
**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 9, 2022**

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 December 9, 2022, or the Effective Date, Eagle Pharmaceuticals, Inc., or the Company, entered into a definitive settlement agreement, or the Settlement Agreement, with Accord Healthcare, Inc., or Accord, relating to the Company's product BENDEKA® (rapidly infused bendamustine hydrochloride). This settlement resolves patent litigation brought by the Company and its marketing partners Teva Pharmaceuticals International, GmbH and Cephalon, Inc. relating to the alleged infringement of Orange Book listed United States Patent Nos. 11,103,483 and 9,572,887, or the Asserted Patents, with respect to Accord's 505(b)(2) New Drug Application, or NDA, No. 212209. Pursuant to the terms of the Agreement, the Company will grant Accord a license to market Accord's product made under NDA 212209 in the United States beginning on January 17, 2028 (subject to U.S. Food and Drug Administration approval), or earlier under certain circumstances. Additionally, in accordance with the Agreement, the parties will terminate all ongoing litigation among the Company, Teva Pharmaceuticals International, GmbH and Cephalon, Inc. and Accord regarding the Asserted Patents pending in the United States District Court for the District of Delaware. The Agreement is confidential and subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice.

On December 12, 2022, the Company issued a press release announcing the Settlement Agreement.

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.

Safe Harbor for Forward-Looking Statements

This Current Report on Form 8-K 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," "opportunity," "estimate," 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 resolution of patent litigation and all related settlement terms, including dates of market entry and the potential for earlier market entry under certain circumstances and submission of the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review; the strength of the Company's intellectual property rights for BENDEKA and BELRAPZO; and the expected expansion, defense and enforcement of intellectual property rights. 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, European Medicines Agency and other governmental regulations applicable to product approvals; 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" sections of the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission (the "SEC") on March 8, 2022, the Company's Quarterly Reports on Form 10-Q for the quarter ended March 31, 2022, June 30, 2022 and September 30, 2022, filed with the SEC on May 9, 2022, August 9, 2022, and November 9, 2022, respectively, 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.

Item 9.01 Financial Statements and Exhibits.

| Exhibit No. | Description |
|----------------------|--|
| 99.1 | Press Release of the Company, dated December 12, 2022. |
| 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: December 12, 2022

EAGLE PHARMACEUTICALS, INC.

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

EAGLE[®]

PHARMACEUTICALS

Eagle Pharmaceuticals Reaches Settlement Agreement with Accord Healthcare, Inc. Related to BENDEKA[®] (bendamustine hydrochloride)

Woodcliff Lake, N.J. – December 12, 2022 -- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) (“Eagle” or the “Company”) today announced that it has reached a settlement agreement with Accord Healthcare, Inc. (“Accord”). Eagle had asserted its Orange Book-listed patents against Accord related to Accord’s new drug application (“NDA”) referencing BENDEKA[®]. The settlement agreement provides that Accord has the right to market its product beginning January 17, 2028, or earlier based on certain circumstances. The settlement agreement is confidential and subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice.

The settlement with Accord follows Eagle’s previously announced settlement with Hospira, Inc. (“Hospira”) regarding two Orange Book-listed patents, which granted Hospira the right to market its product beginning January 17, 2028, or earlier based on certain circumstances.

“We are pleased with the settlement. Eagle intends to continue to expand and vigorously enforce its intellectual property rights around BENDEKA and our bendamustine franchise,” stated Scott Tarriff, President and Chief Executive Officer of Eagle.

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 vasopressin, 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. Additional information is available on Eagle’s website at www.eagleus.com.

Forward-Looking Statements

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Investor Relations for Eagle Pharmaceuticals, Inc.:

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