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): December 18, 2018

Eiger BioPharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36183**	**33-0971591**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2155 Park Blvd. **Palo Alto, California** **(Address of principal executive offices)**	**94306** **(Zip Code)**

Registrant's telephone number, including area code: (650) 272-6138

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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 December 18, 2018, the Company issued a press release entitled "Eiger Announces PRIME Designation Granted by European Medicines Agency for Lonafarnib for Treatment of Hepatitis Delta Virus Infection." A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated December 18, 2018, titled "Eiger Announces PRIME Designation Granted by European Medicines Agency for Lonafarnib for Treatment of Hepatitis Delta Virus Infection."

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.

Eiger BioPharmaceuticals, Inc.

Dated: December 18, 2018

By: /s/ Sriram Ryali
Sriram Ryali
Chief Financial Officer

Exhibit 99.1

Eiger Announces PRIME Designation Granted by European Medicines Agency for Lonafarnib for Treatment of Hepatitis Delta Virus Infection

- Phase 3 HDV “D-LIVR” International Study Initiating

PALO ALTO, Calif., December 18, 2018 — Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization of targeted therapies for rare and ultra-rare diseases, today announced the European Medicines Agency (EMA) has granted PRIME (PRIority MEdicines) designation for lonafarnib for the treatment of hepatitis delta virus (HDV) infection. Eiger’s application was supported by data from Phase 2 clinical studies of lonafarnib treatment in HDV-infected patients, achieving endpoints which reflect an improvement in liver condition and virologic response rarely observed in untreated HDV patients. Lonafarnib is a first-in-class prenylation inhibitor for the treatment of Hepatitis Delta Virus (HDV) infection.

The PRIME designation is awarded by the EMA to promising medicines that target an unmet medical need. These medicines are considered priority medicines by the EMA. To be accepted for PRIME, a medicine has to show its potential to benefit patients with unmet medical needs based on early clinical data. Through PRIME, the EMA offers enhanced support to medicine developers including early interaction and dialogue and a pathway for accelerated evaluation by the agency. The program is intended to optimize development plans and expedite the review and approval process so that these medicines may reach patients as early as possible.

“We are very pleased that the European Medicines Agency has granted PRIME designation for lonafarnib, as there is an urgent medical need to treat HDV, the most serious form of viral hepatitis,” said David Apelian, MD, PhD, MBA, Chief Operating Officer and Executive Medical Officer. “With the recent granting of Breakthrough Designation by Food and Drug Administration, we look forward to collaborating with both the FDA and EMA to accelerate development of this important therapy for HDV-infected patients.”

Eiger has initiated the D-LIVR Study, the first-ever, global registration trial with the potential to bring two separate, approved lonafarnib-based treatment options to HDV patients.

About Lonafarnib

Lonafarnib is a well-characterized, late-stage, orally active inhibitor of farnesyl transferase, an enzyme involved in modification of proteins through a process called prenylation. HDV uses this host cell process inside liver cells to complete a key step in its life cycle. Lonafarnib inhibits the prenylation step of HDV replication inside liver cells and blocks the virus life cycle at the stage of assembly. Lonafarnib has been dosed in over 120 HDV-infected patients across international academic centers and is in Phase 3

development for HDV with a single, pivotal trial. Lonafarnib has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), and Fast Track and Breakthrough Designation by U.S. FDA. Lonafarnib is not approved for any indication, and is licensed from Merck Sharp & Dohme Corp. (known as MSD outside of the United States and Canada).

