**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 13, 2020**



**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** | | **Name of each exchange** |  |
| **Symbol(s)** | | **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 2.02.** **Results of Operations and Financial Condition.**

On March 13, 2020, Eiger BioPharmaceuticals, Inc. reported its financial results for the quarter and year ended December 31, 2019. A copy of the press release titled “Eiger BioPharmaceuticals Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Business Update,” is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto and is incorporated herein by reference.

The information in this item 2.02 and in the press release attached as Exhibit 99.1 to this Current Report on Form 8-K 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 Section 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information in this item 2.02 and in the press release attached as Exhibit 99.1 to this Current Report on Form 8-K 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 9.01.** **Financial Statements and Exhibits.**

**(d) Exhibits.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Exhibit** |  |  |  | **Description** |  |  |
| **No.** |  |  |  |  |
| 99.1 |  | [Press release, dated March 13, 2020, titled “Eiger BioPharmaceuticals Reports Fourth Quarter and Full Year 2019 Financial Results and](#page4) | | | |  |
|  |  | [Provides Business Update.”](#page4) |  | | |  |

**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: March 13, 2020

By: /s/ Sriram Ryali



Sriram Ryali

Chief Financial Officer

**Exhibit 99.1**

**Eiger BioPharmaceuticals Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Business Update**

* **Progeria MAA Submission Completed and Accelerated Assessment Granted by EMA**
* **Progeria NDA Submission Complete by End of March 2020**
* **Phase 3 HDV Global D-LIVR Study Enrolling and Dosing**

**PALO ALTO, Calif., March 13, 2020** — Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization oftargeted therapies for serious rare and ultra-rare diseases, today reported financial results for the fourth quarter and full year 2019 and provided a business update.

“We are pleased to announce the submission of the MAA for lonafarnib in Progeria and Progeroid Laminopathies and look forward to completing the NDA submission by end of the month as planned,” said David Cory, President and CEO of Eiger. “Site activations, enrollment, and dosing are ongoing in our global Phase 3 HDV study, D-LIVR, and we expect to complete enrollment in 2020. We are closely monitoring the potential impact of COVID-19 on the timing and conduct of D-LIVR. We will remain responsive to any developments and take necessary steps to protect our patients and the integrity of the study.”

**Recent Highlights and Upcoming Milestones**

***Lonafarnib in Hepatitis Delta Virus (HDV)***

* *Enrollment of Phase 3 D-LIVR study (N=400) planned to complete in 2020*

***Lonafarnib in Progeria and Progeroid Laminopathies***

* *Marketing Authorization Application (MAA) to EMA completed*
* *Accelerated Assessment for MAA granted by EMA*
* *New Drug Application (NDA) to FDA on-track for completion by end of March 2020*

***Peginterferon Lambda (lambda) in HDV***

* *Positive End of Phase 2 meeting with FDA with agreement on single Phase 3 study*
* *Plan to finalize Scientific Advice with EMA*
* *End-of-Treatment data from LIFT (lambda combo with lonafarnib) at EASL 2020*

***Corporate***

* *Appointed Eldon Mayer as Executive Vice President and Chief Commercial Officer*

**Fourth Quarter and Full Year 2019 Financial Results**

Cash, cash equivalents, and short-term investments as of December 31, 2019 totaled $95.0 million compared to $100.4 million at December 31, 2018, a decrease of $5.4 million.

The Company reported net losses of $16.9 million, or $0.69 per share, and $70.3 million, or $3.08 per share, for the fourth quarter and full year 2019, respectively, as compared to $16.5 million, or $0.93 per share, and $52.4 million, or $3.84 per share, for the same periods in 2018.

Research and Development expenses were $11.9 million and $51.8 million for the fourth quarter and full year 2019, respectively, as compared to

$12.0 million and $37.1 million for the same periods in 2018. The increase in full year 2019 expenses was primarily due to costs associated with the Phase 3 D-LIVR HDV study, including drug supply costs, which ramped-up in 2019, employee-related costs from increased headcount and an increase in regulatory related expenses.

General and Administrative expenses were $4.6 million and $17.1 million for the fourth quarter and full year 2019, respectively, as compared to $4.1 million and $14.0 million for the same periods in 2018. The increases in fourth quarter and full year 2018 were primarily due to increases in employee-related costs, including stock-based compensation, from increased headcount and outside services for legal, consulting, advisory and accounting services.

Total operating expenses include total non-cash expenses of $1.6 million and $6.6 million for the fourth quarter and full year 2019, respectively, as compared to $1.6 million and $5.7 million for the same periods in 2018.

As of December 31, 2019, the company had 24.5 million of common shares outstanding.

**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 completed an MAA submission for lonafarnib for the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies and plans to complete a New Drug Application (NDA) submission by end of March 2020. 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 anticipating significant milestones in 2020, the

timing of our ongoing and planned clinical development, including planned NDA submission in first quarter 2020 for Progeria and Progeroid Laminopathies; the potential for approval of our lonafarnib product candidate in the US and EU for Progeria and Progeroid Laminopathies; our progression and enrollment of our Phase 3 D-LIVR study in HDV; our announcement of data from the trial of lambda and lonafarnib boosted with ritonavir for HDV (LIFT); our plans to advance Peginterferon Lambda in HDV in the US and EU; our plans for continued advancement of avexitide in registration trials; our ability to transition into a commercial stage biopharmaceutical company; our ability to finance the continued advancement of our development pipeline products; that the company’s expectations regarding the effects of COVID-19 on the Company’s trials and development may be incorrect, 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 Annual Report on Form 10-K for the year ended December 31, 2019 to be filed March 13, 2020 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.

**Investors and Media:**

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