

Karyopharm Therapeutics Inc.
Form 8-K
October 12, 2017

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): October 11, 2017

Karyopharm Therapeutics Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

85 Wells Avenue, 2nd Floor

001-36167
(Commission

File Number)

26-3931704
(IRS Employer

Identification No.)

02459

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Newton, Massachusetts

(Address of Principal Executive Offices)

(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 1.01. Entry into a Material Definitive Agreement.

Effective October 11, 2017, Karyopharm Therapeutics Inc. (the *Company*) entered into a License Agreement (the *Agreement*) with Ono Pharmaceutical Co., Ltd., a corporation organized and existing under the laws of Japan (*Ono*), pursuant to which the Company granted Ono exclusive rights to develop and commercialize, at its own cost, selinexor (KPT-330), the Company's lead, novel, oral Selective Inhibitor of Nuclear Export (SINE) compound, as well as KPT-8602, the Company's second-generation oral SINE compound, for the diagnosis, treatment and/or prevention of all human oncology indications (the *Field*) in Japan, Republic of Korea, Republic of China (Taiwan) and Hong Kong as well as in the ten Southeast Asian countries currently comprising the Association of Southeast Asian Nations (the *Ono Territory*). In addition, upon Ono's election and the parties' full execution of a manufacturing technology transfer plan and satisfaction of other specified conditions (the *Manufacturing Election*), the Company will grant to Ono non-exclusive rights to manufacture selinexor, KPT-8602 and products containing such compounds in or outside of the Ono Territory solely for development and commercialization in the Field in the Ono Territory.

Under the terms of the Agreement, the Company will receive an upfront cash payment of ¥2.5 billion (US\$22.3 million), and the Company retains all rights to selinexor and KPT-8602 outside the Ono Territory. The Company is entitled to receive up to ¥10.15 billion (US\$90.5 million at the current exchange rate) in milestone payments from Ono if certain development goals are achieved and up to ¥9.0 billion (US\$80.2 million at the current exchange rate) in milestone payments from Ono if certain sales milestones are achieved. The Company is further eligible to receive royalties in the low double digits based on future net sales of selinexor and KPT-8602 in the Ono Territory, subject to certain customary adjustments.

The Company is responsible for conducting certain development activities and ongoing clinical trials involving selinexor and KPT-8602 at its own cost and expense. The Company expects to continue all ongoing clinical trials involving selinexor and KPT-8602 as they are currently being conducted. As part of the Agreement, Ono will also have the right to participate in global clinical studies of selinexor and KPT-8602, and will bear the cost and expense for patients enrolled in clinical studies in the Ono Territory. Ono is responsible for seeking regulatory and marketing approvals for selinexor and KPT-8602 in the Ono Territory, as well as any development of the products specifically necessary to obtain such approvals. Ono is also responsible for the commercialization of products containing selinexor or KPT-8602 in the Field in the Ono Territory at its own cost and expense.

Subject to Ono's Manufacturing Election, the Company will furnish clinical supplies of drug substance to Ono for use in Ono's development efforts pursuant to a clinical supply agreement to be entered into by the Company and Ono, and Ono may elect to have the Company provide commercial supplies of drug product to Ono pursuant to a commercial supply agreement to be entered into by the Company and Ono, in each case the costs of which will be borne by Ono.

Each party has also agreed to indemnify the other party from certain liabilities specified in the Agreement.

The Agreement will continue in effect on a product-by-product, country-by-country basis until the later of the tenth anniversary of the first commercial sale of the applicable product in such country or the expiration of specified patent protection and regulatory exclusivity periods for the applicable product in such country. However, the Agreement may be terminated earlier by (i) either party for breach of the Agreement by the other party or in the event of the insolvency or bankruptcy of the other party, (ii) Ono on a product-by-product basis for certain safety reasons or on a product-by-product, country-by-country basis for any reason with 180 days' prior notice or (iii) the Company in the event Ono challenges or assists with a challenge to certain of the Company's patent rights.

As previously disclosed by the Company in its Annual Report on Form 10-K for the year ended December 31, 2016, the Company is a party to a research agreement with the Multiple Myeloma Research Foundation, or MMRF. Under this research agreement, the Company is obligated to make certain payments to MMRF, including if the Company out-licenses selinexor. The terms of this research agreement do not apply to KPT-8602. In connection with the transactions contemplated under the Agreement, the Company expects that it will be obligated to pay to MMRF

approximately ¥225 million (approximately US\$2.0 million) of the upfront cash payment from Ono, as well as a percentage of any milestone payments from Ono and a mid-single-digit percentage of any royalty payments from Ono. The maximum aggregate amount the Company may be obligated to pay to MMRF under the research agreement is \$6.0 million.

The Company expects to file the Agreement as an exhibit to its Annual Report on Form 10-K for the year ending December 31, 2017. The foregoing description of certain terms of the Agreement is intended to be a summary of the material terms and is qualified in its entirety by reference to the text of the Agreement when filed.

A copy of the Company's press release announcing the entry into the Agreement 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

Exhibit

Number	Description of Exhibit
99.1	<u>Press release issued by Karyopharm Therapeutics Inc. on October 12, 2017</u>

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: October 12, 2017

By: /s/ Christopher B. Primiano
Christopher B. Primiano
Senior Vice President, Operations, Business
Development, General Counsel and Secretary