

May 8, 2015



# Neuralstem Reports First Quarter 2015 Financial Results And Provides Business and Clinical Update

GERMANTOWN, M.D., May 8, 2015 /PRNewswire/ -- Neuralstem, Inc. (NYSE MKT: CUR) a biopharmaceutical company using neural stem cell technology to develop small molecule and cell therapy treatments for central nervous system diseases, reported its financial results for the three months ended March 31, 2015 and provided a business and clinical update.

"Neuralstem made substantial clinical progress this quarter in both our cell therapy and small molecule programs. We announced positive top-line safety data and encouraging secondary efficacy data for our Phase II ALS clinical trial, and look forward with anticipation to the release of the comprehensive data and analysis," said Richard Garr, Neuralstem CEO. "Additionally, as we began to prepare for the NSI-189 MDD Phase II trial, we announced a second NSI-189 indication, cognitive deficit in schizophrenia, in which we will also commence a trial in 2015."

## Neurogenic Small Molecule Program

- **Regulatory and clinical preparation for NSI-189 Phase II clinical trial for the treatment of MDD.** Maurizio Fava, M.D., Slater Family Professor of Psychiatry at Harvard Medical School, Massachusetts General Hospital is the principal investigator for the anticipated approximately 150-patient, multi-site clinical trial in 2015.
- **Preparation for NSI-189 Phase Ib clinical trial for the treatment of cognitive deficit in schizophrenia.** Cognitive deficit in schizophrenia is a prominent characteristic of the disorder that is correlated with hippocampal atrophy in this patient population.

## Cell Therapy

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

- **Announced top-line data for the Phase II NSI-566 ALS trial.** Topline data concluded that the Phase II ALS clinical trial met the primary safety endpoints and established what we believe to be the maximum safe-tolerated dose of 16 million cells delivered in 40 injections. Secondary efficacy endpoints, such as the Amyotrophic Lateral Sclerosis Functional Rating Scale, or ALSFRS, and grip strength were evaluated at nine months post-surgery to assess the potential therapeutic benefit of disease stabilization. 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. As a result of the clear safety and strong treatment effects, a larger Phase II efficacy trial will be commenced in 2015.

### **NSI-566 spinal cord-derived cell therapy under development for the treatment of chronic spinal cord injury (cSCI)**

- **The Phase I cSCI clinical trial is ongoing.** Patients are being treated and evaluated in the Phase I trial for cSCI at the UCSD School of Medicine, supported and funded by the UCSD Sanford Stem Cell Clinical Center. The four-patient stem cell transplantation safety trial is followed by six-month post-surgery observation period. With UCSD's collaboration, we anticipate to report top-line data in the fourth quarter of 2015.

### **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 continues to proceed in its collaborative Phase I/II ischemic stroke trial with BaYi Brain Hospital in Beijing. The Phase II portion of the study, a 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.

### **Business Highlights**

Neuralstem announced the appointment of Jonathan Lloyd Jones to the position of Chief Financial Officer, effective May 18, 2015. Mr. Lloyd Jones brings to the position more than 25 years of corporate finance and business development experience. He previously served as Chief Financial Officer at Columbia Laboratories (Juniper Pharmaceuticals), CFO and VP of Corporate Development at TetraLogic, and Senior Director, Corporate Development at Genzyme Corporation (Sanofi-Aventis). Mr. Lloyd Jones is a Chartered Accountant who holds a MBA degree from the Wharton School of the University of Pennsylvania a BS from the University of Bradford.

Neuralstem's President and CEO, Richard Garr presented an overview of the company's cell therapy and neurogenic small molecule clinical trials at three investor conferences in the first quarter of 2015: Biotech Showcase in San Francisco, BIO CEO & Investor Conference in New York City, and Barclays Global Healthcare Conference in Miami.

In March, New Zealand issued a patent (623207) for "Methods for Treating and/or Reversing Neurodegenerative Diseases and/or Disorders."

