**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): August 6, 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:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Common** | **Title of each class** |  | **Trading Symbol(s)** | **Name of each exchange on which registered** | |  |
|  |  |  |  |  |  |
| **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 August 6, 2020, Eiger BioPharmaceuticals, Inc. reported its financial results for the quarter ended June 30, 2020. A copy of the press release titled “Eiger BioPharmaceuticals Reports Second Quarter 2020 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 August 6, 2020, titled “Eiger BioPharmaceuticals Reports Second Quarter 2020 Financial Results and Provides](#page5) | | | |  |
|  |  | [Business Update.”](#page5) | | | |  |
|  |  |  |  |  |  |  |

**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: August 6, 2020

By: /s/ Sriram Ryali



Sriram Ryali

Chief Financial Officer

**Exhibit 99.1**

**Eiger BioPharmaceuticals Reports Second Quarter 2020 Financial Results and Provides Business Update**

PALO ALTO, Calif., August 6, 2020 /PRNewswire/ — 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 second quarter 2020 and provided a business update.

“Eiger is executing toward multiple important milestones across our pipeline, including anticipated FDA approval of ZokinvyTM in Progeria and Progeroid Laminopathies,” said David Cory, President and CEO. “Our Phase 3 HDV D-LIVR trial continues to enroll and dose patients with full enrollment expected in 2021, and we plan for end-of-treatment and end-of-study data from our Phase 2 HDV LIFT study of peginterferon lambda in combination with lonafarnib this year. In addition, we look forward to results from multiple ongoing investigator sponsored studies of peginterferon lambda in COVID-19 patients.”

**Recent Highlights and Upcoming Milestones**

***ZokinvyTM (lonafarnib) in Progeria and Progeroid Laminopathies***

* *New Drug Application (NDA) accepted for filing by FDA with priority review and Prescription Drug User Fee Act (PDUFA) target action date of November 20, 2020*
* *Marketing Authorization Application (MAA) under review by EMA will follow a standard review timeline. EMA request for inspections, in addition to travel restrictions due to COVID-19, will delay EMA from completing its review within the framework of previously granted accelerated assessment.*

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

* *Phase 3 D-LIVR study (N=400) continues to enroll and dose patients*
* *Full enrollment expected in 2021*

***Peginterferon Lambda in HDV***

* *Phase 2 LIFT (combo with lonafarnib) end-of-treatment data planned for EASL 2020; end-of-study data planned for AASLD 2020*
* *Single, Phase 3 study design agreement with FDA and EMA*

***Peginterferon Lambda in COVID-19***

* *Six International Investigator Sponsored Studies in progress*

**Second Quarter 2020 Financial Results**

Cash, cash equivalents, and short-term investments as of June 30, 2020 totaled $90.8 million.

The Company reported net loss of $15.3 million, or $0.60 per share, for second quarter 2020, as compared to $17.5 million, or $0.75 per share, for second quarter 2019.

Research and Development expenses were $9.8 million for second quarter 2020, as compared to $12.9 million for second quarter 2019. The decrease was primarily due to a decrease in regulatory expenses and lower clinical trial related expenses, including clinical material costs.

General and Administrative expenses were $4.9 million for second quarter 2020, as compared to $4.2 million for second quarter 2019. The increase was primarily due to an increase in outside legal, consulting, advisory and accounting services.

Total operating expenses include total non-cash expenses of $1.8 million for second quarter 2020, as compared to $1.8 million for the same period in 2019.

As of June 30, 2020, the Company had 27,241,640 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.

Eiger’s lead clinical programs target Hepatitis Delta Virus (HDV) infection, the most serious form of human viral hepatitis. Eiger is developing two complementary treatments for HDV. Lonafarnib is a first-in-class, oral prenylation inhibitor in a global Phase 3 trial. Peginterferon lambda is a first-in-class, well-tolerated type III interferon entering Phase 3.

Eiger has filed an NDA and MAA for lonafarnib for the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies. FDA PDUFA date is November 20, 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 anticipating significant milestones in 2020 and 2021, the timing of our ongoing and planned clinical development, including the potential for approval of our lonafarnib product candidate in the U.S. and EU for Progeria and Progeroid Laminopathies; our progression and enrollment of our Phase 3 D-LIVR study in HDV; our ability to maintain supply of our clinical trial materials; our announcement of data from the trial of Lambda and lonafarnib boosted with ritonavir for HDV (LIFT); our plans to advance Lambda in HDV in the U.S. and EU; our plans for continued advancement of avexitide in registration trials; and our plans to initiate and conduct clinical studies of Lambda in coronavirus; 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 additional applicable risks and uncertainties described in the “Risk Factors” sections in the Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 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:**

