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): **August 19, 2021**

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 1.01 Entry into a Material Definitive Agreement.

On August 19, 2021, Eagle Pharmaceuticals, Inc., or the Company, entered into a license agreement, or the License Agreement, with Combioxin SA, or Combioxin, under which the Company was granted exclusive, worldwide development and commercialization rights to CAL02, a novel first-in-class antitoxin agent ready for Phase 2b/3 development for the treatment of severe pneumonia in combination with traditional antibacterial drugs. The Company will be solely responsible for the development, regulatory, manufacturing and commercialization activities of CAL02. Combioxin will assist the Company in transitioning the manufacturing and supply of CAL02 to the Company.

The Company and Combioxin will establish a joint development committee to review and discuss the overall strategy for the development and regulatory activities of CAL02, oversee the activities under the License Agreement, including with respect to clinical trials and manufacturing activities, and perform such other functions as expressly set forth in the License Agreement or allocated to it by the parties.

The Company will make an upfront cash payment of $10 million as well as up to $105 million in total development and sales milestone payments. In addition, the Company will pay tiered royalty payments at royalty rates ranging in low double digit percentages on the net sales of all products sold, subject to certain adjustments as provided in the License Agreement. The Company is also obligated to make certain payments based upon amounts received by sublicensees under the License Agreement.

The License Agreement will remain in effect, unless terminated earlier, until the last to expire royalty term under the License Agreement. The Company may terminate the License Agreement for convenience, in its entirety or on a country-by-country basis or product-by-product basis, with at least ninety (90) days' prior written notice at any time prior to the first commercial sale of CAL02, and with at least one hundred eighty (180) days' prior written notice at any time after the first commercial sale of CAL02. Combioxin may terminate the License Agreement upon failure to achieve certain development milestones as provided in the License Agreement. Each party has the right to terminate the License Agreement for the other party's material breach of its obligations under the License Agreement, subject to cure rights. Either party may terminate the License Agreement if the other party declares bankruptcy. Upon termination, any license granted by Combioxin to the Company will terminate, provided if the License Agreement is terminated on a country-by-country basis or product-by-product basis, such termination will only apply to the terminated country or terminated product.

The License Agreement includes, among other provisions, representation and warranties, indemnification obligations, confidentiality, publicity, audit and inspection, and intellectual property sharing provisions in favor of each party that are customary for an agreement of this nature.

The foregoing description of the material terms of the License Agreement is qualified in its entirety by reference to the complete text of the License Agreement, a copy of which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021.

Item 7.01 Regulation FD Disclosure.

On August 25, 2021, the Company issued a press release announcing the Licensing Agreement with Combioxin.

A copy of this press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information contained in this Item 7.01, including Exhibit 99.1, is being "furnished" and shall not be deemed filed for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section or Sections 11 and 12 (a)(2) of the Securities Act. The information in this Item 7.01, including Exhibit 99.1, shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act or into any filing or other document pursuant to the Exchange Act, except as otherwise expressly stated in such filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release of the Company, dated August 25, 2021.
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: August 25, 2021

EAGLE PHARMACEUTICALS, INC.

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

Exhibit 99.1

For Immediate Release

Eagle Pharmaceuticals Announces Worldwide Licensing Agreement with Combioxin SA for Phase 2b/3, Novel First-in-Class Antitoxin Agent CAL02 in Development for Combination Use with Antibiotics for the Treatment of Severe Pneumonia

-- CAL02 neutralizes toxic virulence effectors ("VEs") produced by bacteria; VEs play a decisive role in the development of long-term, severe and fatal pneumonia complications --

-- Results of first-in-human[1] clinical trial published in *The Lancet Infectious Diseases*, where accompanying comments characterized CAL02 as "One step closer to precision medicine for infectious diseases," describing "this study a medical breakthrough" --

-- Potential to address significant unmet need in the treatment of severe pneumonia, which accounts for 2.4 million deaths per year globally --

-- Eagle anticipates ten years of regulatory exclusivity --

-- Eagle to host CAL02 Investor Event on September 9, 2021 --

WOODCLIFF LAKE, NJ—August 25, 2021—Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that it has entered into a worldwide licensing agreement with Combioxin SA ("Combioxin"), a clinical-stage biotechnology company based in Epalinges, Switzerland, for the commercial rights to CAL02, a novel first-in-class antitoxin agent ready for Phase 2b/3 development for the treatment of severe pneumonia in combination with traditional antibacterial drugs.

