

**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): January 6, 2022

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 2.02. Results of Operations and Financial Condition.

In connection with the press release described in Item 8.01 below, on January 6, 2022, Eiger BioPharmaceuticals, Inc. (the “Company”) provided, on a preliminary and unaudited basis, certain estimates regarding its cash, cash equivalents and investments as of December 31, 2021. The estimate is a preliminary estimate based on currently available information and does not present all necessary information for a complete understanding of the Company’s financial condition as of December 31, 2021 or the Company’s results of operations for the year ended December 31, 2021.

Item 8.01. Other Events.

On January 6, 2022, the Company issued a press release titled “Eiger BioPharmaceuticals Announces Outlook and Planned 2022 Catalysts and Milestones.” A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Forward-Looking Statements

Statements in this report that are not strictly historical in nature constitute “forward-looking statements.” Such statements include, but are not limited to the cash, cash equivalents and investments as of December 31, 2021. Such forward-looking statements involve known and unknown risks, uncertainties and other factors. More information about the risks the Company faces is included under the headings “Risk Factors” in the Company’s most recently filed documents with the U.S. Securities and Exchange Commission. The Company is providing this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this report as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits.**

Exhibit No.	Description
99.1	Press release, dated January 6, 2022, titled “Eiger BioPharmaceuticals Announces Outlook and Planned 2022 Catalysts and Milestones.”
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: January 6, 2022

By: /s/ Sriram Ryali

Sriram Ryali
Chief Financial Officer



**Eiger BioPharmaceuticals Announces
Outlook and Planned 2022 Catalysts and Milestones**

- Phase 3 HDV *D-LIVR* (Lonafarnib) Study Topline Data Planned by End of 2022
- Phase 3 HDV *LIMIT-2* (Peginterferon Lambda) Study Enrolling and Dosing
- Phase 3 COVID-19 *TOGETHER* (Peginterferon Lambda) Study Topline Data 1H22
- Zokinvy MAA CHMP Opinion Expected 1H22
- Strong Cash Position of Approximately \$106 Million

Palo Alto, Calif., January 6, 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 provided the company’s outlook across multiple pipeline programs and operations, including planned 2022 catalysts and milestones.

“This is a pivotal year for Eiger as we plan for topline data from the landmark *D-LIVR* study by year end. *D-LIVR* is the largest trial conducted in HDV and if positive will support regulatory filings for Lonafarnib-based regimens,” said David Cory, President and CEO of Eiger. “HDV is a large unmet medical need with over 12 million people suffering from this devastating disease around the globe. Our second registration enabling clinical trial in HDV, *LIMIT-2*, a Phase 3 study of Peginterferon Lambda, is now enrolling and dosing. Lonafarnib and Peginterferon Lambda are well positioned to become foundational therapies to treat and cure HDV.”

Program Highlights

HDV Platform

Lonafarnib for Hepatitis Delta Virus Infection

- First-in-class, oral prenylation inhibitor
- *D-LIVR* Phase 3 study with potential approval of two Lonafarnib-based regimens
 - All oral Lonafarnib / ritonavir and in combination with peginterferon alfa
 - Fully enrolled N=407
 - Topline data planned by end of 2022

Peginterferon Lambda for Hepatitis Delta Virus Infection

- First-in-class well-tolerated interferon
- Potential to be interferon of choice in HDV combination therapies
- *LIMIT-2* Phase 3 study of Peginterferon Lambda monotherapy for HDV
 - Enrolling and dosing patients, targeting N=150

Avexitide for Rare Metabolic Disorders

- Granted Breakthrough Therapy Designation for Congenital Hyperinsulinism (HI)
- Granted Rare Pediatric Disease Designation for HI – PRV eligible
- Phase 3 ready in 2022

Zokinvy® for Progeria and Processing-Deficient Progeroid Laminopathies

- Successful U.S. commercial launch
 - Approximately 80% of identified U.S. patients converted to commercial supply
- EMA review of MAA
 - Ongoing discussions with CHMP primarily focused on additional statistical analyses of clinical data; CHMP opinion expected in first half of 2022

Peginterferon Lambda for COVID-19 Infection

- Novel mechanism of action, agnostic to variants and mutations
- *TOGETHER* Phase 3 study enrolling, targeting N=1,600
- Second positive interim futility analysis (N=1,003) completed in December 2021
- Topline data planned in 1H22

Corporate

- Appointed Kim Sablich, biopharma commercial expert, to Board of Directors
- Appointed Erik Atkisson as General Counsel and Chief Compliance Officer
- Cash, cash equivalents and investments of \$106 million to begin 2022

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, our anticipated significant milestones in 2022; the timing of our ongoing and planned clinical development; the sufficiency of our cash, cash equivalents and investments to fund our operations; expectations regarding the timing and availability of topline data from our Phase 3 *D-LIVR* study in HDV; the ability to fully enroll the Phase 3 *LIMIT-2* study; initiating a Phase 3 study for avexitide in congenital hyperinsulinism; the approval of Zokinvy in jurisdictions outside of the U.S., including the EU; and the potential of peginterferon lambda to be an effective therapy for newly diagnosed outpatients with COVID-19; and the possibility of 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 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.

Investors and Media:

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