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): December 6, 2023

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** **(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 obligation 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(s)	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 December 6, 2023, Eagle Pharmaceuticals, Inc., or the Company, issued a press release announcing that its abstract, a post-hoc analysis of two multicenter, placebo-controlled, Phase III studies evaluating amisulpride (a selective dopamine D2/D3 antagonist) as an antiemetic in patients with established postoperative nausea and vomiting, has been selected for a poster presentation at the 77th PGA (PostGraduate Assembly in Anesthesiology), being held December 8-11, 2023, in New York City. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of 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 Securities Act, 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..

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release dated December 6, 2023.
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.

Date: December 6, 2023

EAGLE PHARMACEUTICALS, INC.

By: /s/ Brian Cahill
Brian Cahill
Chief Financial Officer

Exhibit 99.1

Eagle Pharmaceuticals to Present Abstract on Post-hoc Analysis of Amisulpride at the 77th PGA (PostGraduate Assembly in Anesthesiology) in New York City

-- BARHEMSYS® (amisulpride) Injection is the first and only antiemetic approved by the U.S. Food and Drug Administration ("FDA") for rescue treatment of postoperative nausea and vomiting ("PONV") despite prophylaxis[1] and is also approved for the treatment of PONV in patients who have not received prophylaxis and for the prevention of PONV --

-- In patients who experience PONV, the incidence of nausea is substantially greater than the incidence of vomiting[2,3] --

-- This post-hoc analysis of pivotal trials demonstrates that Barhemsys provides statistically significant (p=0.006) nausea relief in patients with established PONV --

-- A single 10 mg dose of intravenous amisulpride significantly reduced patients' nausea across multiple measures, including significant nausea, use of rescue medication, and evolution of nausea over time, and the adverse event profile was comparable between the placebo and 10 mg amisulpride arms –

-- Unique J-code for Barhemsys (J-0184) from CMS effective on January 1, 2024 --

[1] FDA labels for other recommended treatments do not include treatment after failed prophylaxis.

[2] Habib AS, et al. *Anesthesiology*. 2019; 130(2):203-212.

[3] Habib AS, et al. Curr Med Res Opin. 2006; 22(6):1039-1099.

WOODCLIFF LAKE, N.J. — December 6, 2023 — Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that its abstract, a post-hoc analysis of two multicenter, placebo-controlled, Phase III studies evaluating amisulpride (a selective dopamine D2/D3 antagonist) as an antiemetic in patients with established postoperative nausea and vomiting, has been selected for a poster presentation at the 77th PGA (PostGraduate Assembly in Anesthesiology), being held December 8-11, 2023, in New York City. The conference is sponsored by the New York State Society of Anesthesiologists and is a global platform for presenting anesthesia's latest science and technologies.

"PONV contributes to prolonged post-anesthesia care unit and hospital stays and is distressing to patients and healthcare providers," stated Mike Greenberg, MD, Vice President of Medical Affairs at Eagle Pharmaceuticals. "In patients who experience PONV, nausea occurs much more frequently than vomiting. This analysis details pooled data on nausea-related outcomes from two Phase III trials. We are pleased to share that the proportion of patients with PONV experiencing substantial nausea in these studies was statistically significantly lower in the amisulpride 10 mg group than in the placebo group. We believe Barhemsys presents an opportunity for a much-needed therapeutic option for these patients," concluded Dr. Greenberg.

Details of the poster presentation are as follows:

Abstract Title: Amisulpride Provides Significant Nausea Reduction in Patients with Established Postoperative Nausea and Vomiting: Pooled Results from Two Phase III Trials

