STEMCELLS INC
Form 8-K
November 19, 2015

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): November 18, 2015

StemCells, Inc.

(Exact name of registrant as specified in its charter)

Delaware	000-19871	94-3078125
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)
7707 Gateway Blvd, Suite 140, Newark, California		94560
(Address of principal executive offices)		(Zip Code)

Registrant s telephone number, including area code: 510.456.4000

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.

With this Form 8-K filing, StemCells, Inc. (the "Company") is providing an update on its two Phase II clinical programs and presenting interim data from the first cohort in its Phase II Pathway Study in spinal cord injury. While enrollment into the Company's Phase II Radiant Study in dry AMD is taking longer than previously anticipated, both studies are actively enrolling at multiple sites in North America. Additional sites are being initiated in both studies and patient enrollment is expected to accelerate in 2016. The Company intends to provide an update on both of its Phase II clinical programs at its next analyst call.

The preliminary data from the Pathway Study show a pattern of overall motor improvement in four of the six patients comprising the first cohort in the study. These motor improvements consisted of gains in both upper extremity muscle strength and increases in measures of dexterity based on multiple clinical assessments. There have been no adverse events attributed to the cells.

A copy of the Company's press release, which issued earlier today and summarizes the preliminary data from the Pathway Study, is attached to this Form 8-K as item 99.1.

Item 9.01 Financial Statements and Exhibits.

(d)
Exhibit 99.1 Press Release, dated November 18, 2015, announcing preliminary data from the Company's Pathway Study.

Apart from statements of historical fact, the text of this press release constitutes forward-looking statements within the meaning of the U.S. securities laws, and is subject to the safe harbors created therein. These statements include, but are not limited to, statements regarding the future business operations of StemCells, Inc. (the "Company"); statements about the prospect and timing of patient enrollment in the Company's two Phase II studies and in particular whether enrollment rates will increase in 2016, if at all; statements about the nature and significance of the treatment effect seen in the Pathway Study; statements about whether the Company will be able to enroll additional clinical sites in either or both of its clinical programs; and statements about and the prospect for continued clinical development of the Company's HuCNS-SC cells in both spinal cord injury and dry AMD or in either program. 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 uncertainties about whether preliminary data in any Phase I or Phase II clinical study will prove to be reproducible or biologically meaningful in any future clinical study; risks whether the FDA or other applicable regulatory agencies, including applicable institutional review boards at one or more clinical trial sites, will permit the Company to continue clinical testing or conduct future clinical trials; uncertainties regarding the Company's ability to obtain the increased capital resources needed to continue its current and planned research and development operations; uncertainty as to whether HuCNS-SC cells 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 whether results in preclinical research in animals will be indicative of future clinical results in humans; uncertainties regarding the Company's manufacturing capabilities given its increasing clinical commitments; uncertainties regarding the validity and enforceability of the Company's patents; uncertainties as to whether the Company will become profitable; 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, 2014 and in its subsequent reports on Forms 10-Q and 8-K.

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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.

November 18, 2015

By: Kenneth Stratton

Name: Kenneth Stratton
Title: General Counsel

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Exhibit Index

Exhibit No.	Description
99.1	Press release dated November 18, 2015