# 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): **January 13, 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**<br>**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 7.01 Regulation FD Disclosure.**

On January 13, 2021, Eagle Pharmaceuticals, Inc., or the Company, will present the attached presentation of the Company's products and product candidates at the 39th Annual J.P. Morgan Healthcare Conference, taking place virtually on January 11-14, 2021.

A copy of the above-referenced presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The information furnished pursuant to Item 7.01 of this current report, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section, and shall not be deemed incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing. The furnishing of the information in this Current Report on Form 8-K is not intended to, and does not, constitute a determination or admission by the Company that the information in this Current Report on Form 8-K 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 January 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: January 13, 2021

**EAGLE PHARMACEUTICALS, INC.**

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

**Exhibit 99.1**

# Forward Looking Statements

This presentation 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 such as: the number and timing of potential product launches; development initiatives and potential indications for RYANODEX, including the potential for RYANODEX as a treatment for nerve agent exposure, acute radiation syndrome, traumatic brain injury and Alzheimer's disease (EA-112); the timing of potential product launches for Vasopressin and the period of market exclusivity for Vasopressin; the Company's clinical development plan for its fulvestrant product candidate, EA-114, as well as the development efforts for the other product candidates in its portfolio; the timing, scope or likelihood of regulatory filings and approvals from the FDA for the Company's product candidates, including the Company's ability to work with the FDA to finalize the Special Protocol Assessment and advance the development of RYANODEX for brain damage secondary to nerve agent exposure; the timing of the Company's PEMFEXY launch, if ever; the success of the Company's collaborations with its strategic partners and the timing and results of these partners' preclinical studies and clinical trials; and the Company's plans and ability to advance the products in its pipeline. 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 COVID-19 pandemic, including disruption or impact in the sales of the Company's marketed products; interruptions or other adverse effects to clinical trials; delays in regulatory review; manufacturing and supply chain interruptions; adverse effects on healthcare systems; disruption in the operations of the Company's third party partners and disruption of the global economy, and the overall impact of the COVID-19 pandemic on the Company's business, financial condition and results of operations; risks that the Company's business, financial condition and results of operations will be impacted by the spread of COVID-19 in the geographies where the Company's third-party partners operate; whether the Company will incur unforeseen expenses or liabilities or other market factors; risks that results from in vitro laboratory tests of RYANODEX are not necessarily predictive of future clinical trial and in vivo results; whether the Company will successfully implement its development plan for its fulvestrant product candidate, EA-114, or other product candidates; delay in or failure to obtain regulatory approval of the Company's product candidates; whether the Company can successfully market and commercialize its product candidates; the success of the Company's relationships with its partners, including the United States Army Medical Research Institute of Chemical Defense, University of Pennsylvania, Teva, Tyme, NorthShore University HealthSystem and SymBio and the parties' ability to work effectively together; the availability and pricing of third party sourced products and materials; the outcome of litigation involving any of the Company's products or that may have an impact on any of the Company's products; successful compliance with the FDA and other governmental regulations applicable to product approvals, manufacturing facilities, products and/or businesses; general economic conditions, including the potential adverse effects of public health issues, including the COVID-19 pandemic, on economic activity and the performance of the financial markets generally; the strength and enforceability of the Company's intellectual property rights or the rights of third parties; competition from other pharmaceutical and biotechnology companies and the potential for competition from generic entrants into the market; the risks inherent in the early stages of drug development and in conducting clinical trials; and those risks and uncertainties identified in the "Risk Factors" sections of the Company's Annual Report on Form 10-K for the year ended December 31, 2019 as updated by the company's subsequent filings with the 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 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.





EAGLE PHARMACEUTICALS

# 10 Programs - Potential for 5 Launches in the Next 3 Years

| | Product | Indication | Potential Market Advantage | Development Stage | In-House/Partnership |
|---|---|---|---|---|---|
| CNS/METABOLIC CRITICAL CARE | RYANODEX* | 1. Nerve Agent (NA) Exposure | First in class | Initiating dose ranging studies in another animal model using IV administration with arm using an IM formulation of EA-111. Preliminary results expected to allow the Company to update its SPA with FDA | United States Army Medical Research Institute of Chemical Defense |
| | | 2. Acute Radiation Syndrome (ARS) | | Completed POC study; entering first of two registration animal studies under FDA Animal Rule; next, Eagle expects to conduct a GLP study in a validated animal model | EAGLE (in-house) |
| | | 3. Traumatic Brain Injury (TBI)/Concussion | | Preclinical animal study in progress; expect study results with NorthShore University HealthSystem in 1H 2021 | NorthShore University HealthSystem Dr. Julian Bailes |
| | | 4. Alzheimer's Disease (AD) | | Completed preclinical animal study | EAGLE University of Pennsylvania |
| | | 5. Anti-viral | | Preclinical | EAGLE (in-house) |
| | EA-111 | 6. NCE related to dantrolene | | Preclinical and toxicology studies in progress | EAGLE (in-house) |
| | VASOPRESSIN* | 7. Increase blood pressure during vasodilatory shock | First to file† | Submitted responses to all of FDAs outstanding questions; patent trial date now set for February 1, 2021; anticipate launch with 180-day market exclusivity | EAGLE (in-house) |
| ONCOLOGY | SM-88 | 8. Pancreatic and Other Cancers | First in Class | Pivotal studies underway for pancreatic cancer | TYME Tyme Technologies |
| | EA -114 (fulvestrant) | 9. HR+/HER2- Advanced Breast Cancer (BC) | Best in Class | Held positive Type C meeting with FDA; in process of gaining agreement on formal clinical study protocol | EAGLE (in-house) |
| | PEMFEXY* (liquid injection) | 10. Nonsquamous Non-Small Cell Lung Cancer (NSCLC) – malignant pleural mesothelioma | First to Market | Approval granted on February 10, 2020; Q1 2022 launch; unique J-code established by CMS; granted supplement approval for 500mg multiple-dose vial | EAGLE (in-house) |

* Royalty obligation
† First to file ANDA referencing VASOSTRICT; submission accepted for filing by FDA March 2018





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Thank You