

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

GERMANTOWN, Md., Aug. 8, 2014 /PRNewswire/ -- Neuralstem, Inc. (NYSE MKT: CUR) today reported its financial results for the three months and six months ended June 30, 2014 and provided a business and clinical update.

"We are pleased to report that 2014 has already seen the company achieve several major milestones. In late July, we completed the last of the surgeries in the NSI-566/ALS Phase II trial. Each of the patients in the final cohort 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," said Karl Johe, PhD, Neuralstem's Chairman and Chief Scientific Officer.

"Our FDA-approved NSI-566 Phase I trial to treat chronic spinal cord injury (cSCI) is scheduled to commence in the coming weeks at the University of California, San Diego, School of Medicine, following approval by UCSD's Institutional Review Board during the second quarter," said Dr. Johe. "The open-label, ascending-dose study of patients with thoracic spinal cord injuries utilizes the same proprietary spinal platform and floating cannula developed for the ALS trials, as well as the same NSI-566 spinal cord cells. Patients in this trial will have an American Spinal Injury Association AIS-A level of impairment (considered to be in complete paralysis) and will be between one and two years post injury. The trial is generously supported by, and will be conducted in its entirety at, UCSD under the guidance of Principal Investigator, Joseph Ciacci, MD."

Dr. Johe continued: "During the second quarter, the company achieved another major milestone when data from the lb trial of our neurogenic small molecule compound to treat MDD was presented at two prestigious academic conferences held in June: the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting, and the International College of Neuropyschopharmacology (CINP) Annual Meeting. The extremely robust NSI-189 Phase lb data showed statistical significance; and clinically meaningful improvement of both depression and cognitive symptoms in the active therapy patients, compared to placebo across all clinical measurements. Further, the improvements persisted eight weeks after 28-day treatment stopped.

"We believe the biomarker data (quantitative EEG), which was included in the CINP conference presentation, confirms that NSI-189 is affecting key circuitry common in both mood control and cognition, involving hippocampal neurogenesis and synaptogenesis," added Dr. Johe. "Combined with the significant clinical improvements of the patients, these findings validate our hypothesis that NSI-189 stimulates the neurogenesis of hippocampal stem cells, altering the fine structures within the hippocampus in a manner that is long-lasting. We are encouraged that NSI-189 may be affecting the physical structure of the human brain in these depression patients and may modify progression of cognitive impairment diseases, as well.

"With such positive data supporting this novel neurogenesis-based platform, we and fellow investigators, including lead study author, Dr. Maurizio Fava, Executive Vice Chair, Department of Psychiatry, Executive Director, Clinical Trials Network and Institute, Massachusetts General Hospital, are preparing the Phase II trial application. We plan to launch a multi-site NSI-189/Phase II MDD study late in the first quarter of 2015. This next clinical trial will test two doses (40mg once a day and 40mg twice a day), along with a randomized, double-blinded, placebo control group, in approximately 150 patients with confirmed diagnosis of recurrent MDD, with the aim of confirming these extremely promising results in a larger clinical setting," concluded Dr. Johe.

"We closed the second quarter of 2014 with a cash position of nearly \$30 million, which gives a solid

foundation to execute on the company's business plan through mid-2016," said Richard Garr, Neuralstem's President and CEO. "As Neuralstem's products advance in the clinic in both cell therapy and neurogenic pharmaceuticals, we are building the infrastructure necessary to accelerate our programs towards NSI-566 and NSI-189 commercialization. To that end, my fellow Directors and I were pleased to welcome Sandy Smith as a Director during the second quarter. Sandy is the former President, International Group, and Executive Vice President of Genzyme Corporation. His experience directing global commercialization for one of the world's most successful rare disease companies, where he was directly responsible for launching 12 new products in diverse therapeutic areas, will prove invaluable as we take the company to the next level. Sandy's appointment follows that of Catherine Sohn, PharmD, who spearheaded global commercialization at GlaxoSmithKline, one of the world's largest pharmaceutical companies. We are already benefitting from this level of expertise and experience being added to Neuralstem's Board. We are extremely pleased to have Sandy's and Cathy's guidance during this time of pivotal inflection points for our product development in both the Company's cell therapy and small molecule programs.

"During this past quarter, we further strengthened our global IP portfolio with the issuance of a neurogenic small molecule patent, validated in 34 countries, by the European Patent Organisation. We also received notice of issuance of the second U.S. patent for the floating spinal cannula surgical device used in cell therapy. This brings our total patents to 87 issued and 59 pending," said Garr.

"Dr. Johe and I would like to acknowledge with deep gratitude the brave patients and their families and caregivers who are allowing this breakthrough cell therapy and novel neurogenic drug advancements in the clinic. We also thank our exceptional collaborators, among them: NSI-189/psychiatric/small molecule trial consultant, Maurizio Fava, MD, NSI-566/ALS principal investigator, Eva L. Feldman, MD, PhD, and NSI-566/cSCI lead collaborator, Martin Marsala, MD, PhD. We also want to acknowledge the leading institutions that serve as sites for this ground-breaking work, including the University of Michigan, Emory University, Massachusetts General, and University of California, San Diego," concluded Garr.

