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 30, 2018**

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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 o

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. o

Item 8.01 Other Events.

On August 30, 2018, Eagle Pharmaceuticals, Inc., or the Company, issued a press release announcing the completion of enrollment of the Company's second clinical study to further evaluate the safety and efficacy of RYANODEX® (dantrolene sodium for injectable suspension) for the treatment of exertional heat stroke, an investigational new indication for the product.

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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release dated August 30, 2018

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.

Eagle Pharmaceuticals, Inc.

Dated: August 30, 2018

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

For Immediate Release

Eagle Pharmaceuticals Concludes Enrollment of Second Safety and Efficacy Study at Hajj to Evaluate RYANODEX for Exertional Heat Stroke
—Preliminary Analysis: RYANODEX Provides Benefit for Patients—
—Eagle Plans to Meet with FDA to Discuss Next Steps—

WOODCLIFF LAKE, N.J.—August 30, 2018—Eagle Pharmaceuticals, Inc. ("Eagle" or "the Company") (Nasdaq: EGRX) today announced completion of enrollment of the Company's second clinical study to further evaluate the safety and efficacy of RYANODEX® (dantrolene sodium for injectable suspension) for the treatment of exertional heat stroke ("EHS"), an investigational new indication for the product.

The randomized and double-blinded study was conducted at four Emergency Departments in the Makkah region of Saudi Arabia during the 2018 Hajj Season, which took place August 19-24, 2018. The study enrolled seven severely ill EHS patients. Based on a preliminary analysis of the data, EHS patients who received RYANODEX plus Standard of Care ("SOC"), which consists of body cooling by physical methods and supportive measures, showed an additive benefit compared to patients receiving cooling only.

The two treatment groups had comparable baseline characteristics, including severe hyperthermia and severe neurological dysfunction. Patients randomized to Group A (RYANODEX plus SOC) had a mean baseline core body temperature of 107.8 °F and mean Glasgow Coma Scale (GCS) score of 5. Similarly, patients in Group B (SOC only) had a mean core body temperature of 107.2 °F and mean GCS score of 5 at baseline. A GCS score of 5 represents severe brain injury.

Preliminary evaluation of the data show that of the four patients dosed with RYANODEX, two had restoration of neurological functioning, and another patient showed substantial improvement over the course of the study. The fourth patient, who had an initial core body temperature of 112.1 °F, remained unchanged. In contrast, the SOC group had three patients. One patient had restoration of neurological functioning, one remained with severe impairment and one subject showed further deterioration of neurological functioning.

This preliminary assessment is consistent with the data from the study conducted in 2015, in which patients dosed with RYANODEX plus SOC showed an additive benefit compared to patients receiving SOC only.

During the 2018 Hajj, overall emergency room visits were dramatically decreased from previous years due to well-implemented crowd management, lower temperatures, lower humidity and other external factors. As a result, the number of EHS patients available for study enrollment was also significantly less than in previous years, and therefore much lower than anticipated. The Company intends to complete the analysis of the data and meet with the U.S. Food and Drug Administration ("FDA") to discuss next steps.

"Our preliminary evaluation of the data indicates that the patients receiving RYANODEX showed an improved outcome compared to patients treated with cooling only. We have now conducted two randomized, controlled studies and have obtained comparable results in both studies. We have 41 subjects for a rare disease with FDA fast-track and Orphan Drug designations, and no other approved drugs to treat EHS," stated Scott Tarriff, Chief Executive Officer.

"Based upon the collective results of our two clinical trials as well as other work performed by the Company and researchers around the world, we believe there is sufficient data to provide evidence of safety and efficacy for the use of RYANODEX for the treatment of EHS. We plan to meet with the FDA to discuss the next steps in making this very important product available to those afflicted with exertional heat stroke," concluded Tarriff.

This study was conducted in compliance with all current FDA regulations and is the second trial conducted by Eagle. The study intended to provide confirmatory evidence of the Company's initial safety and efficacy study of RYANODEX for EHS conducted in September 2015 and to satisfy the FDA's requirements to amend Eagle's original NDA.

Additional details about the study can be found at www.ClinicalTrials.gov (ClinicalTrials.gov Identifier: NCT03600376).

