

Neuralstem Reports Fiscal 2014 Fourth Quarter Financial And Year-End Business Results

GERMANTOWN, Md., March 16, 2015 /PRNewswire/ -- Neuralstem, Inc. (NYSE MKT: CUR) (the "Company" or "Neuralstem") today reported its financial results for the fourth quarter and year ended December 31, 2014.

"Neuralstem has progressed into a clinical development stage company focused on the central nervous system (CNS)," said Richard Garr, Neuralstem President and CEO. "During 2014 we added two established industry leaders as Independent Directors, Catherine Angell Sohn, Pharm.D. and Sandford Drexel Smith. Dr. Sohn is the former Senior Vice President of Business Development and Strategic Alliance, GSK Consumer Healthcare, at GlaxoSmithKline. Mr. Smith is the former Executive Vice President of Genzyme Corporation. The Company moved forward two lead clinical assets: our small molecule neurogenic drug candidate NSI-189 and our spinal derived neural stem cell therapeutic candidate NSI-566. We established and/or grew clinical research programs with leading investigators at Emory University, University of California, San Diego (UCSD), University of Michigan and Massachusetts General Hospital. Our investigators published and presented proof of principle data in both lead assets as highlighted below. In 2015, we plan to begin clinical development of our NSI-189 small molecule drug in a second indication for the treatment of cognitive deficit from schizophrenia, and we plan to initiate a Phase II clinical trial for the ongoing development program for the treatment of major depressive disorder (MDD). The cell therapy programs in amyotrophic lateral sclerosis (ALS), chronic spinal cord injury (cSCI) and stroke will also move forward. We expect this to be another important year continuing our development and progress across both platforms."

2014 Clinical Program and Business Highlights

Neurogenic Small Molecule Platform Clinical Development

- NSI-189 Phase II clinical trial for the treatment of MDD is expected to commence in the second quarter of 2015. Maurizio Fava, M.D., Slater Family Professor of Psychiatry at Harvard Medical School, Massachusetts General Hospital is the principal investigator for the 150-patient, multi-site clinical trial.
- **Top-line data for the NSI-189 Phase Ib MDD trial.** The data was presented at the American Society of Clinical Psychopharmacology (ASCP) and the International College of Neuropyschopharmacology (CiNP) annual meetings. The randomized, placebo-controlled, dose-escalation study showed clinically meaningful and statistically significant results in depressive and cognitive measurements at the end

of the 28-day dosing period. Moreover, therapeutic benefits were sustained over the 8-week follow-up period signaling possible hippocampal neurogenesis.

- NSI-189 MDD biomarker data. In November 2014, researchers presented Phase Ib blood-based biomarker data and analysis for MDD in a poster at the CNS Summit, which identified a rapid and persistently efficacious response.
- Expansion of NSI-189 development program to a second indication for the treatment of cognitive deficit in schizophrenia. Cognitive deficit in schizophrenia is a prominent characteristic of the disorder that is correlated with the occurrence of hippocampal atrophy in this patient population. Commencement of the Company's NSI-189 cognitive deficit in schizophrenia Phase Ib trial is expected in 2015.

Cell Therapy Platform Clinical Development

NSI-566 spinal cord-derived stem cell therapy under development for the treatment of ALS

- Top-line data for the Phase II NSI-566 ALS trial. Topline ALS Phase II data were released on March 12, 2015. Our top-line data in the Phase II ALS clinical trial met the primary safety endpoints and established what we believe to be the maximum tolerated dose of 16 million cells delivered in 40 injections. The secondary efficacy endpoints of ALSFRS and grip strength at nine months post-surgery demonstrated statistical significance in a comparison between responders and non-responders at nine months post-surgery; and as in the Phase I trial, disease stabilization was seen in the responders. We plan to present the full Phase II trial data later in 2015. This dose-escalating trial treated 15 ambulatory patients in five cohorts. Each of the three patients in the final cohort received a total dose of 40 injections of 400,000 cells, 20 injections each in the cervical and lumbar regions, for a total 16 million transplanted cells per patient. A larger, controlled Phase II trial is expected to commence in 2015.
- Phase I cell survival study data. In November 2014, a long-term NSI-566 ALS Phase I cell survival study, entitled "Analysis of graft survival in a trial of stem cell transplant in ALS," was published in the journal "Annals of Clinical and Translational Neurology." Researchers concluded that NSI-566 cells survived for the entire postoperative period of each of the autopsied patients studied from nine to thirty months post-transplantation. They also concluded that long-term immunosuppression was most likely not required for long-term survival of the cells.

NSI-566 spinal cord-derived cell therapy under development for the treatment of cSCI

• **Commencement of Phase I cSCI.** The first two patients have been treated in a Phase I trial for cSCI at the UCSD School of Medicine, supported by the UCSD Sanford Stem Cell Clinical Center. The four-patient stem cell transplantation safety trial is currently enrolling patients and expects to report full data in the fourth quarter of 2015, following a six-month post-surgery study for each patient.