Second Quarter Clinical Program and Business Highlights

In June, Neuralstem's NSI-189/MDD Phase Ib data was reported at the annual meetings of both the American Society of Clinical Psychopharmacology (ASCP), and the International College of Neuropyschopharmacology (CINP).

- "A Phase Ib Randomized, Double-Blind, Placebo-Controlled, Multiple-Dose Escalation Study Evaluating the Effects of NSI-189 Phosphate, A Neurogenic Compound, in Patients with Major Depressive Disorder (MDD)," was presented at the ASCP Annual Meeting by Marlene Freeman, MD, Medical Director, Clinical Trials Network and Institute, Massachusetts General Hospital, and Associate Professor of Psychiatry, Harvard Medical School. Data showed a clinically meaningful reduction in cognitive and depressive symptoms across all measures in depressed patients on NSI-189 active therapy against the control group, continuing for the duration of the trial, eight weeks after the 28-day treatment had stopped. A large effect was reported in all four scales employed in the study that are commonly used to assess clinical levels of depression and improvement: Montgomery-Asberg Depression Rating Scale (MADRS), Clinician Global Impression–Improvement (CGI-I), Symptoms of Depression Questionnaire (SDQ), and Cognitive and Physical Functioning Questionnaire (CPFQ). Based on the results, the investigators concluded that a neurogenesis-based platform could identify promising new treatments for MDD.
- "Effects of NSI-189, a neurogenic compound, on quantitative electroencephalography (qEEG) in patients with major depressive disorder (MDD) during a phase 1b randomized, double-blinded, placebo controlled, multiple ascending dose study" was the title of a poster presented by [Brett English, PharmD, PhD, Adjunct Assistant Professor at USC School of Pharmacy and Senior Director for Scientific Affairs at PAREXEL] at the CINP Annual Meeting. The NSI-189/MDD Phase Ib qEEG data showed significantly increased brain wave patterns in the hippocampal region of the brain, and increased electrical coherence in the prefrontal cortical region, which is a pro-cognitive signal. Researchers concluded that these electrophysiological changes are consistent with the neurogenic hypothesis of the drug mechanism, which involves long-term structural changes in the hippocampus.

In June, Neuralstem received issuance of EPO Patent # 2470182 (Synthesis of a Neurostimulative

Piperazine), that was validated in 34 countries: Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, Great Britain, Greece, Croatia, Hungary, Ireland, Iceland, Italy, Lithuania, Luxembourg, Latvia, Monaco, Macedonia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, Slovakia and Turkey, for a total of 35 European patents.

In June, Neuralstem shares were added to the broad-market Russell 300[®] Index. Annual reconstitution of Russell's U.S. indexes captures the 4,000 largest U.S. stocks as of the end of May, ranking them by total market capitalization. Membership in the Russell 3000, which remains in place for one year, brings automatic inclusion in the large-cap Russell 1000[®] Index or small-cap Russell 2000[®] Index as well as the appropriate growth and value style indexes.

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.

In May, Neuralstem's President and CEO, Richard Garr, presented a talk entitled, "Sustainable Growth of Regenerative Medicine: Ensuring Long Term Development and Patient Access to Transformative Cell Therapies," at the World Stem Cells & Regenerative Medicine Congress, in London, UK.

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 study will enroll 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) and are between one and two years post injury. NSI-566/cSCI patients will also receive post-surgery immunosuppressive therapy as tolerated for three months.

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."

In April, the United States Patent Office issued Patent #8,708,962, the second U.S. patent for the floating spinal cannula and method of use, to which Neuralstem holds exclusive license.

Second Quarter Financial Results

For the three months ended June 30, 2014, the Company reported a net loss of approximately \$6,751,000 or \$0.08 per share, compared with a net loss of approximately \$6,252,000 or \$0.09 per share, for the comparable 2013 period. The increase in net loss was due primarily due to a \$278,000 increase in operating loss due to an increase in legal, consulting and professional fees included in our general and administrative expenses related to patent, litigation and other corporate matters. This is coupled with a \$227,000 increase in other expenses primarily due to a \$705,000 increase in non-cash expense related to modifications of certain stock purchase warrants, partially offset by \$250,000 of income from a legal settlement in the current period and prior period including a \$188,000 non-cash expense for the change in fair value of our warrant liability.

