

August 15, 2018



Neuralstem Provides Business Update and Reports Second Quarter 2018 Fiscal Results

- Phase 2 clinical trial initiated to further evaluate NSI-566 as treatment for ischemic stroke
- NSI-189 Granted Orphan Drug Designation for the Treatment of Angelman Syndrome -
- Jim Scully appointed interim chief executive officer -

GERMANTOWN, Md., Aug. 15, 2018 (GLOBE NEWSWIRE) -- Neuralstem, Inc. (Nasdaq:CUR), a biopharmaceutical company focused on the development of nervous system therapies based on its neural stem cell and small molecule compound technologies, provides a business update and reported its financial results for the second quarter ended June 30, 2018.

"We are pleased to report a productive second quarter of 2018 as we continue to advance our pipeline of innovative neural stem cell and small molecule therapies," said Jim Scully, interim Chief Executive Officer of Neuralstem. "We are especially excited about the advancement of our lead stem cell therapy candidate, NSI-566, into a Phase 2 trial in ischemic stroke, as well as its potential application to other areas of unmet medical need. Additionally, based on encouraging preclinical data, we look forward to exploring our small molecule NSI-189's potential treatment applications, including Angelman Syndrome and Alzheimer's Disease."

Clinical Highlights

NSI-566, is a spinal cord-derived neural stem cell line that is being evaluated to treat paralysis associated with stroke, Amyotrophic Lateral Sclerosis (ALS) and chronic spinal cord injury (cSCI). NSI-566 is Neuralstem's lead stem cell therapy candidate.

- In July, Neuralstem announced initiation of a Phase 2 clinical trial evaluating NSI-566 as a potential treatment for ischemic stroke. This trial, which will be a randomized, double-blind, controlled study, is based on the positive results from the open-label Phase 1 safety study and is intended to further test the safety and efficacy of NSI-566 to reverse paralysis in stroke patients where half of their body has been partially paralyzed. James Li, Ph.D., Executive Vice President of Asia Operations of Suzhou Neuralstem Ltd, will be managing this trial which will be taking place at Bayi Brain Hospital in Beijing, China, and commenced on August 1, 2018. In Phase 1, NSI-566 treatment of 9 chronically hemiparetic stroke patients resulted in statistically significant improvement from baseline of motor functioning and clinical status.
- In June, the Company announced the results from a study published in *Cell Stem*

Cell that support the potential therapeutic application of transplanted NSI-566 in patients with chronic spinal cord injury (cSCI). The manuscript, entitled “A First-in-Human, Phase I Study of Neural Stem Cell Transplantation for Chronic Spinal Cord Injury,” presented a detailed analysis of motor and sensory function and electrophysiology results which showed improvement in three of the four patients after NSI-566 transplantation. The study’s primary objective was to evaluate the safety of NSI-566 transplantation in subjects with stable thoracic spinal cord injury, and additional endpoints measured included changes in neurologic deficits, neurophysiology, and neuropathic pain.

- In May, the Company announced the results from a study published in the *Annals of Clinical and Translational Neurology* in a manuscript entitled “Long-term Phase 1/2 Intraspinal Stem Cell Transplantation Outcomes in Amyotrophic Lateral Sclerosis” that support the potential of transplanted human spinal cord-derived neural stem cells (HSSC) to stabilize functioning of ALS patients. The study evaluated the impact of HSSC transplantation on functional outcomes, as measured using the ALSFRS-R scale, and on a composite statistic that combined functional and survival outcomes. Results were evaluated against matched controls derived from two historical datasets and showed significantly better ALSFRS-R scores at 24 months, as well as the composite functional/survival score in subjects receiving HSSC. The ALS Functional Rating Scale-Revised (ALSFRS-R) is a validated questionnaire that measures physical function in performing activities of daily living (ADLs).

NSI-189, is a small molecule benzylpiperazine-aminopyridine, in clinical development for MDD and in preclinical development for Angelman syndrome, irradiation-induced cognitive impairment, Type 1 and Type 2 diabetes, and stroke.

- In August, the Company announced it had been granted orphan drug designation by the FDA for the treatment of Angelman Syndrome. In pre-clinical models, NSI-189 has demonstrated the ability to restore long term potentiation (LTP), a measure of synaptic plasticity and an in vitro biomarker of memory. Angelman Syndrome (AS) is a rare congenital genetic disorder caused by a lack of function in the UBE3A gene on the maternal 15th chromosome. It affects approximately one in 15,000 people - about 500,000 individuals globally. Symptoms of AS include developmental delay, lack of speech, seizures, and walking and balance disorders. Patients with AS may never walk or speak and require life-long care. Life expectancy is normal which places a significant burden on patients and caregivers. There are currently no FDA-approved therapies for the treatment of Angelman syndrome. The FDA's orphan-drug designation program provides special status and incentives to encourage the development of drugs for diseases affecting fewer than 200,000 people in the U.S. Orphan drug designation confers seven years of market exclusivity upon FDA approval, as well as other development incentives, such as tax credits related to clinical trial expenses, an exemption from the FDA-user fee and FDA assistance in clinical trial design.
- In July, the Company presented preclinical data at the Alzheimer's Association International Conference in Chicago, Illinois, demonstrating that oral administration of NSI-189 in a mouse model of Alzheimer's Disease leads to a significant

