

March 10, 2014



## Neuralstem Announces 2013 Financial Results

ROCKVILLE, Md., March 10, 2014 /PRNewswire/ -- Neuralstem, Inc. (NYSE MKT: CUR) today provided an update on its clinical trials program and reported its 2013 financial results for the year ended December 31, 2013.

(Logo: <https://photos.prnewswire.com/prnh/20061221/DCTH007LOGO>)

"2013 was an exciting year for advancement in our NSI-566 cell therapy clinical programs," said Karl Johe, PhD, Neuralstem's Chairman of the Board and Chief Scientific Officer. "Our Phase II ALS trial commenced in September, with increased dosing levels of our spinal cord cells towards what we expect to be the maximum safe therapeutic dose for the final cohort in this trial. At the close of 2013, we expanded our NSI-566 programs globally with the dosing of the first patient in our ischemic stroke trial in China. We also filed our IND to treat acute spinal cord injury in South Korea."

Dr. Johe continued, "We expect to receive IRB approval and to transplant the first patient at UC San Diego School of Medicine, in our FDA-approved NSI-566 chronic spinal cord injury (cSCI) Phase I trial this Spring.

"2013 also brought significant progress in our neurogenic small molecule program. The company completed dosing of Phase Ib patients for NSI-189, in major depressive disorder (MDD), in August. A comprehensive review of the data is currently underway. Measurements include tolerability, pharmacokinetics, and pharmacodynamic effects including hippocampal volume by MRI, BDNF/CRH/other factors in blood, urine biomarkers, cortisol in saliva, qEEG, MADRS, NGH Depression Questionnaire, and Columbia-Suicidal Severity Rating Scale. While this data analysis will take us through the second quarter of 2014, the early review is encouraging. We expect to be commencing a Phase II trial in NSI-189 MDD in the second half of this year," concluded Dr. Johe.

"As we advance to new clinical levels in both our cell therapy and neurogenic small molecule programs in multiple CNS indications around the world, we are encouraged by the enthusiasm and support of leading institutional investors, including dedicated healthcare investors. Our recent financings have strengthened our cash balance, establishing a strong foundation for all of our programs going forward," said Richard Garr, Neuralstem's President and CEO. "My fellow Directors and I are also very pleased to have recently welcomed Dr. Catherine Sohn to our Board. Dr. Sohn's extensive experience directing global commercialization for one of the world's largest pharmaceutical companies will prove invaluable as our clinical progress moves our company to the next level of development.

"Among the many highlights of 2013, Dr. Johe and I were pleased to grant licenses to IP surrounding our proprietary 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, for academic research," continued Garr. "We further strengthened our global IP portfolio to 49 issued and 60 pending patents, with the addition of 37 patents and applications both in the U.S. and internationally during the past year.

"Dr. Johe and I continue to applaud the tremendous dedication, skill and tireless commitment of the great minds and skilled surgical hands that are helping us achieve our aim of effectively treating CNS diseases and conditions that have doggedly remained huge unmet medical needs for so long. We are all very encouraged by the data and excited about the clinical progress planned in the

months ahead. We praise and thank the brave patients and their families and caregivers who are helping us develop treatments that have the promise of hope for so many," added Garr.

### **Business Highlights for 2013**

*NSI-566: Cell Therapy Lead Candidate – ALS Phase I and II Clinical Trials (amyotrophic lateral sclerosis, or Lou Gehrig's disease)*

In February, the NSI-566/ALS Phase I trial officially concluded, six months after the final surgery at Emory University Hospital in Atlanta.

In April, Neuralstem received FDA approval to commence the NSI-566/ALS Phase II trial, following the excellent safety and tolerability demonstrated in Phase I. The Phase II dose escalation and safety trial expands to two centers: Emory University Hospital, and the ALS Clinic at the University of Michigan Health System, in Ann Arbor, subject to IRB approvals.

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," was 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 data results from all 15 patients at the Romanian Neurological Society Congress. 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, and an unpaid consultant to Neuralstem.

In June, Dr. Feldman gave the grand plenary address at the Canadian Neurological Sciences Federation Annual Congress, which included a presentation of the final NSI-566/ALS Phase I results, which included new cervical cohort data.

