# 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): **August 5, 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**<br>**Woodcliff Lake, NJ**<br>(Address of principal executive offices) | **07677**<br>(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 o

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. o

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 |

**Item 7.01 Regulation FD Disclosure.**

On August 5, 2019, Eagle Pharmaceuticals, Inc., or the Company, issued a press release announcing a clinical development plan to support the submission of a New Drug Application for the Company's fulvestrant formulation.

A copy of the above-referenced press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information furnished pursuant to Item 7.01 of this current report, including Exhibit 99.1, shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended. As such, this information shall not be incorporated by reference into any of the Company's reports or other filings made with the Securities and Exchange Commission. 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 | Press Release of the Company dated August 5, 2019 |

**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: August 5, 2019

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

**Exhibit 99.1**

**For Immediate Release**

**Eagle Pharmaceuticals Announces Clinical Development Plan of Innovative Product Intended to Deliver Maximum Estrogen Receptor Inhibition in Patients with Estrogen Receptor (ER)-Positive Breast Cancer**

— Eagle plans to conduct a Pilot Study shortly followed by a Pivotal Trial —

— Pivotal Trial expected to be completed within approximately 12 months of commencing enrollment —

WOODCLIFF LAKE, NJ—August 5, 2019 — Eagle Pharmaceuticals, Inc. ("Eagle" or the "Company") (Nasdaq: EGRX) today announced a clinical development plan to support the submission of a New Drug Application (NDA) for the Company's innovative fulvestrant formulation. Fulvestrant, an estrogen receptor antagonist with no agonist properties, is approved by the U.S. Food and Drug Administration (FDA) for the treatment of advanced hormone-related breast cancers. The therapeutic effect of fulvestrant relies on its ability to inhibit estrogen receptors (ER) in cancer cells by binding to and downregulating, or blocking, the ER in breast cancer cells. Recent studies have shown that higher residual ER availability is associated with early disease progression.

Eagle's original formulation of fulvestrant was studied in a clinical trial conducted in 2018 in healthy post-menopausal women. The study was conducted in 600 subjects over 140 days; 300 subjects received the branded product FASLODEX® and 300 subjects received Eagle's formulation. A detailed review of the study data led to the hypothesis that the unique properties of Eagle's formulation would potentially allow for greater inhibition of estrogen receptors. Based on this hypothesis, Eagle has recently completed additional work designed to further enhance its proprietary drug formulation.

In March and June 2019, Eagle met with the FDA and mutually agreed to a clinical program that could provide an efficient approval pathway for the Company's fulvestrant formulation. The main goal of the clinical research program is to determine if the unique properties of Eagle's fulvestrant formulation will result in greater inhibition of estrogen receptors, potentially leading to improved efficacy outcomes, including lower disease progression rates, compared to current treatment options.

Eagle intends to begin a pilot study shortly in healthy female volunteers to evaluate the pharmacokinetics and safety of its novel formulation. Once the pilot study results are reviewed, a clinical pivotal trial designed to evaluate fulvestrant exposure and estrogen receptor inhibition based upon the parameters determined with the FDA will be conducted in a target patient population. Depending on recruitment rates and other factors, Eagle believes the pivotal study could be completed within approximately 12 months of commencing enrollment.

"The opportunity to develop a new treatment option that has the potential to better address the epidemic of breast cancer affecting millions of women in the U.S. and worldwide is an important priority for Eagle.

Following a thorough review of the data from our previous study, we believe that our fulvestrant product has a unique profile that may allow it to achieve a greater level of estrogen receptor inhibition, and we are encouraged by the guidance provided by FDA to develop a clinical path to further explore the potential of our novel formulation. If successful, the Eagle product could provide a meaningful improvement and a new option to treat this breast cancer patient population," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

Breast cancer is the most commonly diagnosed cancer in women, with more than 2.8 million breast cancer survivors in the U.S. today; approximately 290,000 women are diagnosed in the U.S. annually. Hormone receptor-positive (HR+) breast cancer is the most common clinical subtype, with the estrogen receptor (ER) being expressed in approximately 70% of those diagnosed.

**About Fulvestrant**

Fulvestrant is indicated as a monotherapy treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy, or HR-positive advanced breast cancer in postmenopausal women with disease progression following endocrine therapy, or as a combination therapy for the treatment of: (1) HR-positive, HER2-negative advanced or metastatic breast cancer in postmenopausal women in combination with ribociclib as initial endocrine based therapy or following disease progression on endocrine therapy, or (2) HR-positive, HER2-negative advanced or metastatic breast cancer in combination with palbociclib or abemaciclib in women with disease progression after endocrine therapy.

**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.

**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 and phrases such as "will," "expected," "we believe," "committed," "plan," "promise," "may," "enables," "potential," and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding future events, including: the Company's plans with respect to the commercial availability of fulvestrant; the Company's plans and ability to successfully develop and commercialize its novel fulvestrant formulation; the Company's intention to begin a pilot study to evaluate the pharmacokinetics and safety of its fulvestrant formulation and conduct a subsequent clinical trial, including the timing of such studies; and the efficacy of the Company's fulvestrant formulation, including the ability to achieve a greater level of estrogen receptor inhibition. All 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 the Company can

successfully advance fulvestrant for the treatment of cancer patients; whether Eagle's studies will support the safety and efficacy of fulvestrant for the treatment of cancer patients; whether the FDA will ultimately approve fulvestrant for the treatment of cancer patients; whether the Company will incur unforeseen expenses or liabilities or other market factors; the effect of competitive factors and Eagle's reactions to those factors; the pace and extent of market adoption of Eagle's products and technologies; uncertainty in the process of obtaining regulatory approval or clearance for Eagle's products; the success of Eagle's growth strategies; timing and achievement of product development milestones; the outcome of ongoing or future litigation; the impact and benefits of market development; Eagle's ability to protect its intellectual property; dependence upon third parties; unexpected new data, safety and technical issues; market conditions; other risks inherent to drug development and commercialization; and 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.

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

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