EAGLE PHARMACEUTICALS, INC.
Form 8-K
September 26, 2017

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 20, 2017**

Eagle Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36306**	**20-8179278**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

50 Tice Boulevard, Suite 315	
Woodcliff Lake, NJ	**07677**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: **(201) 326-5300**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company o

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. o

Item 1.01 Entry into a Material Definitive Agreement

License Agreement

On September 20, 2017, Eagle Pharmaceuticals, Inc. (the Company) entered into a Product Collaboration and License Agreement, effective as of September 19, 2017, (the License Agreement) with SymBio Pharmaceuticals Limited (SymBio) for the rights to develop and commercialize the Company s bendamustine hydrochloride ready-to-dilute (RTD) injection product and rapid infusion (RI) injection product (collectively, the Products) in Japan. Under the License Agreement, SymBio will be responsible for all development of the Products in Japan and for obtaining and maintaining all regulatory approvals of the Products in Japan, with a target for regulatory approval of a Product in Japan in 2020. SymBio will bear all costs of development of the Products in Japan except that, if Japanese regulatory authorities require a certain clinical study to be conducted as a condition for approving one of the Products in Japan, Eagle will share 50% of the out-of-pocket costs of that clinical study up to a specified dollar amount. SymBio will also be responsible, at its sole cost, for all marketing, promotion, distribution and sales of the Products in Japan and is obligated to launch the Products and meet certain minimum detailing, promotion and marketing commitments in connection with commercialization of the Products in Japan.

SymBio currently markets in Japan TREAKISYM®, a lyophilized powder formulation of bendamustine hydrochloride indicated for chronic lymphocytic leukemia (CLL), relapsed or refractory low-grade Hodgkin s lymphoma (NHL), mantle cell lymphoma (MCL), and as a first line treatment of low-grade NHL and MCL. Under the License Agreement, SymBio may continue to market TREAKISYM® in Japan and SymBio will be permitted to develop and market certain other bendamustine hydrochloride products in Japan for limited indications.

Pursuant to the terms of the License Agreement, the Company and SymBio will enter into a separate supply agreement, under which the Company will be responsible for manufacturing and supplying the Products to SymBio for development and commercialization in Japan. After a period of time following launch of a Product, SymBio will have the right to assume the responsibility for manufacturing of the Products in and for Japan. Under the License Agreement, the Company will retain the right to control the prosecution, maintenance and enforcement of the Company s patents covering the Products, both inside and outside of Japan.

Under the License Agreement, the Company will receive an upfront cash payment of $12.5 million, and is eligible to receive a milestone payment upon approval of a Product in Japan and a milestone payment upon achievement of certain cumulative net sales of the Products in Japan. After regulatory approval of a Product in Japan, the Company will also receive tiered, low double-digit royalties on net sales of the Products in Japan for so long as there are patents covering the Products in Japan or regulatory exclusivity for the Products in Japan.

Pursuant to the terms of the License Agreement, SymBio will have the right to terminate the License Agreement for any reason (without cause) following certain notice. The Company will have the right to terminate the License Agreement if SymBio fails to conduct material development or commercialization of the Products over a certain time period, or if SymBio challenges any of the Company s patents covering the Products. In addition, the Company and SymBio will each have the right to terminate the License Agreement in the event of the other party s material breach and failure to cure, or, under certain circumstances, in the event of the other party s bankruptcy or violation of anti-corruption laws.

The foregoing description of the material terms of the License Agreement does not purport to be complete and is subject to, and is qualified in its entirety by, reference to the full terms of the License Agreement, which the Company intends to file as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2017. The Company intends to seek confidential treatment for certain portions of the License Agreement pursuant to a confidential treatment request to be submitted to the U.S. Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

Item 7.01 **Regulation FD Disclosure.**

The Company will present the attached presentation of the Company s business model, products and product candidates to various investors from time to time.

A copy of the above referenced presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information furnished pursuant to Item 7.01 of this current report, including Exhibit 99.1, shall not be deemed to be filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended. As such, this information shall not be incorporated by reference into any of the Company s reports or other filings made with the Securities and Exchange Commission. The furnishing of the information in this current report is not intended to, and does not, constitute a determination or admission by the Company that the information in this current report is material or complete, or that investors should consider this information before making an investment decision with respect to any security of the Company.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits

Exhibit No.	Description
99.1	Presentation of the Company dated September 2017

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.

Eagle Pharmaceuticals, Inc.

Dated: September 26, 2017

By: /s/ Scott Tarriff
Scott Tarriff
Chief Executive Officer