

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): April 1, 2020

EIGER BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36183
(Commission
File Number)

33-0971591
(IRS Employer
Identification No.)

Eiger BioPharmaceuticals, Inc.
2155 Park Blvd.
Palo Alto, California 94306
(Address of principal executive offices, including zip code)

(650) 272-6138

(Registrant's telephone number, including area code)

Not Applicable

(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))
-

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock (par value \$0.001 per share)	EIGR	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 (§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 April 1, 2020, Eiger BioPharmaceuticals, Inc. issued a press release titled “Eiger BioPharmaceuticals Provides Update on Clinical Development Activities and Business Operations During COVID-19 Pandemic.” A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press release, dated April 1, 2020, titled “Eiger BioPharmaceuticals Provides Update on Clinical Development Activities and Business Operations During COVID-19 Pandemic.”</u>

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: April 1, 2020

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

Eiger BioPharmaceuticals Provides Update on Clinical Development Activities and Business Operations During COVID-19 Pandemic

- **HDV Phase 3 D-LIVR Study Progressing; Impact to Timeline**
- **Peginterferon Lambda Investigator-Sponsored Studies in COVID-19 Initiating**

PALO ALTO, Calif. April 1, 2020 -- Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization of targeted therapies for serious rare and ultra-rare diseases, today provided an update on the impact of the rapidly progressing global COVID-19 (SARS-CoV-2) pandemic. Eiger has put into place remote operations and new policies to maintain the safety and well-being of our employees, while working to maintain business continuity as this unprecedented global situation continues to evolve. The company has taken appropriate steps to ensure the safety of patients and the integrity of the HDV Phase 3 D-LIVR trial. We have also begun supporting multiple Investigator-Sponsored Studies of Peginterferon Lambda in COVID-19.

HDV Phase 3 D-LIVR Study

Eiger continues to prioritize the safety and well-being of Phase 3 D-LIVR study patients, while considering regulatory, institutional, and government guidance and policies. The company is working closely with clinical sites across twenty countries to enable remote patient study visits, use of local labs for safety monitoring, and home delivery of study drug to ensure study continuity and integrity. The company now anticipates that the COVID-19 pandemic will shift the completion of D-LIVR study enrollment into 2021.

“The COVID-19 pandemic represents a significant, ongoing public health threat and has created an unprecedented burden on healthcare systems across the globe. In order to ensure the safety of D-LIVR study participants, and also in accordance with the recently issued guidance documents from the FDA and EMA, we continue to assess and make appropriate adjustments to the D-LIVR study,” said David Cory, President and CEO of Eiger. “While recruitment and dosing are on-going at active sites in D-LIVR, we are making adjustments including extending screening windows and delaying remaining key site activations to allow healthcare practitioners and sites to focus on patient care during the COVID-19 pandemic.”

Eiger has adequate clinical drug product supply for the D-LIVR study and does not anticipate any interruption in availability of study drug to patients.

Peginterferon Lambda in COVID-19

Eiger is supplying Peginterferon Lambda (Lambda) and is assisting in the protocol design of multiple Investigator-Sponsored Studies that are being initiated to evaluate the safety and efficacy of Lambda in patients diagnosed with COVID-19. These studies will

assess a 180 mcg, once-weekly, subcutaneous dose of Lambda, and will enroll at academic centers across the U.S., as well as international sites.

Lambda interferon plays a key role in the targeted innate immune response against viral pathogens that infect the respiratory tract, gastrointestinal tract and liver. Upon infection of airway epithelial cells, type III IFNs, like lambda interferon, are produced first and act as the initial line of defense to limit virus spread at the epithelial barrier without triggering inflammation. Preclinical studies have shown potent antiviral effects of lambda interferon against influenza, SARS coronavirus, rotavirus, norovirus, and reovirus.

“Interferons have demonstrated antiviral activity against SARS coronavirus (SARS-CoV) in a previous human clinical study,” said Colin Hislop, MD, Senior Vice President of Clinical and Development Operations. “The genetic similarities between SARS-CoV and SARS-CoV-2 support peginterferon lambda’s potential to provide clinical benefit for patients infected with COVID-19.”

About Peginterferon Lambda (Lambda)

Lambda is a well-characterized, late-stage, first-in-class, type III interferon (IFN) that stimulates immune responses that are critical for the development of host protection during viral infections. Lambda targets type III IFN receptors which are distinct from the type I IFN receptors targeted by IFN alfa, resulting in activation of the same Jak-STAT signal transduction cascade. Lambda type III receptors are highly expressed on epithelia of the lung, gastrointestinal tract and liver with limited expression on hematopoietic and central nervous system cells, which may reduce off-target effects and improve tolerability of Lambda.

Eiger licensed worldwide rights to Lambda from Bristol-Myers Squibb. Eiger is developing Lambda as a monotherapy and in combination with lonafarnib boosted with ritonavir. Lambda has been administered to over 3,000 subjects in 19 clinical trials of HBV, HCV and HDV. Lambda is an investigational agent and not yet approved for any indication. Eiger has received Orphan Designation by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), and Fast Track and Breakthrough Therapy Designation by FDA for Lambda in HDV.

About Eiger

Eiger is a late-stage biopharmaceutical company focused on the development and commercialization of first-in-class, well-characterized drugs for serious rare and ultra-rare diseases for patients with high unmet medical needs, for which no approved therapies exist.

Eiger has completed an NDA and MAA submission for lonafarnib for the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid

Laminopathies. Eiger has also established a global Managed Access Program, expected to span greater than 40 countries, to ensure all children and young adults with Progeria and Progeroid Laminopathies have access to treatment.

The company's lead program is in Phase 3, developing lonafarnib, a first-in-class oral prenylation inhibitor for the treatment of Hepatitis Delta Virus (HDV) infection. The company is also advancing peginterferon lambda, a first-in-class interferon, toward registration for the treatment of HDV. For additional information about Eiger and its clinical programs, 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 anticipating significant milestones in 2020, the timing of our ongoing and planned clinical development, including the potential for approval of our lonafarnib product candidate in the US and EU for Progeria and Progeroid Laminopathies; our progression and enrollment of our Phase 3 D-LIVR study in HDV; our ability to complete enrollment of D-LIVR in 2021; our ability to maintain supply of our clinical trial materials; our announcement of data from the trial of peginterferon lambda and lonafarnib boosted with ritonavir for HDV (LIFT); our plans to advance peginterferon lambda in HDV in the US and EU; our plans to initiate clinical studies of peginterferon lambda in coronavirus; our plans for continued advancement of avexitide in registration trials; our ability to transition into a commercial stage biopharmaceutical company; our ability to finance the continued advancement of our development pipeline products; that the company's expectations regarding the effects of COVID-19 on the Company's trials and development may be incorrect, and the potential for success of any of our product candidates.

These statements concern product candidates that have not yet been approved for marketing by the U.S. Food and Drug Administration (FDA). No representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

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 Annual Report on Form 10-K for the year ended December 31, 2019 and Eiger's subsequent filings with the SEC. Eiger does not

assume any obligation to update any forward-looking statements, except as required by law.



SOURCE Eiger BioPharmaceuticals, Inc.

Investors and Media:

Ingrid Choong, PhD
Sr VP, Clinical Development
(650) 619-6115
ichoong@eigerbio.com

Sri Ryali
CFO
(650) 272-6138
sryali@eigerbio.com