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# Form 8-K

Neuralstem, Inc. - CUR

Filed: June 11, 2010 (period: June 11, 2010)

Report of unscheduled material events or corporate changes.

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# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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## FORM 8-K

### CURRENT REPORT

Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): June 11, 2010

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### Neuralstem, Inc.

(Exact name of registrant as specified in Charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**000-1357459**

(Commission File No.)

**52-2007292**

(IRS Employee Identification No.)

**9700 Great Seneca Highway, Rockville, Maryland 20850**

(Address of Principal Executive Offices)

**(301) 366-4841**

(Issuer Telephone number)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - ☒ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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## Item 8.01 Other Events

On June 11, 2010, Neuralstem, Inc. (the “Company”) made available on its website a letter from management to its shareholders regarding the Company’s developments over the past year. The Company anticipates this letter will be mailed to shareholders along with the Company’s Proxy Statement and Annual Report in connection with the 2010 Annual Meeting of Shareholders. A copy of the letter is attached to this Form 8-K as Exhibit 99.01 and is incorporated herein by reference.

The information contained in this Current Report on Form 8-K and the exhibits attached hereto shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall such information or such exhibits be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing. The information set forth in or exhibits to this Form 8-K shall not be deemed an admission as to the materiality of any information in this report on Form 8-K.

### Additional Information

The Company plans to mail to its shareholders a proxy statement in connection with the 2010 Annual Meeting of Shareholders. The Company and its respective directors and executive officers may be deemed to be participants in the solicitation of proxies. Information regarding our directors and executive officers is contained in the Company’s proxy statement filed with the Securities and Exchange Commission (“SEC”) on June 4, 2010. The proxy statement contains important information about the Company and related matters, including the current security holdings of the Company’s respective officers and directors.

The written materials described above and other documents filed by the Company with the SEC will be available free of charge from the SEC’s website at [www.sec.gov](http://www.sec.gov).

## Item 9.01 Financial Statement and Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
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99.01	Letter to Shareholders
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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report on Form 8-K to be signed on its behalf by the undersigned hereunto duly authorized.

Neuralstem, Inc.

Date: June 11, 2010

/s/ Richard Garr

By: Richard Garr  
Chief Executive Officer



Dear Fellow Shareholders,

June 10, 2010

The past year has been a year of great progress for our company: we strengthened our balance sheet despite the challenging financial environment; we added to our Intellectual Property assets with the issuance of two new important patents; and we launched the world's first FDA approved Neural Stem Cell Clinical Trial to treat Amyotrophic Lateral Sclerosis (ALS), commonly referred to as Lou Gehrig's disease. We believe that this coming year will mark even greater strides forward as we continue the ALS trial, move into a clinical trial to treat spinal cord injury; move our small molecule drug into the clinic for hopefully both Alzheimer's Disease and Major Depression; and continue to expand into Asia with the creation of our wholly owned subsidiary Neuralstem China 神腦生物医药公司 (Sun-Now Biopharmaceutical Company), as well as pursue strategic development in India.

First, a note on our ongoing Phase I clinical trial at Emory University to treat ALS: As we announced on May 24<sup>th</sup>, 2010, after reviewing the safety data from the first cohort of 3 patients, the Independent Data Safety Monitoring Board gave the approval to move to the second cohort of 3 patients, the first of whom was transplanted on May 26<sup>th</sup>. The first cohort of 3 patients received only 5 injections each, unilaterally. The second cohort of patients is receiving 10 injections each, bilaterally, in the lower spinal cord. Demonstrating the safety of the increased dosage is a critical element in what we hope will ultimately be the delivery of our cells through 15 injections for ALS patients. The surgery on the third patient, performed in April, was the subject of a special feature by Dr. Sanjay Gupta M.D., a neurosurgeon and CNN's chief medical correspondent on Anderson Cooper's AC360°. In addition to remarkable footage of the actual surgery, the piece contains insights into the program from the Principal Investigator, Dr. Eva Feldman and the Emory neurosurgeon conducting the surgeries, Dr. Nick Boulis. For those of you who have not watched it, a link can be found on our website [www.neuralstem.com](http://www.neuralstem.com); I highly recommend watching it.