Date: **December 10, 2023**
Time: **3:30pm ET**
Location: **Room 4, Monitor 7**

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 PEMFEXY®, RYANODEX®, BENDEKA®, BELRAPZO®, TREAKISYM® (Japan), and BYFAVO® and BARHEMSYS® through its wholly owned subsidiary Acacia Pharma Inc. Eagle's oncology and CNS/metabolic critical care pipeline includes product candidates with the potential to address underserved therapeutic areas across multiple disease states, and the company is focused on developing medicines with the potential to become part of the personalized medicine paradigm in cancer care. 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,” “could,” “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 with respect to: the potential benefits of Barhemsys, including its potential to present a therapeutic option for patients with PONV; the ability of Barhemsys and other products and product candidates to address underserved therapeutic areas across multiple disease states; the Company’s ability to develop medicines with the potential to become part of the personalized medicine paradigm in cancer care; and the anticipated unique J-code with CMS and the benefits associated therewith. All 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 timing and ability of the Company’s reporting of financial and business results, the Company’s ability to recruit and hire a new Chief Executive Officer, the impacts of the post- COVID-19 environment and geopolitical factors such as the conflicts between Russia and Ukraine and Gaza and Israel; delay in or failure to obtain regulatory approval of the Company's or its partners’ product candidates and successful compliance with FDA, European Medicines Agency and other governmental regulations applicable to product approvals; changes in the regulatory environment; the uncertainties and timing of the regulatory approval process; whether the Company can successfully market and commercialize its product candidates; the success of the Company's relationships with its partners; 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; competition from other pharmaceutical and biotechnology companies and the potential for competition from generic entrants into the market; unexpected safety or efficacy data observed during clinical trials; clinical trial site activation or enrollment rates that are lower than expected; the risks inherent in drug development and in conducting clinical trials; risks inherent in estimates or judgments relating to the Company’s critical accounting policies, or any of the Company’s estimates or projections, which may prove to be inaccurate; the Company’s ability to maintain its listing on the Nasdaq Stock Market; unanticipated factors in addition to the foregoing that may impact the Company’s financial and business projections and guidance and may cause the Company’s actual results and outcomes to materially differ from its projections and guidance; 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, 2022, filed with the Securities and Exchange Commission (the “SEC”) on March 23, 2023, the Company’s Quarterly Reports on Form 10-Q for the quarter ended March 31, 2023, filed with the SEC on May 9, 2023, and for the quarter ended June 30, 2023, filed with the SEC on August 8, 2023, and its other subsequent filings with the SEC. Readers are cautioned not to place undue reliance on these forward-looking statements. 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.

Indication and Important Safety Information for Barhemsys® (amisulpride) Injection[4]

Indication

Barhemsys is a selective dopamine-2 (D_2) and dopamine-3 (D_3) receptor antagonist indicated in adults for prevention of PONV either alone or in combination with an antiemetic of a different class and treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis.

Important Safety Information

Contraindication

Barhemsys is contraindicated in patients with known hypersensitivity to amisulpride.

QT Prolongation

Barhemsys causes dose- and concentration-dependent prolongation of the QT interval. The recommended dosage is 10 mg as a single intravenous (IV) dose infused over 1 to 2 minutes.

Avoid Barhemsys in patients with congenital long QT syndrome and in patients taking droperidol.

Electrocardiogram (ECG) monitoring is recommended in patients with pre-existing arrhythmias/cardiac conduction disorders, electrolyte abnormalities (e.g., hypokalemia or hypomagnesemia), congestive heart failure, and in patients taking other medicinal products (e.g., ondansetron) or with other medical conditions known to prolong the QT interval.

Adverse Reactions

The most common adverse reaction, reported in ≥ 2% of adult patients who received Barhemsys 10 mg (N=418) and at a higher rate than placebo (N=416), in clinical trials for the treatment of PONV was infusion site pain (6% vs. 4%).

Use in Specific Populations

Pregnancy

Available data with amisulpride use in pregnant women are insufficient to establish a drug associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes.

---

[4] https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209510s005lbl.pdf

Lactation

Amisulpride is present in human milk. There are no reports of adverse effects on the breastfed child and no information on the effects of amisulpride on milk production.

Barhemsys may result in an increase in serum prolactin levels, which may lead to a reversible increase in maternal milk production. In a clinical trial, serum prolactin concentrations in females (n=112) increased from a mean of 10 ng/mL at baseline to 32 ng/mL after Barhemsys treatment and from 10 ng/mL to 19 ng/mL in males (n=61). No clinical consequences due to elevated prolactin levels were reported.

To minimize exposure to a breastfed infant, lactating women may consider interrupting breastfeeding and pumping and discarding breast milk for 48 hours after receiving a dose of Barhemsys.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Drug Interactions

- Barhemsys causes dose- and concentration-dependent QT prolongation. To avoid potential additive effects, avoid use of Barhemsys in patients taking droperidol.
- ECG monitoring is recommended in patients taking other drugs known to prolong the QT interval (e.g., ondansetron).
- Reciprocal antagonism of effects occurs between dopamine agonists (e.g., levodopa) and Barhemsys. Avoid using levodopa with Barhemsys.

Investor Relations for Eagle Pharmaceuticals, Inc.:

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

Public Relations for Eagle Pharmaceuticals, Inc.:

Faith Pomeroy-Ward
T: 817-807-8044
E: faith@eagleus.com