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): **October 23, 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**	**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 October 23, 2023, Eagle Pharmaceuticals, Inc., or the Company, released a press release announcing that Centers for Medicare & Medicaid Services has established a unique, product-specific billing code and granted transitional pass-through payment status for Barhemsys (amisulpride) injection.

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.

Exhibit No.	Description
99.1	Press Release of the Company, dated October 23, 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.

Dated: October 23, 2023

EAGLE PHARMACEUTICALS, INC.

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

Exhibit 99.1

Eagle Pharmaceuticals Granted Unique J-Code and Pass-Through Status for BARHEMSYS® from CMS

-- J-code is effective January 1, 2024, and transitional pass-through status became effective October 1, 2023, facilitating patient access --
-- BARHEMSYS is the first and only antiemetic approved by the 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 --

WOODCLIFF LAKE, N.J. — October 23, 2023 — Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that Centers for Medicare & Medicaid Services ("CMS") has established a unique, product-specific billing code and granted transitional pass-through payment status for Barhemsys (amisulpride) injection. The new Healthcare Common Procedure Coding System ("HCPCS") Level II code ("J-code") is J-0184 "Injection, amisulpride, per 1 mg" and will be effective on January 1, 2024, replacing the C-code (C-9153), which will be discontinued. Beginning October 1, 2023, Barhemsys became eligible for separate reimbursement outside of the surgical bundled payment in both the ambulatory surgery center ("ASC") and hospital outpatient department ("HOPD") care settings.

In addition to clinical complications that may negatively affect patient outcomes, PONV can delay hospital discharge; result in re-admission after in-patient procedures; and lead to day-case patients being admitted to the hospital, all of which can increase healthcare costs.[2] By reducing these risks, Barhemsys offers the potential for significant economic savings to hospitals and ambulatory centers.

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

[2] Chatterjee S, Rudra A, Sengupta S. Current concepts in the management of postoperative nausea and vomiting. Anesthesiol Res Pract. 2011;2011:748031. doi: 10.1155/2011/748031. Epub 2011 Nov 3. PMID: 22110499; PMCID: PMC3216269.

“Receiving pass-through status, as well as a J-code, is an ideal combination that will facilitate patient access to this important therapeutic,” stated Scott Tarriff, President and Chief Executive Officer of Eagle. “Barhemsys is a significant product opportunity for Eagle, and we are pleased with its growing adoption, giving us confidence in our ability to build on this momentum.”

“Post operative nausea and vomiting, also known as PONV, is a common complication of surgery that occurs in approximately 30% of all surgical patients and 80% of high-risk patients[3]. Barhemsys is the only drug with an FDA-approved indication to treat patients who have failed PONV prophylaxis. With its potential to improve patient outcomes and enhance throughput, Barhemsys addresses an important unmet medical need in a space that lacks proven and approved therapeutics,” said Valentin Curt, MD, Senior Vice President, Clinical Drug Development and Interim Chief Medical Officer at Eagle Pharmaceuticals.

J-codes are reimbursement codes used by commercial insurance plans, Medicare, Medicare Advantage, and other government payers for physician-administered drugs like Barhemsys and are intended to simplify the claims submission and documentation process, facilitating access for patients.

Transitional pass-through payments provide additional payment for new devices, drugs, and biologicals that meet eligibility criteria for a period of at least two years but not more than three years.

The granting of pass-through status helps streamline the reimbursement process and facilitates patient access to Barhemsys.

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.

[3] Sébastien Pierre, Rachel Whelan, Nausea and vomiting after surgery, Continuing Education in Anaesthesia Critical Care & Pain, Volume 13, Issue 1, February 2013, Pages 28–32, https://doi.org/10.1093/bjaceaccp/mks046

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 Company’s ability to develop innovative medicines that address unmet medical needs; the potential of Barhemsys to offer unique or meaningful therapeutic benefits to patients and potentially improving the treatment regimen for patients, and improving patient outcomes; the maintenance of pass-through status and the application for a 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 impacts of the post- COVID-19 environment and geopolitical factors such as the conflict in Ukraine; 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; 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 Report on Form 10-Q for the quarter ended March 31, 2023, filed with the SEC on May 9, 2023, the Company’s Quarterly Report on Form 10-Q 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.

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

Important Safety Information for BARHEMSYS® (amisulpride) Injection[4]

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 5 mg or 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

Common adverse reactions reported in ≥ 2% of adult patients who received BARHEMSYS 5 mg (n=748) and at a higher rate than placebo (n=741) in clinical trials for the prevention of PONV were: chills (4% vs. 3%), hypokalemia (4% vs. 2%), procedural hypotension (3% vs. 2%), and abdominal distention (2% vs. 1%).

Serum prolactin concentrations were measured in one prophylaxis study where 5% (9/176) of BARHEMSYS-treated patients had increased blood prolactin reported as an adverse reaction compared with 1% (1/166) of placebo-treated patients.

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%).

[4] https://bynder.acaciapharma.com/m/5d7c2cd0d58865f7/original/Barhemsys-Prescribing-Information.pdf

Use in Specific Populations

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.

Renal Impairment

Avoid BARHEMSYS in patients with severe renal impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min/1.73 m2). The pharmacokinetics of amisulpride in patients with severe renal impairment have not been adequately studied in clinical trials. Amisulpride is known to be substantially excreted by the kidneys, and patients with severe renal impairment may have increased systemic exposure and an increased risk of adverse reactions.

No dosage adjustment is necessary in patients with mild to moderate renal impairment

(eGFR ≥ 30 mL/min/1.73 m2).

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.