amelioration and/or improvement in cognition measures and anxiety. Results were presented in a poster titled 'Effect of Neurogenic Compound NSI-189 on Indices of Cognition and Anxiety in a Mouse Model (5XFAD) of Alzheimer's Disease.' The study was carried out by Dr. Corinne Jolival's laboratory at the University of California, San Diego, and found that treatment with NSI-189 significantly improved learning ability as well as retention, short-term memory and anxiety levels of mice.

Corporate Highlights

- Effective August 1, Jim Scully was appointed as interim chief executive officer by the Board of Directors. Mr. Scully succeeds Mr. Rich Daly, former Neuralstem president and chief executive officer. Mr. Scully brings to Neuralstem a wealth of experience from a range of senior executive roles in the pharmaceutical and broader healthcare industry, including leadership roles in financial and strategic planning, global business development and general management at Takeda Pharmaceuticals, Astellas Pharmaceuticals, Abbott Laboratories and Walgreens.
- Also, effective August 1, the Board of Directors appointed William Oldaker as Chairman of the Board. Mr. Oldaker has served as a director of Neuralstem since April 2007. Additionally, he is a founder and partner in the Washington, D.C. law firm, Oldaker & Willison PLLP, and is a member of the Colorado, D.C. and Iowa Bar Associations, the Bar Association for the Court of Appeals, D.C., and the Bar of the United States Supreme Court.

Financial Results for the Quarter Ended June 30, 2018

Cash Position and Liquidity: At June 30, 2018, cash and investments was \$7.1 million as compared to \$9.7 million at March 31, 2018. The \$2.6 million decrease reflects a \$0.6 million loss for the period adjusted for certain non-cash items including a \$1.4 million gain related to the change in fair value of our liability classified warrants, \$760,000 net cash outflows related to changes in operating assets and liabilities, and \$200,000 of share-based compensation. The Company expects its existing cash, cash equivalents and short-term investments to fund its operations based on its current operating plans, into the first quarter of 2019.

Operating Loss: Operating loss for the second quarter ended June 30, 2018 was \$2.0 million compared to a loss of \$4.2 million for the comparable period of 2017. Operating loss for the six months ended June 30, 2018 was \$4.4 million compared to a loss of \$8.5 million for comparable period of 2017.

The decrease in operating loss for both the three- and six-month periods was primarily related to decreases in clinical trial and related costs due to the completion of the NSI-189 Phase 2 clinical trial, decreases in personnel, facility and related expenses due to ongoing corporate restructuring and cost reduction efforts offset by revenues from a milestone-based royalty and reimbursements under a National Institute of Health (NIH) grant.

Net Loss: Net loss for the second quarter ended June 30, 2018 was \$0.6 million, or \$0.04 per share (basic), compared to a loss of \$4.6 million, or \$0.39 per share (basic), for the comparable period of 2017. The decrease in net loss was primarily due to a decrease

in operating loss and the non-cash charges related to the change in the fair value of liability classified warrants.

Net loss for the six months ended June 30, 2018 was \$2.8 million, or \$0.18 per share (basic), compared to a loss of \$12.2 million, or \$1.06 per share (basic), for the comparable period of 2017. The decrease in net loss was primarily due to a decrease in operating loss and the non-cash charges related to the change in the fair value of liability classified warrants and warrant inducement expenses in the 2017 period and a decrease in interest expense related to our long-term debt which matured in April 2017.

Research and Development Expenses: The \$1.0 million of research and development expenses for the quarter ended June 30, 2018 represents a \$1.6 million, or 61% decrease over the comparable period of 2017. This decrease was primarily attributable to a \$710,000 decrease in personnel and facility expenses due to ongoing corporate restructuring and cost reduction efforts, a \$310,000 decrease in clinical trial and related costs due to the completion of our NSI-189 Phase 2 clinical trial and a \$410,000 decrease in non-cash share-based compensation expense along with \$90,000 of reimbursements under a NIH grant.

The \$2.2 million of research and development expenses for the six months ended June 30, 2018 represents a \$3.3 million, or 60% decrease over the comparable period of 2017. This decrease was primarily attributable to a \$1.8 million decrease in personnel and facility expenses due to ongoing corporate restructuring and cost reduction efforts, a \$540,000 decrease in clinical trial and related costs due to the completion of the NSI-189 Phase 2 clinical trial, a \$720,000 decrease in our non-cash share-based compensation expense along with \$180,000 of reimbursements under a NIH grant.

