

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

ROCKVILLE, Md., Nov. 16, 2010 /PRNewswire-FirstCall/ -- Neuralstem, Inc. (NYSE Amex: CUR) reported its financial results for the three months and nine months period ended September 30, 2010 and provided a business and clinical update.

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"Neuralstem continues to make solid progress as we transition to a clinical stage company with products in development," said Richard Garr, Neuralstem's President & CEO. "The third quarter saw us complete the non-ambulatory cohort of our ALS trial at Emory University, in Atlanta, Georgia. We have now begun transplanting the next cohort of patients, all of whom will be ambulatory. We also filed an IND (Investigational New Drug) application with the FDA to begin the first neural stem cell trial to treat Chronic Spinal Cord Injury in the U.S. The third quarter also saw the opening of our wholly-owned subsidiary Neuralstem China, Suzhou Neuralstem Biopharmaceutical Company, Ltd. in China, where we have leased office and lab space, including a therapeutic level manufacturing space to grow our cells. We anticipate starting clinical trials in China in 2011. The Company also completed the pre-clinical work preliminary to filing an IND to treat major depression with our first small molecule drug candidate. We expect to start a trial in the first quarter of 2011."

Further, Neuralstem's Chairman and Chief Scientific Officer, Karl Johe, PhD, participated in the World Stem Cell Summit's Plenary Session: "Current and Future Clinical Trials and Stem Cell Therapies," in Detroit, Michigan. Video replay of the session, as well as a keynote presentation by Dr. Eva Feldman, entitled "The Promise of Stem Cells and Regenerative Medicine," is available at: <a href="http://www.worldstemcellsummit.com/2010-summit-webcast">http://www.worldstemcellsummit.com/2010-summit-webcast</a>.

# **Clinical Program and Business Highlights**

During the quarter, the company received three Federal grants, totaling\$733,438, through the Patient Protection and Affordable Care Act, which supports investments in qualifying therapeutic discovery projects. The funds will be used to advance three Neuralstem programs: The ALS stem cell trial; the small molecule drug candidate program; and the IGF1 program, which is focused on engineering Neuralstem's spinal cord neurons to overexpress molecules that could be beneficial in treating ALS.

Neuralstem also updated the progress of its ongoing Phase I human clinical trial of the company's spinal cord stem cells in the treatment of ALS (Amyotrophic Lateral Sclerosis, or Lou Gehrig's disease) at Emory University in Atlanta, Georgia. The company announced that, after reviewing the safety data from the first six non-ambulatory patients, the trial's Safety Monitoring Board has unanimously approved moving to the next group of ALS patients, all of whom will be ambulatory.

A study on Neuralstem's spinal cord stem cells in rats with stroke showed significant increase in some key motor skill and strength measures. The study was presented by Neuralstem collaborator, Dr. Shinn-Zong Lin, M.D., Ph.D. at the Stem Cells USA & Regenerative Medicine Conference.

Neuralstem also filed an Investigational New Drug (IND) application with the United States Food and Drug Administration (FDA) to begin a Phase I clinical trial for chronic spinal cord injury with its spinal cord stem cells. This multicenter Phase I safety trial will enroll a total of 16 long-term, or chronic, spinal cord injury patients, with an American Spinal Injury Association (ASIA) Grade A level of impairment, one-to-two years post-injury. ASIA A refers to a patient with no motor or sensory function in the relevant segments and is considered to be complete paralysis.

The company also received notification that the United States Patent and Trademark Office (USPTO) has upheld the patentability, without amendment, of all claims in U.S. Patent No. 5,753,506 and intends to issue a reexamination certificate in due course. This patent describes methods of culturing and expanding neural stem cells. A reexamination request had been filed by a third-party requestor in September of 2009.

#### **Third Quarter and Nine Months Financial Results**

Cash, cash equivalents and short-term marketable securities at September 30, 2010 totaled approximately \$11.6 million, compared with approximately \$2.3 million at December 31, 2009.

The Company reported a third quarter 2010 net loss of\$3.9 million or \$0.09 per share, compared with a net loss of \$5.1 million, or \$0.15 per share a year ago. The change from 2009 to 2010 was primarily due to increased research spending related to the clinical trials which began in January 2010, and to the costs of completing preclinical trial studies for new indications, offset by non-cash gains related to our warrant accounting. Net loss attributable to common stockholders for the first nine months of 2010 was \$15,648,540, or \$0.37 per share, compared with\$7,380,751, or \$0.22 per share, for the comparable period in 2009. The increase was primarily attributable to increases in R&D and legal fees, and non cash stock-based compensation expense, and non-cash expenses related to our warrant accounting.