Under the Agreement, Eagle will be solely responsible for further clinical development of CAL02 and will make an upfront payment, followed by additional payments upon achievement of development milestones, regulatory approval and based upon commercial sales. Eagle expects to invest $35 million to achieve interim results. These interim results are expected in the first half of 2023.

CAL02 is designed to be an add-on therapy to antibiotics to neutralize virulence effectors. CAL02 consists of liposomes that capture and neutralize bacterial toxins produced by a broad range of Gram-positive and Gram-negative bacteria. Bacterial toxins play a critical role in severe, complicated, and resistant infections. They are known to dysregulate inflammation, cause organ damage and impede immune defense. Unlike traditional antibacterial drugs, CAL02 does not target bacteria directly.

[1]Laterre PF, Colin G, Dequin PF, Dugernier T, Boulain T, Azeredo da Silveira S, Lajaunias F, Perez A, François B. CAL02, a novel antitoxin liposomal agent, in severe pneumococcal pneumonia: a first-in-human, double-blind, placebo-controlled, randomised trial. Lancet Infect Dis. 2019 Jun;19(6):620-630. doi: 10.1016/S1473-3099(18)30805-3. Epub 2019 May 2. PMID: 31056427.

The first-in-human clinical trial results show a favorable safety profile when administered in combination with standard antibiotics to patients with severe community-acquired bacterial pneumonia ("CABP") hospitalized in the intensive care unit ("ICU"). Furthermore, as compared to patients under placebo, patients who were treated with CAL02 presented a faster clinical improvement, including a significantly faster resolution of organ dysfunctions (as per Sequential Organ Failure Assessment score).

"We are excited to be part of this potentially groundbreaking advancement in the treatment of severe bacterial pneumonia. Despite the widespread availability of antibiotic drugs today, pneumonia is still the leading cause of infectious mortality in the world. CAL02's ability to neutralize virulence effectors could fill a significant medical gap by offering physicians a new treatment that has the potential to dramatically improve patient outcomes. We believe that CAL02 could change the standard of care for patients and have a broad therapeutic impact, especially in critical situations. This deal, along with the recent Landiolol transaction, broadens our pipeline and provides opportunities for continued leadership in the hospital acute care space," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

"We are thrilled to partner with Eagle Pharmaceuticals, which has shown tremendous commitment to bringing innovative solutions in the hospital acute care space. This transaction represents a significant milestone in the development of CAL02, and we believe that it will bring about a true transformation in the treatment of severely infected patients around the world," said Dr. Samareh Azeredo da Silveira Lajaunias, Managing Director of Combioxin SA.

"Pneumonia remains one of the deadliest infectious diseases in the world. In addition to the associated morbidity and mortality, severe pneumonia represents a major economic burden due to how it prolongs hospitalization. Targeting virulence effectors, CAL02 addresses the fundamental damage of severe community-acquired pneumonia. In its first-in-human clinical trial, a randomized, double-blind, placebo-controlled study, CAL02 was shown to be as safe as placebo and resulted in significantly fewer ICU days. CAL02 has the potential to transform the care for severe pneumonia," said Professor of Medicine Andrew Shorr, MD, Georgetown University.

Clinical Status and Regulatory Path Forward

Preclinical data were published in *Nature Biotechnology*, followed by numerous peer-reviewed articles. The results of the first-in-human clinical trial (randomized, double-blind, placebo-controlled, multi-center), which was carried out in ICU patients with severe CABP, were published in *The Lancet Infectious Diseases*, in May 2019, and the study was described as a "medical breakthrough,"

The clinical development plan has been discussed with the U.S. Food and Drug Administration ("FDA") and the European Medicines Agency ("EMA"). FDA and EMA each indicated no requirement of further dose finding for Phase 2b, and that empiric use of CAL02 could be added to the standard of care antibacterial drug therapy prior to pathogen identification given its mechanism of action.

"CAL02 could represent a true paradigm shift in terms of the treatment cascade for bacterial pneumonia patients. With an estimated 350,000 patients requiring treatment in the ICU in the U.S. in 2020, CAL02 could provide a significant opportunity to improve patient outcomes and save lives," stated Judith Ng-Cashin, MD, Chief Medical Officer of Eagle Pharmaceuticals.

The Company plans to advance the clinical program and initiate a robust Phase 2b/3 study in the first half of 2022. CAL02 is an acute care drug, and therefore the Company expects a fast turnaround to receive individual patient results.

