

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

ROCKVILLE, Md., Aug. 9, 2013 /PRNewswire/ -- Neuralstem, Inc. (NYSE MKT: CUR) today reported its financial results for the three months ended June 30, 2013 and provided a business and clinical update.

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"The focus of the second quarter was preparation for the start of several trials, both in the U.S. and internationally, in the second half of the year. We expect to begin our NSI-566 ALS Phase II trial in August or September, at both Emory and the University of Michigan. The trial, with generous funding from the National Institutes of Health and the ALS Association, will focus on cervical area injections and an increase in both the number of injections each patient receives, as well as the number of cells in each injection," said Karl Johe, PhD, Neuralstem's Chairman of the Board and Chief Scientific Officer. "Principal Investigator, Dr. Eva Feldman, presented Phase I ALS data at two international congresses, this past quarter, focusing on results of early onset patients with no bulbar symptoms. This group showed a clear slowing of disease progression or actual improvement over a several year span."

"Institutional Review Board approvals at multiple sites are also expected during this summer for our NSI-566 chronic spinal cord injury trial, approved by the FDA in January," said Dr. Johe. "This trial, which uses the same cells and procedure proven safe and well-tolerated in the ALS trial, will treat eight patients with T2-T12 complete paralysis. The primary endpoints of the trial are to demonstrate safety and toxicity of NSI-566 to treat chronic spinal cord injury. Secondary exploratory endpoints of the Phase I trial include: evaluating the ability of NSI-566 transplantation to positively affect AIS level, ISNC SCI motor and sensory index scores, bowel and bladder function, pain, UAB IMR scores, SCIM scores, evoked sensory and motor potentials, and electromyogram (EMG). The trial centers will be announced when all IRB approvals are obtained."

Dr. Johe continued, "Internationally, patients for the NSI-566 ischemic stroke Phase I/II trial, inBeijing, have been recruited and we expect to begin dosing patients, at the world-class BaYi Brain Hospital, in August or September. This trial will test direct injections into the brain of NSI-566 for the first time, via one-time treatments into the stroke area using well-accepted stereotactic intracerebral injection procedures. The first phase of the stroke trial will enroll up to 18 patients and will be a dose escalation trial to determine the maximum safe dose. We expect this phase to take seven or eight months to complete, before advancing to Phase II, a multi-site, randomized, controlled, single-blind study with up to 100 patients, which is designed to evaluate efficacy and safety for clinical proof-of-concept. Additionally, we have been in active discussions with the Korean FDA regarding our acute spinal cord injury trial, and we expect to file an IND there later this year. We are also preparing an ALS Phase II IND for a trial in Mexico City, which we expect to file in the third quarter of this year.

"In this past quarter, scientific journal, STEM CELL RESEARCH AND THERAPY, reported the most recent study from our collaborators at the UC San Diego School of Medicine, which demonstrated that intraspinal grafting of NSI-566 during the acute phase could represent a safe and effective treatment that ameliorates post-injury motor and sensory deficits. Based on the rat data, such cell therapy in humans may provide both qualitative and quantitative benefits and lead to significant long-term improvement of the structural integrity of a trauma-injured spinal cord. We look forward to our continued collaboration with Dr. Martin Marsala and his team at UC San Diego, as one of the centers in our upcoming spinal cord injury trial," Dr. Johe said. "This month, researchers at UC Irvine reported in CELL TRANSPLANTATION – THE REGENERATIVE MEDICINE JOURNAL that NSI-566 reverses cognitive defect in brain-irradiated rats. The transplanted animals improved hippocampal spatial memory as well as intact amygdala function, in a model similar to clinical irradiation intervention given to treat brain cancer patients. In clinical translation, this suggests early cell therapy treatment could prevent cognitive complications due to an irradiation therapy. We are broadening our neural stem cell therapy programs from treating motor deficits to treating cognitive deficits, which involve two distinct anatomical circuits, pathogenic mechanisms, and treatment strategies."

Dr. Johe concluded: "Finally, development of our novel neurogenic small molecule NSI-189 also advanced in the second quarter. The FDA approved the third and final cohort in our major depressive disorder Phase Ib trial, and dosing has nearly been completed. We expect data from the trial to be available in the second half of the year."

"We continued to strengthen our substantial global IP portfolio in the second quarter. A U.S. patent covering the use of expanded spinal cord stem cells to treat ALS joins past patent claims covering methods of culturing and treating neurodegenerative conditions with our NSI-566 cells," said Richard Garr, Neuralstem President and CEO. "Dr. Johe and I would like to extend our continued deep appreciation to our patients, their families and caregivers for their continued support and dedication to our ALS trial.