Results of 2015 Study

Eagle's initial study was conducted from September 22-27, 2015, at the Emergency Departments of four hospitals during the Hajj pilgrimage in the Makkah region, Saudi Arabia.

The open-label, randomized, 2-arm study was primarily designed to assess the change in the level of neurological impairment in subjects suffering from the symptoms of EHS, from baseline to 90 minutes post-randomization, using the Glasgow Coma Scale ("GCS").

The use of a validated and well-known instrument to evaluate neurological functioning, such as the Glasgow Coma Scale, provides a reliable assessment of CNS impairment and its progression over time.

The study enrolled 34 EHS patients between 18-45 years of age.

Subjects were randomized 1:1 into two groups to receive either RYANODEX plus SOC, (Group A, n=17), or SOC alone (Group B, n=17).

Per study protocol, all subjects experienced exertional physical activity within the previous 24 hours, and demonstrated hallmark clinical features of EHS, including:

- Presence of neurological impairment, evaluated using the Glasgow Coma Scale ("GCS");
- Baseline core body temperature of 104° F (40° C) or greater; and,
- Tachycardia (at least 100 heart beats per minute).

Baseline disease characteristics were comparable between the two groups, including a mean GCS score (Group A: 6.1 vs. Group B: 5.9) representing severe neurological impairment, and severe hyperthermia (Group A: 106.5° F (41.4° C) vs. Group B: 106.7° F (41.5° C).

Efficacy

Patients were evaluated at baseline and at regular time intervals post-randomization for changes in level of consciousness using GCS, and core body temperature.

Study results showed that a greater proportion of patients treated with Ryanodex plus SOC exhibited a clinically meaningful improvement in their neurological functioning (GCS $\geq$ 13) within 90 minutes (29.4%) and within 24 hours post-randomization (47.1%), compared with SOC only-treated subjects (11.8% and 23.5%, respectively).

In addition, pre-specified odds ratio analysis showed that odds of achieving a GCS score $\geq$ 13 within 90 minutes postrandomization was about 3 times greater for subjects in the Ryanodex plus SOC group than for subjects who received SOC-only and remained almost unchanged at or prior to 24 hours postrandomization. Also, the median time to reach first rectal temperature $\leq$ 38°C was shorter in the Ryanodex plus SOC group (90.0 minutes) than in the SOC only group (103.0 minutes).

Safety

Overall, safety findings were comparable between the two study groups, and there were no serious drug-related adverse events. Fewer patients experienced treatment-emergent adverse events in Group A (64.7%), as compared to Group B (76.5%), and the incidence of serious adverse events in each of the two treatment arms was comparable. In summary, the safety results of the study are consistent with the known, and well characterized, safety profile of RYANODEX.

About the Glasgow Coma Scale

The Glasgow Coma Scale ("GCS") is a validated tool that functions as a common scoring system among medical practitioners for measuring and describing the varying degrees of level of consciousness in a person following an acute brain injury.[1]

Widely accepted as reliable and objective, this scoring system is used by trained staff at the site of a potential brain injury, as well as in emergency departments and intensive care units. The GCS was selected for this study as an objective and accurate method to measure the state of mental impairment and the subsequent improvement of test subjects.

The GCS measures three key functions: Eye Opening, Motor Response and Verbal Response.

Eye Opening (E)
4 = spontaneous
3 = to voice
2 = to pain
1 = none

Verbal Response (V)
5 = normal conversation
4 = disoriented conversation
3 = words, but not coherent
2 = no words, only sounds
1 = none

Motor Response (M)
6 = normal
5 = localized to pain
4 = withdraws to pain
3 = decorticate posture (an abnormal posture that can include rigidity, clenched fists, legs held straight out, and arms bent inward toward the body with the wrists and fingers bend and held on the chest)
2 = decerebrate (an abnormal posture that can include rigidity, arms and legs held straight out, toes pointed downward, head and neck arched backwards)
1 = none

[1] Teasdale G, Jennett B. (1974). "Assessment of coma and impaired consciousness. A practical scale." Lancet 13 (2): 81—4. [2] "What Is the Glasgow Coma Scale?" www.brainline.org, n.d. Web. <http://www.brainline.org/content/2010/10/what-is-the-glasgow-coma-scale.html>.

