

**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 5, 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 August 5, 2021, Eiger BioPharmaceuticals, Inc. reported its financial results for the quarter ended June 30, 2021. A copy of the press release titled “Eiger BioPharmaceuticals Reports Second 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 August 5, 2021, titled “Eiger BioPharmaceuticals Reports Second 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: August 5, 2021

By: /s/ Sriram Ryali

Sriram Ryali
Chief Financial Officer



Eiger BioPharmaceuticals Reports Second Quarter 2021 Financial Results and Provides Business Update

- *HDV Platform Strategy Rapidly Advancing*
- *Phase 3 HDV D-LIVR (Lonafarnib) >90% Enrolled; On-Track for Full Enrollment in 2021*
- *Phase 3 HDV LIMIT-2 (Lambda) On-Track for First Patient to Enroll in 2021*
- *All Five Rare Disease Programs Now Have Breakthrough Therapy Designation*
- *Company to Host Conference Call Today at 4:30 PM ET*

Palo Alto, Calif., August 5, 2021 /PRNewswire/ — Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), a commercial-stage biopharmaceutical company focused on the development and commercialization of targeted therapies for serious rare and ultra-rare diseases, today reported its second quarter 2021 financial results and provided a business update.

“Our rapidly advancing HDV platform strategy, which includes Lonafarnib and Peginterferon Lambda, provides multiple opportunities to deliver a win for HDV patients and positions us to be a leader in this space,” said David Cory, President and CEO of Eiger. “We are on track to complete enrollment in our Phase 3 HDV *D-LIVR* study this year, setting up pivotal topline data release in late-2022. Additionally, *LIMIT-2*, our Phase 3 study of Peginterferon Lambda for HDV, is on track to enroll its first patient by end of 2021.”

Program Updates and Upcoming Milestones

HDV Platform Strategy

Lonafarnib for HDV

- Only oral therapy in development for HDV
- Phase 3 *D-LIVR* (N=400) is the largest global study in HDV
 - Provides multiple opportunities for approval of Lonafarnib-based regimens: an all-oral and a combination with peginterferon alfa
 - > 90% enrolled, including patients randomized to date and patients in screening that are expected to be randomized
 - Full enrollment expected before end of 2021
 - Pivotal topline data release expected in late-2022

Peginterferon Lambda for HDV

- Well-tolerated interferon administered as a weekly subcutaneous injection
- Phase 3 *LIMIT-2* (N=150) is a pivotal study of Peginterferon Lambda as a single agent for HDV
 - First patient enrolled expected by end of 2021

Avexitide for Rare Metabolic Disorders

- FDA Breakthrough Therapy Designation granted for congenital hyperinsulinism
- Phase 3-enabling manufacturing, device development, and regulatory activities are ongoing in 2021
- Phase 3 studies for post-bariatric hypoglycemia and congenital hyperinsulinism could begin as early as 2022

Zokinvy® for Progeria and Processing-Deficient Progeroid Laminopathies

- EMA approval expected by end of 2021
- Recipient of 2021 NORD Industry Innovation Award
- Nominee for 2021 Prix Galien USA Best Pharmaceutical Product Award

Peginterferon Lambda for COVID-19

- Phase 3 *TOGETHER* study enrolling patients across clinical sites in Brazil
- Interim futility data analysis potentially by end of 2021
- Positive data could support submission for emergency use authorization

Corporate

- Cash and investments of \$139.8 million at the end of second quarter 2021 is expected to fund planned operations into fourth quarter 2023

Second Quarter Financial Results

Net revenues from Zokinvy product sales were \$2.1 million for second quarter 2021. The company commercially launched Zokinvy in the U.S. in January 2021 and reported \$3.6 million in first quarter 2021, which included initial inventory stocking at the specialty pharmacy.

Research and Development expenses were \$14.3 million for second 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, headcount related expenses, including stock-based compensation expense, and regulatory consulting services.

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

Selling, General and Administrative expenses were \$5.9 million for the second quarter of 2021, as compared to \$4.9 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 \$2.7 million for the second quarter of 2021, as compared to \$1.8 million for the same period in 2020.

Eiger reported a second quarter 2021 net loss of \$19.2 million, or \$0.57 on a per share basis. This compares to a net loss of \$15.3 million, or \$0.60 on a per share basis, for the second quarter of 2020.

