# 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 10, 2010

# StemCells, Inc.

(Exact name of registrant as specified in its charter)

Delaware

000-19871

(Commission File Number)

(State or other jurisdiction of incorporation)

3155 Porter Drive, Palo Alto, California

(Address of principal executive offices)

Registrant's telephone number, including area code:

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))

94-3078125

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

94304

(Zip Code)

650.475.3100

### Item 8.01 Other Events.

On February 10, 2010, StemCells, Inc. announced the first transplant of its proprietary HuCNS-SC® therapeutic candidate (purified human neural stem cells) in a patient in its Phase I clinical trial in Pelizaeus-Merzbacher Disease.

The full text of the press release is attached hereto as Exhibit 99.1.

#### 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.

February 11, 2010

StemCells, Inc.

By: /s/ Kenneth Stratton

Name: Kenneth Stratton Title: General Counsel Exhibit Index

Exhibit No.

Description

99.1

Press Release of StemCells, Inc. dated February 10, 2010

#### **CONTACT:**

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# STEMCELLS, INC. ANNOUNCES FIRST HUMAN NEURAL STEM CELL TRANSPLANT IN LANDMARK MYELINATION DISORDER TRIAL

# Phase I Study Targets "Communication Highway" of the Brain in Children with PMD

**PALO ALTO, Calif., February 10, 2010** – StemCells, Inc. (NASDAQ: STEM) announced today that its proprietary HuCNS-SC<sup>®</sup> human neural stem cells have been used to treat the first patient enrolled in its Phase I clinical trial in Pelizaeus-Merzbacher Disease (PMD), a myelination disorder that afflicts male children. The stem cells were administered yesterday at the University of California, San Francisco (UCSF) Children's Hospital by direct injection into the brain of a patient with connatal PMD, the most severe form of the disease. This marks the first time that neural stem cells have been transplanted as a potential treatment for a myelination disorder, and the second clinical trial involving the use of HuCNS-SC cells in a neurodegenerative disease.

Myelin is the substance that surrounds and insulates nerve cells' communications fibers (also known as axons). Without sufficient myelination, these fibers are unable to properly transmit nerve impulses, leading to a progressive loss of neurological function. Multiple sclerosis, transverse myelitis and certain types of cerebral palsy are more commonly known myelination disorders that also affect the central nervous system. Patients with PMD are born with a defective gene, which leads to insufficient myelin in the brain. Those with the most severe form of the disease, connatal PMD, lose the ability to walk and talk and eventually die, often before the age of 10. Currently, there are no effective treatments for PMD.

Stephen Huhn MD, FACS, FAAP, Vice President and Head of the CNS Program at StemCells, Inc., said, "The dosing of this first patient marks the beginning of a new chapter in the search for novel approaches to treat PMD and other myelination disorders. Cell therapy represents hope for those with diseases that small molecules and other biologics have been unable to address. Our ultimate goal in this clinical development program is to improve the outlook for these patients by establishing the basis for a safe and effective treatment option that could significantly slow or prevent the progression of the disease. While the primary focus in this first trial is safety, we will also be looking for evidence of new myelin formation in the patients' brains following the transplantation of our cells, as well as any signs of improved neurological function."

President and CEO Martin McGlynn stated, "We are extremely grateful to the family of this child, and to the clinicians and staff at UCSF, for bringing us one step closer to our goal of realizing a cell-based treatment for devastating myelination disorders that impact the central nervous system."

The trial is being directed by a team of prominent researchers at UCSF Children's Hospital, one of the leading medical centers in the United States for neonatology, pediatric neurology and neurosurgery. The principal investigator is David H. Rowitch, M.D., Ph.D., Chief of Neonatology at UCSF Children's Hospital, Professor of Pediatrics and Neurological Surgery, member of the Eli and Edythe Broad Center of Regeneration Medicine and Stem Cell Research, and a Howard Hughes Medical Institute investigator. The study co-investigators are Nalin Gupta, M.D., Ph.D., Chief of Pediatric Neurological Surgery, and Jonathan B. Strober, M.D., Director of Clinical Services for Child Neurology and Director of the Muscular Dystrophy Clinic at UCSF Children's Hospital.

#### About the PMD Clinical Trial

The Phase I trial is designed to assess the safety and preliminary effectiveness of HuCNS-SC cells as a potential treatment for PMD. The trial is expected to enroll four patients with connatal PMD. All patients will be transplanted with HuCNS-SC cells, and will be immunosuppressed for nine months. Following transplantation, the patients will be evaluated regularly over a 12-month period in order to monitor and evaluate the safety and tolerability of the HuCNS-SC cells, the surgery, and the immunosuppression. In addition, magnetic resonance imaging (MRI) of the brain post-transplant may enable the measurement of new myelin formation. As the Company intends to follow the effects of this therapy long-term, a separate four-year observational study will be initiated at the conclusion of this trial. Interested parties may find more information on patient enrollment at <a href="http://neonatology.ucsf.edu/nbri/pmd-trial/">http://neonatology.ucsf.edu/nbri/pmd-trial/</a> or by visiting <a href="http://neonatology.ucsf.edu/nbri/pmd-trial/">www.clinicaltrials.gov</a>.

