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): **April 19, 2022**

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 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 April 19, 2022, or the Effective Date, Eagle Pharmaceuticals, Inc., or the Company, entered into a definitive settlement agreement, or the Settlement Agreement, with Hospira, Inc., or Hospira, 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 Hospira's 505(b)(2) New Drug Application, or NDA, No. 211530. Pursuant to the terms of the Agreement, the Company will grant Hospira a license to market Hospira's product made under NDA 211530 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 Hospira 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 April 19, 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 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," "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: statements regarding the resolution of patent litigation and all related settlement terms, including the date 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; statements regarding the strength of the Company's intellectual property rights for BENDEKA and BELRAPZO and the defense and enforcement of intellectual property rights; the timing, scope or likelihood and timing of regulatory filings and approvals from the FDA for the Company's product candidates; and the ability of the Company's executive team to execute on the Company's strategy and build stockholder value. 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 and geopolitical events such as the conflict in Ukraine, 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 or other events on the Company's business, financial condition and results of operations; whether the Company will incur unforeseen expenses or liabilities or other market factors; whether the Company will successfully implement its development plan for its product candidates; delay in or failure to obtain regulatory approval of the Company's or its partners' product candidates; whether the Company can successfully market and commercialize its product candidates; the success of the Company's relationships with its partners; the availability and pricing of third party sourced products and materials; the outcome of litigation involving any of its 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 and geopolitical events, 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 factors in addition to the foregoing that may impact the Company's expectations, including among other things, any potential business development transactions, acquisitions, restructurings or legal settlements, in addition to any unanticipated factors, that may cause the Company's actual results and outcomes to materially differ; and those risks and uncertainties identified in the "Risk Factors" section 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, 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 Current Report on Form 8-K 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 April 19, 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: April 19, 2022

EAGLE PHARMACEUTICALS, INC.

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

Exhibit 99.1

For Immediate Release

Eagle Pharmaceuticals Reaches Settlement Agreement with Hospira Related to BENDEKA® (bendamustine hydrochloride) until January 17, 2028

WOODCLIFF LAKE, N.J. — April 19, 2022 — Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that it has reached a settlement agreement with Hospira, Inc ("Hospira"). Eagle had asserted two Orange Book-listed patents against Hospira related to its new drug application ("NDA") referencing BENDEKA®. The settlement agreement provides that Hospira has the right to market its product beginning January 17, 2028, or earlier based on certain circumstances.

"We are pleased with the outcome of the settlement, as we continue to expand and vigorously defend the intellectual property around BENDEKA and our bendamustine franchise through patent enforcement and litigation," stated Scott Tarriff, President and Chief Executive Officer.

Eagle previously asserted several Orange Book-listed patents against Slayback Pharma LLC, Apotex Inc. ("Apotex") et al, Mylan Laboratories Limited ("Mylan"), and Fresenius Kabi USA, LLC ("Fresenius"), related to their respective abbreviated new drug applications (ANDA's) referencing BENDEKA. On July 6, 2020, the District Court for the District of Delaware had held these asserted patents both valid and infringed. Apotex, Mylan, and Fresenius appealed this ruling. Prior to the appellate hearing, Eagle settled the litigation with Fresenius, which can market its products beginning in January 2029, or earlier based on certain circumstances. On August 13, 2021, the United States Court of Appeals for the Federal Circuit affirmed that the asserted patents were both valid and infringed. Apotex filed a petition for certiorari on December 14, 2021, which the Supreme Court denied on February 22, 2022. The settlement agreement is confidential and subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice.

As previously reported, the U.S. Patent and Trademark Office granted Eagle U.S. Patent No. 11,103,483, entitled "Formulations of Bendamustine," which is listed in the Orange Book and expires in January 2031.

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 injection, PEMFEXY™, RYANODEX®, BENDEKA®, BELRAPZO®, TREAKISYM (Japan), and its 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

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 “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: statements regarding the resolution of patent litigation and all related settlement terms, including the date 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; statements regarding the strength of the Company’s intellectual property rights for BENDEKA and BELRAPZO and the defense and enforcement of intellectual property rights; the timing, scope or likelihood and timing of regulatory filings and approvals from the FDA for the Company’s product candidates; and the ability of the Company’s executive team to execute on the Company’s strategy and build stockholder value. 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 and geopolitical events such as the conflict in Ukraine, 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 or other events on the Company's business, financial condition and results of operations; whether the Company will incur unforeseen expenses or liabilities or other market factors; whether the Company will successfully implement its development plan for its product candidates; delay in or failure to obtain regulatory approval of the Company's or its partners’ product candidates; whether the Company can successfully market and commercialize its product candidates; the success of the Company's relationships with its partners; the availability and pricing of third party sourced products and materials; the outcome of litigation involving any of its 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 and geopolitical events, 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 factors in addition to the foregoing that may impact the Company’s expectations, including among other things, any potential business development transactions, acquisitions, restructurings or legal settlements, in addition to any unanticipated factors, that may cause the Company’s actual results and outcomes to materially differ; and those risks and uncertainties identified in the “Risk Factors” section 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, 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.

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