BRAINSTORM CELL THERAPEUTICS INC.
Form 8-K
June 02, 2014

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): June 1, 2014

Brainstorm Cell Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-54365**	**20-8133057**
(State or other jurisdiction of incorporation)	*(Commission File No.)*	*(IRS Employer Identification No.)*

605 Third Avenue, 34th Floor
New York, NY **10158**
(Address of principal executive offices) *(Zip Code)*

(646) 666-3188

(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure

On June 2, 2014, Brainstorm Cell Therapeutics Inc. (the "Company") announced that interim results from the Company's Phase IIa ALS trial conducted at Hadassah Medical Center in Jerusalem, Israel were presented on June 1, 2014 at the Joint Congress of European Neurology by Principal Investigator Professor Dimitrios Karussis. The positive safety and preliminary efficacy results observed in this study are consistent with results observed in the Company's previous Phase I/II trial. Between these two studies, a total of 26 patients have been treated with NurOwn™, the Company's stem cell therapy candidate for ALS.

Prof. Karussis summarized the results from both phases of the ALS clinical trial, and presented an interim analysis of the data for the first 10 out of 14 patients in the current Phase IIa trial. Results from the last four patients will be analyzed following completion of their six month follow-up period. In all 26 patients who received NurOwn™ in the two trials, no treatment-related serious adverse events were observed. In the three month pre-treatment "run-in" period, 71% of the patients showed progression of disease with decline in neurological function. In contrast, in the three months post-transplantation with NurOwn™, 63% of the patients who received intrathecal (IT), or combined (IT) and intramuscular (IM) administration, showed stabilization or improvement in neurological function, as measured by their revised ALS functional rating score (ALSFRS-R). According to Prof. Karussis, these differences in the preliminary analysis were statistically significant at p=0.035, chi-square test.

Additionally, as Prof. Karussis discussed during his presentation, in both phases of the trial, 63% of the patients treated with NurOwn™ via IT or combined IT and IM administration were defined as "responders" (slower progression of disability or improvement in their neurological function) at 3 months post-treatment, based on both their ALSFRS-R score and Forced Vital Capacity (FVC), an indication of respiratory function. The six patients treated with NurOwn™ in the earlier Phase I/II trial via IM administration only, primarily exhibited a localized positive effect. Similarly, in the same Phase I/II trial, the IT transplanted patients also showed indications of neurotrophic and regenerative effects, as evidenced by an increase in Compound Muscle Action Potential (CMAP) in the treated arm.

On June 2, 2014, the Company issued a press release announcing the interim results presented by Prof. Karussis.

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

The exhibit listed in the Exhibit Index below is filed with this report.

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.

June 2, 2014 Brainstorm Cell Therapeutics Inc.

By: /s/ Chaim Lebovits
Chaim Lebovits
President

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated June 2, 2014