

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

ROCKVILLE, Md., May 12, 2014 /PRNewswire/ -- Neuralstem, Inc. (NYSE MKT: CUR) today reported its financial results for the three months ended March 31, 2014 and provided a business and clinical update.

"During the first guarter of 2014, we continued to advance the NSI-566 cell therapy platform through human clinical trials. We have completed treatment of the fourth cohort in our ALS Phase II escalating dose trials, in collaboration with our sites at University of Michigan, Emory and Massachusetts General. Patients 10, 11 and 12 each received a total of 8 million cells (20 bilateral injections of 400,000 cells) into the cervical region of the spinal cord. As our Principal Investigator, Dr. Eva Feldman, noted in her complete Phase I data analysis this past quarter, we believe that increasing total cell dose, by increasing the number of injections and the number of cells per injection, may increase both the duration and magnitude of the potential benefit. This is consistent with our hypothesized neuroprotective mechanism-of-action for this cell therapy," said Karl Johe, PhD, Neuralstem's Chairman of the Board and Chief Scientific Officer. "We are now treating the fifth and final cohort in the Phase II ALS trial. During May, these patients will undergo lumbar transplantation and then return for the cervical treatment during a second surgery approximately four weeks later. Each of these patients will then have received a total of 16 million NSI-566 neural stem cells, through 40 surgical injections of 400,000 cells per injection. The trial will conclude after an observation period of six months from the last surgery. Our hope and expectation is that the data from this trial will enable a registration trial that can start in early 2015."

Dr. Johe continued: "The second indication for NSI-566 in the U.S. is chronic spinal cord injury (cSCI). This FDA-approved trial will be conducted in its entirety at the University of California, San Diego, School of Medicine, under the guidance of Principal Investigator, Joseph Ciacci, MD. The Phase I trial is being made possible, in part, by generous financial support from UCSD. The eight patients will have AIS-A level impairment, or complete paralysis, between one and two years after injury.

"Turning to Neuralstem's neurogenic small molecule drug program, we are currently completing our review of the data from our NSI-189 Phase Ib randomized placebo controlled trial to treat major depressive disorder. While that task is ongoing, the early review is encouraging enough that we have already committed to filing a Phase II trial application and hope to start that trial later this year," concluded Dr. Johe.

"2014 is a pivotal year for Neuralstem," said Richard Garr, Neuralstem's President & CEO. "We are advancing to new clinical levels on both the small molecule and cell therapy

platforms in multiple indications. Along with our collaborators, we are proud to be pushing for breakthroughs in the field of neurogenic medicine."

Mr. Garr added: "As the Company's clinical programs mature, my fellow Directors and I were pleased to have welcomed Dr. Catherine Sohn and Mr. Sandy Smith to our Board. Dr. Sohn formerly spearheaded global commercialization for one of the world's largest pharmaceutical companies, and Mr. Smith was directly responsible for launching 12 new products in diverse therapeutic areas for one of the world's most successful rare disease companies. Their expertise will prove invaluable as we build the infrastructure necessary to move our company to the next level of development."

First Quarter Clinical Program and Business Highlights

In March, a study entitled, "Behavioral and Histopathological Assessment of Adult Ischemic Rat Brains after Intracerebral Transplantation of NSI-566RSC Cell Lines" was published in the peer-reviewed journal, PLOS ONE. The study, whose lead author was Cesar V. Borlongan, PhD, Professor, Department of Neurosurgery, Morsani College of Medicine and Director of University of South Florida's Center of Excellence for Aging and Brain Repair, showed that ischemic-stroke rats transplanted with NSI-566 in the brain experienced functional improvements. Furthermore, the grafts survived and differentiated into neurons. The researchers concluded that NSI-566 are potent cell donors for transplantation therapy to treat paralysis in stroke patients.

In March, the final results from the NSI-566/ALS Phase I trial were published in the peer-reviewed journal, ANNALS OF NEUROLOGY. In "Intraspinal Neural Stem Cell Transplantation in Amyotrophic Lateral Sclerosis: Phase I Trial Outcomes," results were updated from Phase I interim data, reported earlier, to include data from the last six patients in the trial. These six patients were the first to receive cervical stem cell transplants. The results showed that NSI-566 cells can be safely transplanted in both the lumbar and cervical spinal cord segments, did not accelerate disease progression, and warrant further study on dosing and therapeutic efficacy.

In March, President and CEO Richard Garr presented an NSI-566 clinical trials program update at the eighth annual Bio-Europe Spring Conference 2014.

In February, Richard Garr presented an NSI-566 clinical update at the sixteenth annual BIO CEO & Investor Conference 2014.