General and Administrative Expenses: The \$1.3 million of general and administrative expenses for the second quarter ended June 30, 2018 represents a \$380,000, or 23% decrease over the comparable period of 2017. This decrease was primarily attributable to a \$400,000 decrease in payroll and related expenses due to corporate restructuring and cost reduction efforts coupled with a \$40,000 decrease in non-cash share-based compensation expense partially offset by a \$70,000 increase in tax and insurance expenses.

The \$2.4 million of general and administrative expenses for the six months ended June 30, 2018 represents a \$530,000, or 18% decrease over the comparable period of 2017. This decrease was primarily attributable to a \$560,000 decrease in payroll and related expenses coupled with a \$40,000 decrease in consulting and professional service expenses due to corporate restructuring and cost reduction efforts partially offset by a \$90,000 increase in our tax and insurance expenses.

Neuralstem, Inc.

Unaudited Condensed Consolidated Balance Sheets

June 30,

December 31,

	<u>2018</u>	<u>2017</u>
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 7,092,832	\$ 6,674,940
Short-term investments	-	5,000,000
Trade and other receivables	478,722	312,802
Current portion of related party receivable, net of discount	-	58,784
Prepaid expenses	343,428	402,273
Total current assets	<u>7,914,982</u>	<u>12,448,799</u>
Property and equipment, net	128,017	172,886
Patents, net	814,023	883,462
Related party receivable, net of discount and current portion	343,281	365,456
Other assets	33,004	13,853
Total assets	<u>\$ 9,233,307</u>	<u>\$ 13,884,456</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	\$ 713,068	\$ 875,065
Accrued bonuses	-	418,625
Other current liabilities	52,933	220,879
Total current liabilities	<u>766,001</u>	<u>1,514,569</u>
Warrant liabilities	2,283,833	3,852,882
Other long term liabilities	8,270	1,876
Total liabilities	<u>3,058,104</u>	<u>5,369,327</u>
STOCKHOLDERS' EQUITY		
Preferred stock, 7,000,000 shares authorized, \$0.01 par value; 1,000,000 shares issued and outstanding at both June 30, 2018 and December 31, 2017	10,000	10,000
Common stock, \$0.01 par value; 300,000,000 shares authorized, 15,160,014 shares issued and outstanding at both June 30, 2018 and December 31, 2017	151,600	151,600
Additional paid-in capital	217,485,751	217,050,174
Accumulated other comprehensive income	1,142	2,631
Accumulated deficit	(211,473,290)	(208,699,276)
Total stockholders' equity	<u>6,175,203</u>	<u>8,515,129</u>
Total liabilities and stockholders' equity	<u>\$ 9,233,307</u>	<u>\$ 13,884,456</u>

Neuralstem, Inc.

Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenues	\$ 252,500	\$ 2,500	\$ 255,000	\$ 5,000
Operating expenses:				
Research and development expenses	1,014,780	2,585,079	2,184,221	5,487,165
General and administrative expenses	1,260,692	1,635,652	2,442,746	2,968,073
Total operating expenses	<u>2,275,472</u>	<u>4,220,731</u>	<u>4,626,967</u>	<u>8,455,238</u>
Operating loss	<u>(2,022,972)</u>	<u>(4,218,231)</u>	<u>(4,371,967)</u>	<u>(8,450,238)</u>
Other income (expense):				
Interest income	19,514	14,013	37,263	34,896
Interest expense	(772)	(15,728)	(2,692)	(154,460)
Change in fair value of derivative instruments	1,378,830	(341,611)	1,569,049	(3,082,925)
Fees related to issuance of inducement warrants and other expenses	(1,646)	(87,635)	(5,667)	(563,719)
Total other income (expense)	<u>1,395,926</u>	<u>(430,961)</u>	<u>1,597,953</u>	<u>(3,766,208)</u>
Net loss	<u>\$ (627,046)</u>	<u>\$ (4,649,192)</u>	<u>\$ (2,774,014)</u>	<u>\$ (12,216,446)</u>
Net loss per share - basic and diluted	<u>\$ (0.04)</u>	<u>\$ (0.39)</u>	<u>\$ (0.18)</u>	<u>\$ (1.06)</u>
Weighted average common shares outstanding - basic and diluted	<u>15,144,243</u>	<u>11,906,334</u>	<u>15,130,666</u>	<u>11,525,730</u>
Comprehensive loss:				
Net loss	\$ (627,046)	\$ (4,649,192)	\$ (2,774,014)	\$ (12,216,446)
Foreign currency translation adjustment	(1,604)	(384)	(1,489)	(555)
Comprehensive loss	<u>\$ (628,650)</u>	<u>\$ (4,649,576)</u>	<u>\$ (2,775,503)</u>	<u>\$ (12,217,001)</u>

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 its Annual Report on Form 10-K for the year ended December 31, 2017, and its Quarterly Report on Form 10-Q for the three months ended March 31, 2018, filed with the Securities and Exchange Commission (SEC), 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.