
**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): **June 17, 2021**

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))

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 June 17, 2021, Eagle Pharmaceuticals, Inc. issued a press release announcing that it has responded to the Complete Response Letter for its Abbreviated New Drug Application for vasopressin received from the U.S. Food and Drug Administration in February 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
<u>99.1</u>	<u>Press Release of the Company dated June 17, 2021.</u>
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: June 17, 2021

EAGLE PHARMACEUTICALS, INC.

By: /s/ Scott Tarriff

Scott Tarriff

Chief Executive Officer



For Immediate Release

Eagle Pharmaceuticals Submits Response to Complete Response Letter from FDA for Vasopressin

WOODCLIFF LAKE, NJ—June 17, 2021—Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) (“Eagle” or the “Company”) today announced that it has responded to the Complete Response Letter (“CRL”) for its Abbreviated New Drug Application (“ANDA”) for vasopressin received from the U.S. Food and Drug Administration (“FDA”) in February 2021.

“We appreciate FDA’s insights and based on our post-CRL meeting, believe that we have now responded fully and completely to the CRL. Our ANDA is currently prioritized by FDA and also flagged as a COVID priority. We anticipate having final approval in time to launch the product this year. Vasopressin is an important program for us, with the potential to bring a great deal of value to our shareholders,” stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

Eagle is first to file an ANDA referencing Vasostriect, which had total U.S. sales of \$786 million in 2020.

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 potential timing of commercial launch of vasopressin; and the ability of the Company’s product candidates, including vasopressin, to deliver value to stockholders. 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, 2020 filed with the Securities and Exchange Commission (the “SEC”) on March 5, 2021, as updated by the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, filed with the SEC on May 10, 2021, and its other subsequent filings with the SEC. 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.:

Lisa M. Wilson
In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com
