

BRAINSTORM CELL THERAPEUTICS INC.

Form 8-K

April 22, 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): April 21, 2015

Brainstorm Cell Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware

001-36641

20-7273918

(State or other jurisdiction of incorporation) (Commission File No.) (IRS Employer Identification No.)

3 University Plaza Drive, Suite 320

Hackensack, NJ

07601

(Address of principal executive offices) (Zip Code)

(201) 488-0460

(Registrant's telephone number, including area code)

N/A

(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))

Item 8 .01 Other Events.

On April 21, 2015, BrainStorm Cell Therapeutics Inc. (the “Company”) issued a press release announcing that it is presenting results from its phase 2a study of NurOwn® in amyotrophic lateral sclerosis (ALS) at a poster session at the American Academy of Neurology annual meeting, taking place in Washington D.C. on April 21, 2015. In addition to previously disclosed topline results, further data and analyses are being presented for the first time.

Among the new results is a piecewise linear regression analysis of all subjects who received intrathecal (IT) administration in the Company’s phase 2a study and the prior phase 1/2 study. At six months post-treatment, there was a statistically significant improvement in the estimated rate of decline in Forced Vital Capacity (FVC), from -5.1% per month pre-treatment to -1.2% per month post-treatment (two-sided $p=0.036$) and a nearly significant improvement in the rate of ALS Functional Rating Score-Revised (ALSFRS-R) decline, from -1.2 points per month pre-treatment to -0.6 points per month post treatment (two-sided $p=0.052$).

Also being reported for the first time are local positive effects of intramuscular administration. 3D volumetric analysis using MRI revealed an improvement in the rate of decline in muscle mass in the right arm, the site of NurOwn® administration, through one month post-treatment, as compared to the left arm. Electromyography demonstrated a trend of stabilization of the compound motor axon potential in the right musculocutaneous nerve as compared to deterioration observed in the left.

The foregoing description is qualified in its entirety by reference to the Press Release filed as Exhibit 99.1 hereto, which exhibit is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
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99.1	Press Release dated April 21, 2015
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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.

April 21, 2015 Brainstorm Cell Therapeutics Inc.

By: /s/ Tony Fiorino, MD, PhD
Tony Fiorino, MD, PhD
Chief Executive Officer