Second Quarter Clinical Program and Business Highlights

NSI-566:

In April, Neuralstem received FDA approval to commence the NSI-566 Phase II trial, for ALS, following the excellent safety and tolerability demonstrated in Phase I. The Phase II dose escalation and safety trial will expand to two centers: Emory University Hospital in Atlanta, Georgia, where Phase I was completed, and ALS Clinic at the University of Michigan Health System, in Ann Arbor, Michigan, subject to approval by the Institutional Review Board at each institution.

In April, final data on the intraspinal delivery method employed in the NSI-566/ALS Phase I trial was presented at the American Association of Neurological Surgeons Annual Meeting. "Intraspinal Stem Cell Transplantation in ALS, A Phase I Trial: Cervical Microinjection Safety Outcomes," presented by Jonathan Patrick Riley, MD, of the Department of Neurological Surgery at Emory University.

In May, Neuralstem's NSI-566/ALS principal investigator, Eva Feldman, MD, PhD presented updated Phase I trial data results from all 15 patients at the Romanian Neurological Society Congress in a talk entitled, "Recent Therapeutic Advances in Stem Cell Therapy." Dr. Feldman reported that six study patients have a stable, very slowly progressing or improved disease course at more than 700-to-approximately-850 days post-surgery. She stated that these patients share two common clinical characteristics: no bulbar features of ALS, a form of the disease that destroys motor neurons in the corticobulbar area of the brainstem, and they received stem cell transplantation early in the course of their disease (at an average of two years, one month after symptom-onset). Dr. Feldman is Director of the A. Alfred Taubman Medical Research Institute and Director of Research of the ALS Clinic at the University of Michigan Health System.

In May, a University of California, San Diego study reported in STEM CELL RESEARCH AND THERAPY, showed that rats transplanted with NSI-566 cells, three days after a spinal cord injury at L3 (lumbar 3), showed improvement along several measures of motor function and a reduction of spasticity. The study, "Amelioration of Motor/Sensory Dysfunction and Spasticity in a Rat Model of Acute Lumbar Spinal Cord Injury by Human Neural Stem Cell Transplantation," was led by principal investigator, Martin Marsala, MD, of the UCSD School of Medicine. The study demonstrated that intraspinal grafting of NSI-566 cells during the acute phase of a spinal cord injury could represent a safe and effective treatment that ameliorates post-injury motor and sensory deficits.

In June, Neuralstem's NSI-566/ALS principal investigator, Eva Feldman, MD, PhD gave the grand plenary address at the Canadian Neurological Sciences Federation Annual Congress, which included a presentation of the final Phase I results including new cervical cohort data. The results are expected to be published in the fall of 2013.

Subsequent Events:

In August, UC Irvine researchers published a paper in the scientific journal, CELL TRANSPLANTATION – THE REGENERATIVE MEDICINE JOURNAL, which reported that NSI-566 cells 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 that is similar to a potential clinical intervention given to treat brain cancer patients.

NSI-189:

In April, the FDA approved Neuralstem to treat the third and final cohort in the ongoing Phase Ib NSI-189 trial in major depressive disorder (MDD). Phase Ib is testing the safety of escalating doses of NSI-189 for 28 daily administrations in 24 depressed patients in three cohorts, and is expected to conclude in 3Q13.

In April, Neuralstem announced an initiative to investigate feasibility of a NSI-189 trial to treat cognitive and psychiatric impairment of former NFL players from traumatic brain injury. These injuries can result in long-term and serious loss of cognitive function, depression, a shorter life span and, as has been reported in some high-profile NFL cases, death by suicide.

Corporate News:

In April, Neuralstem received notice of allowance for patent application 12/404,841, which covers methods of treatment of ALS with expanded spinal cord stem cells, including NSI-566.

In May, Richard Garr presented at the Annual World Stem Cells and Regenerative Medicine Congress inLondon.

Second Quarter Financial Results

For the second quarter of 2013, the Company reported a net loss of approximately\$6,252,000 or \$0.09 per share, compared with a net loss of approximately \$2,376,000 or \$0.04 per share, for the comparable 2012 period. The increase in net loss was primarily due to a non-cash charge of approximately \$2,405,000 related to the modification of certain stock purchase warrants, \$439,000 of interest expense related to the Company's long term debt, an increase of approximately \$266,000 in share-based compensation expense, a non-cash charge of approximately\$188,000 related to the change in

fair value of the Company's derivative instruments and an approximately \$186,000 increase in research and development costs related to an increase in headcount and the ramping up of our clinical trial and research efforts.

