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 3, 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**	**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 3, 2022, Eagle Pharmaceuticals, Inc., or the Company, and Enalare Therapeutics Inc., or Enalare, issued a press release announcing that the U.S. Food and Drug Administration has granted Orphan Drug Designation to ENA-001. 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.

Exhibit No.	Description
99.1	Press Release of the Company, dated October 3, 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: October 3, 2022

EAGLE PHARMACEUTICALS, INC.

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

Exhibit 99.1

For Immediate Release

Eagle Pharmaceuticals and Enalare Therapeutics Announce FDA Orphan Drug Designation for ENA-001 for the Treatment of Apnea of Prematurity, a New Chemical Entity Being Developed as an Agnostic Respiratory Stimulant

-- ENA-001, with a novel mechanism of action as an agnostic respiratory stimulant, has previously been granted Rare Pediatric Disease Designation for the treatment of Apnea of Prematurity by the FDA with eligibility for a priority review voucher --

-- The compound is also being developed for post-operative respiratory depression and community drug overdose --

WOODCLIFF LAKE, N.J. and PRINCETON, N.J. — October 3, 2022 — Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") and Enalare Therapeutics Inc. ("Enalare") today announced that the U.S. Food and Drug Administration ("FDA") has granted Orphan Drug Designation ("ODD") to ENA-001 for the treatment of Apnea of Prematurity ("AoP"), a new chemical entity with a novel mechanism of action as a respiratory stimulant. AoP is a development disorder attributed to immaturity of the pulmonary system characterized by either cessation of breathing for more than 20 seconds or cessation of breathing that lasts less than 20 seconds but is accompanied by either bradycardia or hypoxemia. The condition affects approximately 25% of all preterm infants.[1]

ENA-001 is designed to work peripherally by inhibiting Big Potassium (BK) ion channels in the carotid bodies, which are located in the neck. By inhibiting these channels, ENA-001 utilizes the body's own ventilation control system to stimulate breathing and it does so across multiple causes (etiologies) of respiratory depression.

"Eagle has a great deal of confidence in ENA-001, and the granting of Orphan Drug Designation by the FDA validates our belief in its potential to help this very vulnerable population of premature infants. More broadly, we believe that this compound can play an important role in addressing a significant unmet medical need, notably for patients with post-operative respiratory depression and in combatting community drug overdose. With its compelling clinical and health economic value propositions, ENA-001 is an excellent long-term opportunity for Eagle and would fit well within our hospital/critical care portfolio," stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

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[1] Martin RJ, Abu-Shaweesh JM, Baird TM (2004) Apnoea of prematurity. Paediatr Respir Rev, 5 Suppl A, S377-382.

“We are extremely gratified to receive Orphan Drug Designation for ENA-001 in the treatment of neonates experiencing Apnea of Prematurity. This is an important milestone that builds on the Rare Pediatric Designation granted by the FDA for ENA-001 last December. Currently, pharmacologic treatment for these neonates is typically limited to caffeine or other methylxanthines. We are eager to advance this program and bring improved options for the preterm infants facing this challenging respiratory condition,” said Herm Cukier, President and CEO of Enalare Therapeutics.

In August 2022, Eagle made an equity investment of $12.5 million in Enalare, with a commitment to invest another $12.5 million six months later and make two potential follow-on equity investments of $15 million each contingent upon (i) the commencement of the ENA-001 Phase 2 clinical trial, and (ii) the ENA-001 Phase 2 clinical trial reaching 50% enrollment. Eagle also has the option to acquire the remaining Enalare shares for an aggregate purchase price ranging from $100-$175 million plus royalty rights ranging from 9%-12% on all future global net sales of any Enalare product, paid to the ex-Eagle holders of Enalare shares at the time of acquisition.

