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): March 17, 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 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 March 17, 2022, Eiger BioPharmaceuticals, Inc. issued a press release titled “Eiger’s Single-dose Peginterferon Lambda for COVID-19 Reduced Risk of Hospitalization or ER Visits by 50% in a Predominantly Vaccinated Population in Phase 3 TOGETHER Study.” 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 March 17, 2022, titled “Eiger’s Single-dose Peginterferon Lambda for COVID-19 Reduced Risk of Hospitalization or ER Visits by 50% in a Predominantly Vaccinated Population in Phase 3 TOGETHER Study.”
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: March 17, 2022

Eiger BioPharmaceuticals, Inc.

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

Eiger's Single-dose Peginterferon Lambda for COVID-19 Reduced Risk of Hospitalization or ER Visits by 50% in a Predominantly Vaccinated Population in Phase 3 *TOGETHER* Study

- Second largest study to date in COVID-19 outpatients (N=1,936)
- Highly superior compared to placebo, with a probability of superiority of 99.91% on the primary endpoint
- 60% reduced risk of COVID-19-related death
- Primary endpoint achieved across multiple SARS-CoV-2 variants, including omicron
- Eiger plans to submit data to FDA for Emergency Use Authorization (EUA)
- Management to host conference call today at 8:30 AM ET

Palo Alto, Calif., March 17, 2022 /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 diseases, today announced that Peginterferon Lambda (Lambda) significantly reduced the risk of COVID-19-related hospitalizations or emergency room visits greater than six hours by 50% (primary endpoint) and death by 60% in the Phase 3 *TOGETHER* study, a multi-center, randomized, double-blind, placebo-controlled study of non-hospitalized adult patients with COVID-19, who are at high risk of progressing to severe illness.

The Phase 3 *TOGETHER* study of Lambda is the second largest study to date of a COVID-19 therapeutic. Final analyses evaluated data from 1,936 patients, with 84% of patients having received at least a single dose of any COVID-19 vaccine.

Final analyses using a Bayesian analytic framework showed:

- Lambda highly superior compared to placebo on the primary endpoint, with a probability of superiority of 99.91%, surpassing the prespecified superiority threshold of 97.6%
- 50% risk reduction was observed [95% Bayesian credible interval (95% BCI): 23–69%] of COVID-19-related hospitalizations or emergency room visits compared to placebo in patients treated ≤7 days of symptom onset

    - 2.7% of patients (25 / 916) who received Lambda were hospitalized or had ER visits through Day 28, compared to 5.6% of patients (57 / 1020) who received placebo
- Risk reduction of COVID-19-related hospitalizations was observed:
    - 42% (95% BCI: 5–66%) risk reduction when treated ≤7 days of symptom onset
    - 60% (95% BCI: 18–82%) risk reduction when treated ≤3 days of symptom onset
- One COVID-19-related death in Lambda group; four in placebo group
- Incidence of any treatment emergent adverse events was similar between Lambda and placebo groups, which were primarily injection site reactions

In addition, viral sequencing was conducted on all patients. The primary endpoint was achieved across all variants tested, including omicron. Based on these data, Eiger believes Lambda has the potential to be effective against any new arising variants.

Eiger plans to discuss the results with FDA and submit an EUA as soon as possible.

“These data demonstrate that a single subcutaneous injection of Lambda has the potential to be a convenient, ‘one and done’ treatment to reduce the severity of COVID-19, reducing hospitalizations and death – even in a vaccinated population,” said Eiger President and CEO, David Cory. “With the continued global impact of COVID-19, we are encouraged by this data and look forward to supporting the global public health response. We’re thankful to the patients, investigators, and sites who participated in this clinical trial, and we look forward to discussing these results with FDA and submitting an EUA application to add Lambda to the evolving armamentarium of COVID-19 therapeutics.”

Lambda stimulates immune responses critical to innate defenses with a mechanism of action potentially agnostic to variants of SARS-CoV-2 and resistance concerns with other treatments. If authorized, Lambda could be prescribed more broadly to help reduce illness severity, hospitalizations, and deaths, as well as reduce the probability of infection following exposure, among adults.