NSI-566 spinal cord derived stem cell therapy under development for the treatment

of motor deficits in stroke

• Advancement in Phase I/II ischemic stroke trial. Neuralstem continued to enroll patients in its collaborative Phase I/II ischemic stroke trial with BaYi Brain Hospital in Beijing. The Phase II, controlled proof-of-concept study, is expected to commence in 2015. The trial is sponsored by Neuralstem's wholly owned subsidiary, Suzhou Sun-Now Biopharmaceutical Co. Ltd. ("Neuralstem China"), which was formed to develop Neuralstem's cell therapy products in China.

NSI-532.IGF second generation gene engineered cell therapy

- Expansion of cell therapy development program to include a second cell line engineered to express human insulin-like growth factor 1 (IGF-1). NSI-532.IGF cells are a cortical neural stem cell line engineered to deliver IGF-1, which is intended to provide an extra therapeutic benefit. This is the first instance in which Neuralstem is working to demonstrate the ability of it cells to act as a stable CNS delivery vehicle for gene therapy.
- NSI-532.IGF preclinical Alzheimer's data. In October 2014, the first data were
 presented at the Congress of Neurological Surgeons Annual Meeting. In a
 presentation titled, "Peri-hippocampal stem cell transplantation rescues cognitive
 decline in Alzheimer's disease," University of Michigan Medical School researchers
 concluded that Neuralstem's NSI-532.IGF cells rescued spatial learning and memory
 deficits in mice with an animal model of Alzheimer's disease.

2014 Business Highlights

Board of Directors: Neuralstem appointed two independent directors to its Board of Directors in 2014, Catherine Angell Sohn, Pharm.D. and Sandford Drexel Smith. Dr. Sohn is the former Senior Vice President of Business Development and Strategic Alliance, GSK Consumer Healthcare, at GlaxoSmithKline. Mr. Smith is the former Executive Vice President of Genzyme Corporation.

Financial: In January 2014, Neuralstem closed a \$20 million registered direct offering with proceeds intended to fund its ongoing clinical trials and corporate operations.

Financial Results for the Year Ended December 31, 2014

Cash, cash equivalents and short-term investments on hand was approximately \$27.5 million at December 31, 2014, compared to approximately \$16.8 million at December 31, 2013. The increase was primarily due to our raising approximately \$19.5 million, net, through the sale of our common stock and warrants, and approximately \$4.2 million, net, from our October 2014 debt amendment transaction, partially offset by cash used in our operations.

In the year ended December 31, 2014, we reported a net loss of approximately \$22.6 million or \$0.26 per share, compared to a loss of approximately \$19.8 million or \$0.27 per share in the year ended December 31, 2013. Our operating loss in the year ended December 31, 2014 was approximately \$17.4 million, compared to a loss of approximately

\$12.5 million in the year ended December 31, 2013. The increase in operating loss was primarily attributable to an increase of approximately \$3.7 million in general and administrative expenses coupled with an increase of approximately \$1.0 million in research and development expenses.

The increase in research and development expenses was primarily attributable to an increase of approximately \$0.7 million in payroll and related expenses due to increased salaries and headcount, an increase of approximately \$0.1 million in project and lab expenses and an increase of approximately \$0.1 million in travel and related expenses due to our clinical trial activities. These increased expenses are all related to a ramping-up of our pre-clinical and clinical trial efforts and are expected to continue into subsequent periods.

The increase in general and administrative expenses was primarily attributable to an increase of approximately \$2.0 million in non-cash stock based compensation expenses primarily related to financial advisory and consultant services' achieving a performance based milestone that resulted in a term extension of certain common stock purchase warrants, an increase of approximately \$1.0 million in legal and professional fees related to patent, litigation and other corporate matters, an increase of approximately \$0.6 million in consulting fees primarily related to new business development efforts and an increase of approximately \$0.2 million in payroll and related expenses due to current year headcount increases.

In addition, in the year ended December 31, 2014 we recorded approximately \$5.2 million of other expenses, primarily comprised of approximately \$3.1 million related to our extension of certain common stock purchase warrants, approximately \$1.6 million of interest expenses principally related to our long-term debt, a loss of approximately \$0.4 million on our debt amendment transaction and approximately \$0.3 million related to the change in fair value of the Company's warrant liabilities, partially offset by approximately \$0.3 million of income from a milestone payment from a legal settlement.

Neuralstem, Inc.

