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 21, 2021

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.)

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 December 21, 2021, Eiger BioPharmaceuticals, Inc. issued a press release titled "Eiger BioPharmaceuticals Announces First Patient Enrolled in LIMT-2: A Phase 3 Study of Peginterferon Lambda in Patients with Chronic Hepatitis Delta Virus (HDV) Infection." 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.

Exhibit No.	Description
99.1	Press release, dated December 21, 2021, titled "Eiger BioPharmaceuticals Announces First Patient Enrolled in LIMT-2: A Phase 3 Study of Peginterferon Lambda in Patients with Chronic Hepatitis Delta Virus (HDV) Infection."
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: December 21, 2021

Eiger BioPharmaceuticals, Inc.

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

Exhibit 99.1

Eiger BioPharmaceuticals Announces First Patient Enrolled in *LIMT-2*: A Phase 3 Study of Peginterferon Lambda in Patients with Chronic Hepatitis Delta Virus (HDV) Infection

Palo Alto, Calif., December 21, 2021 / PRNewswire / — Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), a commercial-stage biopharmaceutical company focused on the development of innovative therapies to treat and cure Hepatitis Delta Virus (HDV) and other serious rare diseases, today announced that the first patient has been enrolled in *LIMT-2*, a Phase 3 study of 48-week treatment with Peginterferon Lambda in patients with chronic hepatitis delta virus (HDV) infection. *LIMT-2* will include 50 sites across 13 countries and a target enrollment of 150 patients.

"*LIMT-2* is a single pivotal study to support approval of Peginterferon Lambda for the treatment of HDV," said David Cory, President and CEO of Eiger. "We believe that a well tolerated interferon will be preferred by physicians and HDV patients, leading to better compliance and improved outcomes. We now have two promising investigational treatments in Phase 3 for HDV, Lonafarnib and Peginterferon Lambda, which we expect will become foundational therapies to treat and cure HDV."

"There are now multiple late-stage, promising investigational treatments in development for HDV, each with a different mechanism of action and formulation for different routes of administration," said Pietro Lampertico, MD, PhD, *LIMT-2* Principal Investigator, Professor of Gastroenterology, Director of the Gastroenterology and Hepatology Division, and Head of the "A. M. e A. Migliavacca" Center for Liver Disease at the Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico, University of Milan, Italy. "It's an exciting time for both patients and physicians as we look toward the potential of multiple approved treatment options for the greater than 12 million HDV patients around the globe suffering from this severe disease."

About Phase 3 *LIMT-2* Study

LIMT-2 is a randomized, open-label, parallel-arm study that will randomize patients with chronic HDV infection to one of two treatment groups, applying a 2:1 allocation ratio: Peginterferon Lambda 180 mcg QW for 48 weeks with 24 weeks follow-up (Arm 1, n=100), or no treatment for 12 weeks followed by Peginterferon Lambda treatment for 48 weeks with 24 weeks of follow-up (Arm 2, n=50). All patients will receive tenofovir or entecavir throughout the study duration.

The primary analysis will compare the proportion of patients with a Durable Virologic Response (DVR), defined as HDV RNA below the limit of quantitation (BLQ) at 24-weeks post-treatment in the Peginterferon Lambda treatment group (Arm 1) to the proportion of patients with HDV RNA BLQ after 12 weeks of no treatment in the comparator group (Arm 2). This post-treatment DVR endpoint is most meaningful for both regulatory agencies and physicians as it demonstrates durability of response to treatment and potential for an HDV cure. Approximately 150 patients will be enrolled in 13 countries across 50 investigator sites.

About Peginterferon Lambda

Peginterferon 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. Peginterferon 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 hepatocytes with limited expression on hematopoietic and central nervous system cells, which may reduce off-target effects and improve tolerability of Peginterferon Lambda.

In Phase 2, Peginterferon Lambda was dosed once weekly in HDV infected patients for 48 weeks with 24-week follow-up. 36% of patients who received Peginterferon Lambda achieved a DVR.

Eiger licensed worldwide rights to Peginterferon Lambda from Bristol-Myers Squibb. Eiger is developing Peginterferon Lambda as a monotherapy and in combination with Lonafarnib boosted with ritonavir. 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 Peginterferon Lambda in HDV.

About Hepatitis Delta Virus (HDV)

HDV is the most severe form of human viral hepatitis. HDV occurs only as a co-infection in individuals infected with hepatitis B virus (HBV). HDV leads to more severe liver disease than HBV alone and is associated with accelerated liver fibrosis, liver cancer, and liver failure. It is estimated that 60% of HDV infected patients die within ten years. Approved nucleos(t)ide treatments for HBV only suppress HBV DNA, do not affect HBsAg and have no impact on HDV.

HDV is a disease with a significant impact on global health, which may affect greater than 12 million people worldwide. Globally, HDV infection is reported to be present in approximately 5% of patients with chronic HBV.

About Eiger Eiger is a commercial-stage biopharmaceutical company focused on the development of innovative therapies to treat and cure Hepatitis Delta Virus (HDV) and other serious rare diseases. The Eiger HDV platform includes two first-in-class therapies in Phase 3 that target critical host processes involved in viral replication. All five Eiger rare disease programs have been granted FDA Breakthrough Therapy Designation.

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 within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. 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. Forward-looking statements are our current statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, the timing of our ongoing and planned clinical development; the sufficiency of our cash, cash equivalents and investments to fund our operations; the ability to activate sites and fully enroll the Phase 3 *LIMT-2* study; the potential of Peginterferon Lambda to be an effective therapy for HDV; and the generation of clinical trial data to support its submission for regulatory approval. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Eiger makes, including additional applicable risks and uncertainties described in the “Risk Factors” sections in the Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 and Eiger’s subsequent filings with the SEC. The forward-looking statements contained in this press release are based on information currently available to Eiger and speak only as of the date on which they are made. Eiger does not undertake and specifically disclaims any obligation to update any forward-looking statements, whether as a result of any new information, future events, changed circumstances or otherwise.

SOURCE Eiger BioPharmaceuticals, Inc.

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