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 1, 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 June 1, 2022, Eagle Pharmaceuticals, Inc., or the Company, issued a press release announcing that AOP Orphan Pharmaceuticals GmbH, with whom it entered into a licensing agreement in August 2021, has submitted a new drug application to the U.S. Food and Drug Administration seeking approval of landiolol, a novel therapeutic, for the short-term reduction of ventricular rate in patients with supraventricular tachycardia, including atrial fibrillation and atrial flutter.

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.

Exhibit No.	Description
99.1	Press Release of the Company, dated June 1, 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: June 1, 2022

EAGLE PHARMACEUTICALS, INC.

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

Exhibit 99.1

For Immediate Release

Eagle Pharmaceuticals Announces Submission of New Drug Application to U.S. Food and Drug Administration for Landiolol, a Beta-1 Adrenergic Blocker

-- Submission seeks approval for landiolol for the short-term reduction of ventricular rate in patients with supraventricular tachycardia, including atrial fibrillation and atrial flutter --

-- Expected approval mid-year 2023, if accepted by FDA for filing, based on feedback from U.S. Food and Drug Administration ("FDA") provided during AOP Health's Type C meeting --

-- Enrollment of study of pediatric patients with supraventricular tachycardia is underway in Europe and is designed to serve as the basis for proposed pediatric study plans for a future FDA submission --

-- If landiolol is approved, Eagle expects five years of new chemical entity exclusivity --

WOODCLIFF LAKE, NJ—June 1, 2022—Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that AOP Orphan Pharmaceuticals GmbH, a member of the AOP Health Group ("AOP Health"), with whom Eagle entered into a licensing agreement in August 2021, submitted a new drug application ("NDA") to the U.S. Food and Drug Administration ("FDA") for landiolol, a short-acting, intravenous ("IV"), cardio-selective beta-1 adrenergic blocker. The submission seeks approval for landiolol for the short-term reduction of ventricular rate in patients with supraventricular tachycardia ("SVT"), including atrial fibrillation and atrial flutter.

"The submission of the landiolol NDA is a significant step forward for our company, as we look to bring this important therapeutic candidate to the U.S. market and to expand our footprint in the acute care setting. We believe that landiolol has the potential to become a cornerstone therapy in the management of tachycardia in critically ill patients. Landiolol has differentiated clinical characteristics and an established safety profile, and we look forward to working with FDA during the course of the review process," stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

"We are successfully diversifying our revenue stream, anticipated to grow from three commercial products just last year to eight upon the closing of the anticipated Acacia Pharma transaction, and nine with landiolol, if approved. We look forward to the potential of adding another strong product to our portfolio and to leveraging our highly capable hospital-based sales force," concluded Tarriff.

Landiolol is an ultra-short-acting, cardio-selective, beta-1 adrenoceptor blocker, which reduces heart rate and has a minimal effect over cardiac contractility (inotropy). Landiolol is designed for use in emergency, critical care, and operating room settings. It is registered in several European countries for the treatment of tachycardic supraventricular arrhythmias and non-compensatory sinus tachycardia.

Landiolol is already commercially available in Japan (Onoact®) and several European markets as RAPIBLOC®. Multiple clinical studies in these geographies demonstrate that landiolol is a safe and effective option for the rapid short-term control of tachyarrhythmias (Syed YY. Landiolol: A Review in Tachyarrhythmias. Drugs. 2018 Mar;78(3):377-388. doi: 10.1007/s40265-018-0883-9. PMID: 29470800.). A Type C meeting was held with FDA in July 2020, at which time AOP Health proposed a submission strategy in which it would provide summaries of pre-existing safety and efficacy data and a meta-analysis of published randomized controlled trials. The FDA tentatively agreed with this methodological approach and deemed data sets adequate to support a proposed NDA.

The management of rapid heart rate (tachycardia) in critically ill patients can be quite complicated regardless of the underlying cause. Beta blockers, also known as beta-adrenergic blocking agents, are a class of drugs that lower heart rate by blocking the neurotransmitters norepinephrine and epinephrine from binding to receptors. These neurotransmitters contribute to the development of tachycardia. β-1 receptor beta blockers are used frequently in critical care settings to manage tachycardia; however, the available β-1 beta blockers in the U.S. can have the unwanted effects of decreasing the contractility, or muscle strength, of the heart, and of lowering blood pressure to a greater extent than landiolol.

Landiolol is ultra-short acting, with a rapid on and off effect that allows clinicians to quickly control heart rate with minimal impact on blood pressure. In addition, with a β1:β2 ratio of 255:1, landiolol is the most cardioselective beta blocker, which the Company believes will result in the least potential impact on respiratory function among available β-blockers. The Company believes that clinicians will welcome landiolol as a key therapeutic tool for the more precise management of tachycardia in the critical care setting.

There are additional clinical settings for which landiolol has the potential to improve patient management. Enrollment in LANDI-SEP, a European clinical trial studying landiolol in patients with tachycardia and septic shock, is complete. Importantly, landiolol is also being studied in a pediatric population, for whom no intravenous beta-blocker drug products are approved in the U.S. for ventricular rate control. The FDA has tentatively agreed that this study could form the basis for proposed pediatric study plans for a future submission to FDA.

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 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, the timing of and AOP Health’s ability to obtain any regulatory approval of landiolol; the anticipated benefits of landiolol and its potential acceptance by clinicians; the timing, progress and results of additional trials of landiolol and the ability of such trial results to support regulatory filings and approvals; anticipated actions by the FDA; the Company’s ability to support the commercial launch of landiolol in the United States, if approved; the expected duration of new chemical entity exclusivity; the potential market opportunity for landiolol; the ability of the Company’s product candidates, including landiolol, to deliver value to stockholders; and expectations with respect to the proposed acquisition with Acacia Pharma, including the expecting timing and ability to successfully consummate the transaction on the contemplated terms or at all, including the acquisition of two additional commercial products in the proposed acquisition. 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 ongoing military conflict between Ukraine and Russia and related sanctions against Russia, 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 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 our 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; factors in addition to the foregoing that may impact the Company’s financial projects and guidance, 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 from its projections and guidance;; 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 and its other subsequent filings with the SEC, including the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, which the Company expects to file with the SEC on May 9, 2022. 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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