Clinicians use the GCS to assess the eye opening response, the verbal response, and the motor response in patients with an impaired level of consciousness. The total GCS score is the sum of the scores for each of these functions, classified as follows[2]:

Classification	Total Glasgow Coma Scale Score
Severe	3 — 8
Moderate	9 — 12
Mild	13 — 15

About Exertional Heat Stroke

The two types of heat stroke — classical and exertional - are the most severe forms of heat illness. Classical heat stroke often results from passive exposure to heat, as observed during heat waves, and mostly affects very young and elderly people. In contrast, EHS is a rare disease, mostly impacting young - otherwise healthy - people, performing intense physical activity in hot weather environments. EHS is a life-threatening and unpredictable condition, characterized by an acute hyperthermic-hypermetabolic status, which may result in severe neurological, renal and liver damage, or even death, if not treated promptly. Currently, the treatment of EHS is limited to body surface cooling and supportive measures; despite the use of cooling, up to 30% of EHS victims suffer long-term neurological sequalae.

About RYANODEX

RYANODEX® (dantrolene sodium) for injectable suspension is indicated for the treatment of malignant hyperthermia in conjunction with appropriate supportive measures, and for the prevention of malignant hyperthermia in patients at high risk.

Important Safety Information

RYANODEX® is not a substitute for appropriate supportive measures in the treatment of malignant hyperthermia, including:

Discontinuing triggering anesthetic agents

Increasing oxygen

Managing the metabolic acidosis

Instituting cooling when necessary

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[2] "What Is the Glasgow Coma Scale?" www.brainline.org, n.d. Web. <http://www.brainline.org/content/2010/10/what-is-the-glasgow-coma-scale.html>.

Administering diuretics to prevent late kidney injury due to myoglobinuria (the amount of mannitol in RYANODEX® is insufficient to maintain diuresis).

Precautions should be taken when administering RYANODEX® preoperatively for the prevention of malignant hyperthermia, including monitoring vital signs, avoiding known triggering agents, and monitoring for early clinical and metabolic signs of malignant hyperthermia that may indicate additional treatment is needed.

The administration of dantrolene sodium is associated with loss of grip strength and weakness in the legs, as well as drowsiness, dizziness, dysphagia, dyspnea, and decreased inspiratory capacity. Patients should not be permitted to ambulate without assistance until they have normal strength and balance. Care must be taken to prevent extravasation of RYANODEX® into the surrounding tissue due to the high pH of the reconstituted RYANODEX® suspension and potential for tissue necrosis.

RYANODEX® full Prescribing Information can be found at www.RYANODEX.com

About Eagle Pharmaceuticals, Inc.

Eagle is a specialty pharmaceutical company focused on developing and commercializing injectable products that address the shortcomings, as identified by physicians, pharmacists and other stakeholders, of existing commercially successful injectable products. Eagle's strategy is to utilize the FDA's 505(b)(2) regulatory pathway. Additional information is available on the company'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 such as "will," "continue," "may," "believe," "intends," "anticipate(s)," "plan," "enables," "potentially," "entitles," and similar expressions are intended to identify forward-looking statements. These statements include statements regarding future events including, but not limited to: the safety and efficacy of RYANODEX for the treatment of EHS; FDA approval of the use of RYANODEX for the treatment of EHS; the timing and level of success of a future launch of RYANODEX; successful compliance with FDA and other governmental regulations applicable to manufacturing facilities, products and/or businesses; the commercial success of Eagle's commercial portfolio, including RYANODEX, if and when launched; and other factors that are discussed in Eagle's Annual Report on Form 10-K for the year ended December 31, 2017, and its other filings with the U.S. Securities and Exchange Commission. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond Eagle's control, that could cause actual results to differ materially from those

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expressed in, or implied or projected by, the forward-looking information and statements. Such risks include, but are not limited to: whether the FDA will ultimately approve RYANODEX for the treatment of EHS; whether Eagle's studies will support the safety and efficacy of RYANODEX for the treatment of EHS; whether Eagle's management and/or board of directors will be effective in managing Eagle's business, future growth and market protection, including with respect to RYANODEX; whether Eagle will maintain successful compliance with the FDA and other governmental regulations; and other risks described in Eagle's filings with the U.S. Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and we do not undertake any obligation to revise and disseminate forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of or non-occurrence of any events.

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