

**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 3, 2022

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 3, 2022, Eiger BioPharmaceuticals, Inc. reported its financial results for the quarter ended September 30, 2022. A copy of the press release titled “Eiger BioPharmaceuticals Reports Third Quarter 2022 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 3, 2022, titled “Eiger BioPharmaceuticals Reports Third Quarter 2022 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.

Dated: November 3, 2022

Eiger BioPharmaceuticals, Inc.

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



Eiger BioPharmaceuticals Reports Third Quarter 2022 Financial Results and Provides Business Update

- Phase 3 HDV *D-LIVR* (lonafarnib-based regimens) Study Topline Data in December
- Phase 3 HDV *LIMIT-2* (peginterferon lambda) Study Activating Sites and Enrolling Patients
- Phase 3 Congenital Hyperinsulinism *Avant* (avexitide) Program Initiated
- Strong Cash Position: \$121.0 Million in Cash, Cash Equivalents, and Total Investments

Palo Alto, Calif., November 3, 2022 /PRNewswire/ — Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), a commercial-stage biopharmaceutical company focused on the development of innovative therapies for hepatitis delta virus (HDV) and other serious diseases, today reported financial results for third quarter 2022 and provided a business update.

“We look forward to reporting topline data next month from our landmark Phase 3 *D-LIVR* study of lonafarnib-based regimens for the treatment of hepatitis delta virus, an important milestone for Eiger and patients suffering from HDV,” said David Cory, President and CEO, Eiger. “The *D-LIVR* readout will be the first of many potentially value-creating catalysts across our late-stage pipeline of multiple FDA Breakthrough Therapy designated programs in Phase 3, including peginterferon lambda for HDV and avexitide for congenital hyperinsulinism.”

Business Highlights

Hepatitis Delta Virus Platform

Lonafarnib-Based Regimens for HDV

- First-in-class, oral prenylation inhibitor
- *D-LIVR* Phase 3 study to support registration of two lonafarnib-based regimens
 - Oral lonafarnib/ritonavir and combination with peginterferon alfa
 - Topline Week 48 data expected in December

Peginterferon Lambda for HDV

- First-in-class, well-tolerated interferon
- Potential to be interferon of choice in HDV combination therapies

- *LIMIT-2* Phase 3 study of peginterferon lambda monotherapy
 - Enrolling patients, targeting N=150

Combination of Peginterferon Lambda and Lonafarnib/Ritonavir for HDV

- Combination of Eiger's two proprietary HDV therapies in development
- *LIFT-2* Phase 2 study in collaboration with National Institutes of Health initiating in 2022
 - Single arm study (N=30), 48 weeks of treatment with 24 weeks of follow-up

Zokinvy® (lonafarnib) for Progeria and Processing-Deficient Progeroid Laminopathies

- Granted marketing authorization in EU and U.K.
- Reimbursement agreed in Germany

Avexitide for Rare Metabolic Disorders

- Phase 3 *Avant* congenital hyperinsulinism (HI) program initiated
- Breakthrough Therapy designation for HI
- Rare Pediatric Disease designation for HI – Priority Review Voucher eligible

Financial Guidance

- \$121.0 million in cash, cash equivalents, and total investments as of September 30, 2022 expected to fund planned operations through 2024
- Ability to access up to an additional \$35.0 million over two tranches under existing debt facility, with the availability of both tranches being based on predetermined regulatory and clinical milestones, to support funding of potential HDV commercial launch

Third Quarter 2022 Financial Results

Total revenue was \$4.0 million in third quarter 2022 compared to \$3.0 million for the same period in 2021. The increase was primarily driven by an increase in units shipped during the quarter.

Cost of sales was \$1.2 million for third quarter 2022 as compared to \$0.3 million for the same period in 2021. The increase was primarily driven by a one-time write-off of a non-conforming batch of inventory.

Research and Development expenses were \$22.2 million for third quarter 2022, as compared to \$18.1 million for the same period in 2021. The increase is primarily driven by personnel related costs, including stock-based compensation, from additional headcount, contract manufacturing expenditures related to timing of production of clinical materials across programs, and clinical trial related expenses.

Selling, General and Administrative expenses were \$7.0 million for third quarter 2022, as compared to \$6.5 million for the same period in 2021. The increase was primarily in outside services, including consulting and advisory services to support the company's growth.

