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 8, 2022

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	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 8, 2022, Eiger BioPharmaceuticals, Inc. issued a press release titled "Eiger Announces Both Lonafarnib-based Treatments in Pivotal Phase 3 *D-LIVR* Trial in Hepatitis Delta Virus (HDV) Achieved Statistical Significance Against Placebo in Composite Primary Endpoint." 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 8, 2022, titled "Eiger Announces Both Lonafarnib-based Treatments in Pivotal Phase 3 *D-LIVR* Trial in Hepatitis Delta Virus (HDV) Achieved Statistical Significance Against Placebo in Composite Primary Endpoint."
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.

Eiger BioPharmaceuticals, Inc.

Dated: December 8, 2022

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

Eiger Announces Both Lonafarnib-based Treatments in Pivotal Phase 3 *D-LIVR* Trial in Hepatitis Delta Virus (HDV) Achieved Statistical Significance Against Placebo in Composite Primary Endpoint

- *Lonafarnib/ritonavir response rate of 10.1% (p=0.0044)*
- *Lonafarnib/ritonavir in combination with peginterferon alfa response rate of 19.2% (p<0.0001)*
- *Peginterferon alfa comparator arm, included for contribution of effect, response rate of 9.6%*
- *Key secondary endpoint of proportion of patients with improvement in histological response rate demonstrated with statistical significance in combination arm vs placebo*

PALO ALTO, Calif., Dec. 8, 2022 — Eiger BioPharmaceuticals, Inc. (Nasdaq: EIGR), a commercial-stage biopharmaceutical company focused on the development of innovative therapies for hepatitis delta virus (HDV) and other serious diseases, today announced topline primary Week 48 data from its landmark Phase 3 *D-LIVR* study (N=407) evaluating lonafarnib, a first-in-class prenylation inhibitor, in two regimens in patients with chronic HDV: lonafarnib boosted with ritonavir alone (all-oral) and in combination with peginterferon alfa (combination). The composite primary endpoint was a ≥2 log decline in HDV RNA and normalization of alanine aminotransferase (ALT) at the end of 48 weeks of treatment compared to placebo.

Topline Week 48 results showed that both treatment arms achieved statistical significance over placebo in the composite primary endpoint as well as the component virologic and biochemical responses. Study participants receiving the all-oral therapy and combination therapy showed a composite response of 10.1% (p=0.0044) and 19.2% (p <0.0001), respectively, compared to those receiving placebo (1.9%). Study participants receiving the all-oral therapy and combination therapy showed statistically significant improved rates of ALT normalization of 24.7% (p=0.003) and 34.4% (p<0.0001), respectively, compared to those receiving placebo (7.7%). A peginterferon alfa comparator arm was included in the study to show contribution of effect. The composite response rate in the all-oral arm was comparable to the peginterferon alfa arm (10.1% vs 9.6%). The composite response rate in the combination arm was twice that of the peginterferon alfa arm (19.2% vs 9.6%).

The key secondary histological endpoint was defined as ≥2-point improvement in histological activity index (HAI) and no worsening of Ishak fibrosis scoring as determined by blinded assessment of paired liver biopsies (n=229) collected at baseline and Week 48. This was demonstrated in 35 of 66 patients (53%, p=0.0139) with statistical significance in the combination arm versus 8 of 30 patients (27%) receiving placebo. Response was demonstrated in 35 of 107 patients (33%, p=0.61) in the all-oral arm versus placebo. Response in the peginterferon alfa comparator arm was 10 of 26 patients (38%).

Remaining secondary endpoints including virologic, biochemical, and composite responses at Week 72 (24-weeks post-treatment) are being collected and are expected to be reported mid-2023.

“We would like to extend our sincere gratitude to the patients, investigators, and clinical study sites for their participation in this well-controlled, landmark study,” said David Cory, President and CEO, Eiger. “As we continue to analyze these topline data to fully understand the efficacy and safety profile of lonafarnib-based treatments in chronic HDV, we look forward to a pre-NDA meeting with FDA in the coming quarter and seeing the full dataset including the 24-week post-treatment data.”

“The results of this landmark study highlight three key findings,” said Ohad Etzion, MD, Director, Department of Gastroenterology and Liver Diseases at Soroka University Medical Center and *D-LIVR* study co-lead investigator. “First, a small subset of patients with chronic HDV infection may achieve virologic and biochemical improvements with an all-oral regimen after 48 weeks of treatment. Second, combining lonafarnib and ritonavir with peginterferon alfa demonstrated the potential to nearly double the response rate. And third, and perhaps most importantly, based on these data, combination treatment may lead to significant histologic improvement, a generally accepted surrogate for improved future clinical outcomes for patients. We look forward to the 24-week post-treatment results of this study for assessment of the potential for finite therapy for chronic HDV infection.”

The majority of treatment emergent adverse events (TEAEs) were mild or moderate in severity. The most frequent TEAEs associated with lonafarnib treatment were gastrointestinal. Nine percent and 8% of patients discontinued treatment from the lonafarnib oral and combination therapy arms, respectively, compared to 2% of patients in each of the peginterferon alfa and placebo groups. In the lonafarnib treatment groups, 8% and 14% of patients, respectively, reported serious treatment-emergent adverse events, compared with 10% in the peginterferon alfa group and 4% in the placebo group. There were two deaths in the study: one patient treated with peginterferon alfa died due to decompensated cirrhosis that was attributed to drug therapy. The other death in the lonafarnib/ritonavir arm was deemed unrelated to study drug.