In September, Neuralstem's NSI-566/ALS Phase II dose escalation and safety trial commenced. The multicenter trial is designed to treat up to 15 ambulatory ALS patients in five different dosing cohorts. The first 12 patients will receive injections in the cervical region of the spinal cord only, and the final three patients will receive both cervical and lumbar injections.

In October, University of Michigan Health System treated its second patient, which represented the completion of the first of the NSI-566/ALS Phase II trial's five cohorts in less than a month's time.

In October, Dr. Feldman gave an update on the NSI-566/ALS trial at the annual American Neurological Association Meeting.

*NSI-566: cSCI Phase I Clinical Trial (chronic spinal cord injury)*

In January, the FDA approved NSI-566 for a Phase I trial to treat cSCI. The open-label, multi-site, ascending-dose study 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 nine months and two years post injury.. 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.

*NSI-189: Neurogenic Small Molecule Lead Compound: Major Depressive Disorder Phase I Trial*

In April, the FDA approved treatment of the third and final cohort in the ongoing NSI-189/major

depressive disorder (MDD) Phase Ib. Phase Ib tested the safety of escalating doses of NSI-189 for 28 daily administrations in 24 depressed patients in three cohorts. NSI-189 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 an NSI-189 trial to treat cognitive and psychiatric impairment of former NFL players from traumatic brain injury.

#### *NSI-566 Research Papers*

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 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.

#### *Licenses and Intellectual Property*

In January, Neuralstem received issuance of U.S. Patent #8,362,262 (Small Molecule: Divisional Compositions and Methods of Use), and issuance of PCT Patent #2337517 (Licensed: Floating Cannula and Method of Use) and in four European countries: Germany, France, Italy and United Kingdom, for a total of five European patents.

In February, the company granted licenses to IP 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, for academic research.

In March, Neuralstem received issuance of EP Patent # 1576134 (Small Molecule: Method for Discovering Neurogenic Agents) and in ten European countries: Belgium, Switzerland, Germany, France, United Kingdom, Ireland, Luxembourg, Netherlands and Sweden, for a total of 11 European patents.

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 the third quarter, Neuralstem received issuance of Japan Patent # 5266297, and filed a new patent application in South Korea, 10-2013-7020263, both related to the company's existing stem cell technology. The company also filed a new U.S. patent application 61/844,165, which covers methods of treating cognitive defects with spinal cord neural stem cells.

#### *Additional Corporate News*

In March, Neuralstem President and CEO Richard Garr was named the 15<sup>th</sup> 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.

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

In September, President and CEO Richard Garr presented at the Stem Cells & Regenerative Medicine Congress. NSI-566/ALS Phase I patient, Ted Harada, also spoke about his experience with ALS and treatments at the congress.

In September, the company raised aggregate gross proceeds of \$4,556,000 in a registered direct offering.

*Subsequent Events:*

In January 2014, Neuralstem appointed Catherine Sohn, Doctor of Pharmacy (Pharm.D.), to its Board of Directors, bringing the total number of board members to six. 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 2014, 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 2014, President and CEO Richard Garr presented a business overview and NSI-566 clinical update at the sixth annual 2014 Biotech Showcase.

In February 2014, Richard Garr presented an NSI-566 clinical trials program update at the 16<sup>th</sup> annual BIO CEO & Investor Conference 2014.

**Results of Operations for the Year Ended December 31, 2013**

In the year ended December 31, 2013, the company reported a net loss of approximately \$19,832,000 or \$0.27 per share, compared to a loss of approximately \$10,122,000 or \$0.17 per share in the year ended December 31, 2012. The Company's 2013 operating loss was approximately \$12,524,000 compared to a loss of \$10,156,000 in 2012. The increase in operating loss consisted primarily of an increase of \$1,028,000 in research and development expenses coupled with a \$1,008,000 increase in general and administrative expenses.

The increase in research and development expenses was primarily attributable to an approximately \$389,000 increase in project and lab expenses, a \$136,000 increase in personnel related expenses due to the hiring of additional research and development personnel, a \$147,000 increase in travel expenses all due to the ramping up of our clinical trial and research efforts coupled with a \$277,000 increase in share-based compensation.

The increase in general and administrative expenses was primarily attributable to an approximately \$494,000 increase in professional services, a \$444,000 increase in share-based compensation, a \$77,000 increase in insurance premiums and a \$57,000 increase in charitable donations, partially offset by a \$92,000 decrease in bonus and personnel related expenses.

