

**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, 2020

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, 2020, Eiger BioPharmaceuticals, Inc. (the “Company”) announced that on a preliminary and unaudited basis, it estimates that it had approximately \$95 million in cash, cash equivalents and investments as of December 31, 2019. 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, 2019 or the Company’s results of operations for the year ended December 31, 2019.

The information in this item 2.02 shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information in this item 2.02 shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Eiger BioPharmaceuticals, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01. Other Events.

On January 6, 2020, the Company issued a press release titled “Eiger Updates on 2019 Progress and 2020 Milestones Expected.” 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, 2019. 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.**

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | <u>Press release, dated January 6, 2020, titled “Eiger Updates on 2019 Progress and 2020 Milestones Expected.”</u> |

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, 2020

By: /s/ Sriram Ryali

Sriram Ryali
Chief Financial Officer

Eiger Updates on 2019 Progress and 2020 Milestones Expected

- **Progeria Rolling NDA Planned for Completion in 1Q 2020**
- **HDV Phase 3 D-LIVR Study Enrollment Planned to Complete in 2020**
- **Commercial Focus on Progeria Launch Preparation and HDV Market Building**
- **Strong Balance Sheet with ~\$95M in Cash and Investments to Begin 2020**

PALO ALTO, Calif., January 6, 2020 — Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), a late-stage biopharmaceutical company focused on the development and commercialization of targeted therapies for serious rare and ultra-rare diseases, today updated on progress across its product pipeline, including clinical and regulatory program planned milestones, and commercial preparation.

Lonafarnib in Progeria and Progeroid Laminopathies

- Rolling New Drug Application (NDA) with FDA initiated in December 2019
- Rolling NDA submission planned to complete in 1Q 2020
- Marketing Authorization Application (MAA) planned to EMA in 1Q 2020
- Commercial launch preparation underway

Lonafarnib in Hepatitis Delta Virus (HDV) Phase 3 D-LIVR Study

- Lonafarnib is the only oral agent in development for HDV
- Over 80 global sites activated in 2019
- Strategic geographic and high enrolling sites activating early in 2020
- Enrollment planned to complete in 2020
- Topline data planned in 2021
- HDV market building underway

Peginterferon Lambda (Lambda) in HDV

- Positive Phase 2 LIFT (Lambda combo) interim end-of-treatment results reported
 - 53% of patients with HDV RNA BLOQ at Week 24
 - 36% of patients with HDV RNA undetectable at Week 24
- End of Phase 2 meeting for Lambda monotherapy planned with FDA in 1Q 2020
- Additional Phase 2 LIFT data expected at EASL and AASLD 2020

Avexitide in Post-Bariatric Hypoglycemia (PBH) and Congenital Hyperinsulinism (CHI)

- Positive End of Phase 2 meeting with FDA for Avexitide in PBH in 2019
- Avexitide PBH Phase 3 study design guidance finalized with FDA
- Assessing strategic options to advance Avexitide in PBH and CHI

“Eiger begins 2020 with four late-stage, FDA Breakthrough Therapy Designation Programs, with first-in-class therapies, targeting rare and ultra-rare diseases with high unmet medical needs with no approved treatments,” said David Cory, President and CEO of Eiger. “We are focused on commercial preparation for an anticipated approval of Lonafarnib in Progeria and Progeroid Laminopathies in 2020 and HDV market development as we prepare for Phase 3 data from our D-LIVR trial in 2021.”

Financial Guidance

At December 31, 2019, the Company had approximately \$95M in cash, cash equivalents and investments. The company expects 2020 cash burn for planned operations to be generally in-line with 2019 burn.

About Eiger

Eiger is a late-stage biopharmaceutical company focused on the development and commercialization of first-in-class, well-characterized drugs for serious rare and ultra-rare diseases for patients with high unmet medical needs, for which no approved therapies exist.

Eiger has initiated a rolling New Drug Application (NDA) submission process for lonafarnib to treat Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies. The company’s lead program is in Phase 3, developing lonafarnib, a first-in-class oral prenylation inhibitor for the treatment of Hepatitis Delta Virus (HDV) infection. The company is also advancing peginterferon lambda, a first-in-class interferon, toward registration for the treatment of HDV. 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 that involve substantial risks and uncertainties. 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. These forward-looking statements include terminology such as “believe,” “will,” “may,” “estimate,” “continue,” “anticipate,” “contemplate,” “intend,” “target,” “project,” “should,” “plan,” “expect,” “predict,” “could,” “potentially” or the negative of these terms. Forward-looking statements are our current statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned clinical development, including planned completion of a rolling NDA submission by first quarter 2020, followed by submission of an MAA in first quarter 2020 for lonafarnib in Progeria and Progeroid Laminopathies; our progression and enrollment of our Phase 3 D-LIVR study in HDV; our planned advancement of Lambda and lonafarnib boosted with ritonavir for HDV; our

plans to hold an end of Phase 2 meeting for Lambda in HDV in first quarter 2020; our plans for continued advancement of avexitide; our ability to transition into a commercial stage biopharmaceutical company; our ability to finance the continued advancement of our development pipeline products; and the potential for success of any of our product candidates. These statements concern product candidates that have not yet been approved for marketing by the U.S. Food and Drug Administration (FDA). No representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

Various important factors could cause actual results or events to differ materially from the forward-looking statements that Eiger makes, including the risks described in the “Risk Factors” sections in the Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 and Eiger’s subsequent filings with the SEC. Eiger does not assume any obligation to update any forward-looking statements, except as required by law.



SOURCE Eiger BioPharmaceuticals, Inc.

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