Eagle anticipates ten years of regulatory exclusivity, including five years as a new chemical entity and five years as a qualified infectious disease product ("QIDP") under the Generating Antibiotic Incentives Now ("GAIN") Act. Eagle believes that CAL02 could be eligible for fast track and breakthrough therapy designations. In addition, Eagle believes a CAL02 new drug application for the treatment of severe CABP may qualify for priority review. The Company expects to build a meaningful patent portfolio for this asset.

Large Unmet Medical Need

Complications associated with CABP represent a significant unmet medical need. CAL02 has the potential to transform the standard of care for patients with CABP, which accounts for an estimated 2.4 million deaths per year globally. In the U.S., about one million adults seek hospital care for pneumonia every year, and 50,000 die from this disease. Older patients with chronic illnesses are at the greatest risk for severe infection, complications and mortality. For children, pneumonia is the most common reason for hospitalization, and it is the world's leading cause of death among children under the age of five. Pneumonia is also the most common cause of sepsis and septic shock, responsible for 50% of all episodes, and can result in admission to the ICU. Hospital-acquired pneumonia has a higher mortality rate than any other hospital-acquired infection.

Pneumonia places a huge burden on the U.S. healthcare system and is among the top ten costly conditions seen during inpatient hospitalizations. Despite the availability of antibiotics, the death rate from pneumonia in the U.S. has seen little improvement in the past half century.

Eagle management will host a CAL02 Investor Event as follows:

Date	Thursday, September 9, 2021
Time	8:30 A.M. EDT
Toll free (U.S.)	877-876-9174
International	785-424-1669
Webcast (live and replay)	www.eagleus.com, under the "Investor" section

A replay of the conference call will be available for one week after the call's completion by dialing 888-214-7993 (U.S.) or 402-220-4931 (International) and entering conference call ID EGRX0909. The archived webcast will be available for 30 days at the aforementioned URL.

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 RYANODEX®, BENDEKA®, BELRAPZO®, 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.

About CAL02

CAL02 is an investigational innovative anti-infective drug that acts as a trap for bacterial virulence effectors (toxins) which contribute to infection-related complications, sepsis, septic shock and death. CAL02 consists of liposomes engineered to clear away the virulence effectors produced by the most relevant bacteria seen in severe pneumonia. CAL02 is poised to play a key role in the fight against anti-microbial resistance, since its action is complementary to that of antibiotics and does not appear to give rise to drug resistance. Because of its safety profile, its breadth of activity and the fact that it is not conducive to the emergence of any new resistance, CAL02 could be administered empirically, as soon as patients with a suspected or confirmed pneumonia show signs of severity. 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 patients.

About Combioxin

Combioxin SA is a Swiss-based clinical-stage biotechnology company founded in 2015. The company is committed to the development of disruptive treatments for severe infections. Combioxin is a recipient of the Swiss FIT SEED program and is a spin-off of LASCCO SA, a company that propels academic discovery-stage inventions into life science ventures. Additional information is available on Combioxin's website at www.combioxin.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," "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 concerning the licensing agreement between the Company and Combioxin and the timing and ability to obtain regulatory approval of CAL02; statements regarding the collaboration between the Company and Combioxin, including statements about CAL02's ability to address unmet need in patients with severe pneumonia and its other anticipated benefits and expected duration of regulatory exclusivity for CAL02, if approved; CAL02's potential acceptance by clinicians; the timing, progress and results of additional trials of CAL02 and the ability of such trial results to support regulatory filings and approvals; anticipated actions by FDA, EMA and other regulatory agencies; the Company's ability to support the commercial launch of CAL02, if approved; anticipated future payments, including upfront and milestone payments, from the Company to Combioxin; the anticipated market opportunity for CAL02; and the ability of the product candidates in the Company's pipeline to deliver value to stockholders. 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, including CAL02, and successful compliance with FDA, EMA and other governmental regulations applicable to product approvals; whether the Company will successfully implement its development plan for its product candidates, including CAL02; the inability to recognize the anticipated benefits of the collaboration between the Company and Combioxin; whether the Company can successfully collaborate with its partners and market and commercialize its product candidates; the outcome of litigation involving any of its products or that may have an impact on any of its products; possible safety and efficacy concerns; risks that preliminary results from clinical trials are not necessarily predictive of future clinical trial results; 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" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission (the "SEC") on March 5, 2021, as updated by the Company's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2021 and June 30, 2021, filed with the SEC on May 10, 2021 and August 9, 2021, respectively, and its other subsequent filings with the SEC. 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

Media Relations for Eagle Pharmaceuticals, Inc.:
Faith Pomeroy-Ward
T: 817-807-8044
E: faith@fpwservices.com