

# Neuralstem Reports Third Quarter 2015 Financial Results

# Adds Depth to Management Team with Appointment of Industry Veterans as Second Asset Advances towards Phase 2

GERMANTOWN, Md., Nov. 9, 2015 /PRNewswire/ -- Neuralstem, Inc. (Nasdaq: CUR) a biopharmaceutical company leveraging its unique human neural stem cell-derived platform to identify and develop novel neurogenic therapies for diseases of the central nervous system (CNS), today reported its financial results and business update for the three and nine months ended September 30, 2015.

Neurogenic Oral, Small Molecule Program with NSI-189 – Advancing to Phase 2.

- NSI-189 Major Depressive Disorder (MDD) Program: Neuralstem filed its Phase II clinical trial protocol for the treatment of MDD with the FDA in September, 2015. Maurizio Fava, M.D., Slater Family Professor of Psychiatry at Harvard Medical School, Massachusetts General Hospital will be the principal investigator. The Company expects to enroll its first patient in this study in the first guarter of 2016.
- NSI-189 for the treatment of cognitive deficit in schizophrenia: The Company plans to commence a Phase Ib clinical trial protocol for the treatment of cognitive deficit in schizophrenia in 2016.

Neurogenic Stem Cell Therapy Program with NSI-566 – Combined Phase 1 and 2 data presented.

- NSI-566 human neural stem cell therapy, under development for the treatment of ALS:
  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, presented nine month Phase II and combined Phase I and Phase II data at the American Neurological
  Association (ANA) Annual Meeting in September. The data showed that the intra-spinal
  transplantation of the human neural stem cells (NSI-566) was safe and well-tolerated. There
  appeared to be no acceleration in disease progression due to the therapeutic intervention with
  NSI-566. The Company is currently in discussions with the FDA for a larger, controlled,
  registration directed clinical trial.
- NSI-566 spinal cord-derived cell therapy under development for the treatment of chronic spinal cord injury (cSCI): In October, Joseph Ciacci, M.D., UCSD School of Medicine, presented initial safety data from the Phase I stem cell transplantation clinical trial with NSI-566. Dr. Ciacci reported that there had been no serious adverse events, that implantation of stem cells in cSCI patients is feasible and, that implantation of stem cells in the spinal cord injury patients has been safe and well tolerated. The last surgery was completed in July and now patients are currently in a 6-month post-observation period. The trial is being conducted at the UCSD School of Medicine, supported and funded by the UCSD Sanford Stem Cell Clinical Center.
- NSI-566 spinal cord derived stem cell therapy under development for the treatment of motor deficits in stroke: 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 2016. The trial is sponsored by

Neuralstem's wholly owned subsidiary, Suzhou Neuralstem Biopharmaceuticals Co., Ltd. ("Neuralstem China").

# Neuralstem Adds Depth to its Senior Management Team with Appointment of Industry Veterans as Second Asset Advances toward Phase 2.

- Neuralstem appointed Andrew Moniz as Vice President, Clinical Trials Operations in September 2015. Mr. Moniz joins the Company from <u>Worldwide Clinical Trials</u>, <u>Inc.</u> where he was <u>Vice</u> <u>President, Global Clinical Operations</u>. Worldwide Clinical Trials is a global CRO providing fullservice drug development services to the pharmaceutical and biotechnology industries.
- Jonathan Lloyd Jones, CPA, MBA, joined the company in May as Chief Financial Officer. Mr. Lloyd Jones was most recently Chief Financial Officer at Columbia Laboratories (Juniper Pharmaceuticals, NASDAQ: JNP), Before then, Mr. Lloyd Jones was CFO and VP of Corporate Development at TetraLogic Pharmaceuticals, a venture-backed pharmaceutical company and Vice President, Finance, at TransMolecular, a privately-held, clinical stage biotech company. From 1996-2006, Mr. Lloyd Jones was Sr. Director, Corporate Development at Genzyme Corporation (now Sanofi).