“Lambda has demonstrated a reduction of risk in COVID-19-related hospitalizations or deaths in this clinical study in a predominantly vaccinated population, something that no other investigational drug has achieved – this is a game-changing event,” said Principal Investigator, Professor of Health Research Methods, Evidence, and Impact at McMaster University, Hamilton, Canada, Edward Mills, PhD, who is leading the *TOGETHER* study with Co-Investigator, Associate Professor of Medicine, Pontifical Catholic University of Minas Gerais, Brazil, Gilmar Reis, MD, PhD. “The COVID-19 pandemic

continues to be a global public health emergency, and outpatient treatments that can be quickly and efficiently administered to newly diagnosed SARS-CoV-2 patients are desperately needed with a goal of reducing COVID-19 complications."

About *TOGETHER* Study

TOGETHER is a multi-center, investigator-sponsored, randomized, placebo-controlled adaptive platform Phase 3 study evaluating therapeutics in newly diagnosed, high-risk, non-hospitalized patients with COVID-19. *TOGETHER* is the largest placebo-controlled study in COVID-19 and has evaluated eleven different therapeutic agents for non-hospitalized COVID-19 patients. This evaluation of Lambda versus placebo was the second largest study to date of a COVID-19 therapeutic. Eligibility criteria required that all patients had laboratory-confirmed mild or moderate COVID-19, with symptom onset within 7 days of study randomization. High-risk criteria were defined by patients having at least one of the following, including but not limited to: > age 50, diabetes, hypertension, CV disease, lung disease, kidney disease, obesity, etc. The study enrolled patients regardless of vaccination status or variant strain of SARS-CoV-2. The primary endpoint was a clinical outcome comparing hospitalizations or emergency room visits greater than six hours after a single subcutaneous injection of Lambda versus placebo. The DSMB provided independent oversight for the trial and had previously discontinued other therapeutics due to observed futility. The *TOGETHER* study recruited from twelve sites in Brazil. For more information, please visit www.clinicaltrials.gov (NCT04727424) and www.togethertrial.com.

About Peginterferon Lambda

Lambda is a 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 and has been well-tolerated in clinical studies.

Lambda is to be administered as a single subcutaneous injection so that it can be prescribed and administered at the first sign of infection or at first awareness of an exposure, potentially helping patients avoid severe illness that can lead to hospitalization and death.

IFN lambdas are critical for maintaining a balanced antiviral response in the respiratory tract. They are induced at lower viral burden before type I IFNs to limit the initial infection by inducing viral resistance to cells and helping them deal with the virus load. IFN lambda lacks the strong pro-inflammatory effects of type I IFNs and are tissue-protective and anti-inflammatory. Administration of IFN lambda has been shown to suppress viral replication while stopping 'cytokine storm' from developing.

Eiger is developing Lambda for the treatment of HDV infection. Lambda has been administered to over 3,000 subjects in 23 clinical trials of HBV, HCV, HDV and COVID-19. 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, and Fast Track and Breakthrough Therapy Designation by FDA for Lambda in HDV.

Eiger licensed worldwide rights to Lambda from Bristol-Myers Squibb.

CONFERENCE CALL

At 8:30 AM Eastern Time today, March 17, 2022, Eiger will host a conference call to discuss the results of the Phase 3 *TOGETHER* study. The live and replayed webcast of the call will be available through the company's website at www.eigerbio.com. To participate in the live call by phone, dial (844) 743-2495 (U.S.) or (661) 378-9529 (International) and enter conference ID 8990285. The webcast will be archived and available for replay for at least 90 days after the event.

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 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, 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, our anticipated significant milestones in 2022; the timing of our ongoing and planned clinical development; our ability to obtain an Emergency Use Authorization from FDA for Peginterferon Lambda for COVID-19; our capability to provide sufficient quantities of any of our product candidates, including Peginterferon Lambda, to meet anticipated full-scale commercial demands; our ability to finance the continued advancement of our development pipeline products; 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 additional applicable risks and uncertainties described in the “Risk Factors” sections in the Annual Report on Form 10-K for the year ended December 31, 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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