

**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): **July 9, 2018**

**Eagle Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction  
of incorporation)

**001-36306**

(Commission File Number)

**20-8179278**

(IRS Employer Identification No.)

**50 Tice Boulevard, Suite 315  
Woodcliff Lake, NJ**

(Address of principal executive offices)

**07677**

(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))

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 8.01 Other Events.**

On July 9, 2018, Eagle Pharmaceuticals, Inc., or the Company, issued a press release announcing that (i) consistent with the order issued by the U.S. District Court for the District of Columbia, or the Court, the U.S. Food and Drug Administration, or the FDA, has granted seven years of orphan drug exclusivity in the U.S., for BENDEKA™ (bendamustine hydrochloride injection, or bendamustine HCl), a liquid, low-volume (50 mL) and short-time 10-minute infusion formulation of bendamustine hydrochloride, and (ii) the FDA filed a motion with the Court asking the Court to clarify that the order was not intended to affect applications referencing TREANDA®.

A copy of the full text of the press release referenced above 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 No.	Description
99.1	<a href="#">Press Release dated July 9, 2018</a>

**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: July 9, 2018

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

**For Immediate Release****FDA Grants Eagle Seven Year Orphan Drug Exclusivity for BENDEKA (bendamustine hydrochloride injection)**

**WOODCLIFF LAKE, N.J. — July 9, 2018** — Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) (“Eagle” or the “Company”) announced today that the U.S. Food and Drug Administration (FDA) has granted seven years of orphan drug exclusivity (ODE) in the U.S., for BENDEKA™ (bendamustine hydrochloride injection, or bendamustine HCl), a liquid, low-volume (50 mL) and short-time 10-minute infusion formulation of bendamustine hydrochloride.

As a result, and consistent with the order issued by the U.S. District Court for the District of Columbia (the Court) on June 8, 2018, the FDA will not approve any drug applications referencing BENDEKA until the ODE expires in December 2022. Additionally, on July 7, 2018, the FDA filed a motion with the Court asking it to clarify that the order was not intended to affect applications referencing TREANDA®. Eagle continues to believe that an appropriate application of ODE would first allow generic TREANDA entrants in December 2022, rather than November 2019, and expects to vigorously defend the scope of its exclusivity grant.

**About Eagle Pharmaceuticals, Inc.**

Eagle is a specialty pharmaceutical company focused on developing and commercializing injectable products that address the shortcomings, as identified by physicians, pharmacists and other stakeholders, of existing commercially successful injectable products. Eagle’s strategy is to utilize the FDA’s 505(b) (2) regulatory pathway. Additional information is available on the company’s website at [www.eagleus.com](http://www.eagleus.com).

**Eagle’s Forward-Looking Statements:**

This press release 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 such as “likely,” “will,” “may,” “can,” “could be,” “believe,” “intends,” “anticipate(s),” “plan,” “enables,” “potentially,” “entitles,” and similar expressions are intended to identify forward-looking statements. These statements include statements regarding future events including, but not limited to: the FDA’s ability to approve any drug applications referencing BENDEKA prior to December 2022; the Court’s response to the FDA’s motion; the ability of generic TREANDA products to enter the market prior to 2022; Eagle’s market protection for BENDEKA; successful compliance with FDA and other governmental regulations; and other factors that are discussed in Eagle’s Annual Report on Form 10-K for the year ended December 31, 2017, and its other filings

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with the U.S. Securities and Exchange Commission. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond Eagle’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. Such risks include, but are not limited to: whether Eagle’s management and/or board of directors will be effective in managing Eagle’s business, future growth and market protection, including with respect to BENDEKA; the Court’s response to the FDA’s motion; whether Eagle will maintain successful compliance with FDA and other governmental regulations; as well as the other risks described in Eagle’s filings with the U.S. Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and we do 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.

**Contact:****Investor Relations for Eagle Pharmaceuticals, Inc:**

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