

# Neuralstem Reports Second Quarter Financial Results and Provides Business and Clinical Update

ROCKVILLE, Md., Aug. 10, 2011 /PRNewswire/ -- Neuralstem, Inc. (NYSE Amex: CUR) reported its financial results for the three months and six months period ended June 30, 2011 and provided a business and clinical update.

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"The Company reached two U.S. clinical trial milestones and one important international milestone in the second Quarter," said Neuralstem's Chairman and Chief Scientific Officer Karl Johe, PhD. "We completed the first 12 ALS patients' lumbar-area transplantations, and have been approved by the trial's Safety Monitoring Board to proceed to cervical-area injections. Under our approved protocol, this data must also be reviewed by the FDA to proceed to the next step of the trial which will entail cervical-area transplantations in ambulatory ALS patients. This is an important step as we believe that the cervical injections may ultimately help patients with their breathing and swallowing."

"The dosing of healthy volunteers is near completion in our FDA-approved Phase Ia safety trial evaluating NSI-189, our first small molecule compound, for the treatment of major depression. Upon review of the data and approval, we will test the safety and tolerability of escalating doses of daily administration for 28 days in depressed patients in a Phase Ib trial. We hope to start the Ib trial early this fall," continued Dr. Johe. "Internationally, we entered into an agreement for a trial to treat chronic motor disorder from ischemic stroke with BaYi Brain Hospital in Beijing. We believe this trial will commence in early 2012. This will be the first trial where the Company's neural stem cells will be injected directly into the brain."

Richard Garr, Neuralstem's President and CEO, added, "During the second Quarter, we executed an agreement with Sumitomo's Summit Pharmaceuticals International Corporation for exclusive rights to market our lead neuroregenerative small molecule drug, NSI-189, to the Japanese pharmaceutical development community. While we plan to retain our development rights for NSI-189 through Phase II in most parts of the world, the Japanese market is the exception for which we are aggressively seeking an early-stage development and licensing partner. We are honored to be working with Summit to achieve this end.

"We were pleased to receive notice of allowance for two additional U.S. Patent Applications that cover three new neurogenic compounds," continued Garr. "We believe that our portfolio of neurogenic compounds, which includes NSI-189, will be at the forefront of novel treatments for psychiatric and cognitive diseases that focus on neural

regeneration. Further, as the patents run out on many CNS drugs, we believe Neuralstem is well-positioned to provide value to our future development partners. We are not only able to identify neurogenic and neuroprotective compounds by screening against our cells, but we can identify novel, patentable compounds, across a diverse chemical library.

"Looking forward, we are broadening our therapeutic reach into oncology," stated Garr. "A cutting-edge brain cancer preclinical program, which had been in the early stages in collaboration with Dr. John Zhang and Loma Linda University, has recently been funded with a U.S. Department of Defense contract award of \$1.6 million (Neuralstem will receive \$625,000 of the award), renewable via milestones for four years. Our engineered neural stem cells will act as delivery vehicles for anti-cancer therapeutics, a technology which will have wide ramifications for the future use of our cells in multiple indications.

"Management and the Board continue to work to find ways to conserve capital in these challenging financial times," said Garr. "We are committed to continuing with the Company's 'outsource' model which enables the most efficient use of cash, and most flexibility managing its burn rate."

# **Clinical Program and Business Highlights**

Cellular Therapy: Phase I Clinical Trial in ALS amyotrophic lateral sclerosis, or Lou Gehrig's disease) at Emory University

- In June, the trial's Safety Monitoring Board unanimously approved advancing the ALS Phase I trial to neural stem cell transplantations in the cervical region upon reviewing the safety data from the first 12 patients who received lumbar injections. It was announced that the cervical portion of the trial would proceed upon subsequent approval by the FDA.
- In April, interim trial data was reported to show no safety concerns with no serious unresolved adverse effects on the initial nine patients, both nonambulatory and ambulatory. Of the three ambulatory patients who were treated, all were reported to remain ambulatory with no serious adverse events secondary to transplantation. The data was presented by Eva Feldman, MD, PhD, the Phase I trial's Principal Investigator, at the American Academy of Neurology (AAN) Annual Meeting.

