

# Neuralstem Reports Year End 2016 Fiscal Results and Business Update

Expects to Report NSI-189 Phase 2 major depressive disorder study results in Q3 ahead of schedule

GERMANTOWN, Md., March 23, 2017 (GLOBE NEWSWIRE) -- Neuralstem, Inc. (Nasdaq:CUR), a biopharmaceutical company focused on the development of nervous system therapies based on its neural stem cell technology, reported its financial results for the fourth quarter and year ended December 31, 2016.

"We are pleased with the execution over the past year that includes securing a strategic investment, beating guided clinical timelines and providing additional transparency to the markets," commented Rich Daly, Chairman and CEO. "Fiscal 2017 is poised to be another strong year for Neuralstem as we approach our largest milestone to date, the results of our Phase 2 major depressive disorder (MDD) clinical study in the third quarter. We are committed to continuing to explore NSI-189 mechanism of action (MOA) and potential therapeutic benefits in additional indications."

# **Clinical Highlights**

- NSI-189 Phase 2 MDD results expected 4 months ahead of schedule in 3Q17.
   Neuralstem's Phase 2 clinical study evaluating NSI-189 for the indication of MDD was initiated in May 2016. The company announced 50% enrollment in September 2016 and last patient enrolled in February 2017. 220 subjects were randomized for a 12-week interventional study with NSI-189 or placebo followed by another 24 weeks of non-interventional observation-only study.
- NSI-189 preclinical data suggest pro-cognitive potential. Treatment of mouse brain slices with NSI-189 produced a time- and concentration-dependent enhancement in short-term (STP) and long-term potentiation (LTP), an in vitro model of memory. NSI-189 treatment of brain slices from a mouse model of Angelman Syndrome, a maternally inherited human condition that causes neurologic impairments including cognitive deficits, was able to restore LTP to normal levels. Furthermore, NSI-189 treatment of rats in a radiation-induced brain injury model also ameliorated cognitive impairment and preserved hippocampal neurogenesis.
- NSI-189 preclinical data is suggestive of the potential for broader application in nervous system diseases. Data obtained from studies using a rodent model of ischemic stroke demonstrate that NSI-189 can reverse stroke-induced motor and neurological deficits, and that this may involve upregulation of neurotrophic or neurogenic factors. In addition, NSI-189 proved to be effective in the prevention and reversal of peripheral neuropathies in a mouse model of Type 1 diabetes and in the

prevention of peripheral neuropathies in a mouse model of Type 2 diabetes. Data from these studies included reversal of neuropathic pain and decreased nerve conductance due to diabetes.

# **Corporate Highlights**

- Strategic investment of \$20 million. In December 2016, Neuralstem closed a strategic transaction with Tianjin Pharmaceutical Group International Holdings Co., LTD.'s (TJPH or Tianjin) whereby Tianjin purchased \$20 million of our securities. The transaction was announced on September 12, 2016.
- Rich Daly appointed CEO. In February 2016, Rich Daly was appointed President and Chief Executive Officer of Neuralstem. Subsequently in June 2016, he was appointed Chairman of the Board of Directors. Mr. Daly has over 25 years of pharmaceutical expertise including executive leadership roles at Takeda, AstraZeneca, Bristol-Myers Squibb and Abbott. He serves on the board of directors of Synergy Pharmaceuticals and Catalyst Pharmaceuticals.
- 1-for-13 reverse stock split. In January 2017, the Company executed a 1-for-13 reverse stock split of the Company's common stock. The reverse stock split enabled Neuralstem to regain compliance with the \$1.00 minimum bid price condition and thereby fulfill all of the NASDAQ Capital Market continued listing requirements.

### Financial Results for the Year Ended December 31, 2016

Cash Position: Cash, cash equivalents and short-term investments on hand was approximately \$20.2 million at December 31, 2016, compared to approximately \$12.2 million at December 31, 2015. The increase resulted from cash raised of approximately \$28.1 million, net primarily from our financings in May and December 2016, partially offset by use of cash to fund our NSI-189 clinical programs and to meet our debt repayment obligations. As of December 31, 2016 we had approximately \$3.8 million of debt outstanding as compared to \$8.3 million at December 31, 2015.

**Net Loss:** In the year ended December 31, 2016, we reported a net loss of approximately \$21.1 million or \$2.53 per share on a split-adjusted basis, compared to a loss of approximately \$20.9 million or \$2.99 per share in the year ended December 31, 2015. Our operating loss in the year ended December 31, 2016 was approximately \$20.6 million, compared to a loss of approximately \$19.2 million in the year ended December 31, 2015.

**R&D Expenses:** Research and development expenditures, at \$13.2 million, increased by approximately \$0.5 million in 2016 as compared to expenditures of \$12.6 million in 2015. The increase in research and development expenses was primarily attributable to severance payments made as a result of our reduction in force in May together with an increase in bonus accrual year over year, partially offset by a reduction in ongoing payroll costs.

**G&A Expenses:** General and administrative expenses increased by approximately \$1.0 million dollars to \$7.4 million in the year ended December 31, 2016 as compared to \$6.5 million for the year ended December 31, 2015. The increase was primarily attributable to

an increase in legal and professional fees associated with company financing activities, product licensing and Nasdaq compliance efforts, and to severance payments made as a result of our reduction in force in May together with an increase in bonus accrual year over year, partially offset by a reduction in ongoing payroll costs.