In January, Neuralstem announced that the first patient was treated, on December 27, 2013, in the NSI-566 Phase I/II trial to treat motor deficits from ischemic stroke at BaYi Brain Hospital in Beijing. The trial is sponsored by Neuralstem's wholly owned subsidiary, Neuralstem China (Suzhou Sun-Now Biopharmaceutical Co. Ltd.), which was formed to develop Neuralstem's cell therapy products in China. The stroke motor deficit trial, expected to last two years, is the first in which Neuralstem's cells are being transplanted directly into the patient's brain.

In January, Neuralstem appointed Catherine Sohn, Doctor of Pharmacy (Pharm.D.), to its Board of Directors. Dr. Sohn is the former Senior Vice President of Business Development and Strategic Alliance, GSK Consumer Healthcare, at GlaxoSmithKline,

where she spearheaded global commercialization for this \$8 billion division and led a series of international licensing deals. Earlier during her 28-year tenure at GlaxoSmithKline, Dr. Sohn established the U.S. Vaccine Business Unit, leading to the launch of the company's first vaccine in the U.S., which grew to more than \$100 million in sales. She was also involved in the U.S. launch of the company's CNS product, Paxil, which subsequently grew to more than \$1 billion in sales.

In January, Neuralstem closed a \$20 million registered direct offering from leading institutional investors, including dedicated healthcare investors, with proceeds intended to fund its ongoing clinical trials and for working capital and general corporate purposes.

In January, Richard Garr presented a business overview and NSI-566 clinical update at the sixth annual 2014 Biotech Showcase.

Subsequent Events:

In April, the FDA-approved NSI-566 Phase I trial to treat chronic spinal cord injury (cSCI) was approved to commence at the University of California, San Diego, School of Medicine by its Institutional Review Board. The open-label, ascending-dose study has a one-year completion goal and will enroll up to eight patients with thoracic spinal cord injuries who have an American Spinal Injury Association AIS-A level of impairment (patients who are considered to be in complete paralysis) between one and two years post injury. NSI-566/cSCI patients will also receive post-surgery immunosuppressive therapy as tolerated and physical therapy for three months. The trial study period will end six months post-surgery for each patient.

In April, NSI-566/ALS Principal Investigator, Eva Feldman, PhD, MD, presented published Phase I data at the Keystone Symposia, "Engineering Cell Fate and Function." Dr. Feldman took part in a workshop, organized in collaboration with California Institute for Regenerative Medicine, called "Clinical Progress for Stem Cell Therapies. Dr. Feldman also provided the first public update on Phase II of the trial.

In May, Sandford Drexel Smith was appointed to Neuralstem's Board of Directors. Mr. Smith is the former President, International Group, and Executive Vice President of Genzyme Corporation. As President of the International Group, Mr. Smith opened markets in Latin America, China, India, Russia and Eastern Europe, establishing more than 45 offices worldwide, and was responsible for the launch of 12 new products in diverse therapeutic areas. He grew Genzyme's international business to \$3.1 billion, or 60% of the company's total revenues. In 2011, Genzyme was acquired by Sanofi, one of the world's largest healthcare companies.

First Quarter Financial Results

For the first quarter of 2014, the Company reported a net loss of approximately \$5,919,000 or \$0.07 per share, compared with a net loss of approximately \$3,590,000 or \$0.05 per share, for the comparable 2013 period. The increase in net loss was primarily comprised of a \$2,286,000 increase in operating loss due to a non-cash charge of approximately \$2,018,000 related to a consultant achieving a performance based milestone which resulted in a term extension of certain common stock purchase warrants

and an increase of approximately \$227,000 in legal and professional fees, partially offset by a \$233,000 decrease in project and lab expenses related to certain projects not continuing into the first quarter of 2014 and the cost of certain studies in 2014 being subsidized by third parties.

The net loss in the first quarter of 2014 also included other expenses comprised of approximately \$432,000 in interest expense related to our long term debt and a \$334,000 non-cash expense related to the change in the fair value of the our derivative instruments. The first quarter of 2013 included a \$667,000 non-cash expense related to the modification of certain stock purchase warrants.

Our cash, cash equivalents and short-term investments on hand was approximately \$33,343,000 at March 31, 2014, compared to approximately \$16,846,000 at December 31, 2013. The increase of approximately \$16,497,000, was primarily due to our raising \$18.7 million through our January 2014 registered direct offering coupled with \$1.4 million of proceeds from the exercise of certain common stock purchase warrants, partially offset by cash used in operations.

Neuralstem, Inc.

