
**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): **February 1, 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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ITEM 8.01 OTHER EVENTS.

On February 1, 2005, StemCells, Inc. (the “Company”) issued a press release announcing that it has been in communication with the U.S. Food and Drug Administration (FDA) regarding the filing of the Company’s first Investigational New Drug (IND) application. 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
President and Chief Executive Officer

Date: February 1, 2005

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release

**Company Contact:**

Judi Lum
Chief Financial Officer
(650) 475-3100

Media Contact:

Schwartz Communications, Inc.
(781) 684-0770 or (415) 512-0770
stemcells@schwartz-pr.com

STEMCELLS, INC. ANNOUNCES COMMUNICATIONS WITH FDA ON PROPOSED PHASE I CLINICAL TRIAL

PALO ALTO, Calif., (February 1, 2005) - StemCells, Inc. (NASDAQ: STEM) today announced that it has been in communication with the U.S. Food and Drug Administration (FDA) regarding the filing of the Company's first Investigational New Drug (IND) application. The filing, announced on January 4, 2005, is for a Phase I clinical trial of StemCells' proprietary neural cell therapy product-HuCNS-in Batten disease. The FDA has orally informed the Company that it has suggestions and questions related to the proposed trial that require additional information from the Company and has placed the proposed trial on hold. Consistent with normal FDA procedures, the FDA is expected to formally communicate the precise nature of these issues in writing to StemCells within 30 days. In the interim, StemCells expects to be in active dialogue with the FDA to address the outstanding issues. It is important to note that none of the FDA's suggestions or questions are related to contaminated embryonic stem cells that have been the matter of media attention recently. StemCells, Inc. does not use embryonic stem cells, and does not use mouse feeder cells in any way in preparing its stem cells. All cells prepared by StemCells, Inc. are grown in serum-free media and do not come into contact with cells from animals.

"We appreciate the care with which the FDA is reviewing our IND for this important trial," commented Martin McGlynn, chief executive officer of StemCells. "This is the first time that the FDA has been asked to review a proposed clinical trial involving the use of a purified composition of human neural stem cells as the potential therapeutic agent. We look forward to working with the FDA with the goal of resolving all outstanding issues both thoroughly and expeditiously."

If approved by the FDA, the proposed study would mark the first-ever FDA-approved clinical trial to use a purified composition of human neural stem cells as the potential therapeutic agent. The 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. If approved by the FDA, the study will be conducted at Lucile Packard Children's Hospital/Stanford University Medical Center (LPCH/SUMC), upon approval by the university's Investigational Review Board (IRB).

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, expectations regarding FDA actions and the Company's response to these actions, the Company's ability to resolve questions raised by the FDA and to initiate clinical trials, the timing of such trials, and other future operations of 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 uncertainty as to whether the FDA will remove the clinical hold on the Company's proposed initial clinical trial and permit the Company to proceed to clinical testing despite the novel and unproven nature of the Company's technology; uncertainty regarding the specific nature of the concerns the FDA has regarding the IND for this clinical trial, which will not be known definitively until receipt of the written response from the FDA and which could include concerns not identified by the FDA in its oral notification to the Company of the clinical hold on the proposed trial; uncertainties regarding the Company's ability to satisfy the FDA's concerns, if at all, or without conducting extensive and time consuming additional preclinical studies; the risk that, even if approved, the Company's initial clinical trial could be substantially delayed beyond its expected dates; 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 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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