 2012.

SOURCE Neuralstem, Inc.