

**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): November 7, 2019

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.

On November 7, 2019, Eiger BioPharmaceuticals, Inc. reported its financial results for the quarter ended September 30, 2019. A copy of the press release titled “Eiger BioPharmaceuticals Reports Third Quarter 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 that 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.

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | <u>Press release, dated November 7, 2019, titled “Eiger BioPharmaceuticals Reports Third Quarter 2019 Financial Results and Provides Business Update.”</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.

Dated: November 7, 2019

Eiger BioPharmaceuticals, Inc.

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

Eiger BioPharmaceuticals Reports Third Quarter 2019 Financial Results and Provides Business Update

- Successful Pre-NDA and Pre-MAA Meetings for Progeria & Progeroid Laminopathies
- Positive Phase 2 LIFT Lambda Combo Data as Late-Breaker at AASLD
- First-Ever Phase 3 HDV International D-LIVR Study Enrolling and Dosing
- Strong Balance Sheet with \$109.9M in Cash & Investments

PALO ALTO, Calif., November 7, 2019 — Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization of targeted therapies for serious rare and ultra-rare diseases, today reported financial results for the three and nine months ended September 30, 2019 and provided a business update.

“We are advancing four Breakthrough Therapy Designation programs into late stages, all with first-in-class therapies targeting rare diseases with no approved treatments,” said David Cory, Eiger President and CEO. “We recently completed successful pre-NDA and pre-MAA meetings with both FDA and EMA for Progeria and Progeroid Laminopathies and plan to submit an NDA by year-end. We recently announced positive results from the HDV lambda and lonafarnib combination LIFT study, which will be presented as an oral late-breaker at AASLD. Our Phase 3 HDV global D-LIVR study continues to activate sites, enroll and dose patients. We look forward to updating on continued progress in the future.”

Recent Highlights

Lonafarnib in Progeria and Progeroid Laminopathies

- *Positive pre-NDA meeting with FDA*
- *Positive pre-MAA meeting with EMA*

Peginterferon Lambda (lambda) in Hepatitis D Virus (HDV)

- *Late-breaking oral presentation of positive Phase 2 LIFT (lambda + lonafarnib boosted with ritonavir) interim end-of-treatment results accepted for AASLD*
 - *95% of patients achieved primary endpoint of >2 log reduction in HDV RNA*
 - *>50% of patients were HDV RNA undetectable or BLOQ*
 - *Adverse events were mostly mild to moderate*
- *Breakthrough Therapy Designation granted by FDA*

Avexitide in Post-Bariatric Hypoglycemia (PBH)

- *Positive End of Phase 2 meeting with FDA for avexitide in PBH*

Upcoming Milestones

- *Oral presentation of Phase 2 LIFT interim end-of-treatment results in HDV at AASLD*
- *NDA submission for Progeria and Progeroid Laminopathies by year-end, followed by MAA submission in the first quarter of 2020*
- *Phase 3 D-LIVR study in HDV (N=400) enrollment update after year-end*
- *End of Phase 2 meeting for lambda monotherapy in HDV in the first quarter of 2020*

Third Quarter 2019 Financial Results

Cash, cash equivalents, and short-term investments as of September 30, 2019 totaled \$109.9 million compared to \$125.3 million at June 30, 2019, a decrease of \$15.4 million.

The Company reported a net loss of \$18.6 million, or \$0.76 per share for third quarter 2019, as compared to \$17.1 million, or \$1.20 per share, for the same period in 2018.

Research and Development expenses were \$14.1 million for third quarter 2019, as compared to \$13.2 million for the same period in 2018, an increase of \$0.9 million. The increase was primarily due to employee-related costs, including stock-based compensation, and expenditures related to our clinical programs.

General and Administrative expenses were \$4.2 million for third quarter 2019, as compared to \$3.6 million for the same period in 2018, an increase of \$0.6 million. The increase was primarily due to additional employee-related costs, including stock-based compensation.

Third quarter 2019 operating expenses include total non-cash expenses of \$1.8 million, as compared to \$1.5 million for the same period in 2018.