Ingrid Choong, PhD

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Sri Ryali

1. 272-6138 sryali@eigerbio.com

**Eiger BioPharmaceuticals Inc.**

**Condensed Consolidated Balance Sheets**

(in thousands)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Six Months Ended** | | | | **Year Ended** | | |  |
|  |  | **June 30,** | | | **December 31,** | | |  |
|  |  | **2020** |  |  |  | **2019(1)** |  |  |
|  |  | **(unaudited)** |  | |  |  |  |  |
| **ASSETS** |  |  |  |  |  |  |  |  |
| Cash and cash equivalents | $ | 62,813 | |  | $ | 39,373 | |  |
| Debt securities, available-for-sale |  | 27,962 | |  |  | 55,621 | |  |
| Prepaid expenses and other current assets |  | 6,564 |  |  |  | 5,390 |  |  |
| Total current assets |  | 97,339 | |  |  | 100,384 | |  |
| Property and equipment, net |  | 616 | |  |  | 590 | |  |
| Operating lease right-of-use assets |  | 1,421 | |  |  | 1,654 | |  |
| Other assets |  | 3,781 |  |  |  | 2,511 |  |  |
| Total assets | $ | 103,157 | |  | $ | 105,139 | |  |
| **LIABILITIES AND STOCKHOLDERS’ EQUITY** |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| Current liabilities | $ | 16,147 | |  | $ | 16,949 | |  |
| Other liabilities |  | 28,519 | |  |  | 31,710 | |  |
| Stockholders’ equity |  | 58,491 | |  |  | 56,480 | |  |
| Total liabilities and stockholders’ equity | $ | 103,157 |  |  | $ | 105,139 |  |  |
|  |  |  |  |  |  |  |  |  |

1. Derived from the audited financial statements, included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2019.

**Eiger BioPharmaceuticals Inc.**

**Condensed Consolidated Statements of Operations Financial Data**

(in thousands, except per share and share amounts)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **Three Months Ended** | | | | | |  |  | **Six Months Ended** | | | | | |  |
|  |  |  | **June 30,** | | | |  |  |  |  | **June 30,** | | | |  |  |  |
|  |  |  | **(unaudited)** | | | | | |  |  | **(unaudited)** | | | | | |  |
|  |  |  | **2020** |  |  |  | **2019** |  |  |  | **2020** |  |  |  | **2019** |  |  |
| Operating expenses: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Research and development(1) | $ | | 9,754 | | $ | | 12,936 | | $ | | 19,235 | | $ | | 25,804 | |  |
| General and administrative(1) |  |  | 4,873 | |  |  | 4,225 | |  |  | 10,114 | |  |  | 8,282 | |  |
| Total operating expenses |  |  | 14,627 |  |  |  | 17,161 |  |  |  | 29,349 |  |  |  | 34,086 |  |  |
| Loss from operations |  |  | (14,627) | |  |  | (17,161) | |  |  | (29,349) | |  |  | (34,086) | |  |
| Interest expense |  |  | (891) | |  |  | (869) | |  |  | (1,775) | |  |  | (1,634) | |  |
| Interest income |  |  | 186 | |  |  | 502 | |  |  | 553 | |  |  | 1,013 | |  |
| Other income (expense), net |  |  | 6 |  |  |  | 1 |  |  |  | 6 | |  |  | (9) | |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Net loss | $ | | (15,326) | | $ | | (17,527) | | $ | | (30,565) | | $ | | (34,716) | |  |
| Net loss per common share: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Basic and diluted | $ | | (0.60) | | $ | | (0.75) | | $ | | (1.22) | | $ | | (1.63) | |  |
| Shares used to compute net loss per common share: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Basic and diluted |  |  | 25,501,514 | |  |  | 23,408,652 | |  |  | 25,001,432 | |  |  | 21,338,551 | |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

1. Includes stock-based compensation expense of:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Three Months Ended** | | | | | | **Six Months Ended** | | | | | | |
|  |  |  | **June 30,** | | |  |  |  | **June 30,** | | | | | |
|  |  |  | **2020** |  |  | **2019** |  |  | **2020** |  |  |  | **2019** |  |
| Research and development |  | $ | 398 |  | $ | 442 |  | $ | 787 |  |  | $ | 807 |  |
| General and administrative |  |  | 1,064 |  |  | 1,045 |  |  | 2,304 | |  |  | 1,875 | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Total stock-based compensation expense |  | $ | 1,462 |  | $ | 1,487 |  | $ | 3,091 | | $ | | 2,682 | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |