

Neuralstem Reports Fourth Quarter and Year End 2015 Fiscal Results and Business Update

FDA Approval to Commence Phase 2 Major Depressive Disorder Clinical Trial

Strengthening of Executive Leadership

GERMANTOWN, Md., March 14, 2016 /PRNewswire/ -- Neuralstem, Inc. (Nasdaq: CUR), a biopharmaceutical company focused on the development of central nervous system therapies based on its neural stem cell technology, reported its financial results for the fourth quarter and year ended December 31, 2015.

Clinical Program and Business Highlights

Business Highlights

- The Company strengthened its executive team with the appointment of Richard Daly as President and Chief Executive Officer, Jonathan Lloyd Jones as Chief Financial Officer and Andy Moniz as Vice President of Clinical Operations.
- In January 2016, the Company announced an initiative to pursue collaborations for its stem cell therapy programs to utilize additional expertise, expedite clinical and regulatory pathways and secure funding.
- Recently, the FDA approved the commencement of the NSI-189 Phase 2 clinical trial for the treatment of Major Depressive Disorder.

"The FDA approval to commence our Phase 2 Major Depressive Disorder (MDD) trial is a meaningful milestone for the Company," commented Richard Daly. "We believe NSI-189 may provide this large patient population with an alternative therapy without many of the typical side effects of current commercial drugs. Our strengthened team provides incremental expertise and we are committed to executing a diligently run trial to deliver data in the second half of 2017."

Neurogenic Small Molecule Platform Clinical Development

Lead asset, NSI-189 Phase 2 clinical trial for the treatment of major depressive disorder (MDD)

• In late February 2016, the FDA approved the commencement of our NSI-189 Phase 2 clinical trial for the treatment of major depressive disorder. The double-blind, randomized, placebo-controlled, 220 subject study is expected to enroll the first

subject in the second quarter of 2016. For information on the trial please visit <u>https://clinicaltrials.gov/show/NCT02695472</u>.

Cell Therapy Platform Clinical Development

• In January 2016, Karl Johe, Founder and Chief Scientific Officer, presented at the Phacilitate Cell & Gene Therapy World Conference. He concluded that the collective trial data analysis showed the cells consistently demonstrated biological activity in all three program indications: amyotrophic lateral sclerosis (ALS), chronic spinal cord injury (cSCI), and motor deficits due to ischemic stroke.

NSI-566 Phase 1 safety trial for the treatment of cSCI

In January 2016, the Company reported preliminary six-month follow-up Phase 1 safety data on all four subjects. The stem cell treatment demonstrated feasibility and safety. A self-reported ability to contract some muscles below the level of injury was confirmed via clinical and electrophysiological follow-up examinations in one of the four patients treated. There was no change in the clinical status of the three other patients. This study was completed with the collaboration of the UCSD School of Medicine, supported by the UCSD Sanford Stem Cell Clinical Center; substantially all of the clinical costs of this study have been funded by grants arranged through the University.

NSI-566 Phase 1 / 2 safety trial for the treatment of amyotrophic lateral sclerosis (ALS)

• In September 2015, nine-month Phase 2 and combined Phase 1 and Phase 2 data on the NSI-566 trial in amyotrophic lateral sclerosis (ALS) was presented at the American Neurological Association Annual Meeting by the principal investigator, Eva Feldman, MD, PhD, Director of the A. Alfred Taubman Medical Research Institute and Director of Research of the ALS Clinic at the University of Michigan Health. The data showed that the intraspinal transplantation of the cells was safe and well tolerated. In January 2016, the Company announced that it is in discussions with various governmental, State and non-profit organizations regarding funding grants for the next trial; the initiation of the trial will be dependent upon significant funding from such sources.

NSI-566 Phase 1 safety trial for the treatment of motor deficits in stroke

• The Company completed dosing the second of three planned cohorts in a Phase 1/2 clinical trial at BaYi Brain Hospital in Beijing. The trial is being conducted by Neuralstem China, at BaYi Brain Hospital in Beijing, China.

Financial Results for the Year Ended December 31, 2015

Cash, cash equivalents and short-term investments on hand was approximately \$12.2 million at December 31, 2015, compared to approximately \$27.5 million at December 31, 2014. The decrease was associated with cash used in our operations.

In the year ended December 31, 2015, we reported a net loss of approximately \$20.9 million or \$0.23 per share, compared to a loss of approximately \$22.6 million or \$0.26 per share in the year ended December 31, 2014.

Our operating loss in the year ended December 31, 2015 was approximately \$19.2 million, compared to a loss of approximately \$17.5 million in the year ended December 31, 2014. The increase in operating loss was primarily attributable to an increase of approximately \$4.3 million in research and development expenses partially offset by a decrease of general and administrative expenses of approximately \$2.6 million.

The increase in research and development expenses was primarily attributable to an increase in headcount, and an increase clinical, pre-clinical and CMC expenses, all related to the ramp-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 in non-cash stock based compensation expense and a decrease in legal, consulting and other external advisory fees. These were partially offset by an increase in personnel and related expenses associated with changes in headcount.

