
**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): **September 23, 2020**

Eagle Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36306
(Commission File Number)

20-8179278
(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:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
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 September 23, 2020, Eagle Pharmaceuticals, Inc. issued a press release announcing that its marketing partner, SymBio Pharmaceuticals Limited, received regulatory approval for TREAKISYM ready-to-dilute (250 ml) liquid formulation from the Pharmaceuticals and Medical Devices Agency in Japan, covering all indications for which TREAKISYM is currently approved, including low-grade non-Hodgkin's lymphoma, mantle cell lymphoma, and chronic lymphocytic leukemia.

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. The information contained in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act except as expressly provided by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated September 23, 2020
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: September 23, 2020

EAGLE PHARMACEUTICALS, INC.

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

**For Immediate Release****Eagle Pharmaceuticals' Japanese Licensing Partner, Symbio, Receives Approval of TREAKISYM Ready-To-Dilute ("RTD") Formulation, with Launch Expected in January 2021**

- Eagle to receive \$5 million milestone payment -
- RTD and Rapid Infusion ("RI") formulations could generate \$10 million - \$25 million annually for Eagle -

WOODCLIFF LAKE, N.J.— September 23, 2020 — Eagle Pharmaceuticals, Inc. ("Eagle" or the "Company") (NASDAQ: EGRX) today announced that its marketing partner, Symbio Pharmaceuticals Limited ("Symbio"), has received regulatory approval for TREAKISYM ready-to-dilute ("RTD") (250 ml) liquid formulation from the Pharmaceuticals and Medical Devices Agency ("PMDA") in Japan. The approval covers all indications for which TREAKISYM is currently approved (low-grade non-Hodgkin's lymphoma, mantle cell lymphoma, and chronic lymphocytic leukemia). Approval for the additional indication of r/r DLBCL is currently under review by the PMDA, which will create another large market opportunity beyond the current indications. As a result of the approval of TREAKISYM, Eagle will receive a \$5 million milestone payment.

With this approval, Symbio will convert its current lyophilized formulation of TREAKISYM to the new RTD liquid formulation upon launch in January 2021.

In addition, Symbio is currently conducting a clinical safety trial for the ten-minute RI (50 ml) liquid formulation and will seek approval in the second half of 2022. Upon approval of the RI formulation, Symbio intends to convert from the RTD product to the new 50 ml liquid version licensed from Eagle. The RTD and RI liquid formulations bring key benefits to patients and healthcare providers in Japan by eliminating the need for manual reconstitution and significantly reducing preparation time.

"We are pleased that Symbio has received regulatory approval for TREAKISYM in Japan. Symbio is an innovator, and we look forward to their successful commercialization of the ready-to-dilute bendamustine product, enabling patients in Japan to benefit from TREAKISYM's key advantages. This approval represents another significant extension of the durability of this important franchise and the successful execution of our business development activities to bring value for Eagle and our shareholders," stated Scott Tarriff, Chief Executive Officer.

According to SymBio, sales in Japan for its current TREAKISYM product totaled \$84.8 million in the twelve months ended June 30, 2020. Together, milestones and royalty payments for the RTD and RI formulations could generate from \$10 million to \$25 million annually for Eagle.

In September 2017, Eagle licensed to SymBio intellectual property necessary to develop, market and sell RTD and RI formulations of TREAKISYM in Japan utilizing Eagle's proprietary technology. As part of the agreement, SymBio assumed responsibility for securing regulatory approval of the TREAKISYM RTD and RI products using the licensed technology in Japan.

The \$5 million milestone payment due upon approval of TREAKISYM RTD is in addition to a \$12.5 million upfront milestone payment Eagle received upon execution of the agreement with SymBio. Eagle is entitled to royalties on future net sales and an additional milestone payment upon achievement of a cumulative sales threshold.

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.

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 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 regarding future events including, the Company’s ability to successfully collaborate with its Japanese licensing partner, SymBio, with respect to the commercialization of SymBio’s product TREAKISYM; the timing of the potential product launch of TREAKISYM; the Company’s and SymBio’s commercialization strategy for TREAKISYM; the timing of potential future milestone payments from SymBio to the Company, if ever, and the amount of such payments, if any; the timing of approval for the additional indication of r/r/ DLBCL, if at all; and the future commercial success of the TREAKISYM RTD and RI formulations. 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: risks that the Company’s or its partners’ business, financial condition and results of operations will be impacted by the spread of COVID-19 in the geographies where such parties operate; whether the Company will incur unforeseen expenses or liabilities or other market factors in connection with COVID-19; the success of the Company’s collaborations with its strategic partners; successful compliance with 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, 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; 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, 2019 as updated by the Company’s subsequent filings with the 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 the Company does 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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