
**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): **January 4, 2005**

StemCells, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

0-19871
(Commission
File Number)

94-3078125
(IRS 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**

(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 (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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TABLE OF CONTENTS

[ITEM 8.01 OTHER EVENTS.](#)

[ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.](#)

[SIGNATURES](#)

[EXHIBIT INDEX](#)

[EXHIBIT 99.1](#)

[Table of Contents](#)

ITEM 8.01 OTHER EVENTS.

On January 4, 2005, StemCells, Inc. (the “Company”) issued a press release announcing that it submitted an investigational new drug application (IND) to the U.S. Food and Drug Administration (FDA) for the Company’s human neural stem cell transplant treatment for Batten disease. The full text of the press release is attached hereto as Exhibit 99.1.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(c) Exhibits.

Exhibit 99.1 Press release

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.

By: /s/ Martin McGlynn
Martin McGlynn
President and Chief Executive Officer

Date: January 11, 2005

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release



StemCells, Inc. (Ticker: STEM, Exchange: NASDAQ)
News Release — January 4, 2005

Company Contact:

Judi Lum
Chief Financial Officer
(650) 475-3100

Media Contact:

Schwartz Communications, Inc.
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STEMCELLS, INC. ANNOUNCES FILING OF IND FOR HUMAN NEURAL STEM CELL TRANSPLANT TREATMENT FOR BATTEN DISEASE

Phase I Clinical Trial at Stanford Would Be First-Ever Using Transplantation of Human Neural (Brain) Stem Cells

PALO ALTO, Calif., (January 4, 2005) - StemCells, Inc. (NASDAQ: STEM) today announced the filing of its first Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA). Subject to approval, the Company plans to begin its first clinical investigation of its human neural (brain) stem cells (HuCNS-SC — StemCells' proprietary neural cell therapy product) in Batten disease. Batten disease is a rare, fatal genetic disorder that affects the central nervous system of children. If approved by the FDA, this would mark the first-ever FDA-approved clinical trial to use a purified composition of human neural stem cells as the potential therapeutic agent.

On approval of the IND by the FDA, the study will be conducted at Lucile Packard Children's Hospital/Stanford University Medical Center (LPCH/SUMC) under the direction of Stephen L. Huhn, MD, FACS, FAAP, Chief of Pediatric Neurosurgery and Gregory M. Enns, MB, ChB, Assistant Professor and Director, Biochemical Genetics Program, Division of Medical Genetics.

"This is truly a significant milestone, not only for StemCells, Inc., but also for all scientists who have been seeking to evaluate possible therapies for neural and neurodegenerative diseases," said Martin McGlynn, chief executive officer of StemCells, Inc. "Our pre-clinical research has shown great promise and this filing is an essential step in discovering how to translate those pre-clinical results into treatment of human victims of terrible disorders like Batten disease and other neurodegenerative lysosomal storage diseases. It is only a first step, though — this is a Phase I, or safety, trial, from which we hope to learn about the behavior of the cells when they are transplanted into a human recipient. There will be many other steps to take before we arrive. But it is our hope that transplantation of human neural stem cells could prove to be a platform technology for a wide range of conditions for which there is now no reliable and effective treatment."

"We are looking forward to working with the scientists at StemCells in this historic clinical trial," said Dr. Huhn, at the Stanford University School of Medicine. "We are exploring new territory, which dictates that we proceed with due caution. I believe, however, that our path has been determined by rigorous research and a well-designed protocol. Physicians have been essentially helpless to assist children suffering from Batten's, and all of us involved in this trial are hoping it will lead to a future in which we will have an efficient treatment, or even a cure. As a pediatric neurosurgeon, I am particularly excited about this avenue of research."

About the Clinical Trial

The proposed Phase I trial is designed to investigate the safety of HuCNS-SC in 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. The trial will be an open label study of two dose levels involving three subjects in each of two cohorts. The primary objective of the trial will be to measure the safety of HuCNS-SC, however, the trial will also evaluate HuCNS-SC's ability to affect the progression of the disease. The patient/subject evaluation will be up to one year post HuCNS-SC transplantation. Candidates from anywhere in the world will be referred by their primary physicians to the Co-principal Investigators at LPCH/SUMC. Potential patients will be tested for eligibility and then evaluated for baseline disease status prior to transplantation. The Company is committed to following the effects of this therapy long-term, so potential trial patients will be asked also to commit to a four year follow-up study.

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 Spielmeier-Vogt-Sjogren-Batten disease. The name is now commonly used to encompass all three forms of NCL. The forms of NCL are classified by age of onset (infantile, late infantile and juvenile) but are more precisely classifiable in terms of the specific enzyme causing the disease. They all have the same basic cause — lack of a lysosomal enzyme — and similar progression and outcome, but are all genetically different. 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 sub-types of the NCLs — infantile and late infantile or, more technically, CLN1 and CLN2 - normally secreted housekeeping lysosomal enzymes are either defective or missing altogether, as a result of gene mutations. Lack of either enzyme causes a buildup of lipofuscin (aggregates of lipids and proteins) primarily in the brain and leads to neuronal cell loss.

In the proposed clinical trial, HuCNS-SC will be transplanted in the CLN1 and CLN2 patients in part to determine if the transplanted cells secrete the missing lysosomal enzymes in the brains of affected individuals. HuCNS-SC have been shown to produce both PPT1 and TPP-I enzymes, providing a scientific justification for enzyme replacement and cellular rescue in this indication. In preclinical models of PPT1 deficiency, the corresponding enzyme activity increases with time after transplantation.

About HuCNS-SC and the Clinical Trial

StemCell's 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.

NCLs are lysosomal storage disorders brought on by inherited genetic mutations in CLN1 gene, which codes for palmitoyl-protein thioesterase 1 (PPT1) and in the CLN2 gene, which codes for tripeptidyl peptidase I (TPP-I). The consequence of these mutations is the accumulation of lipofuscin-like fluorescent inclusions in various cell types that eventually lead to cell degeneration. Presumably, non-

degraded lysosomal substrates accumulate to the point where they interfere with normal cellular and tissue function and lead to the pathological manifestations of the related disease. To correct the major defect in these subjects, enzyme would have to be available in the brain where it can be taken up by the enzyme deficient cells. A property of HuCNS-SC is production of both PPT1 and TPP-I enzymes. Thus, placement of HuCNS-SC in appropriate places in the brain has the prospect of replacing the missing enzyme.

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 100 patent applications pending worldwide. Further information about the Company is available on its web site at: 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"). 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 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; the uncertainty whether the FDA will approve the IND and permit the Company to proceed to clinical testing; the uncertainty regarding the outcome of the Phase I clinical trial and any other trials the Company may conduct in the future; the uncertainty regarding the validity and enforceability of issued patents; the uncertainty whether any products that may be generated in the Company's stem cell programs will prove clinically effective and not cause tumors or other side effects; the uncertainty whether the Company will achieve revenues from product sales or become profitable; uncertainties regarding the Company's obligations in regard to its former encapsulated cell therapy facilities in Rhode Island; 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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