**Equity and Reverse Stock Split:** The Board of Directors approved a 1-for-13 reverse stock split of the Company's common stock effective January 6, 2017. Stockholders' equity and all references to share and per share amounts in the accompanying consolidated financial statements have been retroactively adjusted to reflect the 1-for-13 reverse stock split for all periods presented.

We had 11.0 million and 7.1 million common shares issued and outstanding on a reverse split adjusted basis and 1.0 million and 0 preferred shares issued and outstanding at December 31, 2016 and 2015, respectively.

**Liquidity:** We expect that our existing cash, cash equivalents and short-term investments will fund our anticipated level of operations based on our current operating plans, into the second quarter of 2018.

#### Neuralstem, Inc.

#### **Consolidated Balance Sheets**

December 31

	December 31,			
		2016		2015
ASSETS				
CURRENT ASSETS				
Cash and cash equivalents	\$	15,194,949	\$	4,716,533
Short-term investments		5,000,000		7,517,453
Trade and other receivables		10,491		37,316
Current portion of related party receivable, net of discount		53,081		-
Prepaid expenses		646,195		1,159,782
Total current assets		20,904,716		13,431,084
Property and equipment, net		269,557		343,200
Patents, net		990,153		1,103,467
Related party receivable, net of discount and current portion		424,240		-
Other assets		15,662		71,797
Total assets	\$	22,604,328	\$	14,949,548
LIABILITIES AND STOCKHOLDERS' EQUITY				
CURRENT LIABILITIES				
Accounts payable and accrued expenses	\$	2,343,936	\$	1,455,826
Accrued bonuses		852,963		161,362
Current portion of long-term debt, net of fees and discount		3,705,787		4,545,180
Other current liabilities		430,738		263,104
Total current liabilities		7,333,424	_	6,425,472
Long-term debt, net of fees, discount and current portion		_		3,382,654
Derivative instruments		3,921,917		- · · · · -
Other long term liabilities		18,209		174,144
Total liabilities	_	11,273,550		9,982,270

#### STOCKHOLDERS' EQUITY

Preferred stock, 7,000,000 shares authorized, \$0.01 par value; 1,000,000 and		
0 shares issued and outstanding at December 31, 2016 and 2015,		
respectively	10,000	-
Common stock, \$0.01 par value; 300 million shares authorized, 11,032,858		
and 7,077,362 shares issued and outstanding in 2016 and 2015, respectively	110,329	70,774
Additional paid-in capital	204,239,837	176,852,115
Accumulated other comprehensive income	3,905	3,071
Accumulated deficit	(193,033,293)	(171,958,682)
Total stockholders' equity	11,330,778	4,967,278
Total liabilities and stockholders' equity	\$ 22,604,328	\$ 14,949,548

## Neuralstem, Inc.

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

	Year Ended D			December 31, 2015		
Revenues	\$	16,246	\$	10,417		
Operating expenses:						
Research and development costs	13,155,887		12,637,278			
General and administrative expenses	7,497,202		6,529,667			
Total operating expenses	20	,653,089	19,166,945			
Operating loss	(20,636,843)		(19,156,528 )			
Other income (expense):						
Interest income		58,835		69,549		
Interest expense	(1	(1,141,297)		(1,816,206)		
Gain on related party settlement		458,608		-		
Gain from change in fair value of derivative instruments		660,253		-		
Fees related to issuance of derivative instruments and other		(474 467 )		(716.)		
expenses Tatal other income (cynana)	(474,167)			(716 )		
Total other income (expense)		(437,768)		(1,747,373 )		
Net loss	\$ (21	,074,611 )	\$ (2	20,903,901 )		
Net loss per common share - basic and diluted	\$	(2.53)	\$	(2.99)		
Weighted average common shares outstanding - basic and diluted	8	3,345,992		6,989,764		
Comprehensive loss:						
Net loss	\$ (21	,074,611 )	\$ (	20,903,901 )		
Foreign currency translation adjustment	¥ (=	834	¥ (-	(2,929)		
Comprehensive loss	\$ (21	,073,777 )	\$ (2	20,906,830 )		
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# **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 (CNS) diseases and conditions.

Neuralstem's technology enables the discovery of small molecule compounds by systematic screening of chemical compounds against its proprietary human hippocampal stem cell line. The screening process 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 and peripheral nervous system conditions.

The company has completed Phase 1a and 1b studies evaluating NSI-189, a novel neurogenic small molecule product candidate, for the treatment of major depressive disorder or MDD, and is currently conducting a Phase 2 efficacy study for MDD.

Neuralstem's stem cell therapy product candidate, NSI-566, is a spinal cord-derived neural stem cell line. Neuralstem is currently evaluating NSI-566 in three indications: stroke, chronic spinal cord injury (cSCI), and Amyotrophic Lateral Sclerosis (ALS).

Neuralstem is conducting a Phase 1 safety study for the treatment of paralysis from chronic motor stroke at the BaYi Brain Hospital in Beijing, China. In addition, NSI-566 was evaluated in a Phase 1 safety study to treat paralysis due to chronic spinal cord injury as well as a Phase 1 and Phase 2a risk escalation, safety trials for ALS. Subjects from all three indications are currently in long-term observational follow-up periods and continued to be monitored for safety and possible therapeutic benefits.

# 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, 2016, filed with the Securities and Exchange Commission (SEC) on March 23, 2017, and in other reports filed with the SEC. We do not assume any obligation to update any forward-looking statements.

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Source: Neuralstem, Inc.