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): **June 14, 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 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 June 14, 2023, Eagle Pharmaceuticals, Inc., or the Company, issued a press release announcing that the U.S. Food and Drug Administration has granted Qualified Infectious Disease Product Designation under the Generating Antibiotic Incentives Now Act and Fast Track Designation for CAL02. 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 Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company, dated June 14, 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: June 14, 2023

EAGLE PHARMACEUTICALS, INC.

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

Exhibit 99.1

Eagle Pharmaceuticals Receives FDA Qualified Infectious Disease Product (QIDP) and Fast-Track Designation for CAL02, Providing Five-Year Exclusivity Extension

With QIDP, Eagle expects to receive eight or ten years of regulatory exclusivity upon NDA approval

-- Company believes CAL02 is a new chemical entity (NCE), which would result in five years of marketing exclusivity upon approval or three years without NCE designation; total potential of eight or ten years of exclusivity --

-- Eagle has approved patents running until September 2035, with filed patent applications that would extend into 2037 or later --

-- Eagle may qualify for up to five additional years of patent term exclusivity, up to 2040 --

-- CAL02 is a novel first-in-class anti-toxin drug candidate being developed for Severe Community-Acquired Bacterial Pneumonia (SCABP) --

-- QIDP designation entitles Eagle to an additional five years of exclusivity upon NDA approval --

-- QIDP and fast-track designations underscore the significant unmet medical need in treating SCABP –

-- Eagle's Phase 2 clinical study is underway to assess the efficacy and safety of CAL02 administered intravenously in addition to standard of care in patients with SCABP --

WOODCLIFF LAKE, N.J. — June 14, 2023 — Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that the U.S. Food and Drug Administration (FDA) has granted Qualified Infectious Disease Product (QIDP) Designation under the Generating Antibiotic Incentives Now (GAIN) Act and Fast Track Designation for CAL02, a first-in-class non-biological bacterial virulence neutralizer, anti-infective agent being developed to treat severe community-acquired bacterial pneumonia (SCABP) as an add-on therapy to standard of care.

“Receiving QIDP designation underscores the importance of CAL02 for potentially treating SCABP, and the Fast Track Designation allows us to work even closer with the FDA to bring patients a new treatment option sooner as we would also be eligible to request Priority Review for our application. Antibiotics alone, unfortunately, cannot win the war against pneumonia. CAL02 would serve as an add-on to standard of care antibiotic therapy for the prompt treatment of severe bacterial pneumonia and its devastating consequences. In an era of increasing resistance to standard therapies, CAL02 represents a potential resistance-free empiric therapy to protect organs and prevent pro-inflammatory cascades leading to severe and fatal outcomes. This treatment could represent a true paradigm shift and offer healthcare providers another option in combating this complex disease,” stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals. “Eagle believes that CAL02 is the first potential therapy engineered to neutralize a broad range of bacterial toxins for SCABP to receive QIDP designation, and we look forward to providing updates as CAL02 advances through the clinical program.”

The QIDP designation was created by the GAIN Act implemented in 2012 to encourage the development of treatments for antibiotic-resistant organisms known to cause serious or life-threatening infections.

Eagle believes that CAL02 could also be eligible for breakthrough therapy designation.

Eagle is also further developing the patent estate to protect the intellectual property resulting from the development of this novel, first-in-class therapy. CAL02 is currently protected by issued U.S. Patent No.10,744,089, which extends until September 2035, and may be eligible for Patent Term Extension for up to five years until 2040. CAL02 is also protected by granted counterparts in important markets globally, e.g., Europe and Japan. In addition, CAL02 and its uses are the subject of pending patent families as reflected in published applications WO2017216282, WO2018158375, WO2019201937, WO2019202101, US2023/0028179, US2021/0275452, US2021/0030677, US2021/0259967, and other families under development. These families would provide patent term until approximately 2037 or later.

SCABP is a worldwide prevalent infectious disease associated with high morbidity and mortality, despite the availability of vaccines, effective antibiotic regimens, and state-of-the-art critical care therapy. CAL02 is a novel first-in-class broad-spectrum anti-virulence agent being developed as an add-on to standard of care treatment of SCABP. CAL02 consists of proprietary, engineered liposomes that capture and neutralize bacterial toxins known to dysregulate inflammation, cause organ damage, and impede immune defense. A Phase 1 safety and tolerability trial in SCABP patients was successfully completed, in which encouraging trends for efficacy were observed. The results were published in *The Lancet Infectious Diseases*, where accompanying comments characterized CAL02 as “One step closer to precision medicine for infectious diseases,” describing the study as a “medical breakthrough.”

About the Phase 2 CAL02 Study

A Phase 2 adaptive, randomized, double-blind, placebo-controlled study is underway, designed to assess the efficacy and safety of CAL02 administered intravenously in addition to standard of care in patients with severe community-acquired bacterial pneumonia (SCABP). The study plans to enroll approximately 276 patients with SCABP worldwide. Additional details are available on ClinicalTrials.gov (Identifier: NCT05776004).

About CAL02

CAL02 is an investigational, innovative, first-in-class anti-infective agent that acts as a competitive decoy, or lure, for bacterial virulence factors, which contribute to infection-related complications, sepsis, septic shock, and death. CAL02 consists of proprietary liposomes engineered to capture the virulence factors produced by a broad range of Gram-positive and Gram-negative bacteria causing severe infectious diseases, including severe pneumonia. CAL02 is poised to play a key role in the fight against anti-microbial resistance. Its action is complementary to that of antibiotics, and it does not appear to exert any selective pressure, which can contribute to antibiotic resistance. Because of these characteristics, CAL02 could be administered empirically in combination with standard of care as soon as patients show signs of severe pneumonia. Clinical results to date underscore the potential of CAL02 to transform the standard of care and to dramatically reduce the time and the cost of care for millions of critically ill SCABP patients. Eagle has a worldwide exclusive license on CAL02 acquired from Combioxin SA.

About Virulence Factors

Virulence is a bacteria's ability to infect a host and produce disease. Virulence factors are produced by a variety of pathogens and assist in potentiating infection, evading and suppressing the immune system, and damaging host cells, including immune cells, and organs. Blocking the activities of virulence factors is a new approach that has emerged over the last decade.[1] Anti-virulence drugs, a new class of drugs, target virulence factors of pathogens, effectively disarming infectious pathogens.

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. Additional information is available on Eagle's website at www.eagleus.com.

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9719373/#:~:text=Blocking%20the%20activities%20of%20virulence,and%20consequently%20disarm%20infectious%20pathogens

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 regarding the Company’s expectations for the design and timing of the planned Phase 2 study, including with respect to enrollment and site selection and the timing thereof; statements regarding the potential of CAL02 to be a medical breakthrough and offer unique or meaningful therapeutic benefits to seriously ill patients, potentially improving the treatment regimen for patients with severe community-acquired pneumonia, shortening the duration of illness and improving patient outcomes; statements regarding potential regulatory exclusivity, CAL02’s potential eligibility for fast track and breakthrough therapy designations and the potential for a CAL02 new drug application for the treatment of SCABP to qualify for priority review; statements regarding the Company’s expectation to strengthen the patent portfolio for CAL02; and the potential of the Company’s pipeline and product candidates to address underserved therapeutic areas across multiple disease states. 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, 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 quarters ended March 31, 2023, filed with the SEC on May 9, 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.

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