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): May 6, 2021

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:

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 May 6, 2021, Eiger BioPharmaceuticals, Inc. reported its financial results for the quarter ended March 31, 2021. A copy of the press release titled "Eiger BioPharmaceuticals Reports First 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 May 6, 2021, titled "Eiger BioPharmaceuticals Reports First 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: May 6, 2021

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

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

- *Phase 3 HDV D-LIVR (Lonafarnib) 75% Enrolled; Full Enrollment Planned in 2021*
- *Phase 3 HDV LIMT-2 (Lambda) to Initiate in 2021*
- *Phase 3 COVID-19 TOGETHER Platform Study to Include Lambda Arm*
- *$3.6M U.S. Zokinvy® Net Sales in Q1 2021*

Palo Alto, Calif., May 6, 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 first quarter 2021 financial results and provided a business update.

“The Phase 3 D-LIVR study is now 75% enrolled, and by year-end we expect to complete enrollment of this landmark global study advancing Lonafarnib, the only oral agent in development for HDV, setting the stage for Week 48 end of treatment data in 2022,” said David Cory, President and CEO of Eiger. “In parallel, we will initiate the Phase 3 LIMT-2 study in 2021 to advance Lambda, a well-tolerated interferon, also toward registration for HDV. Most recently, with a goal of developing a convenient, outpatient treatment for COVID-19, we announced that a Lambda arm will be included in the ongoing, multi-center, Phase 3 *TOGETHER* platform study in Brazil.”

Program Updates and Upcoming Milestones

Lonafarnib for HDV

- First and only oral therapy in clinical development for HDV
- Phase 3 D-LIVR study is the largest and only global HDV study
  - Study is 75% enrolled, including patients randomized to date and patients in screening that are expected to be randomized
  - Full enrollment of 400 patients expected by end of 2021

Peginterferon Lambda (Lambda) for HDV

- Well-tolerated interferon for convenient once weekly subcutaneous injection
- Phase 3 LIMT-2 study (N=150) expected to initiate in the second half of 2021

Zokinvy® (lonafarnib) for Progeria

- U.S. commercial launch in January 2021
- EMA approval expected by end of 2021

Lambda for COVID-19

- U.S. IND now open and includes Phase 2/3 study protocol
- Lambda to be included in ongoing Phase 3 *TOGETHER* platform study
    - Recruiting at 11 sites in Brazil with plans to add a site in Toronto, Canada
    - Lambda arm will include up to 800 high-risk, non-hospitalized patients
    - Endpoints align with FDA Guidance for COVID-19 therapeutics

Avexitide for Post-Bariatric Hypoglycemia (PBH) and Congenital Hyperinsulinism (CHI)

- Advancing manufacturing, device, clinical and regulatory activities in 2021
- Registration-enabling studies for PBH and CHI could begin in 2022

Corporate

- Appointed Kim Sablich, Industry Veteran, to Board of Directors in April 2021
- Cash, cash equivalents and investments of $160.5 million at the end of first quarter 2021 expected to fund planned operations into fourth quarter 2023

First Quarter 2021 Financial Results

Eiger reported total net revenue of $3.6 million from Zokinvy product sales for first quarter 2021. Zokinvy launched commercially in the U.S. in January 2021 with first quarter sales including inventory stocking at the specialty pharmacy.

Research and Development expenses were $13.8 million for first quarter 2021 as compared to $9.5 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. The increase was partially offset by lower expenses for regulatory consulting services.

Selling, General and Administrative expenses were $5.6 million for first quarter 2021, as compared to $5.2 million for the same period in 2020. The increase in first quarter 2021 was primarily due to outside consulting and advisory services.

Total operating expenses include non-cash expenses of $2.2 million for first quarter 2021, as compared to $2.0 million same period in 2020.

Eiger reported first quarter 2021 net income of $29.2 million, or $0.85 on a fully-diluted per share basis. This compares to a net loss of $15.2 million, or $0.62 on a per share basis, for first quarter 2020. First quarter 2021 net income was driven by a one-time gain from the sale of the Zokinvy Priority Review Voucher (PRV). The company reported $45.9 million as Other Income, Net, which primarily reflects net PRV sale proceeds.

Cash, cash equivalents, and investments as of March 31, 2021 totaled $160.5 million compared to $128.8 million on December 31, 2020.

As of March 31, 2021, the company had 34.0 million of common shares outstanding.

Conference Call

At 4:30 p.m. Eastern Time today, 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 1090136. 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, with 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, well-tolerated type III 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; 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; 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 PBH and CHI; 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:

Sri Ryali
Email: sryali@eigerbio.com
Phone: 1-650-272-6138

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

	Three Months Ended March 31 2021 (unaudited)	Year Ended December 31, 2020(1)
ASSETS		
Cash and cash equivalents	$ 108,410	$ 28,864
Debt securities, available-for-sale	52,082	99,976
Accounts receivable	639	—
Inventories	1,397	93
Prepaid expenses and other current assets	7,358	8,873
Total current assets	169,886	137,806
Property and equipment, net	659	709
Operating lease right-of-use assets	1,049	1,176
Other assets	3,921	3,903
Total assets	$ 175,515	$ 143,594
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	$ 17,517	$ 16,627
Other liabilities	31,808	31,932
Stockholders' equity	126,190	95,035
Total liabilities and stockholders' equity	$ 175,515	$ 143,594

(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 March 31 (unaudited)	
	2021	2020
Product revenue, net	$ 3,646	$ —
Costs and operating expenses:		
Costs of sales	53	—
Research and development(1)	13,842	9,481
Selling, general and administrative(1)	5,564	5,241
Total costs and operating expenses	19,459	14,722
Loss from operations	(15,813)	(14,722)
Interest expense	(885)	(884)
Interest income	51	367
Other income, net	45,914	—
Income before provision for income taxes	29,267	(15,239)
Provision for income taxes	19	—
Net income (loss)	$ 29,248	$ (15,239)
Net income (loss) per common share:		
Basic	$ 0.86	$ (0.62)
Diluted	$ 0.85	$ (0.62)
Weighted-average common shares outstanding:		
Basic	33,886,896	24,501,350
Diluted	34,220,895	24,501,350

(1) Includes stock-based compensation expense of:

	Three Months Ended March 31	
	2021	2020
Research and development	$ 391	$ 389
Selling, general and administrative	1,158	1,240
Total stock-based compensation expense	$ 1,549	$ 1,629