Of additional importance is that we intend to treat both chronic and acute spinal cord injury with the same spinal cord stem cells utilizing the same injection devices we are using for ALS. The treatment for spinal cord injury will, however, likely only involve a few injections as opposed to the fifteen injection dosage that is ultimately planned for the ALS trial. We therefore add to our knowledge about the surgical route of entry for both the ALS patients and the spinal cord injury patients with each patient we treat in the ALS trial. We expect to file an Investigational New Drug application with the FDA this year to begin a Phase I clinical trial for Chronic Spinal Cord Injury, in what will most likely be a multi-site study in the U.S.

Another important milestone for Neuralstem in 2009 was the issuance of a U.S. Patent entitled "Use of Fused Nicotinamides to Promote Neurogenesis." This patent claims four chemical entities and any pharmaceutical composition including them. The compounds promote neurogenesis - the birth of new neurons in the adult brain. These four molecules with demonstrated neurogenic activity, are first-in-class compounds, were discovered entirely in-house and are owned 100% by Neuralstem. These are the only drugs we are aware of with the demonstrated ability to stimulate neurogenesis of normal adult brain cells, which indicates that they are truly neurogenic. We have been "incubating" the development of this new class of drugs inside the Company. The original development funding of \$2.5 million came from the U.S. Department of Defense, and an additional \$250,000 from the National Institutes of Health. The compounds enhance neurogenesis in the hippocampus. There is now a consensus in the scientific community that neural stem cells exist in this region of the adult brain. Through work done over the past year, we believe that we have the proof of concept needed to justify entering human trials with our lead compound from this group. We expect to be ready to begin the first Phase I trial near the end of 2010 or early in 2011. The two primary targets for the first trials are Alzheimer's disease and Major Depression. The decision has not yet been made as to which will be the first, or whether in fact we may do both. We are committed, however, to moving the small molecule program into the clinic. The key reason for our expansion into small molecule drugs is that these compounds were discovered screening against our human hippocampal stem cells. We believe that our ability to screen against our cells provides a valuable and unique advantage for the discovery of novel compounds for the treatment of diseases of the Central Nervous System. We believe that this first program will be a powerful validation of our screening technology.

Finally, I would like to say a word about our overseas activities. We are still committed to expanding throughout the world. In the first quarter of 2009, scientists at University Hospital Friburg, Germany presented data at the Huntington's Disease Therapeutics Conference in France, entitled, "Validation of Human Neural Stem Cell line in Rodent Model of Huntington's Disease," which demonstrated robust survival of our spinal cord stem cells, integration into the host brain, and early graft-mediated functional effect. This is a major milestone in the process of qualifying our cells into the hospital's existing human trial in Germany to treat Huntington's disease with our cells, as well as supporting our work in the U.S.

Also, we have a strong emphasis on expanding into Asia. Over the next year we believe that CJ Cheljedang, who holds an option on the commercialization rights to our spinal cord cells for South Korea, Vietnam, Singapore, Malaysia and Indonesia, will most likely chose the site and indication for its first clinical trial. And as mentioned above, we are expecting to commence business through our wholly owned subsidiary in China this summer. We believe that China presents tremendous growth opportunity for us both in terms of accelerated product development as well as prospective markets for our therapies.

So as we head into the second half of 2010, once again we have a full plate. We look forward to keeping you up to date as we progress on all these fronts.

Sincerely,

Karl Johe Chairman of the Board & Chief Scientific Officer

I. Richard Garr  
Director, President & Chief Executive Officer

*The statements and certain other information contained in this letter, which can be identified by the use of forward-looking terminology such as "may," "will," "expect," "continue," "remains," "intend," "aim," "towards," "should," "prospects," "could," "future," "potential," "believes," "plans," "likely," "anticipate," "position," "probable," "committed," "achieve," and "focused," or the negative thereof or other variations thereon or comparable terminology, constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbors created thereby. These statements should be considered as subject to the many risks and uncertainties that exist in the Company's operations and business environment. Such risks and uncertainties could cause actual results to differ materially from those projected. These uncertainties include, but are not limited to, economic conditions, the Company's stage of development, the Company's ability to develop a product, the Company's ability to gain FDA approval of its products, market demand and pricing, competitive and cost factors, and other risk factors as for fully described in the Company's filings made with the SEC.*

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