Orphan Drug Designation is granted to drugs or biological products for the treatment of rare diseases or conditions that impact fewer than 200,000 people in the United States. Incentives that come with the designation include eligibility for federal grants, research and development tax credits, waiver of filing fees, and the potential for a seven-year marketing exclusivity period. The designation does not alter the standard regulatory requirements and process for obtaining marketing approval.

ENA-001 is also being developed in an Intramuscular (“IM”) formulation in partnership with the Biomedical Advanced Research and Development Authority (“BARDA”), part of the Administration for Strategic Preparedness and Response in the U.S. Department of Health and Human Services (contract number 75A50122C00072). The funding is provided by BARDA to support the advanced research and development of medical countermeasures (MCM) for chemical, biological, radiological and nuclear (CBRN) agents, pandemic influenza, and emerging infectious diseases that threaten the U.S. civilian population.

The development of ENA-001 is also supported by the National Institute on Drug Abuse (“NIDA”) of the National Institutes of Health (“NIH”) under award number R44DA057133. The content of this document is the responsibility of its authors and does not necessarily represent the official views of the National Institutes of Health.

About ENA-001

Enalare’s lead compound, ENA-001, is a one-of-a-kind new chemical entity (NCE) designed as an agnostic respiratory stimulant. The compound has a novel mechanism of action that affects ventilation via the peripheral chemoreceptor pathways in the carotid body. It utilizes the body’s own ventilation control system to beneficially influence breathing and has been shown to be effective and well tolerated in five human studies to date. With its novel mechanism of action and based on findings to date, it could potentially improve the lives of those impacted by several life-threatening conditions, including community drug overdose, post-operative respiratory depression, and apnea of prematurity. ENA-001 is an investigational compound and is not approved for use by the FDA.

About Apnea of Prematurity

Apnea of Prematurity is a development disorder attributed to immaturity of the pulmonary system characterized by either cessation of breathing for more than twenty seconds or cessation of breathing which lasts less than twenty seconds but is accompanied by either bradycardia or hypoxemia. Apnea of Prematurity affects approximately twenty-five percent of all preterm infants and is inversely correlated with gestational age and birth weight, including nearly 100 percent in neonates with a gestational age of less than 29 weeks or birth weight less than 1,000 grams. Apnea of prematurity exposes these delicate neonates to repeated episodes of hypoxemia which is shown to increase risk of mortality in the NICU as well as short and long-term impaired neurological development.

About Enalare Therapeutics Inc.

Enalare Therapeutics Inc. is a clinical-stage biopharmaceutical company dedicated to developing novel therapies for patients suffering from life-threatening acute respiratory and critical care conditions, including community drug overdose, post-operative respiratory depression, and apnea of prematurity. Enalare maintains global rights to its novel compounds and intends to start additional clinical trials with ENA-001 for several indications in the near term.

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

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 with respect to the development of, potential benefits of and potential FDA submission for ENA-001, including a potential IM formulation that could potentially enable more rapid deployment in emergency situations and the potential to develop an innovative and rapid treatment for respiratory depression in a variety of settings; expectations with respect to the BARDA award providing funding to Enalare to accelerate the development of ENA-001; the achievement of milestones and deliverables; the potential further investment by Eagle in Enalare and Eagle’s development programs, products and pipeline; the potential use of ENA-001 to help preterm infants with respiratory conditions; the ability of ENA-001 and other products and product candidates to address unmet clinical needs, including for patients with post-operative respiratory depression and in combatting community drug overdose; the potential market opportunity for products or product candidates, including ENA-001; and the availability of ODD merits such as potential exclusivity periods and certain research and development tax incentives. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the Company’s or Enalare’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 or Enalare’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; the ability of Enalare to achieve milestones and deliverables under the BARDA agreement and otherwise accelerate and achieve successful results in the development of ENA-001; 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 Report on Form 10-Q for the quarter ended March 31, 2022, filed with the SEC on May 9, 2022, the Company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August 9, 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.

Investor Relations for Eagle Pharmaceuticals, Inc.:

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