

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

ROCKVILLE, Md., May 10, 2013 /PRNewswire/ -- Neuralstem, Inc. (NYSE MKT: CUR) today reported its financial results for the three months ended March 31, 2013 and provided a business and clinical update.

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"The Company continues to progress all of its clinical trial programs, in the U.S. and abroad, as we move into 2013. The FDA has approved our Phase II trial protocol for NSI-566/ALS, which we expect to initiate this summer. The protocol calls for an aggressive dose escalation strategy and adds a second trial center," said Karl Johe, PhD, Neuralstem's Chairman of the Board and Chief Scientific Officer. "We welcome our esteemed collaborators at University of Michigan joining our collaborators at Emory. We look forward to receiving approvals from both Institutional Review Boards in the near term and to commencing the trial, which has generous grant funding from the National Institutes of Health and ALSA.

"Institutional Review Board approvals are also expected during this summer for our NSI-566 chronic spinal cord injury trial, approved by the FDA in January. This trial uses the same cells and procedure proven safe and well-tolerated in the ALS trial. The ALS data was presented at the American Association of Neurological Surgeons Annual Meeting, in April," continued Dr. Johe. "The Phase I/chronic spinal cord injury trial will treat a total of eight patients with T2-T12 complete paralysis. The trial centers will be announced as the IRB approvals are obtained."

Dr. Johe commented further, "Internationally, the NSI-566 trial preparations are progressing well. We anticipate the Phase I/II ischemic stroke trial at BaYi Brain Hospital, in Beijing, will commence this quarter, representing the first-in-human direct stereotactic injections into the brain of NSI-566. The INDs for both acute spinal cord injury Phase I/II in Seoul and ALS Phase I/II in Mexico City are expected to be filed in June.

"Additionally, we were approved by the FDA to treat the third and final cohort of the ongoing Phase Ib major depressive disorder trial with our lead neurogenic small molecule compound, NSI-189. Dosing is proceeding well, and we expect to complete the trial in September," Dr. Johe concluded.

"This past quarter we were pleased to grant licenses for our proprietary intraspinal cell therapy surgical devices and method, used in the Phase I NSI-566/ALS trial, to Cedars-Sinai Medical Center. The licenses are specifically for academic research, enabling a new

era of research and treatment of spinal cord conditions and diseases," stated Richard Garr, Neuralstem President and CEO. "Additionally, we further strengthened our substantial global IP portfolio to include five licensed patent grants in Europe for the floating cannula and cell therapy method of use. Our newest U.S. patent covers the use of expanded spinal cord stem cells to treat ALS and joins past patent claims covering methods of culturing and treating neurodegenerative conditions with our NSI-566 cells. In our neurogenic small molecule program, we received one U.S. patent covering divisional compositions and methods of use, and 11 European patents for method of discovering neurogenic agents.

"Finally, Dr. Johe and I would like to thank our scientific and medical collaborators, and the patients and their families in the ALS community who believe in the science, technology and promise of Neuralstem for appearing at the recent FDA hearing on ALS trials and being vocal with their support," added Garr.

First Quarter Clinical Program and Business Highlights

In January, Neuralstem's lead cell therapy candidate, NSI-566, was approved by the FDA to commence a Phase I trial to treat chronic spinal cord injury (cSI). This open-label, multisite study will enroll up to eight patients with thoracic spinal cord injuries (T2-T12) who have an American Spinal Injury Association AIS-A level of impairment, between one and two years post injury. These patients exhibit no motor or sensory function in the relevant segments at and below the injury, and are considered to be in complete paralysis. Study patients will receive six injections in, or around, the injury site: the first four patients will receive 100,000 cells per injection; the second four patients, 200,000 cells per injection. All NSI-566/cSCI patients will receive post-surgery physical therapy, 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. The primary objective of the study is to determine the safety and toxicity of NSI-566 for the treatment of paralysis and related symptoms due to cSCI. The secondary objectives are to evaluate graft survival in the transplant site by MRI, as well as the effectiveness of transient immunosuppression.

In January, Neuralstem received issuance of U.S. Patent #8,362,262, Divisional Compositions and Methods of Use, part of the small molecule IP; additionally, issuance of PCT Patent #2337517, Floating Cannula and Method of Use, which is exclusively licensed by Neuralstem, and validated in four European countries: Germany, France, Italy and United Kingdom, for a total of five European patents.

In February, Neuralstem's NSI-566 Phase I Clinical Trial in ALS (amyotrophic lateral sclerosis, or Lou Gehrig's disease) officially concluded, six months after the final surgery at Emory University Hospital.

In February, Neuralstem 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 in Los Angeles, CA, for academic research.

In March, Neuralstem received issuance of EP Patent # 1576134, Method for Discovering Neurogenic Agents, which is part of the small molecule IP, and granted in ten European

countries: Belgium, Switzerland, Germany, France, United Kingdom, Ireland, Luxembourg, Netherlands and Sweden, for a total of 11 European patents.

In March, Neuralstem President and CEO Richard Garr was named the 15th most influential person in the stem field in Terrapinn's Total BioPharma's "Top 50 Global Stem Cell Influencers."