For the six months ended June 30, 2013 the Company reported a net loss of approximately \$9,842,000 or \$0.14 per share, compared with a net loss of approximately \$4,829,000, or \$0.09 per share for the comparable 2012 period. The increase in net loss was primarily due to a non-cash charge of approximately \$3,072,000 related to the modification of certain stock purchase warrants, \$488,000 of interest expense related to the Company's long term debt, an approximately\$390,000 increase in research and development costs related to an increase in headcount and the ramping up of our clinical trial and research efforts, an increase of approximately \$372,000 in share-based compensation expense and a non-cash charge of approximately \$182,000 related to the change in fair value of the Company's derivative instruments. In addition, the Company recognized approximately \$105,000 in revenue from third party licensing of certain intellectual properties in the first six months of 2013.

Cash and cash equivalents on hand was approximately \$11,166,000 at June 30, 2013, compared with approximately \$2,540,000 at June 30, 2012. The increase in our cash and cash equivalents of approximately \$8,627,000, was primarily due to proceeds of from our common stock offering in the third quarter of 2012, our March 2013 debt offering and proceeds from exercises of stock purchase warrants in 2013, 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 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 received FDA approval to begin Phase II. 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 the last cohort of 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 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 endedJune 30, 2013.

Neuralstem, Inc.

Unaudited Condensed Balance Sheets

ASSETS

CURRENT ASSETS

\$ 11,166	5,077\$ 7,443,773			
56,755	3,333			
591,847	-			
156,592	205,651			
11,971,271	7,652,757			
189,817	230,397			
984,946	807,357			
592,500	-			
59,568	59,568			
\$ 13,798,102	\$ 8,750,079			
LIABILITIES AND STOCKHOLDERS' EQUITY				
\$ 772,841	\$ 1,199,662			
	56,755 591,847 156,592 11,971,271 189,817 984,946 592,500 59,568 \$ 13,798,102			

Accounts payable and accrued expenses	772,841	1,199,662
Accrued bonus expense	313,088	465,865
Current portion of long term debt, net of discount	1,235,636	-
Derivative instruments	633,997	-
Other current liabilities	10,633	90,776
Total current liabilities	2,966,195	1,756,303
Long term debt, net of discount and current portion	6,363,676	-
Other long term liabilities	55,590	21,143

Total liabilities	9,385,461	1,777,446
Commitments and contingencies		
STOCKHOLDERS' EQUITY		
Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding	-	-
Common stock, \$0.01 par value; 150 million shares authorized, 70,606,448 and 68,189,31 shares outstanding in 2013 and 2012,respectively	⁴ 706,064	681,893
Additional paid-in capital	122,142,469	114,884,915
Accumulated deficit	(118,435,892)	(108,594,175)
Total stockholders' equity	4,412,641	6,972,633
Total liabilities and stockholders' equity	\$ 13,798,102	\$ 8,750,079

Neuralstem, Inc.

Unaudited Condensed Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Revenues	\$ 2,5	500 \$ 78,12	25\$ 105,00	0\$ 234,375
Operating expenses:				
Research and development costs	1,906,387	1,598,696	3,654,734	3,021,060
General and administrative expenses	1,281,210	821,384	2,477,050	1,983,540
Depreciation and amortization	50,505	41,300	100,598	76,246
Total operating expenses	3,238,102	2,461,380	6,232,382	5,080,846
Operating loss	(3,235,602)	(2,383,255)	(6,127,382)	(4,846,471)

Other income (expense):

Interest income	16,635	7,475	26,560	16,190
Interest expense	(439,271)	(601)	(487,528)	(1,454)
Warrant modification expense	(2,405,206)	-	(3,071,942)	-
Loss from change in fair value of derivative instrumer	nts(188,317)	-	(181,799)	-
Litigation Settlement	131	-	374	2,573
Total other income (expense)	(3,016,028)	6,874	(3,714,335)	17,309
Net loss	\$ (6,251,63	0)\$ (2,376,38	1)\$ (9,841,71	7)\$ (4,829,162)
Net loss per share - basic and diluted	\$ (0.0	9)\$ (0.0	4)\$ (0.14	4)\$ (0.09)
Weighted average common shares outstanding - bas and diluted	^{ic} 69,864,599	54,086,405	69,591,602	52,759,811

SOURCE Neuralstem, Inc.