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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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):

October 19, 2005

StemCells, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction  
of incorporation)

000-19871

(Commission  
File Number)

94-3078125

(I.R.S. Employer  
Identification No.)

3155 Porter Drive, Palo Alto, California

(Address of principal executive offices)

94304

(Zip Code)

Registrant's telephone number, including area code:

650.475.3100

Not Applicable

Former name or former address, if changed since last report

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:

- 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 October 20, 2005, StemCells, Inc. announced that that it has received clearance from the U.S. Food and Drug Administration (FDA) to begin a Phase I safety and preliminary efficacy trial of the Company's proprietary human neural stem cell product, HuCNS-SC™, to treat Batten disease. A copy of the press release is attached hereto as Exhibit 99.1.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

StemCells, Inc.

October 20, 2005

By: *Martin McGlynn*

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*Name: Martin McGlynn*

*Title: President and CEO*

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Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	press release

**Company Contact:**  
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## **STEMCELLS, INC. RECEIVES FDA CLEARANCE TO INITIATE PHASE I CLINICAL TRIAL OF NEURAL STEM CELLS TO TREAT BATTEN DISEASE**

*First-Ever FDA-Approved Trial to Transplant Human Neural Stem Cells*

**PALO ALTO, Calif., (October 20, 2005)** – StemCells, Inc. (NASDAQ: STEM) today announced that it has received clearance from the U.S. Food and Drug Administration (FDA) to begin a Phase I safety and preliminary efficacy trial of the Company's proprietary human neural stem cell product - -HuCNS-SC™ - to treat Batten disease. Batten disease is a rare, fatal genetic disorder that affects the central nervous system of children. This is the first-ever FDA-approved clinical trial to use a purified composition of human neural stem cells as a potential therapeutic agent in humans.

"It is truly gratifying that the FDA is permitting this clinical trial to go forward," said Martin McGlynn, President and Chief Executive Officer of StemCells, Inc. "This development is a noteworthy milestone not only for our Company, but also for the entire field of stem cell therapeutics. Most importantly, it offers hope to the children and families afflicted by this disease for which there is now no cure, and to the clinicians who are seeking a treatment for their patients."

"Physicians have been essentially helpless to assist children suffering from Batten disease. This trial opens the possibility that in the future, we may be able to provide relief to our patients and their families from one of the cruelest and most devastating diseases," said Dr. Gregory Enns, Assistant Professor of Pediatrics and Director of the Biochemical Genetics Program, Stanford University School of Medicine.

Dr. Stephen Huhn, Chief of Pediatric Neurosurgery at Packard Children's Hospital at Stanford University, added, "Years of laboratory research are now moving into the clinic, and it is my fervent hope that the proposed neurosurgical intervention will provide some relief for the children with this terrible disease and for the families who care for them. I look forward to participating in the first trial of neural stem cell transplantation for a rare and fatal brain disorder in children that has no effective known treatment."

### **About the Clinical Trial**

The proposed Phase I trial is designed to evaluate the safety and preliminary efficacy of HuCNS-SC™ for the treatment of infantile and late-infantile neuronal ceroid lipofuscinosis (NCL), the most severe forms of a group of disorders commonly referred to as Batten disease. In addition to measuring the safety of HuCNS-SC, the trial will provide initial data on HuCNS-SC's ability to affect the progression of the disease. Potential patients will be tested for eligibility and then evaluated for baseline disease status prior to transplantation of HuCNS-SC. Children enrolled in the study will be evaluated with standardized measures of development, cognition, behavior and language for one year following HuCNS-SC transplantation. The Company is committed to following the effects of this therapy long-term, so trial patients will also be asked to commit to a four-year follow-up study. The Company plans to seek Institutional Review Board (IRB) approval from a number of leading medical institutions, including the Stanford University School of Medicine.

### **About Batten Disease**

Batten disease is named after the British pediatrician who first described the juvenile form of NCL in 1903. It is also known as Spielmeyer-Vogt-Sjogren-Batten disease. The name is now commonly used to encompass all three forms of NCL—infantile, late infantile and juvenile onset. All forms have the same basic cause—lack of a lysosomal enzyme—and have a similar progression and outcome. The different forms of NCL have traditionally been classified by age of onset. Now with genetic testing, the disease is more precisely classifiable in terms of mutations in the specific enzyme causing the disease. Children with Batten disease suffer seizures, progressive loss of motor skills, sight and mental capacity, eventually becoming blind, bedridden and unable to communicate. Today, Batten disease is always fatal.