We had 92.0 million and 87.8 million common shares issued and outstanding at December 31, 2015 and 2014, respectively.

Neuralstem, Inc.

Consolidated Balance Sheets

December 31	,
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	2015	2014	2014	
ASSETS				
CURRENT ASSETS				
Cash and cash equivalents	\$	4,716,53 3 \$	12,518,980	
Short term investments	7,517,453	15,007	,478	

Trade and other receivables	37,316	225,524
Deferred financing fees, current portion	89,562	135,694
Prepaid expenses	1,159,782	274,106
Total current assets	13,520,646	28,161,782
Property and equipment, net	343,200	301,265
Patents, net	1,103,467	1,233,172
Deferred financing fees, net of current portion	9,154	89,143
Other assets	71,797	58,713
Total assets	\$ 15,048,264	\$ 29,844,075

LIABILITIES AND STOCKHOLDERS' EQUITY

CURRENT LIABILITIES

Accounts payable and accrued expenses	\$ 1,455,826	\$ 2,504,978
Accrued bonuses	161,362	646,960
Current portion of long-term debt, net of discount	4,634,742	730,012
Other current liabilities	263,104	126,745
Total current liabilities	6,515,034	4,008,695

Long-term debt, net of discount and current portion	า 3,391,808	8,056,470
Other long term liabilities	174,144	59,574
Total liabilities	10,080,986	12,124,739
STOCKHOLDERS' EQUITY		
Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding	D _	-
Common stock, \$0.01 par value; 300 million share authorized, 92,005,705 and 87,789,679 shares issued and outstanding in 2015 and 2014, respectively	s 920,057	877,897
Additional paid-in capital	176,002,832	167,890,220
Accumulated other comprehensive income	3,071	6,000
Accumulated deficit	(171,958,682)	(151,054,781)
Total stockholders' equity	4,967,278	17,719,336
Total liabilities and stockholders' equity	\$ 15,048,264	\$ 29,844,075

Neuralstem, Inc.

Consolidated Statements of Operations and Comprehensive Loss

Year Ended December 31,

	2015	2014	2013
Revenues	\$ 10,4	41 7 \$18,	83 35 110,000
Operating expenses:			
Research and development costs	12,637,278	8,361,559	7,285,752
General and administrative expense	s 6,529,667	9,093,123	5,348,189
Total operating expenses	19,166,945	17,454,682	12,633,941
Operating loss	(19,156,528)	(17,435,849)	(12,523,941)
Other income (expense):			
Interest income	69,549	67,651	68,000
Interest expense	(1,816,206)	(1,620,776)	(1,394,274)
Warrant modification expense	-	(3,109,850)	(5,017,156)
Loss from change in fair value of derivative instruments	-	(334,133)	(965,329)
Loss on debt extinguishment	-	(445,787)	-
Other expense	(716)	-	-
Litigation settlement	-	250,000	838
Total other income (expense)	(1,747,373)	(5,192,895)	(7,307,921)

Net loss	\$ (20,903,901)	\$ (22,628,744)	\$ (19,831,862)
Net loss per share - basic and dilute	d ^{\$} (0.23)	\$ (0.26)	\$ (0.27)
Weighted average common shares outstanding - basic and diluted	90,866,938	87,086,345	72,279,210
Comprehensive loss:			
Net loss	\$ (20,903,901)	\$ (22,628,744)	\$ (19,831,862)
Foreign currency translation adjustment	(2,929)	(1,241)	7,241
Comprehensive loss	\$ (20,906,830)	\$ (22,629,985)	\$ (19,824,621)

About Neuralstem

Neuralstem's patented technology enables the commercial-scale production of multiple types of central nervous system stem cells, which are being developed as potential therapies for multiple central nervous system diseases and conditions.

Neuralstem's ability to generate neural stem cell lines from human hippocampus, which were used for systematic chemical screening for neurogenesis effect, has led to the discovery and patenting of molecules that Neuralstem believes may stimulate the brain's capacity to generate new neurons, potentially reversing pathophysiologies associated with certain central nervous system (CNS) conditions.

The Company has completed Phase 1a and 1b trials evaluating NSI-189, its first neurogenic small molecule product candidate, for the treatment of major depressive disorder (MDD), and is expecting to initiate a Phase 2 efficacy study for MDD in 2016.

Neuralstem's first stem cell product candidate, NSI-566, a spinal cord-derived neural stem cell line, is under development for treatment of amyotrophic lateral sclerosis (ALS). Neuralstem has completed two clinical studies, in a total of thirty patients, which met

primary safety endpoints. In addition to ALS, NSI-566 is also in a Phase 1 study to treat paralysis due to chronic spinal cord injury, as well as in a Phase 1 study to treat paralysis from ischemic stroke.

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, 2015, and filed with the Securities and Exchange Commission (SEC) on March 14, 2016, and in other reports filed with the SEC.

To view the original version on PR Newswire, visit<u>http://www.prnewswire.com/news-releases/neuralstem-reports-fourth-quarter-and-year-end-2015-fiscal-results-and-business-update-300235424.html</u>

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