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): **February 2, 2021**

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 Stock Market LLC

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 February 2, 2021, Eagle Pharmaceuticals, Inc., or the Company, issued a press release announcing that it has received a Complete Response Letter from the U.S. Food and Drug Administration regarding the Company's Abbreviated New Drug Application for vasopressin.

The Company also announced that the vasopressin trial between the Company and Endo Par Innovation Company, LLC, et al. is now scheduled to begin on July 7, 2021.

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	Press Release of the Company dated February 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Dated: February 2, 2021

EAGLE PHARMACEUTICALS, INC.

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

Exhibit 99.1

For Immediate Release

Eagle Pharmaceuticals Receives Additional FDA Questions Regarding Vasopressin; Court Date Set for July 7, 2021 in Vasopressin Trial

-Company Expects It Will Have 180 Days of Exclusivity-

WOODCLIFF LAKE, N.J. — February 2, 2021 — Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that the U.S. Food and Drug Administration ("FDA") has issued a complete response letter ("CRL") for its Abbreviated New Drug Application ("ANDA") for vasopressin. Eagle has now had two conversations with FDA regarding the CRL and will have an additional meeting with FDA within 30 days. Importantly, Eagle has completed an extensive amount of developmental work and continues to do so for its first-to-file polypeptide, where brand sales of the product are over $700 million annually. In its communication with the Company, FDA restated that it has prioritized Eagle's ANDA, and it is also flagged as a COVID priority.

Eagle believes it can fully respond to the questions raised. There is one additional short duration study that will need to be completed and analyzed. The study will be run either in mid-February or mid-March. Based on similar studies previously run on the Company's vasopressin product, Eagle expects the results will be satisfactory. In addition, the Company expects it will have 180 days of exclusivity.

Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals, stated, "Eagle is aligned with FDA in its desire to approve products that meet all possible safety concerns, especially polypeptides like vasopressin that may be administered to COVID patients. Although this adds some time and cost, we believe all ANDA holders are likely to be held to the same high standards. We will be meeting again with FDA and will respond completely to the CRL shortly."

In other vasopressin news, the patent case against Endo Par Innovation Company, LLC is now scheduled to begin on July 7, 2021. Eagle remains confident about this litigation. Par's asserted patents claim a formulation with a pH of 3.7-3.9. Eagle's proposed ANDA product specifies a pH outside of that range. The Company is confident that its ANDA will be approved in a reasonable timeframe.

"We look forward to being able to continue to show the strength of our positions regarding Endo's patents in court and hope to bring this very important, lower price, high-quality product to market as soon as possible," concluded Tarriff.

About Eagle Pharmaceuticals, Inc.

Eagle is a fully integrated pharmaceutical company with research and development, clinical, manufacturing and commercial expertise. Eagle is committed to developing innovative medicines that result in meaningful improvements in patients' lives. Eagle's commercialized products include RYANODEX®, BENDEKA®, BELRAPZO®, and its oncology and CNS/metabolic critical care pipeline includes product candidates with the potential to address underserved therapeutic areas across multiple disease states. Additional information is available on Eagle's website at www.eagleus.com.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other securities law. 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 concerning the Company's ability to address the questions raised in the CRL for its ANDA for vasopressin and to communicate with FDA regarding the same; the Company's ability to obtain and maintain regulatory approval of its products and product candidates, including vasopressin; the timing, progress and results of the Company's clinical trials, including the additional short duration study with respect to vasopressin; the period of market exclusivity for vasopressin; and the status and timing of pending or future litigation and the strength of the Company's position in any such litigation, including the litigation between the Company and Endo Par Innovation Company, LLC, et al. with respect to vasopressin. 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. Such risks and uncertainties include, but are not limited to: the impacts of the ongoing COVID-19 pandemic, including interruptions or other adverse effects on clinical trials and delays in regulatory review or further disruption or delay of any pending or future litigation; delay in or failure to obtain regulatory approval of the Company's product candidates and successful compliance with FDA and other governmental regulations applicable to product approvals; whether the Company will successfully implement its development plan for its product candidates; whether the Company can successfully market and commercialize its product candidates; the outcome of litigation involving any of its products or that may have an impact on any of its products; the strength and enforceability of the Company's intellectual property rights or the rights of third parties; the risks inherent in drug development and in conducting clinical trials; and those risks and uncertainties identified in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed with the Securities and Exchange Commission on March 2, 2020 as updated by its Quarterly Reports on Form 10-Q for the quarters ended March 31, 2020, June 30, 2020 and September 30, 2020, filed with the SEC on May 11, 2020, August 10, 2020 and November 2, 2020, respectively, and its other subsequent filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Investor Relations for Eagle Pharmaceuticals, Inc.:

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