About Hepatitis Delta Virus (HDV)

Hepatitis Delta is caused by infection with HDV and is considered to be one of the most severe forms of viral hepatitis in humans. Hepatitis delta occurs only as a co-infection in individuals harboring Hepatitis B Virus (HBV). Hepatitis delta leads to more severe liver disease than HBV alone and is associated with accelerated liver fibrosis, liver cancer, and liver failure. Hepatitis delta is a disease with a significant impact on global health, which may affect up to approximately 15-20 million people worldwide. The prevalence of HDV varies among different parts of the world. Globally, HDV infection is reported to be present in approximately 4.3% to 5.7% of chronic Hepatitis B carriers. The prevalence of HDV in patients infected with chronic HBV is even higher in certain regions, including certain parts of Mongolia, China, Russia, Central Asia, Pakistan, Turkey, Africa, Middle East and South America, with an HDV prevalence as high as 60% being reported in HBV-infected patients in Mongolia and Pakistan.

About D-LIVR Study

D-LIVR (**D**elta **L**iver **I**mprovement and **V**irologic **R**esponse in HDV) is an international, multi-center, Phase 3 study of approximately 300 lonafarnib (LNF)-treated patients (total N=400 patients including controls) to evaluate an all-oral arm of LNF boosted with ritonavir (RTV) and a combination arm of LNF boosted with RTV combined with pegylated interferon-alfa (PEG IFN-alfa), with each arm to be compared to a placebo arm (background HBV nucleos(t)ide only), in HDV-infected patients. A PEG IFN-alfa alone arm will be dosed to demonstrate contribution of effect only. The LNF containing arms will not be required to demonstrate superiority over PEG IFN-alfa alone. A combined primary endpoint of ^{3} 2 $\log_{10}$ decline in HDV RNA and ALT normalization at end of 48 weeks of treatment will be used to assess activity of LNF-based regimens versus placebo in the D-LIVR study.

About Eiger

Eiger is a late-stage biopharmaceutical company focused on the accelerated development and commercialization of a pipeline of targeted, first-in-class therapies for rare and ultra-rare diseases. The company's lead program is in Phase 3, developing lonafarnib, a first-in-class prenylation inhibitor for the treatment of Hepatitis Delta Virus (HDV) infection. The company is also preparing an NDA with plans to file in 2019 for lonafarnib in the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies. For additional information about Eiger, please visit www.eigerbio.com.

Note Regarding Forward-Looking Statements

This press release contains “forward-looking” statements that involve substantial risks and uncertainties. “All statements other than statements of historical facts, including statements regarding our future financial condition, timing for and outcomes of clinical results, business strategy and plans and objectives for future operations, are forward looking statements. These forward-looking statements include terminology such as “believe,” “will,” “may,” “estimate,” “continue,” “anticipate,” “contemplate,” “intend,” “target,” “project,” “should,” “plan,” “expect,” “predict,” “could,” “potentially” or the negative of these terms. Forward looking statements are our current statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned clinical development timing expectations and whether larger studies will support the earlier study results identified, including whether the D-LIVR Phase 3 study as a single, pivotal study will be initiated by the end of 2018; whether the D-LIVR Phase 3 study results, if successful, will be sufficient to support registration; the timing of and our ability to initiate or enroll clinical trials, including whether our D-LIVR study can be initiated by the end of this year; our ability to complete and achieve successful clinical study results with any or all of our product candidates in order make timely regulatory filings and obtain and maintain regulatory approvals based on our expected timelines; our ability to move lonafarnib into potentially pivotal clinical studies and file an NDA for progeria in a successful and timely manner; our intellectual property position; and the potential safety, efficacy, reimbursement, convenience clinical and pharmaco-economic benefits of our product candidates as well as the commercial opportunities, including potential market sizes and segments; our ability to finance the continued advancement of our development pipeline products, including our results of operations, cash available, financial condition, liquidity, prospects, growth and strategies; and the potential for success of any of our product candidates.

Various important factors could cause actual results or events to differ materially from the forward-looking statements that Eiger makes, including the risks described in the “Risk Factors” sections in the Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 and Eiger’s periodic reports filed with the SEC. Eiger does not assume any obligation to update any forward-looking statements, except as required by law.

SOURCE: Eiger BioPharmaceuticals, Inc.

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