#### About HuCNS-SC Cells

StemCells' lead product candidate, HuCNS-SC cells, is a highly purified composition of human neural stem cells that are expanded and stored as banks of cells. The Company's preclinical research has shown that HuCNS-SC cells can be directly transplanted in the central nervous system. The transplanted cells are able to engraft, migrate, differentiate into neurons and glial cells, and possess the ability to survive for as long as one year with no sign of tumor formation or adverse effects. These findings show that HuCNS-SC cells, when transplanted, behave like normal stem cells, suggesting the possibility of a continual replenishment of normal human neural cells.

Preclinical studies performed by StemCells and its collaborators provide a rationale for potential therapeutic use of HuCNS-SC cells in myelination disorders. The Company has demonstrated that, when transplanted into an animal model of hypomyelination (shiverer mouse), HuCNS-SC cells engraft and differentiate into mature, specialized cells called oligodendrocytes, and form myelin sheaths around host nerve fibers. The initial myelination data in the shiverer mouse was published in the *Proceedings of the National Academy of Science* (Cummings, et al. 2005) and the results of additional myelination studies were presented at the International Society of Stem Cell Research (ISSCR) *2008 Annual Meeting* in Philadelphia.

StemCells has completed a Phase I clinical trial of its HuCNS-SC cells for the treatment of Neuronal Ceroid Lipofuscinosis (NCL), a fatal brain disorder in children. Data from this trial demonstrated the clinical safety and tolerability of these cells. The Company's HuCNS-SC cells are also in preclinical development for other central nervous system disorders, including retinal degenerative diseases, such as age-related macular degeneration and retinitis pigmentosa, and spinal cord injury.

#### About UCSF

One of the nation's top children's hospitals, UCSF Children's Hospital creates an environment where children and their families find compassionate care at the healing edge of scientific discovery, with more than 150 experts in 50 medical specialties serving patients throughout Northern California and beyond. The hospital admits about 5,000 children each year, including 2,000 babies born in the hospital. Medi-Cal patients constitute more than half of the patient population.

UCSF is a leading university dedicated to promoting health worldwide through advanced biomedical research, graduate-level education in the life sciences and health professions, and excellence in patient care.

#### About StemCells, Inc.

StemCells, Inc. is focused on the development and commercialization of cell-based technologies. In its cellular medicine programs, StemCells is targeting diseases of the central nervous system and liver. StemCells' lead product candidate, HuCNS-SC cells (purified human neural stem cells), is in clinical development for the treatment of two fatal neurodegenerative disorders that primarily affect young children. StemCells also markets specialty cell culture products under the brand SC Proven<sup>®</sup>, and is developing its cell-based technologies for use in drug screening and drug development. The Company has exclusive rights to approximately 55 issued or allowed U.S. patents and approximately 200 granted or allowed non-U.S. patents. Further information about StemCells is available at <u>www.stemcellsinc.com</u>.

Apart from statements of historical fact, the text of this press release constitutes forward-looking statements within the meaning of the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended, and is subject to the safe harbors created therein. These statements include, but are not limited to, statements regarding the potential for the Company's therapies to treat PMD, NCL and other serious neurodegenerative diseases, the potential for its cell-based therapeutics to treat other diseases or disorders, and the future business operations of the Company, including its ability to conduct clinical trials as well as its other research and product development efforts. These forward-looking statements speak only as of the date of this news release. The Company 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 such forward-looking statements due to risks and uncertainties to which the Company is subject, including the fact that additional trials will be required to demonstrate the safety and efficacy of the Company's HuCNS-SC cells for the treatment of any disease; uncertainty as to whether the FDA or other applicable regulatory agencies will permit the Company to continue clinical testing in PMD, NCL or in future clinical trials of proposed therapies for other diseases or conditions given the novel and unproven nature of the Company's technologies; uncertainties about the design of future clinical trials and whether the Company will receive the necessary support of a clinical trial site and its institutional review board to pursue future clinical trials in PMD, NCL or in other diseases or conditions; uncertainties regarding the ability of preclinical research, including research in animal models, to accurately predict success or failure in clinical trials; uncertainties regarding the Company's ability to recruit the patients required to conduct this clinical trial or to obtain meaningful results based on the limited number of patients expected to be enrolled; uncertainties arising as a result of the serious condition of the patients expected to be enrolled; the fact that results obtained in any clinical trial in PMD may not be predicative of results that would be obtained in regard to other myelination disorders; uncertainties regarding the Company's ability to obtain the increased capital resources needed to continue its current and planned research and development operations, including such operations of the company for non-therapeutic applications, and to conduct the research, preclinical development and clinical trials necessary for regulatory approvals; uncertainty as to whether HuCNS-SC and any products that may be generated in the future in the Company's cell-based programs will prove safe and clinically effective and not cause tumors or other adverse side effects; uncertainties regarding the Company's ability to commercialize a therapeutic product and its ability to successfully compete with other products on the market; uncertainties regarding the Company's manufacturing capabilities given its increasing preclinical and clinical commitments; and the increased risks associated with commercializing future cell-based therapeutics, including the potential for product liability claims; and other factors that are described under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2008, and in its subsequent reports on Form 10-Q and Form 8-K.

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