In addition, in 2013 the Company recorded approximately \$7,308,000 of other expenses primarily comprised of \$5,017,000 related to the modification of certain common stock purchase warrants, \$1,394,000 of interest expense related to our March 2013 long term debt and \$965,000 related to the change in fair value of the Company's derivative instruments.

Cash and cash equivalents on hand was approximately \$16,846,000 at December 31, 2013,

compared with approximately \$7,444,000 at December 31, 2012. The increase in our cash and cash equivalents of approximately \$9,402,000, was primarily due to our raising approximately \$13.2 million through the issuance and sale of our common stock and warrants along with \$7.6 million through our March 2013 issuance of debt, partially offset by cash used in operations

**Neuralstem, Inc**

**Consolidated Balance Sheets**

	<b>December 31,</b>	
	<b>2013</b>	<b>2012</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 16,846,052	\$ 7,443,773
Billed and unbilled receivables	10,000	3,333
Deferred financing fees, current portion	507,334	-
Prepaid expenses	255,733	205,651
<b>Total current assets</b>	<b>17,619,119</b>	<b>7,652,757</b>
Property and equipment, net	230,971	230,397
Patents, net	1,137,701	807,357
Deferred financing fees, net of current portion	360,848	-
Other assets	64,897	59,568
<b>Total assets</b>	<b>\$</b>	<b>\$</b>

	19,413,536	8,750,079
--	------------	-----------

## LIABILITIES AND STOCKHOLDERS' EQUITY

### CURRENT LIABILITIES

Accounts payable and accrued expenses	\$ 1,196,190	\$ 1,199,662
---------------------------------------	-----------------	-----------------

Accrued bonuses	465,868	465,865
-----------------	---------	---------

Current portion of long term debt, net of discount	2,763,121	-
--	-----------	---

Derivative instruments	1,417,527	-
------------------------	-----------	---

Other current liabilities	93,426	90,776
---------------------------	--------	--------

<b>Total current liabilities</b>	<b>5,936,132</b>	<b>1,756,303</b>
----------------------------------	------------------	------------------

Long term debt, net of discount and current portion	4,934,210	-
---	-----------	---

Other long term liabilities	124,995	21,143
-----------------------------	---------	--------

<b>Total liabilities</b>	<b>10,995,337</b>	<b>1,777,446</b>
--------------------------	-------------------	------------------

### 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, 77,886,031 and 68,189,314 shares issued and outstanding in 2013 and 2012, respectively	778,860	681,893
---	---------	---------

Additional paid-in capital	136,058,135	114,884,915
Accumulated other comprehensive income	7,241	-
Accumulated deficit	(128,426,037)	(108,594,175)
<b>Total stockholders' equity</b>	<b>8,418,199</b>	<b>6,972,633</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 19,413,536</b>	<b>\$ 8,750,079</b>

**Neuralstem, Inc.**

**Consolidated Statements of Operations and Comprehensive Loss**

	<b>Year Ended December 31,</b>	
	<b>2013</b>	<b>2012</b>
Revenues	\$ 110,000	\$ 407,708
Operating expenses:		
Research and development costs	7,134,301	6,105,984
General and administrative expenses	5,254,915	4,247,037
Depreciation and amortization	244,725	211,143
Total operating expenses	12,633,941	10,564,164
Operating loss	(12,523,941)	(10,156,456)
Other income (expense):		

Interest income	68,000	34,154
Interest expense	(1,394,274)	(2,699)
Warrant modification expense	(5,017,156)	-
Gain (loss) from change in fair value of derivative instruments	965,329	-
Litigation settlement	838	3,484
Total other income (expense)	(7,307,921)	34,939
Net loss	\$ (19,831,862)	\$ (10,121,517)
Net loss per share - basic and diluted	\$ (0.27)	\$ (0.17)
Weighted average common shares outstanding - basic and diluted	72,279,210	58,153,929
Comprehensive loss:		
Net loss	\$ (19,831,862)	\$ (10,121,517)
Foreign currency translation adjustment	7,241	-
Comprehensive loss	\$ (19,824,621)	\$ (10,121,517)

### 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.

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 FDA approval 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 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 [www.neuralstem.com](http://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, 2013.

SOURCE Neuralstem, Inc.