

BRAINSTORM CELL THERAPEUTICS INC.

Form 8-K

March 12, 2019

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): March 12, 2019

Brainstorm Cell Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-36641

(Commission File No.)

20-7273918

(IRS Employer Identification No.)

3 University Plaza Drive, Suite 320

Hackensack, NJ 10019

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01

Regulation FD Disclosure

The Hospital Exemption described in Item 8.01 below and other business matters will be discussed on a conference call to be hosted by the Company today, March 12th, at 08:30 a.m. Eastern Daylight Time. The conference call information is as follows:

Tuesday, March 12, 2018 @ 8:30 a.m. Eastern Daylight Time

US Toll Free: 1-877-423-9813

Toll/International: 1-201-689-8573

Israel Toll Free: 1-809-406-247

Webcast Audio Link: <https://goo.gl/tG7DYn>

Replay Dial-In Numbers

US Toll Free: 1-844-512-2921

Toll/International: 1-412-317-6671

Replay Pin Number: 13688535

Replay Expiry: Tuesday, March 26, 2019, 11:59 p.m.

All information contained in this Item 7.01 of this Form 8-K shall not be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference to such filing. The information in this Item 7.01 shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended.

Item 8.01. Other Events.

In 2017, the Company submitted an application in Israel that would allow amyotrophic lateral sclerosis (“ALS”) patient access to NurOwn® under the Hospital Exemption Pathway (“HE”). This application was recently approved by the

Israeli Ministry of Health (“MOH”), as notified by our partner Tel Aviv Sourasky Medical Center (Ichilov), to support the treatment of 13 ALS patients with NurOwn®.

HE allows for advanced therapy medicinal products, such as NurOwn®, to be made available to a group of patients where there is a critical unmet need and an absence of effective therapeutic alternatives, as agreed upon by the MOH. To qualify for HE, several important criteria must be met, including: product preparation according to specific quality standards (equivalent to those for a licensed product); use in a qualified hospital setting; and administered under the exclusive responsibility of an experienced medical practitioner. The Helsinki Committee at Ichilov, which is composed of bioethicists and other leaders from the Scientific and Medical Community, determined the final inclusion and exclusion guidelines to support HE ALS patient access for NurOwn®. Helsinki is equivalent to the Institutional Review Board (IRB).

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.

By: /s/ Chaim Lebovits

Date: March 12, 2019 Chaim Lebovits

Chief Executive Officer and President