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 12, 2023

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 September 12, 2023, Eiger BioPharmaceuticals, Inc. issued a press release titled "Eiger to Discontinue Phase 3 *LIMT-2* Trial of Peginterferon Lambda in Patients with Chronic Hepatitis Delta." 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 September 12, 2023, titled "Eiger to Discontinue Phase 3 *LIMT-2* Trial of Peginterferon Lambda in Patients with Chronic Hepatitis Delta."
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: September 12, 2023

By: /s/ James Vollins
James Vollins
General Counsel, Chief Compliance Officer & Corporate Secretary

Eiger to Discontinue Phase 3 *LIMT-2* Trial of Peginterferon Lambda in Patients with Chronic Hepatitis Delta

Palo Alto, Calif., September 12, 2023 /PRNewswire/ — Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), a commercial-stage biopharmaceutical company focused on the development of innovative therapies for rare metabolic diseases, today announced its decision to discontinue the Phase 3 *LIMT-2* study of peginterferon lambda in patients with chronic hepatitis delta (CHD). The decision is based on the recommendation of the Data Safety Monitoring Board (DSMB) for the study following its quarterly safety review. In a communication dated September 7, 2023, the DSMB recommended the discontinuation of the *LIMT-2* study due to observations of four patients with hepatobiliary events that resulted in liver decompensation.

“The study discontinuation is disappointing, especially for patients with chronic hepatitis delta who have limited treatment options,” said David Apelian, MD, PhD, MBA, CEO of Eiger. “We will work closely with FDA and our investigators to conduct an orderly termination of the *LIMT-2* study in the interest of patient safety.”

The Phase 3 *LIMT-2* study is an open-label, parallel-arm clinical trial that randomized patients with well-compensated CHD infection to one of two treatment groups: peginterferon lambda 180 mcg QW for 48 weeks with 24 weeks follow-up (Arm 1, n=105), or no treatment for 12 weeks followed by peginterferon lambda treatment for 48 weeks with 24 weeks of follow-up (Arm 2, n=53). In July, the trial completed enrollment of 158 patients in 12 countries across 48 investigator sites.

Dr. Apelian added, “As we look toward the future for Eiger, we will continue to execute on our strategic pivot, announced on June 29 of this year, and seek the financial resources required to advance the Company’s development activities on avexitide in hyperinsulinemic hypoglycemia indications. We continue to evaluate strategic partnering options for our virology assets. Eiger is no longer in active discussions with potential partners for a worldwide license for peginterferon lambda.”

About Eiger

Eiger is a commercial-stage biopharmaceutical company focused on the development of innovative therapies for rare metabolic diseases. Eiger’s lead product candidate, avexitide, is a well characterized, first-in-class GLP-1 antagonist for the treatment of post-bariatric hypoglycemia (PBH) and congenital hyperinsulinism (HI). Avexitide is the only drug in development for PBH with Breakthrough Therapy designation from the FDA.

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, 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, including our development activities for avexitide in hyperinsulinemic hypoglycemia indications; our ability to secure financial resources required to advance avexitide in hyperinsulinemic hypoglycemia indications; our ability to identify, pursue and enter into partnering opportunities for our virology assets; 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” section in Eiger’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 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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