Unaudited Condensed Consolidated Balance Sheets

March 31,	December 31,
2014	2013

ASSETS

CURRENT ASSETS

Cash and cash equivalents	\$	18,342,73	6\$	16,846,052
Short-term investments	15,000	0,000	-	
Billed and unbilled receivables	11,359)	10,0	00
Deferred financing fees, current portion	435,54	17	507,	334

Prepaid expenses	319,616	255,733	
Total current assets	34,109,258	17,619,119	
Property and equipment, net	310,375	230,971	
Patents, net	1,190,625	1,137,701	
Deferred financing fees, net of current portion	248,688	360,848	
Other assets	64,850	64,897	
Total assets	\$ 35,923,796	\$ 19,413,536	

LIABILITIES AND STOCKHOLDERS' EQUITY

CURRENT LIABILITIES

Accounts payable and accrued expenses	\$	1,771,11	1\$	1,662,058
Current portion of long term debt, net of discount	2,849,8	312	2,763	,121
Derivative instruments	-		1,417	,527
Other current liabilities	53,280		93,42	6
Total current liabilities	4,674,2	203	5,936	,132
Long term debt, net of discount and current portion	4,192,5	538	4,934	,210
Other long term liabilities	160,33	8	124,9	95
Total liabilities	9,027,0)79	10,99	5,337

STOCKHOLDERS' EQUITY

Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding	-	-	
Common stock, \$0.01 par value; 150 million shares authorized, 86,688,613 and 77,886,031 shares outstanding in 2014 and 2013,respectively	866,886	778,860	
Additional paid-in capital	160,368,948	136,058,135	
Accumulated other comprehensiveincome	5,977	7,241	
Accumulated deficit	(134,345,094) (128,426,037		
Total stockholders' equity	26,896,717 8,418,199		
Total liabilities and stockholders' equity	\$ 35,923,796	\$ 19,413,536	

Neuralstem, Inc.

Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss

Three Months Ended March 31,

2014 2013

Revenues \$ 4,167\$ 102,500

Operating expenses:

Research and development expenses	1,571,221	1,748,	347
General and administrative expenses	3,519,359	1,195,	840
Depreciation and amortization	90,488	50,093	3
Total operating expenses	5,181,068	2,994,	280
Operating loss	(5,176,901)	(2,891	,780)
Other income (expense):			
Interest income	24,718	9,925	
Interest expense	(432,741)	(48,25	7)
Warrant modification expense	-	(666,7	36)
Gain (loss) from change in fair value of derivative instruments	(334,133)	6,518	
Other income	-	243	
Total other income (expense)	(742,156)	(698,3	07)
Net loss	\$	(5,919,057)\$	(3,590,087)
Net loss per share - basic and diluted	\$	(0.0 ^{\$}) (0.05)	

Weighted average common shares outstanding - basic and diluted	85,750,298	68,700,709
Comprehensive loss:		
Net loss	\$	(5,919,057)\$ (3,590,087)
Foreign currency translation adjustment	(1,264)	-
Comprehensive loss	\$ (5,920,321)	\$ (3,590,087)

About Neuralstem

Neuralstem's patented technology enables the production of neural stem cells of the 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 glial cells. Neuralstem's NSI-566 spinal cord-derived stem cell therapy is in Phase II clinical trials 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. The company has received approval to commence an FDA-approved Phase I safety trial in chronic spinal cord injury at the University of California, San Diego, School of Medicine. Neuralstem is also targeting additional major central nervous system conditions with its NSI-566 cell therapy platform, including ischemic stroke and acute spinal cord injury.

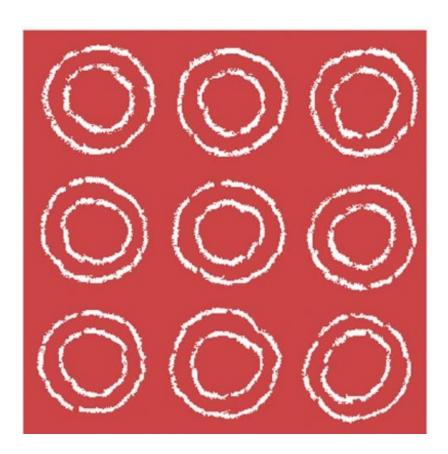
Neuralstem also maintains the ability to generate stable human neural stem cell lines suitable for systematic screening of large chemical libraries. Through this proprietary screening technology, Neuralstem has discovered and patented compounds that may stimulate the brain's capacity to generate neurons, possibly reversing pathologies associated with certain central nervous system conditions. The company has completed a Phase I safety trial evaluating NSI-189, its first neurogenic small molecule product candidate, for the treatment of major depressive disorder (MDD). Additional indications might 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>, 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 the Form 10-Q for the period ended March 31, 2014.



Logo - https://photos.prnewswire.com/prnh/20061221/DCTH007LOGO SOURCE Neuralstem, Inc.