For the six months ended June 30, 2014, the Company reported a net loss of approximately \$12,670,000 or \$0.15 per share, compared with a net loss of approximately \$9,842,000 or \$0.14 per share, for the comparable 2013 period. The increase in net loss was due primarily due to a \$2,561,000 increase in operating loss comprised of a \$1,878,000 to an increase in non-cash stock based compensation mainly due to a consultant achieving a performance based milestone which resulted in a term extension of certain common stock purchase warrants along with a \$390,000 increase in legal, consulting and professional fees included in our general and administrative expenses related to patent, litigation and other corporate matters. This is coupled with a \$268,000 increase in other expenses primarily due to a \$343,000 increase in

interest expense due to the prior year only including 3 months of expense related to our March 2013 debt issuance; a \$152,000 increase in non-cash expense for the change in fair value of our warrant liability partially offset by \$250,000 of income from a legal settlement in the current period.

Our cash, cash equivalents and short-term investments on hand was approximately \$30,232,000 at June 30, 2014, compared to \$16,846,000 at December 31, 2013. The increase of approximately \$13,386,000 was primarily due to our raising net \$18.7 million through our January 2014 registered direct offering coupled with approximately \$1.7 million from the exercise of certain common stock purchase warrants and options partially offset by cash used in our operations.

Neuralstem, Inc.

Unaudited Condensed Consolidated Balance Sheets

	June 30, 2014	December 31, 2013
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 15,232,456	\$ 16,846,052
Short-term investments	15,000,000	-
Billed and unbilled receivables	24,468	10,000
Deferred financing fees, current portion	389,297	507,334
Prepaid expenses	196,209	255,733
Total current assets	30,842,430	17,619,119
Property and equipment, net	310,050	230,971
Patents, net	1,247,498	1,137,701
Deferred financing fees, net of current portion	169,712	360,848

Other assets	58,859	64,897
Total assets	\$ 32,628,549	\$ 19,413,536
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	\$ 2,025,694	\$ 1,662,058
Current portion of long term debt, net of discount	2,952,333	2,763,121
Derivative instruments	-	1,417,527
Other current liabilities	13,139	93,426
Total current liabilities	4,991,166	5,936,132
Long term debt, net of discount and current portion	3,415,984	4,934,210
Other long term liabilities	192,707	124,995
Total liabilities	8,599,857	10,995,337
STOCKHOLDERS' EQUITY		
Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding	-	-
Common stock, \$0.01 par value; 300 million shares authorized, 86,837,455 and 77,886,031 shares outstanding in 2014 and 2013, respectively	868,375	778,860
Additional paid-in capital	164,250,586	136,058,135
Accumulated other comprehensiveincome	6,107	7,241
Accumulated deficit	(141,096,376)	(128,426,037)

Total stockholders' equity	24,02	8,692	8,418,199
Total liabilities and stockholders' equity	\$	32,628,54	9 ⁹ 19,413,536

Neuralstem, Inc.

Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss

	Three Months Ended June 30,		Six Months Ended June 30,					
	2014		2013		2014		2013	
Revenues	\$	5,000)\$	2,50	\$	9,16	575	105,000
Operating expenses:								
Research and development expenses	1,947,558		1,906,387		3,518,779		3,654,	734
General and administrative expenses	1,481,948		1,281,210		5,001,307		2,477,	050
Depreciation and amortization	86,732		50,505		177,220		100,59	98
Total operating expenses	3,516,238		3,238,102		8,697,306		6,232,	382
Operating loss	(3,511,238)		(3,235,602	2)	(8,688,139))	(6,127	,382)
Other income (expense):								
Interest income	17,422		16,635		42,140		26,560)
Interest expense	(397,616)		(439,271)		(830,357)		(487,5	28)
Warrant modification expense	(3,109,850)		(2,405,206	5)	(3,109,850))	(3,071	,942)
Gain (loss) from change in fair value of derivative instruments	-		(188,317)		(334,133)		(181,7	99)

Other income	250,000	131	250,000	374
Total other income (expense)	(3,240,044)	(3,016,028)	(3,982,200)	(3,714,335)
Net loss	\$ (6,751,28)	2 ^{\$} (6,251,630)	\$ (12,670,339)	\$ (9,841,717)
Net loss per share - basic and diluted	\$ (0.08)	\$ (0.09)	\$ (0.15)	\$ (0.14)
Weighted average common shares outstanding - basic and diluted	87,186,586	69,864,599	86,477,797	69,591,602
Comprehensive loss:				
Net loss	\$ (6,751,282)	\$ (6,251,630)	\$ (12,670,339)	\$ (9,841,717)
Foreign currency translation adjustmer	nt130	-	(1,134)	-
Comprehensive loss	\$ (6,751,152)	\$ (6,251,630)	\$ (12,671,473)	\$ (9,841,717)

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 Phase II clinical trials for amyotrophic lateral sclerosis (ALS), often referred to as Lou Gehrig's disease, concluded final surgeries in July 2014. 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 approvals from the FDA and the Institutional Review Board of University of California, San Diego, to commence a Phase I safety trial in chronic 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 Phase Ia and Ib trials evaluating NSI-189, its first neurogenic small molecule product candidate, for the treatment of major depressive disorder (MDD), and is expecting to launch a Phase II NSI-189/MDD study in 2015. 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>, <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, 2013 and Form 10Q, for the period ended June 30, 2014.



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