In two subtypes of NCL, infantile and late infantile, the disorder is brought on by inherited mutations in the *CLN1* gene, which codes for palmitoyl-protein thioesterase 1 (PPT1) or in the *CLN2* gene, which codes for tripeptidyl peptidase I (TPP-I). The consequence of these mutations is either a defective or a missing enzyme that leads to accumulation of lipofuscin-like fluorescent inclusions in various cell types. Presumably, these non-degraded lysosomal substrates accumulate to the point where they interfere with normal cellular and tissue function and ultimately lead to the pathological manifestations of the disease. One way to treat the disease is to provide the brain with a replacement source of functional enzyme that can be taken up by the enzyme-deficient cells.

### **About HuCNS-SC™**

StemCells' human central nervous system stem cells (HuCNS-SC) are a somatic cell therapy product consisting of neural cells prepared under controlled conditions. Neural stem cells, a rare subset of brain cells, are isolated from the human fetal brain, purified, propagated, and tested; they are then frozen in cell banks from which HuCNS-SC doses can be prepared.

A property of HuCNS-SC is that they spread throughout the brain and produce both of the lysosomal enzymes missing in the subtypes of Batten disease being studied in the clinical trial. When HuCNS-SC is transplanted into the brain of a preclinical mouse model developed to mimic the human form of Infantile NCL, the enzyme level increases and continues to do so over time after the transplant. Thus, placement of HuCNS-SC in appropriate places in the brain provides the prospect of long-term delivery of the missing enzyme. The production of both enzymes by HuCNS-SC provides a scientific justification for enzyme replacement and cellular rescue in these two subtypes of Batten disease.

## **About StemCells, Inc.**

StemCells, Inc. is a development stage biotechnology company focused on the discovery, development and commercialization of stem cell-based therapies to treat diseases of the nervous system, liver and pancreas. The Company's stem cell programs seek to repair or repopulate neural or other tissue that has been damaged or lost as a result of disease or injury. StemCells is the first company to directly identify and isolate human neural stem cells from normal brain tissue. These stem cells are expandable into cell banks for therapeutic use, which demonstrates the feasibility of using normal, non-genetically modified cells as cell-based therapies. StemCells is the only publicly traded company solely focused on stem cell research and development and has more than 40 U.S. and 100 non-U.S. patents, as well as more than 100 patent applications pending worldwide. Further information about the Company is available on its web site at: [www.stemcellsinc.com](http://www.stemcellsinc.com).

*Apart from statements of historical facts, the text of this press release constitutes forward-looking statements regarding, among other things, the future business operations of StemCells, Inc. (the "Company") and its ability to conduct clinical trials as well as its research and product development efforts. The forward-looking statements speak only as of the date of this news release. StemCells does not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. Such statements reflect management's current views and are based on certain assumptions that may or may not ultimately prove valid. The Company's actual results may vary materially from those contemplated in the forward-looking statements due to risks and uncertainties to which the Company is subject, including uncertainty regarding whether a suitable site for the clinical trial will be identified, whether the required Institutional Review Board approval will be obtained for any site, and whether results obtained in the animal model of Infantile NCL will be able to be translated into treatment for human conditions; uncertainty as to whether the FDA will permit the Company to continue clinical testing in the Batten disease trial or in future clinical trials of proposed therapies for other diseases or conditions despite the novel and unproven nature of the Company's technology; uncertainties regarding the Company's ability to obtain the capital resources needed to continue its current research and development operations and to conduct the research, preclinical development and clinical trials necessary for regulatory approvals; uncertainty regarding the validity and enforceability of the Company's patents; uncertainty as to whether HuCNS-SC™ and any products that may be generated in the future in the Company's stem cell programs will prove safe and clinically effective and not cause tumors or other side effects; uncertainty as to whether the Company will achieve revenues from product sales or become profitable; and other factors that are described in Exhibit 99 to the Company's Annual Report on Form 10-K titled "Cautionary Factors Relevant to Forward-Looking Statements."*

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