

BRAINSTORM CELL THERAPEUTICS INC.

Form 8-K

September 27, 2013

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): September 27, 2013

Brainstorm Cell Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

000-54365

(Commission File No.)

20-8133057

(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:

☐ 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

Brainstorm Cell Therapeutics Inc. (the “Company”) recently completed treatment of the 12 patients in its ALS Phase IIa dose-escalating clinical trial (the “Clinical Trial”) with the Company’s NurOwn™ technology. The complete and final statistical analysis of the data is expected to be available after 6 months of follow up with the patients. The Company has been informed that one patient in the study expired due to a medical condition unrelated to the Clinical Trial.

The Clinical Trial is being performed at Hadassah Medical Center in Jerusalem, Israel, under the direction of Prof. Dimitrios Karussis, M.D., Ph.D., head of Hadassah's Multiple Sclerosis Center and a member of the International Steering Committees for Bone Marrow and Mesenchymal Stem Cells Transplantation in Multiple Sclerosis (MS). The study is designed to establish the safety and preliminary efficacy of NurOwn at increasing dosages.

For logistical reasons, the Company's upcoming multi-center Phase II clinical trial in the US is expected to begin, subject to FDA approval, in the first quarter of 2014, instead of late 2013 as the Company reported previously.

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.

September 27, 2013 Brainstorm Cell
Therapeutics Inc.

By: /s/ Chaim Lebovits
Chaim Lebovits
President