

**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 4, 2021

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 | 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 4, 2021, Eiger BioPharmaceuticals, Inc. reported its financial results for the quarter ended September 30, 2021. A copy of the press release titled “Eiger BioPharmaceuticals Reports Third Quarter 2021 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 No. | Description |
|--------------------|---|
| 99.1 | Press release, dated November 4, 2021, titled “Eiger BioPharmaceuticals Reports Third Quarter 2021 Financial Results and Provides Business Update.” |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

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: November 4, 2021

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



Eiger BioPharmaceuticals Reports

Third Quarter 2021 Financial Results and Provides Business Update

- Phase 3 HDV *D-LIVR* (Lonafarnib) Enrolled; Topline Data Planned by End of 2022

- Phase 3 HDV *LIMIT-2* (Peginterferon Lambda) Enrolling

- Company to Host Conference Call Today at 4:30 PM ET

Palo Alto, Calif., November 4, 2021 /PRNewswire/ — Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), a commercial-stage biopharmaceutical company focused on the development of innovative therapies to treat and cure Hepatitis Delta Virus (HDV) and other serious rare diseases, today reported its third quarter 2021 financial results and provided a business update.

“The recent completion of enrollment in our Phase 3 HDV *D-LIVR* study of Lonafarnib-based regimens sets up pivotal topline data by the end of 2022,” said David Cory, President and CEO. “Additionally, our Phase 3 HDV *LIMIT-2* study of Peginterferon Lambda is now activating sites and screening patients. Eiger is focused on the development of treatments and a cure for HDV. We are positioned to be a leader in this space with two first-in-class therapies for HDV, offering hope for the over 12 million patients around the globe with this devastating disease.”

Program Updates and Upcoming Milestones

HDV Platform

Lonafarnib for HDV

- First-in-class prenylation inhibitor and only oral agent in development
- *D-LIVR*, largest Phase 3 global study conducted in HDV
 - Fully enrolled with over 400 patients
 - Opportunity for approval of two Lonafarnib-based regimens:
 - All-oral and combination with peginterferon alfa
 - Pivotal topline data planned by end of 2022

Peginterferon Lambda for HDV

- Well-tolerated interferon administered as a weekly subcutaneous injection
- *LIMIT-2* (N=150), pivotal study of Peginterferon Lambda monotherapy
 - Now activating sites and screening patients

Avexitide for Rare Metabolic Disorders

- Phase 3 studies for post-bariatric hypoglycemia and congenital hyperinsulinism could begin as early as 2022

Zokinvy® for Progeria and Processing-Deficient Progeroid Laminopathies

- MAA is under EMA review, with an opinion from the Committee for Medicinal Products for Human Use (CHMP) expected around end of 2021
- Cohort ATU program (Temporary Use Authorization) approved in France
 - First ATU shipment completed

Peginterferon Lambda for COVID-19

- Phase 3 *TOGETHER* study enrolling patients across clinical sites in Brazil
- DSMB interim futility analysis (n=453) recommended study continuation
- Next interim futility data analysis by end of 2021
- Positive data could support emergency use authorization package

Corporate

- Appointed Erik Atkisson General Counsel and Chief Compliance Officer
- Cash and investments of \$120.4 million at the end of third quarter 2021 expected to fund planned operations into fourth quarter 2023

Third Quarter Financial Results

Net revenues from Zokinvy product sales were \$3.0 million for third quarter 2021, as compared to \$2.1 million for second quarter 2021. The increase was primarily driven by modestly higher inventory on-hand at the specialty pharmacy. The company commercially launched Zokinvy in the U.S. in January 2021 and has reported September year-to-date net sales of \$8.8 million.

Cost of Sales were \$0.3 million for third quarter 2021 and is related to certain costs associated with Zokinvy that were incurred after FDA approval.

Research and Development expenses were \$18.1 million for third quarter 2021, as compared to \$9.8 million for the same period in 2020. The increase was primarily due to clinical trial related expenses, including contract manufacturing and headcount related expenses, including stock-based compensation expense.

Selling, General and Administrative expenses were \$6.5 million for the third quarter of 2021, as compared to \$5.0 million for the same period in 2020. The increase was primarily due to outside consulting and advisory services and headcount related expenses, including stock-based compensation expense.

Total operating expenses include non-cash expenses of \$3.0 million for the third quarter of 2021, as compared to \$1.9 million for the same period in 2020.

Eiger reported a third quarter 2021 net loss of \$22.2 million, or \$0.65 on a per share basis. This compares to a net loss of \$15.7 million, or \$0.52 on a per share basis, for the third quarter of 2020.

Cash, cash equivalents, and investments as of September 30, 2021, totaled \$120.4 million compared to \$139.8 million as of June 30, 2021.

As of September 30, 2021, the company had 33,975,800 common shares outstanding.