### NSI-189: Phase la Clinical Trial in Major Depression

• In June, it was announced that Phase Ia NSI-189 dosing to test safety and tolerability in healthy volunteers was advancing to its final cohort and was expected to be completed in the summer. With approval from the FDA, the Company will be on schedule to begin Phase Ib in fall 2011. Phase Ib will test the safety and tolerability of escalating doses of daily administration of NSI-189 for 28 days in patients with major depression. The entire Phase I trial is expected to be approximately one year in duration.

 The Company reported that NSI-189 stimulates new neuron growth in the hippocampus, an area of the brain that is believed to be involved in depression and other diseases and conditions, such as Alzheimer's disease and post-traumatic stress disorder (PTSD).

## Corporate News

In June, the Company receivednotice of allowance for U.S. Patent Applications 12/939,897 and 12/939,914 entitled: "Compositions to Effect Neuronal Growth." The patents cover three new neurogenic compounds and include both structure and method claims for inducing neurogenesis and the growth of new neurons, both in-vitro and in-vivo. These patents were reported to broaden the Company's potential clinical development pipeline.

In June, the Company received a patent covering the transplantation of human neural cells for the treatment of neurodegenerative conditions from the Russian Federation. The claims include methods of culturing the cells as well as treating ALS, spinal cord injuries, traumatic brain injury, multiple sclerosis, cerebral palsy, epilepsy, Huntington's disease and other conditions through cell transplantation. The Company's stated goal was to have the broadest worldwide patent coverage for its core technology.

In June, the Company entered into an exclusive agency licensing agreement with Summit Pharmaceuticals International Corporation, of Tokyo, Japan (SPI), a wholly owned subsidiary of Sumitomo Corporation Group. Under the agreement, SPI will market development and licensing rights to NSI-189 in Japan. It was further reported that the Japanese market is the single exception to corporate strategy which dictates taking NSI-189 through Phase II trials before seeking a partner for worldwide rights.

In April, Neuralstem signed a Memorandum of Understanding with BaYi Brain Hospital in Beijing, one of the premier neurological hospitals inChina, to begin an ischemic stroke program. The preclinical phase includes jointly preparing clinical protocol for the treatment of chronic motor disorders from stroke. BaYi Brain Hospital will present the protocol first for review and approval to the Hospital's Ethics Board, then to the Military Regulatory Agency for review and approval of the trial.

#### **Second Quarter Financial Results**

Cash, cash equivalents and short-term marketable securities at June 30, 2011 totaled \$6,141,843, compared with \$9,261,233 at December 31, 2010.

For the second quarter of 2011, the Company reported an operating loss of\$3,668,868, compared with an operating loss of \$4,195,091, for the comparable 2010 period. The decreased operating loss was due to a planned pause in our ALS clinical trial in the second quarter of 2011 pending a review by our Safety Monitoring Board after the first twelve patients, decreased research spending relating to beginning of clinical trial,

reductions in legal fees, and a \$271,443 decrease in stock based compensation expense. These reductions were partially offset by a \$124,882 increase in personnel costs due to higher headcount.

For the six months ended June 30, 2011 the Company reported a net loss of\$6,750,527 or \$0.14 per share, compared with a net loss of\$11,718,301, or \$0.29 per share a year ago. The reduction in the net loss was due to \$3,919,693 of derivative warrant accounting charges; costs related to starting our ALS clinical trials and the preparation of our FDA application to begin clinical trials for our NSI-189 neurogenic compound in the first half of 2010.

For the six months ended June 30, 2011, cash used in operating activities totaled \$4,500,092, a decrease of \$378,638 or 8% compared to the same period in the prior year. The reduction in cash used was much smaller than the decrease in the net loss for the six months of \$4,967,774 because \$4,505,170 of the expense reductions were non-cash related. Non-cash expense reductions included derivative warrant accounting charges and stock based compensation expense.

#### About Neuralstem

Neuralstem's patented technology enables the ability to produce neural stem cells of the human brain and spinal cord in commercial quantities, and the ability to control the differentiation of these cells constitutively into mature, physiologically relevant human neurons and glia. Neuralstem is in an FDA-approved Phase I safety clinical trial for amyotrophic lateral sclerosis (ALS), often referred to as Lou Gehrig's disease and has been awarded orphan status designation by the FDA.