"We are delighted that Jonathan and Andrew have joined us," said Richard Garr, President and CEO, Neuralstem, Inc. "Their extensive industry experience in clinical development, financial, and business development will be invaluable as Neuralstem advances its two lead products through clinical development."

#### Results of Operations for the Third Quarter Ended September 30, 2015

Cash, cash equivalents and short-term investments on hand was approximately \$18.1 million at September 30, 2015, compared to approximately \$27.5 million at December 31, 2014. The decrease was primarily due to our cash used in operations partially offset by 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.

For the three months ended September 30, 2015, we reported a net loss of approximately \$5.6 million or \$0.06 per share, compared to a net loss of approximately \$4.5 million or \$0.05 per share in the comparable quarter of 2014. Our operating loss for the three months ended September 30, 2015 was approximately \$5.2 million compared to a loss of approximately \$4.1 million in the same quarter of 2014. The increase in operating loss was due to an approximately \$1.3 million increase in research and development expenses partially offset by an approximately \$0.2 million decrease in general and administrative expenses.

The increase in research and development expenses was primarily attributable to an increase of approximately \$1.3 million in project and laboratory expenses. These increased expenses are all related to the expansion 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 legal expenses associated with reduced litigation expenses

#### Results of Operations for the Nine Months Ended September 30, 2015

For the nine months ended September 30, 2015, we reported a net loss of approximately \$16.1 million or \$0.18 per share, compared to a net loss of approximately \$17.1 million or \$0.20 per share in the comparable period of 2014. Our operating loss for the nine months ended September 30, 2015 was approximately \$14.8 million compared to a loss of approximately \$12.8 million in the same period of 2014. The increase in operating loss was due to an approximately \$4.1 million increase in research and development expenses partially offset by an approximately \$2.1 million decrease in

general and administrative expenses.

The increase in research and development expenses was primarily attributable to an increase in project and laboratory expenses, and an increase in payroll and related expenses due to increased salaries and headcount. These increased expenses are all related to the expansion of our preclinical and clinical trial efforts and are expected to continue into subsequent periods.

The decrease in general and administrative expense was primarily due to a decrease in non-cash stock based compensation and a decrease in legal fees related to reduced litigation expense. The decrease in non-cash stock based compensation is 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. These decreases were partially offset by an increase in payroll related expenses due to increased salaries and headcount.

In addition, for the three and nine months ended September 2015, we recognized approximately \$0.5 million and \$1.4 million respectively, of interest expense related to our long-term debt.

Neuralstem, Inc.

#### **Unaudited Condensed Consolidated Balance Sheets**

September 30, 2015December 31, 2014

#### **ASSETS**

#### **CURRENT ASSETS**

Cash and cash equivalents	\$	13,130,795	\$	12,518,980	
Short-term investments	5,017	,453	15,007,4	178	
Trade and other receivables	19,15	9	225,524		
Deferred financing fees, current portion	107,0	96	135,694		
Prepaid expenses		1,289,195		274,106	
Total current assets	19,56	3,698	28,161,7	782	

Property and equipment, net	335,863	301,265	
Patents, net	1,147,153	1,233,172	
Deferred financing fees, net of current portion	22,825	89,143	
Other assets	72,163	58,713	
Total assets	\$ 21,141,702	\$ 29,844,075	

## **LIABILITIES AND STOCKHOLDERS' EQUITY**

#### **CURRENT LIABILITIES**

Accounts payable and accrued expenses	\$	2,036,769	\$	2,504,978
Accrued bonuses	767,98	39	646,960	
Current portion of long-term debt, net of discount	4,457,768		730,012	
Other current liabilities	207,29	92	126,745	
Total current liabilities	7,469,	818	4,008,69	5
Long-term debt, net of discount and current portion	4,625,	394	8,056,47	0
Other long-term liabilities	143,73	30	59,574	
Total liabilities	12,238	3,942	12,124,7	39

## Commitments and contingencies (Note 6)

## STOCKHOLDERS' EQUITY

Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding

Common stock, \$0.01 par value; 300 million shares authorized, 91,786,290 and 87,789,679 shares outstandin in 2015 and 2014, respectively	9 917,8	363	877,897	,
Additional paid-in capital	175,1	174,708	167,890	),220
Accumulated other comprehensive income	3,720	)	6,000	
Accumulated deficit	(167,	193,531)	(151,05	4,781)
Total stockholders' equity	8,902,760		17,719,	336
Total liabilities and stockholders' equity	\$	21,141,702	\$	29,844,075

See accompanying notes to unaudited condensed consolidated financial statements.