Consolidated Balance Sheets

December 31,

2014 2013

ASSETS

CURRENT ASSETS

Cash and cash equivalents	\$	12,518,98	0\$	16,846,052
Short term investments	15,00	07,478	-	
Trade and other receivables	225,	524	10,0	000
Deferred financing fees, current portion	135,6	694	507	,334
Prepaid expenses	274,	106	255	733
Total current assets	28,16	61,782	17,6	519,119
Property and equipment, net	301,2	265	230	971
Patents, net	1,23	3,172	1,13	37,701
Deferred financing fees, net of current portion	89,14	43	360	848
Other assets	58,7 ⁻	13	64,8	97
Total assets	\$ 29,84	44,075	\$ 19,4	13,536
LIABILITIES AND STOCKHOLDERS' EQUITY				
CURRENT LIABILITIES				
Accounts payable and accrued expenses	\$ 2,504	4,978	\$ 1,19	6,190
Accrued bonuses	646,9	960	465	868

Current portion of long term debt, net of discount	730,012	2,763,121	
Derivative instruments	-	1,417,527	
Other current liabilities	126,745	93,426	
Total current liabilities	4,008,695	5,936,132	
Long term debt, net of discount and current portion	8,056,470	4,934,210	
Other long term liabilities	59,574	124,995	
Total liabilities	12,124,739	10,995,337	
STOCKHOLDERS' EQUITY			
Preferred stock, 7,000,000 shares authorized, zero share issued and outstanding	s_	-	
	s_ 877,897	- 778,860	
issued and outstanding Common stock, \$0.01 par value; 300 million shares authorized, 87,789,679 and 77,886,031 shares issued and outstanding in 2014 and 2013,	-	- 778,860 136,058,135	
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Neuralstem, Inc.

Consolidated Statements of Operations and Comprehensive Loss

Year Ended December 31,

	2014	2013
Revenues	\$ 18,833	\$ 110,000
Operating expenses:		
Research and development costs	8,134,753	7,134,301
General and administrative expenses	8,971,299	5,254,915
Depreciation and amortization	348,630	244,725
Total operating expenses	17,454,682	12,633,941
Operating loss	(17,435,849)	(12,523,941)
Other income (expense):		
Interest income	67,651	68,000
Interest expense	(1,620,776)	(1,394,274)

Warrant modification expense	(3,109	,850)	(5,017	,156)
Loss from change in fair value of derivative instruments	(334,1	33)	(965,3	29)
Loss on debt extinguishment	(445,7	87)	-	
Litigation settlement	250,00	00	838	
Total other income (expense)	(5,192	,895)	(7,307	,921)
Net loss	\$ (22,62	8,744)	\$ (19,83	1,862)
Net loss per share - basic and diluted	\$ (0.26)		\$ (0.27)	
Weighted average common shares outstanding basic and diluted	⁻ 87,086	6,345	72,279	9,210
Comprehensive loss:				
Net loss	\$ (22,62)	8,744)	\$ (19,83	1,862)
Foreign currency translation adjustment	(1,241)	7,241	
Comprehensive loss	\$	(22,629,98	5)\$	(19,824,621)

About Neuralstem

Neuralstem's patented technology enables the production of multiple types of central nervous system (CNS) stem cells in commercial quantities for the potential treatment of certain CNS diseases and conditions.

The human neural stem cell lines Neuralstem has generated for chemical screening has led to the discovery and patenting of compounds that may stimulate the brain's capacity to generate neurons, possibly reversing pathologies associated with certain CNS 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 study for MDD and a Phase Ib study for cognitive deficit in schizophrenia in 2015.

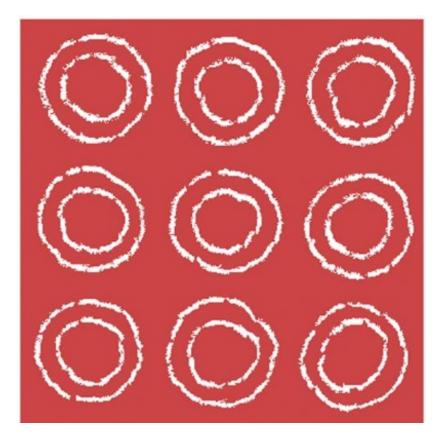
Neuralstem's first stem cell product candidate, NSI-566, a spinal cord-derived neural stem cell line, is in an ongoing clinical trial for the treatment of amyotrophic lateral sclerosis (ALS, or Lou Gehrig's disease). Phase II surgeries were completed in July 2014. A later stage trial is anticipated to commence in 2015 at multiple centers. Neuralstem received orphan designation by the FDA for NSI-566 in ALS. In addition to ALS, NSI-566 is also being tested in a Phase I trial in chronic spinal cord injury at University of California, San Diego School of Medicine. NSI-566 is also in clinical development for the treatment of neurological diseases such as ischemic stroke and acute spinal cord injury.

Neuralstem's next generation stem cell product, NSI-532.IGF, consists of human cortexderived neural stem cells that have been engineered to secrete human insulin-like growth factor 1 (IGF-1). In animal data presented at the Congress of Neurological Surgeons 2014 Annual Meeting, the cells rescued spatial learning and memory deficits in an animal model of Alzheimer's disease.

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 contains "forward-looking statements" made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Such forwardlooking statements relate to future, not past, events and may often be identified by words such as "expect," "anticipate," "intend," "plan," "believe," "seek" or "will." Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Specific risks and uncertainties that could cause our actual results to differ materially from those expressed in our forward-looking statements include 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, 2014, filed with the Securities and Exchange Commission (SEC) on March 16, 2015, and in other reports filed with the SEC.



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