For the third quarter of 2010, the Company reported an operating loss of \$3,923,645, compared with an operating loss of \$2,522,582, for the comparable 2009 period. The increase was due to increased research spending relating to beginning of clinical trials and the costs of completing preclinical trial studies for new indications. General and Administrative spending increased because of rising legal costs and an increase in non-cash stock based compensation expense.

For the nine months ended September 30, 2010, cash used in operating activities totaled \$7,231,609, an increase of \$3,618,525 or 100% compared to the same period in the prior year, primarily attributable to increased research spending related to the beginning of clinical trials, the costs of completing preclinical trial studies for new indications, and increased legal fees.

# About Neuralstem, Inc.

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 a Phase I safety clinical trial for Amyotrophic Lateral Sclerosis (ALS), often referred to as Lou Gehrig's disease. The company is also targeting major central nervous system diseases in addition to ALS, including traumatic spinal cord injury, ischemic spastic paraplegia, and Huntington's disease. The company has also submitted an IND application to the FDA for a Phase I safety trial in chronic spinal cord injury.

Through its 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 plans to initiate clinical trials to treat Alzheimer's disease and major depression with its lead compound, as well as pursue additional indications, including traumatic brain injury, posttraumatic stress syndrome, stroke and schizophrenia.

For more information, please go to www.neuralstem.com

# **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, 2009, and in its quarterly report on Form 10-Q for the period ended September 30, 2010.

Neuralstem, Inc.

#### **Balance Sheets**

September 30, December 31,

2010 2009

(Unaudited)

## ASSETS

#### **CURRENT ASSETS**

Cash and cash equivalents \$ 11,588,824 \$ 2,309,774

Prepaid expenses 302,334 143,600

Total current assets 11,891,158 2,453,374

Property and equipment, net 163,007 196,755

Intangible assets, net 440,195 301,560

Other assets 49,409 55,716

Total assets \$ 12,543,769 \$ 3,007,405

## LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)

## **CURRENT LIABILITIES**

Accounts payable and accrued expenses \$ 1,214,275 \$ 791,607

Accrued bonus expense 509,959 769,215

Fair value of warrant obligations 2,204,157 -

Total current liabilities 3,928,391 1,560,822

#### LONG-TERM LIABILITIES

Fair value of warrant obligations - 6,462,039

Total liabilities 3,928,391 8,022,861

## STOCKHOLDERS' EQUITY (DEFICIT)

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

Common stock, \$0.01 par value; 150 million shares authorized, 46,182,178 and 35,743,831 shares outstanding in 2010 and 2009 respectively 461,822 357,438

Additional paid-in capital 91,368,927 62,193,937

Accumulated deficit (83,215,371) (67,566,831)

Total stockholders' equity (deficit) 8,615,378 (5,015,456)

Total liabilities and stockholders' equity (deficit) \$ 12,543,769 \$ 3,007,405

Statements of Operations

(Unaudited)

Three Months Nine Months

Ended September 30, Ended September 30,

2010 2009 2010 2009

Revenues \$ - \$ - \$ -

Operating expenses:

Research and development

costs 2,112,299 1,308,565 6,625,939 4,195,366

General, selling and

administrative expenses 1,769,013 1,191,480 5,007,662 3,898,666

Depreciation and

amortization 42,333 22,537 101,996 64,757

3,923,645 2,522,582 11,735,597 8,158,789

Operating loss (3,923,645) (2,522,582) (11,735,597) (8,158,789)

Nonoperating

(expense)income:

Interest income 17,406 6,274 32,869 17,054

Interest expense (465) (194) (2,585) (194)

Warrant issuance and

modification expense - - (1,906,800) -

(Loss) gain from change

in fair value of warrant

obligations (23,535) (2,580,481) (2,036,427) 761,178

(6,594) (2,574,401) (3,912,943) 778,038

Net loss attributable to

common shareholders \$ (3,930,239) \$(5,096,983) \$ (15,648,540) \$(7,380,751)

Net loss per share -

basic and diluted \$ (0.09) \$ (0.15) \$ (0.37) \$ (0.22)

Weighted average common

shares outstanding -

basic and diluted 46,163,905 34,562,322 42,412,419 34,027,542

SOURCE Neuralstem, Inc.