Conference Call

At 4:30 PM Eastern Time today, November 4, 2021, Eiger will host a conference call to discuss its financial results and provide a business update. The live and replayed webcast of the call will be available through the company's website at www.eigerbio.com. To participate in the live call by phone, dial (844) 743-2495 (U.S.) or (661) 378-9529 (International) and enter conference ID 9874006. The webcast will be archived and available for replay for at least 90 days after the event.

About Eiger

Eiger is a commercial-stage biopharmaceutical company focused on the development of innovative therapies to treat and cure Hepatitis Delta Virus (HDV) and other serious rare diseases. The Eiger HDV platform includes two first-in-class therapies in Phase 3 that target critical host processes involved in viral replication. All five Eiger rare disease programs have been granted FDA Breakthrough Therapy Designation.

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 within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. 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. Forward-looking statements are our current statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things,

our anticipated significant milestones in 2021 and 2022; the timing of our ongoing and planned clinical development; the sufficiency of our cash, cash equivalents and investments to fund our operations; expectations regarding the timing and availability of topline data from our Phase 3 D-LIVR study in HDV; the ability to activate sites and fully enroll the Phase 3 LIMT-2 study; initiating a Phase 3 study for avexitide in post-bariatric hypoglycemia and congenital hyperinsulinism; the potential approval of Zokinvy in jurisdictions outside of the U.S., including the EU; and the potential of Lambda to be an effective therapy for newly diagnosed outpatients with COVID-19. 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, 2021 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:

Sri Ryali

CFO

Email: sryali@eigerbio.com

Phone: 1-650-272-6138



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

| | <u>September 30,</u> <u>2021</u> <u>(unaudited)</u> | <u>December 31,</u> <u>2020⁽¹⁾</u> |
|---|---|--|
| ASSETS | | |
| Cash and cash equivalents | \$ 49,255 | \$ 28,864 |
| Short-term debt securities | 36,051 | 99,976 |
| Accounts receivable | 2,762 | — |
| Inventories | 2,621 | 93 |
| Prepaid expenses and other current assets | 8,397 | 8,873 |
| Total current assets | <u>99,086</u> | <u>137,806</u> |
| Long-term debt securities | 35,093 | — |
| Property and equipment, net | 581 | 709 |
| Operating lease right-of-use assets | 777 | 1,176 |
| Other assets | 4,740 | 3,903 |
| Total assets | <u>\$ 140,277</u> | <u>\$ 143,594</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities | \$ 22,012 | \$ 16,627 |
| Other liabilities | 28,800 | 31,932 |
| Stockholders' equity | 89,465 | 95,035 |
| Total liabilities and stockholders' equity | <u>\$ 140,277</u> | <u>\$ 143,594</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, 2020.

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) | |
|--|--|--------------------|---|--------------------|
| | 2021 | 2020 | 2021 | 2020 |
| Product revenue, net | \$ 3,039 | \$ — | \$ 8,782 | \$ — |
| Costs and operating expenses: | | | | |
| Cost of sales | 318 | — | 641 | — |
| Research and development ⁽¹⁾ | 18,106 | 9,810 | 46,250 | 29,045 |
| Selling, general and administrative ⁽¹⁾ | 6,466 | 5,027 | 17,916 | 15,141 |
| Total operating expenses | 24,890 | 14,837 | 64,807 | 44,186 |
| Loss from operations | (21,851) | (14,837) | (56,025) | (44,186) |
| Interest expense | (894) | (906) | (2,659) | (2,681) |
| Interest income | 35 | 76 | 119 | 629 |
| Other income (expense), net | 503 | (13) | 46,462 | (7) |
| Income (loss) before provision for taxes | (22,207) | (15,680) | (12,103) | (46,245) |
| Provision for income taxes | 16 | — | 46 | — |
| Net loss | <u>\$ (22,223)</u> | <u>\$ (15,680)</u> | <u>\$ (12,149)</u> | <u>\$ (46,245)</u> |
| Net income (loss) per common share: | | | | |
| Basic and diluted | <u>\$ (0.65)</u> | <u>\$ (0.52)</u> | <u>\$ (0.36)</u> | <u>\$ (1.74)</u> |
| Weighted-average common shares outstanding: | | | | |
| Basic and diluted | <u>33,946,559</u> | <u>29,879,135</u> | <u>33,922,080</u> | <u>26,639,201</u> |

(1) Includes stock-based compensation expense of:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|-----------------|------------------------------------|-----------------|
| | 2021 | 2020 | 2021 | 2020 |
| Research and development | \$ 686 | \$ 367 | \$ 1,627 | \$ 1,154 |
| General and administrative | 1,644 | 1,078 | 4,310 | 3,382 |
| Total stock-based compensation expense | <u>\$ 2,330</u> | <u>\$ 1,445</u> | <u>\$ 5,937</u> | <u>\$ 4,536</u> |