Cash, cash equivalents, and investments as of June 30, 2021, totaled \$139.8 million compared to \$160.5 million on March 31, 2021.

As of June 30, 2021, the company had 33,951,314 common shares outstanding.

Conference Call

At 4:30 PM Eastern Time today, August 5, 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 9482721. 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 and commercialization of targeted therapies for serious rare and ultra-rare diseases.

Eiger's lead clinical programs are focused on the development of foundational therapies for Hepatitis Delta Virus (HDV) infection, the most serious form of viral hepatitis. Eiger's HDV platform strategy includes two complementary HDV treatments. Lonafarnib is a first-in-class, oral prenylation inhibitor in a global Phase 3 trial. Peginterferon lambda is a first-in-class, type III, well-tolerated interferon entering Phase 3.

Zokinvy® for the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and processing-deficient progeroid laminopathies is the Company's first FDA approved product. A Marketing Authorization Application (MAA) is under review by the European Medicines Agency (EMA).

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 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 into the fourth quarter of 2023; our development programs for Zokinvy generally; , and the potential approval of Zokinvy in jurisdictions outside of the U.S., including the EU; our progression and continued enrollment of our Phase 3 D-LIVR study in HDV and expectations regarding the timing and availability of topline data; our ability to maintain supply of our commercial and clinical trial materials; our plans to advance Lambda in HDV in the U.S. and EU; our progression of Lambda for COVID-19 and Avexitide for post-bariatric hypoglycemia and congenital hyperinsulinism; 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 additional applicable risks and uncertainties described in the “Risk Factors” sections in the Quarterly Report on Form 10-Q for the quarter ended March 31, 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:

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

	June 30, 2021	December 31, 2020⁽¹⁾
	<u>(unaudited)</u>	<u></u>
ASSETS		
Cash and cash equivalents	\$ 65,056	\$ 28,864
Short-term debt securities	42,311	99,976
Accounts receivable	1,438	—
Inventories	2,065	93
Prepaid expenses and other current assets	7,933	8,873
Total current assets	<u>118,803</u>	<u>137,806</u>
Long-term debt securities	32,426	—
Property and equipment, net	621	709
Operating lease right-of-use assets	903	1,176
Other assets	4,085	3,903
Total assets	<u>\$ 156,838</u>	<u>\$ 143,594</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	\$ 15,875	\$ 16,627
Other liabilities	31,838	31,932
Stockholders' equity	109,125	95,035
Total liabilities and stockholders' equity	<u>\$ 156,838</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 June 30, (unaudited)		Six Months Ended June 30, (unaudited)	
	2021	2020	2021	2020
Product revenue, net	\$ 2,097	\$ —	\$ 5,743	\$ —
Costs and operating expenses:				
Cost of sales	270	—	323	—
Research and development ⁽¹⁾	14,302	9,754	28,144	19,235
Selling, general and administrative ⁽¹⁾	5,886	4,873	11,450	10,114
Total operating expenses	20,458	14,627	39,917	29,349
Loss from operations	(18,361)	(14,627)	(34,174)	(29,349)
Interest expense	(880)	(891)	(1,765)	(1,775)
Interest income	33	186	84	553
Other income (expense), net	45	6	45,959	6
Income(loss) before provision for taxes	(19,163)	(15,326)	10,104	(30,565)
Provision for income taxes	11	—	30	—
Net loss	\$ (19,174)	\$ (15,326)	\$ 10,074	\$ (30,565)
Net income (loss) per common share:				
Basic	\$ (0.57)	\$ (0.60)	\$ 0.30	\$ (1.22)
Diluted	\$ (0.57)	\$ (0.60)	\$ 0.29	\$ (1.22)
Weighted-average common shares outstanding:				
Basic	33,932,127	25,501,514	33,909,637	25,001,432
Diluted	33,932,127	25,501,514	34,156,877	25,001,432

(1) Includes stock-based compensation expense of:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	\$ 551	\$ 398	\$ 942	\$ 787
General and administrative	1,507	1,064	2,665	2,304
Total stock-based compensation expense	\$ 2,058	\$ 1,462	\$ 3,607	\$ 3,091