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): **December 13, 2019**

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:

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common Stock (par value $0.001 per share)	EGRX	The Nasdaq Global Market

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 ☐

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 Definitive Material Agreement.

Settlement Agreement with Eli Lilly and Company

On December 13, 2019, or the Effective Date, Eagle Pharmaceuticals, Inc., or the Company, entered into a definitive settlement agreement, or the Settlement Agreement, with Eli Lilly and Company, or Lilly, relating to the Company's product PEMFEXY™ (pemetrexed for injection), a branded alternative to ALIMTA®. The Settlement Agreement provides for the settlement of litigation between the Company and Lilly, or the Parties, relating to (i) the alleged infringement of Orange Book listed United States Patent No. 7,772,209, or the Asserted Lilly Patent, with respect to the Company's 505(b)(2) New Drug Application, or NDA, No. 209472, submitted to the U.S. Food and Drug Administration, or FDA, seeking approval for the manufacture and sale in the United States of generic pemetrexed for injection in a 25 mg/mL, 500 mg vial product, or the Eagle NDA, and the NDA product that is the subject of the Eagle NDA, or the Eagle Product, and (ii) the alleged anticompetitive behavior by Lilly with respect to the Asserted Lilly Patent. The Settlement Agreement includes the following terms:

Settlement of Patent Infringement and Antitrust Lawsuits and Antitrust Review

Within three business days after the Effective Date, the Parties will file Stipulations of Dismissal to dismiss all claims and defenses with prejudice in relation to litigation between the Parties in United States District Court for the District of Delaware, or the Court, namely (i) Civil Action No. 1:17-cv-01293-MSG, or the Patent Infringement Lawsuit, concerning the alleged infringement by the Company of the Asserted Lilly Patent, resulting from the filing by the Company of the Eagle NDA, the related certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), and a related Company allegation that the Asserted Lilly Patent's Patent Use Code U-1296 is incorrect, and (ii) Civil Action No. 1:18-cv-01121-MSG, or the Antitrust Lawsuit, concerning an alleged antitrust violation by Lilly with respect to the Asserted Lilly Patent and its Patent Use Code listing in the Orange Book. The entry of the Parties' Stipulation of Dismissal in the Patent Infringement Lawsuit will terminate the 30-month stay of approval of the Eagle NDA that was previously put into effect.

In addition, within ten business days after the Effective Date, the Parties will submit the Settlement Agreement to the U.S. Federal Trade Commission and U.S. Department of Justice for federal antitrust review.

Mutual Release and Covenant Not to Sue

The Parties each release the counterparty from any and all claims relating to (i) the Eagle Product and the Eagle NDA or its filing, (ii) the Asserted Lilly Patent and any other patents owned or controlled by Lilly or its affiliates that are listed now or in the future in the Orange Book as covering products, or the Licensed Patents, under Lilly's NDA No. 021462, or the Lilly NDA, and any other patents or patent applications owned or controlled or licensed, now or in the future, by Lilly or any of its affiliates that claim or cover the making, using, selling, offering for sale or importation of the Eagle Product, or the Other Lilly Patents, in or for the United States, its territories, possessions, protectorates, and the Commonwealth of Puerto Rico, or collectively, the Territory, or (iii) the Patent Infringement Lawsuit.

Lilly and its affiliates also covenant not to sue, or support or encourage any third party to sue, for infringement of the Licensed Patents or Other Lilly Patents with respect to Company's or its affiliates' or its sublicensee (i) making, having made, using, selling, offering for sale, distributing and importation of the Eagle Product in or for the Territory as of and following the Effective Date pursuant to the terms of the Settlement Agreement; and (ii) maintaining with the FDA a "Paragraph IV Certification" for the Eagle NDA under 21 U.S.C. § 355(b)(2)(A)(iv). The Settlement Agreement also provides that (i) the Company covenants not to challenge the Licensed Patents, (ii) Lilly waives, as to the Eagle NDA only, any regulatory exclusivity awarded to Lilly relating to pemetrexed, and (iii) Lilly consents to final FDA approval of the Eagle NDA.

Limited License and Pre-Marketing Rights

Lilly and its affiliates grant to the Company and its affiliates a non-transferable, non-exclusive license under the Licensed Patents to manufacture, have manufactured, use, sell, offer to sell, and import the Eagle Product in the Territory as of and following the effective date of the license, provided that such license to sell shall be limited to not more than nineteen thousand two hundred (19,200) vials of Eagle Product in the Territory prior to April 1, 2022, but will be unlimited thereafter. The material terms of the Settlement Agreement provide that the effective date of the license will be February 1, 2022. The Company does not have any rights to sublicense its rights under this license except to an exclusive sublicensee.

The Settlement Agreement also grants the Company certain pre-marketing rights to engage in discussions with potential customers to make them aware of the upcoming availability of the Eagle Product in the Territory.

Royalty Payments

During the Royalty Term, the Company shall pay to Lilly a royalty of 1.0% of the net sales of the Eagle Product during each of the four thirteen-week periods commencing on January 1 of any calendar year. The Royalty Term means the period commencing on the effective date of the license and ending upon the earliest to occur of the following: (i) the date of a final court decision in favor of a third party holding all of the then adjudicated claims of the Asserted Lilly Patent to be invalid, non-infringed and/or unenforceable; (ii) the date of expiration, disclaimer, abandonment, cancellation, or dedication to the public of the Asserted Lilly Patent with surviving patent term and any regulatory exclusivity attached thereto; and (iii) May 24, 2022.

The foregoing description of the Settlement Agreement does not purport to be complete and is subject to, and is qualified in its entirety by, reference to the complete text of the Settlement Agreement, which the Company intends to file as an exhibit to the Company's Annual Report on Form 10-K for the year ending December 31, 2019.

Safe Harbor for Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking information within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other securities laws. Forward-looking statements are statements that are not historical facts. Words and phrases such as "anticipated," "forward," "will," "would," "may," "remain," "potential," "prepare," "expected," "believe," "plan," "near future," "belief," "guidance," and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding future events including, but not limited to: the outcome of the review by the U.S. Department of Justice and the Federal Trade Commission of the settlement agreement; anticipated timing of final approval of the PEMFEXY NDA by the U.S. Food and Drug Administration, if at all; the timing of Company's PEMFEXY launch; and the success, if any, of the Company's marketing and sales efforts regarding PEMFEXY. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the Company's control, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and the Company does not undertake any obligation to revise and disseminate forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of or non-occurrence of any events.

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: December 19, 2019

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