# Neuralstem, Inc.

# **Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss**

	Three Months End	, Nine Mont	Nine Months Ended September 30,		
	2015	2014	2015	2014	
Revenues	\$	2,500\$	5,000\$	7,917\$	14,167
Operating expenses	:				
Research and development expenses	3,392,086	2,109,880	9,887,750	5,747,922	
General and administrative	1,807,934	2,001,865	4,925,389	7,061,129	

Total operating expenses	5,200,020	4,1	11,745 1	14,813,139	12,809,051
Operating loss	(5,197,520)	(4,1	06,745) (	14,805,222)	(12,794,884)
Other income (expense):					
Interest income	24,149	13,	127 5	53,802	55,267
Interest expense	(464,197)	(36	1,619) (1	1,377,004)	(1,191,976)
Warrant modificatio expense	n	-			(3,109,850)
Loss from change in fair value of derivative instruments	n -	-	-		(334,133)
Other income (expense)	-	-	(	10,326)	250,000
Total other income (expense)	(440,048)	(34	8,492) ( <sup>-</sup>	1,333,528)	(4,330,692)
Net loss	\$	(5,637,568\$)	(4,455,237)\$	(16,138,750	)\$ (17,125,576)
Net loss per share - basic and diluted	\$	(0.06\$)	(0.05)\$	6 (0.18	(0.20)
Weighted average common shares outstanding - basic and diluted	91,569,826	87,3	366,234 9	90,532,073	86,777,197

## Comprehensive loss:

Net loss	\$	(5,637,568\$)	(4,455,237)\$	(16,138,750)\$	(17,125,576)
Foreign currency translation adjustment	(2,275)	3	(2,:	280) (1,1	31)
Comprehensive los	ss\$	(5,639,843\$)	(4,455,234)\$	(16,141,030)\$	(17,126,707)

See accompanying notes to unaudited condensed consolidated financial statements.

#### About Neuralstem

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

Neuralstem's ability to generate human neural stem cell lines for chemical screening has led to the discovery and patenting of compounds that Neuralstem believes may stimulate the brain's capacity to generate neurons, potentially reversing pathologies associated with certain central nervous system (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 initiate a Phase II study for MDD.

Neuralstem's first stem cell product candidate, NSI-566, a human 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 that met primary safety endpoints. In addition to ALS, NSI-566 is also in a Phase I study for the treatment of chronic spinal cord injury at UC San Diego School of Medicine, as well as in clinical development to treat ischemic stroke.

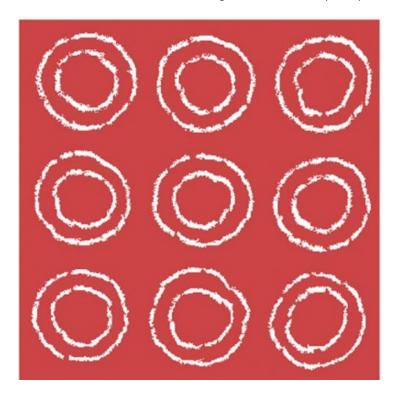
Neuralstem's next generation stem cell product, NSI-532.IGF, consists of human cortex-derived neural stem cells that have been engineered to secrete human insulin-like growth factor 1 (IGF-1). In animal data presented at the Congress of Neurological Surgeons 2014 Annual Meeting, the cells rescued spatial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

For more information, please visit <u>www.neuralstem.com</u> 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, and Form 10-Q for the three and nine months ended September 30, 2015, filed with the Securities and Exchange Commission (SEC), and in other reports filed with the SEC.



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