As of September 30, 2019, Eiger had 24.5 million of common shares outstanding.

About Eiger

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

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. The company is rapidly advancing peginterferon lambda, a first-in-class interferon, toward registration for the treatment of HDV. Eiger is preparing an NDA and MAA for lonafarnib to treat Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies with plans to submit an NDA by year-end 2019, followed by an MAA submission in the first quarter of 2020. 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 NDA submission by year-end 2019, followed by submission of an MAA in first quarter 2020 for 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 Peginterferon Lambda in HDV in first quarter 2020; 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; 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.

Investors: Ingrid Choong, PhD

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Eiger BioPharmaceuticals Inc.
Condensed Consolidated Balance Sheets
(in thousands)

| | <u>Nine Months Ended</u> <u>September 30,</u> <u>2019</u> | <u>Year Ended</u> <u>December 31,</u> <u>2018⁽¹⁾</u> |
|---|---|---|
| | <u>(unaudited)</u> | |
| ASSETS | | |
| Cash and cash equivalents | \$ 19,406 | \$ 61,262 |
| Debt securities, available-for-sale | 90,545 | 39,091 |
| Prepaid expenses and other current assets | 4,459 | 1,492 |
| Total current assets | <u>114,410</u> | <u>101,845</u> |
| Property and equipment, net | 538 | 167 |
| Operating lease right-of-use assets | 1,659 | — |
| Other assets | 3,388 | 436 |
| Total assets | <u>\$ 119,995</u> | <u>\$ 102,448</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities | \$ 16,745 | \$ 10,024 |
| Other liabilities | 31,591 | 25,832 |
| Stockholders' equity | 71,659 | 66,592 |
| Total liabilities and stockholders' equity | <u>\$ 119,995</u> | <u>\$ 102,448</u> |

(1) Derived from the audited financial statements, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

Eiger BioPharmaceuticals Inc.
Condensed Consolidated Statements of Operations Financial Data
(in thousands, except per share and share amounts)

| | Three Months Ended September 30, (unaudited) | | Nine Months Ended September 30, (unaudited) | |
|---|--|--------------------|---|--------------------|
| | 2019 | 2018 | 2019 | 2018 |
| Operating expenses: | | | | |
| Research and development ⁽¹⁾ | \$ 14,059 | \$ 13,196 | \$ 39,863 | \$ 25,080 |
| General and administrative ⁽¹⁾ | 4,247 | 3,643 | 12,529 | 9,874 |
| Total operating expenses | <u>18,306</u> | <u>16,839</u> | <u>52,392</u> | <u>34,954</u> |
| Loss from operations | (18,306) | (16,839) | (52,392) | (34,954) |
| Interest expense | (884) | (681) | (2,518) | (1,574) |
| Interest income | 585 | 371 | 1,598 | 654 |
| Other income (expense), net | (11) | 5 | (20) | (16) |
| Net loss | <u>\$ (18,616)</u> | <u>\$ (17,144)</u> | <u>\$ (53,332)</u> | <u>\$ (35,890)</u> |
| Net loss per common share: | | | | |
| Basic and diluted | <u>\$ (0.76)</u> | <u>\$ (1.20)</u> | <u>\$ (2.40)</u> | <u>\$ (2.92)</u> |
| Shares used to compute net loss per common share: | | | | |
| Basic and diluted | <u>24,437,451</u> | <u>14,255,843</u> | <u>22,261,715</u> | <u>12,290,500</u> |

(1) Includes stock-based compensation expense of:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|-----------------|------------------------------------|-----------------|
| | 2019 | 2018 | 2019 | 2018 |
| Research and development | \$ 559 | \$ 344 | \$ 1,366 | \$ 1,138 |
| General and administrative | 1,090 | 828 | 2,965 | 2,358 |
| Total stock-based compensation expense | <u>\$ 1,649</u> | <u>\$ 1,172</u> | <u>\$ 4,331</u> | <u>\$ 3,496</u> |