Total operating expenses include non-cash expenses of \$4.0 million for third quarter 2022, as compared to \$3.0 million for the same period in 2021.

The Company reported a net loss of \$27.1 million, or \$0.62 per share basis for third quarter 2022. This compares to a net loss of \$22.2 million, or \$0.65 per share basis for the same period in 2021.

Cash, cash equivalents, and total investments as of September 30, 2022 totaled \$121.0 million compared to \$106.1 million as of December 31, 2021.

As of September 30, 2022, the company had 44.0 million common shares outstanding.

Conference Call

At 4:30 PM Eastern Time today, November 3, 2022, 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, please register in advance at <https://register.vevent.com/register/BI87b8efa326b64c63bd59eabef4f465ab> to receive the dial-in number and unique passcode to access the call. 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 for 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, prospective products, preclinical and clinical pipelines, regulatory objectives, 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, the timing of our ongoing and planned clinical development; the sufficiency of our cash, cash equivalents and investments to fund our operations; the likelihood of identifying registration pathways for peginterferon lambda for COVID-19; expectations regarding the timing and availability of topline data from our Phase 3 *D-LIVR* study in HDV; the ability to fully enroll the Phase 3 *LIMT-2* study and Phase 3 *Avant* study; our capability to provide sufficient quantities of any of our product candidates, including peginterferon lambda, to meet anticipated full-scale commercial demands; our ability to finance, independently or through collaborations, the continued advancement of our development pipeline; and the potential for success of any of our products or product candidates. 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, 2022 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.

Investors:

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

	September 30, 2022 (Unaudited)	December 31, 2021 ⁽¹⁾
Assets		
Current assets:		
Cash and cash equivalents	\$ 26,308	\$ 22,221
Short-term debt securities	94,736	66,594
Accounts receivable, net	2,458	2,576
Inventories	2,817	2,612
Prepaid expenses and other current assets	15,970	9,361
Total current assets	142,289	103,364
Long-term debt securities	—	17,262
Property and equipment, net	511	613
Operating lease right-of-use assets	246	653
Other assets	698	4,510
Total assets	<u>\$ 143,744</u>	<u>\$ 126,402</u>
Liabilities and Stockholders' Equity		
Current liabilities	26,119	29,901
Other liabilities	39,317	24,102
Stockholders' equity	78,308	72,399
Total liabilities and stockholders' equity	<u>\$ 143,744</u>	<u>\$ 126,402</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, 2021.

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)	
	2022	2021	2022	2021
Product revenue, net	\$ 4,024	\$ 3,039	\$ 10,038	\$ 8,782
Other revenue	—	—	750	—
Total revenue	<u>4,024</u>	<u>3,039</u>	<u>10,788</u>	<u>8,782</u>
Costs and operating expenses:				
Cost of sales	1,231	318	1,492	641
Research and development	22,198	18,106	56,761	46,250
Selling, general and administrative	6,964	6,466	20,804	17,916
Total costs and operating expenses	<u>30,393</u>	<u>24,890</u>	<u>79,057</u>	<u>64,807</u>
Loss from operations	(26,369)	(21,851)	(68,269)	(56,025)
Interest expense	(1,092)	(894)	(2,912)	(2,659)
Interest income	347	35	613	119
Other (expense) income, net	3	503	(1,044)	46,462
Loss before provision for income taxes	(27,111)	(22,207)	(71,612)	(12,103)
Provision for income taxes	—	16	26	46
Net loss	<u>\$ (27,111)</u>	<u>\$ (22,223)</u>	<u>\$ (71,638)</u>	<u>\$ (12,149)</u>
Net loss per common share:				
Basic	<u>\$ (0.62)</u>	<u>\$ (0.65)</u>	<u>\$ (1.76)</u>	<u>\$ (0.36)</u>
Diluted	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>
Weighted-average common shares outstanding:				
Basic	<u>44,010,553</u>	<u>33,946,559</u>	<u>40,806,581</u>	<u>33,922,080</u>
Diluted	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>

(1) Includes stock-based compensation expense of:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	\$ 856	\$ 686	\$ 2,301	\$ 1,627
General and administrative	1,366	1,644	4,176	4,310
Total stock-based compensation expense	<u>\$ 2,222</u>	<u>\$ 2,330</u>	<u>\$ 6,477</u>	<u>\$ 5,937</u>