### **Results of Operations for the Quarter Ended March 31, 2015**

Cash, cash equivalents and short-term investments on hand was approximately \$28.6 million at March 31, 2015, compared to approximately \$27.5 million at December 31,

2014. The increase was primarily due to our raising approximately \$6.0 million, net through the issuance of our common stock from warrant exercises and from the sale of our common stock largely offset by cash used in our operations.

In the quarter ended March 31, 2015, we reported a net loss of approximately \$5.1 million or \$0.06 per share, compared to a loss of approximately \$5.9 million or \$0.07 per share in the first quarter of 2014. Our operating loss in the quarter ended March 31, 2015 was approximately \$4.6 million compared to a loss of \$5.2 million in the same quarter of 2014. The decrease in operating loss was primarily attributable to a decrease of approximately \$2.1 million in general and administrative expenses largely offset by an increase of approximately \$1.6 million in research and development expenses.

The increase in research and development expenses was primarily attributable to an increase of approximately \$1.2 million in project and lab expenses and an increase of approximately \$0.3 million in payroll and related expenses due to increased salaries and headcount. 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 decrease in general and administrative expenses was primarily attributable to a decrease of approximately \$1.8 million in non-cash stock based compensation largely the result of a first quarter 2014 expense of approximately \$2.0 million in non-cash stock based compensation expense related to a financial advisory and consulting services provider achieving a performance based milestone that resulted in a term extension of certain common stock purchase warrants. This was coupled with a decrease of approximately \$0.5 million in legal fees resulting from insurance claims related to litigation expense. These decreases were partially offset by increases of approximately \$0.1 million in each of consulting fees and payroll related expenses due to increased salaries and headcount.

In addition, in the first quarter of 2015 we recognized approximately \$0.4 million of other expenses primarily comprised of interest expenses related to our long-term debt.

**Neuralstem, Inc.**

## **Unaudited Condensed Consolidated Balance Sheets**

	<b>March 31, 2015</b>	<b>December 31, 2014</b>
--	---------------------------	------------------------------

### **ASSETS**

## CURRENT ASSETS

Cash and cash equivalents	\$ 13,593,461	\$ 12,518,980
Short-term investments	15,032,419	15,007,478
Trade and other receivables	8,173	225,524
Deferred financing fees, current portion	130,677	135,694
Prepaid expenses	388,065	274,106
<b>Total current assets</b>	<b>29,152,795</b>	<b>28,161,782</b>
Property and equipment, net	282,057	301,265
Patents, net	1,242,026	1,233,172
Deferred financing fees, net of current portion	62,992	89,143
Other assets	59,098	58,713
<b>Total assets</b>	<b>\$ 30,798,968</b>	<b>\$ 29,844,075</b>

## LIABILITIES AND STOCKHOLDERS' EQUITY

### CURRENT LIABILITIES

Accounts payable and accrued expenses	\$ 2,129,199	\$ 2,504,978
Accrued bonuses	225,321	646,960
Current portion of long term debt, net of discount	1,929,010	730,012

Other current liabilities	52,856	126,745
<b>Total current liabilities</b>	<b>4,336,386</b>	<b>4,008,695</b>
Long term debt, net of discount and current portion	6,954,895	8,056,470
Other long term liabilities	146,165	59,574
<b>Total liabilities</b>	<b>11,437,446</b>	<b>12,124,739</b>
<b>STOCKHOLDERS' EQUITY</b>		
Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding	-	-
Common stock, \$0.01 par value; 300 million shares authorized, 90,336,643 and 87,789,679 shares outstanding in 2015 and 2014, respectively	903,366	877,897
Additional paid-in capital	174,596,927	167,890,220
Accumulated other comprehensive income	6,013	6,000
Accumulated deficit	(156,144,784)	(151,054,781)
<b>Total stockholders' equity</b>	<b>19,361,522</b>	<b>17,719,336</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 30,798,968</b>	<b>\$ 29,844,075</b>