In addition to ALS, the company is also targeting major central nervous system conditions with its cell therapy platform, including spinal cord injury, ischemic spastic paraplegia, chronic stroke, and Huntington's disease. The company has submitted an IND (Investigational New Drug) application to the FDA for a Phase I safety trial in chronic spinal cord injury.

Neuralstem also has the ability to generate stable human neural stem cell lines suitable for the systematic screening of large chemical libraries. Through this proprietary screening technology, Neuralstem has discovered and patented compounds that may stimulate the brain's capacity to generate new neurons, possibly reversing the pathologies of some central nervous system conditions. The company has nearly completed an FDA-approved Phase Ia safety trial evaluating NSI-189, its first small molecule compound, for the treatment of major depression, and anticipates initiating a Phase Ib trial in the fall. Additional indications could include schizophrenia, Alzheimer's disease and bipolar disorder.

For more information, please go to <u>www.neuralstem.com</u>.

### **Cautionary Statement Regarding Forward Looking Information**

This news release may contain forward-looking statements made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Investors are

cautioned that such forward-looking statements in this press release regarding potential applications of Neuralstem's technologies constitute forward-looking statements that involve risks and uncertainties, including, without limitation, 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, 2010 and the quarterly report on Form 10-Q for the period ended June 30, 2011.

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#### **Balance Sheets**

		June 30, 2011 (Unaudited)	 December 31, 2010
ASSETS			
CURRENT ASSETS			
Cash and cash equivalents	\$	6,141,843	\$ 9,261,233
Prepaid expenses		300,745	246,887
Other current assets		6,243	322,127
Total current assets		6,448,831	9,830,247
Property and equipment, net		335,777	200,084
Intangible assets, net		566,823	500,154
Other assets		68,653	60,875
Total assets	\$	7,420,084	\$ 10,591,360
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#### LIABILITIES AND STOCKHOLDERS' EQUITY

### **CURRENT LIABILITIES**

Accounts payable and accrued expenses	\$ 773,008	\$ 1,032,931
Accrued bonus expense	381,322	453,240
Fair value of warrant obligations	-	1,250,839

Total current liabilities	1,154,330	2,737,010	
Total liabilities	1,154,330	2,737,010	
STOCKHOLDERS' EQUITY			
Preferred stock, 7,000,000 shares authorized, zero shares issued and outstanding	-	-	
Common stock, \$0.01 par value; 150 million shares authorized, 48,486,304 and			
46,897,529 shares outstanding in 2011 and 2010 respectively	484,863	468,975	
Additional paid-in capital	98,485,549	93,339,506	
Accumulated deficit	(92,704,658)	(85,954,131)	
Total stockholders' equity	6,265,754	7,854,350	
Total liabilities and stockholders' equity \$	7,420,084	10,591,360	

#### Neuralstem, Inc.

## **Statements of Operations**

	Three Months Ended June 30,		Six Months		
			Ended .	June 30,	
	2011	2010	2011	2010	
Revenues	\$ -	\$ -	\$ -	\$ -	
On southern surround					
Operating expenses:					
Research and development costs	2,085,671	2,613,676	3,824,399	4,513,640	
General and administrative expenses	1,523,226	1,550,814	3,295,708	3,238,649	
Depreciation and amortization	59,971	30,601	85,264	59,663	
Total operating expenses	3,668,868	4,195,091	7,205,371	7,811,952	
Operating loss	(3,668,868)	(4,195,091)	(7,205,371)	(7,811,952)	
Nonoperating income (expense):					
Litigation settlement	-	-	250,000	-	
Interest income	20,143	9,653	43,035	15,463	
Interest expense	-	(1,462)	-	(2,120)	
Warrant issuance and modification expense	-	-	-	(1,906,800)	
Gain (loss) from change in fair value adjustment of warrant obligations	-	(764,440)	161,809	(2,012,892)	
Total nonoperating income (expense)	20,143	(756,249)	454,844	(3,906,349)	

Net loss attributable to common shareholders	\$(3,648,725)	\$(4,951,340)	\$(6,750,527)	\$(11,718,301)
Net loss per share - basic and diluted	\$(0.08)	\$(0.12)	\$(0.14)	\$(0.29)
Weighted average common shares outstanding - basic and diluted	48,486,304	42,450,338	48,091,019	40,505,586

SOURCE Neuralstem, Inc.