In March, Neuralstem secured \$8 million in debt financing with Hercules Technology Growth Capital to fund the company's capital budget through late 2014.

Subsequent Events:

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 to determine the maximum safe tolerated dose will expand to two centers, Emory University Hospital in Atlanta, Georgia, where Phase I was recently 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. The NSI-566/ALS Phase II trial is designed to treat up to 15 ambulatory ALS patients, in five different dosing cohorts, advancing up to a maximum of 40 direct injections and 400,000 cells per injection, based on safety. This compares to a maximum of 15 injections of 100,000 cells each, directly into the gray matter of the spinal cord, in the completed Phase I trial. The first 12 Phase II 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.

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, included data from all 18 procedures, in 15 patients, and showed the method of intraspinal cell delivery was found to be safe, well-tolerated, and promising for other spinal cord conditions.

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. NSI-189, the lead compound in Neuralstem's neurogenic small molecule platform, is a proprietary new chemical entity that stimulates new neuron growth in the hippocampus, a region of the brain believed to be implicated in MDD, as well as other diseases and conditions such as: traumatic brain injury, Alzheimer's disease, and post-traumatic stress disorder (PTSD).

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.

First Quarter Financial Results

For the first quarter of 2013, the Company reported a net loss of approximately \$3,590,000 or \$0.05 per share, compared with a net loss of approximately\$2,453,000 or \$0.05 per share, for the comparable 2012 period. The increase in net loss was primarily due to a non-cash charge of approximately \$667,000 related to the modification of certain stock purchase warrants coupled with an approximately \$125,000 increase in project and lab expenses related to ramping up of our clinical trial and research efforts and an increase in non-cash stock based compensation expense of approximately \$107,000. In addition, in the first quarter of 2013, the Company recognized approximately \$103,000 in revenue from third party licensing of certain intellectual properties.

Total cash and cash equivalents on hand at March 31, 2013 totaled approximately \$12,659,000 compared to approximately \$7,444,000 at December 31, 2012. The increase in our cash and cash equivalents of approximately \$5,215,000 was primarily due to proceeds from our debt financing transaction completed in the first quarter partially offset by cash used in our 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 <u>www.neuralstem.com</u> or connect with us on <u>Twitter</u>, <u>Facebook</u> and <u>LinkedIn</u>.

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 March 30, 2013.

Neuralstem, Inc.

Unaudited Condensed Balance Sheets

	r	March 31, 2013		December 31, 2012	
ASSETS					
CURRENT ASSETS					
Cash and cash equivalents	\$	12,659,240	\$	7,443,773	
Billed and unbilled receivables		104,255		3,333	
Deferred financing fees, current portion		557,714		-	
Prepaid expenses		220,914		205,651	
Total current assets		13,542,123		7,652,757	
Property and equipment, net		207,697		230,397	
Patent filing fees, net		876,781		807,357	
Deferred financing fees, net of current portion		725,228		-	
Other assets		59,568		59,568	
Total assets	\$	15,411,397	\$	8,750,079	

LIABILITIES AND STOCKHOLDERS' EQUITY

CURRENT LIABILITIES

Accounts payable and accrued expenses	\$ 1,243,754	\$	1,199,662
Accrued bonus expense	410,452		465,865
Current portion of long term debt, net of discount	510,666		-
Derivative instruments	445,680		-
Other current liabilities	42,566		90,776
Total current liabilities	2,653,118		1,756,303
Long term debt, net of discount and current portion	7,042,070		-
Other long term liabilities	22,356		21,143
Total liabilities	9,717,544		1,777,446
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STOCKHOLDERS' EQUITY			
Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding	<u>-</u>		_
Common stock, \$0.01 par value; 150 million shares authorized, 68,797,964 and			
68,189,314 shares outstanding in 2013 and 2012, respectively	687,980		681,893
Additional paid-in capital	117,190,135		114,884,915
Accumulated deficit	(112,184,262)	(108,594,175)
Total stockholders' equity	5,693,853		6,972,633
Total liabilities and stockholders' equity	\$ 15,411,397	\$	8,750,079

Neuralstem, Inc.

Unaudited Condensed Statements of Operations

Three Months Ended March 31,					
2013			2012		
\$	102,500	\$	156,250		
	1,748,347		1,422,364		
	1,195,840		1,162,156		
	50,093		34,946		
	2,994,280		2,619,466		
	(2,891,780)		(2,463,216)		
	\$	\$ 102,500 \$ 1,748,347 1,195,840 50,093 2,994,280	\$ 102,500 \$ 1,748,347 1,195,840 50,093 2,994,280		

Other income (expense):				
Interest income	9,925			8,715
Interest expense	(48,257)			(853)
Warrant modification expense	(666,736)			-
Gain from change in fair value of derivative instruments	6,518		-	
Other income	243		2,57	
Total other income (expense)	(698,307)		10,435	
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Net loss	\$	(3,590,087)	\$	(2,452,781)
Net loss per share - basic and diluted	\$	(0.05)	\$	(0.05)
	-			
Weighted average common shares outstanding - basic and diluted		68,700,709		51,433,217

SOURCE Neuralstem, Inc.