Summary of Topline Data

Response Rate, % (n)				
Virological/Biochemical Endpoints	**Placebo (n=52)**	**LNF + RTV (n=178)**	**LNF + RTV + Alfa (n=125)**	**Alfa (n=52)**
Composite Endpoint	1.9% (1)	10.1% (18) (p=0.0044)	19.2% (24) (p<0.0001)	9.6% (5)
≥2 Log Decline in HDV RNA	3.8% (2)	14.6% (26) (p=0.0026)	32% (40) (p<0.0001)	36.5% (19)
ALT Normalization	7.7% (4)	24.7% (44) (p=0.003)	34.4% (43) (p<0.001)	11.5% (6)
Histological Endpoint	**Placebo (n=30)**	**LNF + RTV (n=107)**	**LNF + RTV + Alfa (n=66)**	**Alfa (n=26)**
≥2-Point Improvement in HAI Score and No Worsening in Ishak Fibrosis Score	27% (8)	33% (35) (p=0.61)	53% (35) (p=0.0139)	38% (10)

LNF=lonafarnib; RTV=ritonavir; Alfa=peginterferon alfa; HAI=histological activity index

Eiger plans to engage with regulatory agencies, beginning with a pre-NDA meeting with FDA anticipated in Q1 2023, to discuss pathways for regulatory submissions. The full *D-LIVR* dataset, including analyses of the 24-week post-treatment period, would be included in potential regulatory submissions. Eiger intends to present *D-LIVR* study results at a future medical congress and publish in a peer-reviewed journal.

ABOUT *D-LIVR*

D-LIVR (**D**elta **L**iver **I**mprovement and **V**irologic **R**esponse in HDV) is a global, multi-center, Phase 3 study to evaluate two lonafarnib-based treatments: an all-oral arm of lonafarnib boosted with ritonavir (n=178) and a combination arm of lonafarnib boosted with ritonavir combined with peginterferon alfa (n=125), with each arm compared to a placebo arm (n=52), in HDV-infected patients after 48 weeks of treatment. The study also includes a peginterferon alfa comparator arm (n=52) used to demonstrate contribution of effect only. The two lonafarnib containing arms are not required to demonstrate superiority over peginterferon alfa. The study also includes a 24-week post-treatment follow up period.

The primary endpoint is a composite of a ≥2 log decline in HDV RNA and ALT normalization at end of 48 weeks of treatment. Key virological and biochemical secondary endpoints include the components of the primary endpoint. The key secondary histological endpoint is defined as ≥2-point improvement in histological activity index (HAI) and no worsening of fibrosis by Ishak

score. Blinded baseline and Week 48 paired liver biopsies were read by a single, central reader. Additional secondary endpoints were included in the post-treatment follow up period. An independent data safety monitoring board reviews the safety data from *D-LIVR* throughout the conduct of the trial, including during the post-treatment follow-up phase.

With 407 patients enrolled across 116 clinical trial sites in 22 countries, *D-LIVR* is a landmark study generating the single largest source of HDV patient data from a well-controlled clinical trial to better understand and characterize this devastating disease.

About Hepatitis Delta Virus (HDV)

HDV is the most severe form of human viral hepatitis, occurring 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 up to 15-20 million people worldwide. Globally, HDV infection is reported to be present in approximately 4% to 6% of patients with chronic HBV.

About Lonafarnib

Lonafarnib is a well-characterized, first-in-class, oral prenylation inhibitor which inhibits a host enzyme, blocking a critical step in HDV viral assembly. Lonafarnib has been dosed in over 450 chronically infected HDV patients across global clinical sites, including the Phase 3 D-LIVR study. Lonafarnib was previously approved by the FDA and in Europe under the trade name Zokinvy® for the treatment of progeria (Hutchinson-Gilford progeria syndrome and progeroid laminopathies). Lonafarnib is not FDA-approved for the treatment of patients with chronic HDV.

Lonafarnib has been granted Orphan Drug designation by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), Fast Track designation and Breakthrough designation by FDA and PRIME designation by EMA. Eiger licensed exclusive worldwide rights to lonafarnib from Merck, known as MSD outside of the U.S and Canada.

About Eiger

Eiger is a commercial-stage biopharmaceutical company focused on the development of innovative therapies for 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.

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, prospective products, preclinical and clinical pipelines, regulatory objectives, 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 timing of additional analyses from our Phase 3 *D-LIVR* study, including virologic, biochemical, and composite responses at Week 72 (24-weeks post-treatment) and histologic improvement; the potential benefits of lonafarnib-based treatments for patients with hepatitis delta virus (HDV), including the potential response rate of lonafarnib boosted with ritonavir in combination with peginterferon alfa; the ability to submit an application for, and obtain marketing approval from, FDA or any other regulatory body for lonafarnib-based treatments for the treatment of HDV; and the potential for success of any of our products or product candidates. 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, 2022 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.

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