**Neuralstem, Inc.**

## Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss

Three Months Ended March 31,

	2015	2014
Revenues	\$ 2,917	\$ 4,167
Operating expenses:		
Research and development expenses	3,134,394	1,571,221
General and administrative expenses	1,434,588	3,519,359
Depreciation and amortization	83,773	90,488
Total operating expenses	4,652,755	5,181,068
Operating loss	(4,649,838)	(5,176,901)
Other income (expense):		
Interest income	13,569	24,718
Interest expense	(453,734)	(432,741)
Loss from change in fair value of derivative instruments	-	(334,133)
Other income	-	-

Total other income (expense)	(440,165)	(742,156)
Net loss	\$ (5,090,003)	(5,919,057)
Net loss per share - basic and diluted	\$ (0.06)	\$ (0.07)
Weighted average common shares outstanding - basic and diluted	89,654,634	85,750,298
Comprehensive loss:		
Net loss	\$ (5,090,003)	\$ (5,919,057)
Foreign currency translation adjustment	13	(1,264)
Comprehensive loss	\$ (5,089,990)	\$ (5,920,321)

### 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

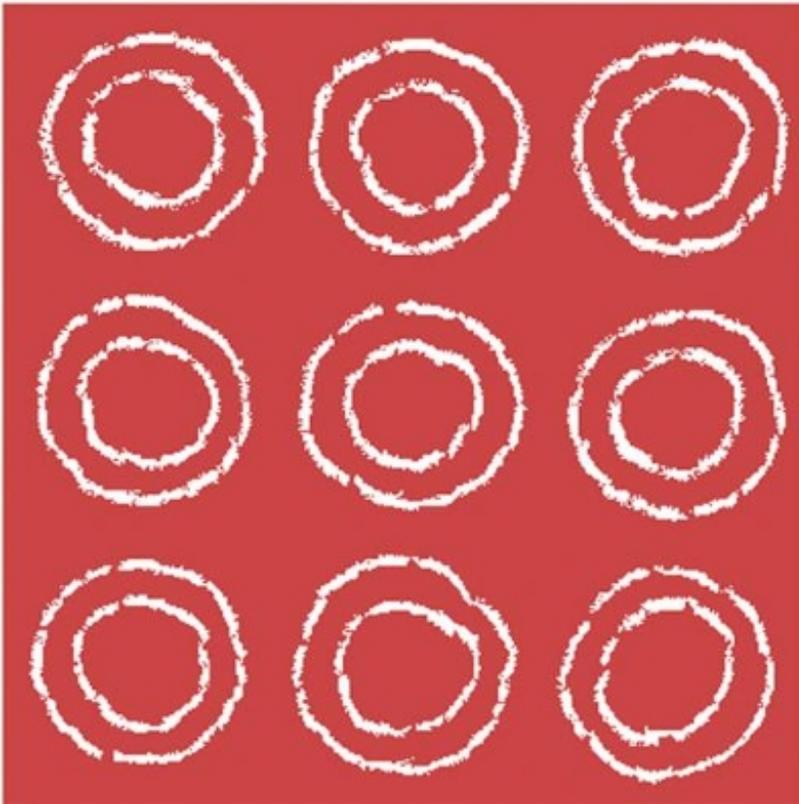
being tested in a Phase I trial in chronic spinal cord injury at University of California, San Diego School of Medicine. NSI-566 is also in clinical development for the treatment of neurological diseases such as ischemic stroke and acute spinal cord injury.

Neuralstem's next generation stem cell product, NSI-532.IGF, consists of human cortex-derived 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 [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 contains "forward-looking statements" made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking 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, Form 10-Q for the period ended March 31, 2015, and in other reports filed with the SEC.



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

To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/neuralstem-reports-first-quarter-2015-financial-results-and-provides-business-and-clinical-update-300080152.html>

SOURCE Neuralstem, Inc.