**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 14, 2019**



**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))

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 14, 2019, Eiger BioPharmaceuticals, Inc. reported its financial results for the quarter and year ended December 31, 2018. A copy of the press release titled “Eiger BioPharmaceuticals Reports Fourth Quarter and Full Year 2018 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 that Section 11 and 12(a)

1. 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.**

1. Exhibits.

|  |  |  |
| --- | --- | --- |
| **Exhibit No.** |  | **Description** |
|  |  |  |  |  |  |
| 99.1 |  | [Press release, dated March 14, 2019, titled “Eiger BioPharmaceuticals Reports Fourth Quarter and Full Year 2018 Financial Results](#page4) |
|  |  | [and 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 14, 2019

By: /s/ Sriram Ryali



Sriram Ryali

Chief Financial Officer

**Exhibit 99.1**

**Eiger BioPharmaceuticals Reports Fourth Quarter and Full Year 2018 Financial Results and Provides Business Update**

* Began 2019 with $100.4 million in cash, cash equivalents & short-term investments
* Enrollment of Phase 3 D-LIVR Study in HDV planned by end of 2019
* NDA and MAA filings for Progeria and Progeroid Laminopathies planned in 2019

**PALO ALTO, Calif., March 14, 2019** — 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 three months and year ended December 31, 2018 and provided a business update.

“We expect 2019 to be a transformative year for Eiger as we plan to file the first-ever NDA and MAA for Progeria and Progeroid Laminopathies and to enroll the first-ever international Phase 3 study in Hepatitis Delta Virus infection,” said David Cory, Eiger President and Chief Executive Officer. “Eiger is poised for significant growth by delivering first-in-class therapies to patients with serious rare and ultra-rare diseases.”

**Recent Highlights**

***Hepatitis D Virus (HDV) Program***

***Lonafarnib in HDV***

* *Lonafarnib+Ritonavir patent portfolio expanded to include US, Europe and Japan*
* *Breakthrough Therapy designation granted by FDA*
* *PRIME designation granted by EMA*
* *First site initiated in Phase 3 D-LIVR study*

***Lambda in HDV***

* *Phase 2 LIMT (mono therapy) end of study results selected as a late-breaker oral presentation at The International Liver Congress™ 2019*
* *Phase 2 LIFT (combo therapy with lonafarnib) dosing at NIH (N=26)*

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

* Breakthrough Therapy designation granted by FDA

***Avexitide in Post-Bariatric Hypoglycemia (PBH) Program***

* *Positive Phase 2 PREVENT 28-day study data (N=18)*

***Corporate Activity***

* *Sri Ryali, MBA, appointed Eiger Chief Financial Officer*

* *Stephana Patton, PhD, JD, pharma industry veteran, appointed Eiger as General Counsel, Corporate Secretary and Chief Compliance Officer*
* *Christine Murray, MS, RAC, industry veteran and Senior Vice President of Global Regulatory Affairs at Ultragenyx Pharmaceutical, Inc., appointed to Board*
* *R&D Day held on December 11, 2018 in NYC*
* *October underwritten public offering raised $47.7 million in net proceeds*

**Anticipated 2019 Milestones**

* *Phase 3 D-LIVR study (N=400) complete enrollment in HDV planned by year-end*
* *Phase 2 LIMT end-of-study study results in HDV oral presentation at EASL*
* *Phase 2 LIFT end-of-treatment study results in HDV planned at AASLD*
* *NDA and MAA filings in Progeria and Progeroid Laminopathies planned*
* *Phase 2 PREVENT end-of-study results in PBH oral presentation at ENDO*
* *End of Phase 2 meeting for avexitide in PBH with regulators planned*

**Fourth Quarter and Full Year 2018 Financial Results**

Cash, cash equivalents, and short-term investments as of December 31, 2018 totaled $100.4 million compared to $41.8 million at December 31, 2017, an increase of $58.6 million.

The Company reported net losses of $16.5 million, or $0.92 per share, and $52.4 million, or $3.82 per share, for the fourth quarter and full year 2018, respectively, as compared to $10.9 million, or $1.11 per share, and $42.4 million, or $4.86 per share, for the same periods in 2017.

Research and Development expenses were $12.0 million and $37.1 million for the fourth quarter and full year 2018, respectively, as compared to

$7.8 million and $29.5 million for the same periods in 2017. The increases in fourth quarter and full year 2018 were primarily due to costs associated with clinical programs, including drug supply costs.

General and Administrative expenses were $4.1 million and $14.0 million for the fourth quarter and full year 2018, respectively, as compared to $2.8 million and $12.0 million for the same periods in 2017. 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.

Total operating expenses include total non-cash expenses of $1.6 million and $5.7 million for the fourth quarter and full year 2018, respectively, as compared to $1.1 million and $4.4 million for the same periods in 2017.

In October, 2018, Eiger announced the closing of its underwritten public offering of 4,830,918 shares of its common stock at a price to the public of $10.35 per share. The offering was made under Eiger’s effective shelf registration statement and resulted in net proceeds to the company of approximately $47.7 million, after deducting underwriting discounts and commissions and offering expenses.

As of December 31, 2018, the company had 19.2 million of common shares outstanding.

