

Karyopharm Therapeutics Inc.
Form 8-K
March 15, 2019

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 14, 2019

Karyopharm Therapeutics Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

001-36167
(Commission
File Number)

26-3931704
(IRS Employer
Identification No.)

85 Wells Avenue, 2nd Floor
Newton, Massachusetts
(Address of Principal Executive Offices)

02459
(Zip Code)

Registrant's telephone number, including area code: **(617) 658-0600**

(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 8.01. Other Events.

On March 14, 2019, Karyopharm Therapeutics Inc. (the Company) issued a press release announcing that the U.S. Food and Drug Administration (FDA) extended from April 6, 2019 until July 6, 2019 the Prescription Drug User Fee Act (PDUFA) action date for the Company's new drug application (NDA) seeking accelerated approval for selinexor in combination with dexamethasone for the treatment of patients with relapsed refractory multiple myeloma who have received at least three prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one anti-CD38 monoclonal antibody. The Company submitted additional, existing clinical information as an amendment to the NDA, which allowed the FDA to extend the PDUFA action date by three months.

A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release issued by Karyopharm Therapeutics Inc. on March 14, 2019

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.

KARYOPHARM THERAPEUTICS INC.

Date: March 15, 2019

By: /s/ Christopher B. Primiano

Christopher B. Primiano
Executive Vice President, Chief Business

Officer, General Counsel and Secretary