**About Eiger**

Eiger is a late stage biopharmaceutical company focused on the development and commercialization of targeted therapies for serious rare and ultra-rare diseases. We innovate by developing well-characterized drugs in newly identified or novel targets in rare diseases. Our mission is to systematically reduce the time and cost of the drug development process to more rapidly deliver important medicines to patients. The company’s lead program is in Phase 3, developing lonafarnib, a first-in-class prenylation inhibitor for the treatment of Hepatitis Delta Virus (HDV) infection. Eiger is also preparing an NDA and MAA for lonafarnib to treat Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies with plans to file in 2019. 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 plans to complete enrollment of our D-LIVR study by the end of 2019, submit an NDA and MAA for Progeria and progeroid laminopathies in 2019, timing of end of treatment data in our LIFT study and progress our Phase 3 study in HDV; 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.

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, 2018 to be filed on March 14, 2019 and Eiger’s periodic reports filed with the SEC. Eiger does not assume any obligation to update any forward-looking statements, except as required by law.



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**Eiger BioPharmaceuticals Inc.**

**Condensed Consolidated Balance Sheets**

(in thousands)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  | **Year Ended** |
|  |  |  |  | **December 31,** |
|  |  |  |  | **2018(1)** | **2017(1)** |  |
|  | **ASSETS** |  |  |  |  |  |  |  |
|  | Cash and cash equivalents | $ | 61,262 | $ | 32,035 |  |
|  | Debt securities, available-for-sale |  |  | 39,091 |  |  | 9,744 |  |
|  | Prepaid expenses and other current assets |  |  | 1,492 |  |  | 712 |  |
|  | Total current assets |  |  | 101,845 |  |  | 42,491 |  |
|  | Property and equipment, net |  |  | 167 |  |  | 79 |  |
|  | Other assets |  |  | 436 |  |  | 312 |  |
|  | Total assets |  | $ | 102,448 |  | $ | 42,882 |  |
|  |  |  |  |  |  |  |  |  |
|  | **LIABILITIES AND STOCKHOLDERS’ EQUITY** |  |  |  |  |  |  |  |
|  | Current liabilities | $ | 10,024 | $ | 7,269 |  |
|  | Other liabilities |  |  | 25,832 |  |  | 13,091 |  |
|  | Stockholders’ equity |  |  | 66,592 |  |  | 22,522 |  |
|  | Total liabilities and stockholders’ equity | $ | 102,448 | $ | 42,882 |  |
|  |  |  |  |  |  |  |  |  |

1. Derived from the audited financial statements, included in the Company’s Annual Report on Form 10-K for the years ended December 31, 2018 and 2017.

**Eiger BioPharmaceuticals Inc.**

**Condensed Consolidated Statements of Operations Financial Data**

(in thousands, except per share and share amounts)

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | **Three Months Ended** |  |  | **Year Ended** |  |  |  |
|  |  |  |  | **December 31,** |  |  |  |  |  |  |  |
|  |  |  |  | **(unaudited)** |  |  |  |  | **December 31,** |  |  |  |
|  |  |  |  | **2018** |  |  |  | **2017** |  |  |  | **2018** |  |  |  | **2017** |  |  |
|  | Operating expenses: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Research and development(1) | $ | 12,011 |  | $ | 7,779 |  | $ | 37,091 |  | $ | 29,519 |  |  |
|  | General and administrative(1) |  |  | 4,082 |  |  |  | 2,806 |  |  |  | 13,956 |  |  |  | 12,001 |  |  |
|  | Total operating expenses |  |  | 16,093 |  |  |  | 10,585 |  |  |  | 51,047 |  |  |  | 41,520 |  |  |
|  | Loss from operations |  |  | (16,093) |  |  | (10,585) |  |  | (51,047) |  |  | (41,520) |  |
|  | Interest expense |  |  | (755) |  |  | (395) |  |  | (2,329) |  |  | (1,524) |  |
|  | Interest income |  |  | 343 |  |  |  | 89 |  |  |  | 997 |  |  |  | 410 |  |  |
|  | Other (expense) income, net |  |  | 4 |  |  |  | (2) |  |  | (12) |  |  | 186 |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Net loss | $ | (16,501) | $ | (10,893) | $ | (52,391) | $ | (42,448) |  |
| Net loss per common share: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Basic and diluted | $ | (0.92) | $ | (1.11) | $ | (3.82) | $ | (4.86) |  |
| Shares used to compute net loss per common share: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Basic and diluted |  |  | 17,926,315 |  | 9,799,328 |  |  |  | 13,711,034 |  | 8,727,935 |  |  |
| (1) Includes stock-based compensation expense of: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | **Three Months Ended** |  |  | **Year Ended** |  |  |  |
|  |  |  |  | **December 31,** |  |  |  |  | **December 31,** |  |  |  |
|  |  |  |  | **2018** |  |  |  | **2017** |  |  |  | **2018** |  |  |  | **2017** |  |  |
|  | Research and development |  | $ | 362 |  |  | $ | 443 |  |  | $ | 1,500 |  |  | $ | 1,214 |  |  |
|  | General and administrative |  |  | 1,149 |  |  |  | 577 |  |  |  | 3,507 |  |  |  | 3,029 |  |  |
|  | Total stock-based compensation expense | $ | 1,511 |  | $ | 1,020 |  | $ | 5,007 |  | $ | 4,243 |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |