# 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): March 10, 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  $\Box$ 

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 March 10, 2022, Eiger BioPharmaceuticals, Inc. reported its financial results for the quarter and year ended December 31, 2021. A copy of the press release titled "Eiger BioPharmaceuticals Reports Fourth Quarter and Full Year 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 <u>Press release, dated March 10, 2022, titled "Eiger BioPharmaceuticals Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Update."</u>
- 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: March 10, 2022

By: /s/ Sriram Ryali

Sriram Ryali Chief Financial Officer



## Eiger BioPharmaceuticals Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Update

- Phase 3 COVID-19 TOGETHER (Lambda) Study Data in March 2022
- Phase 3 HDV D-LIVR (Lonafarnib) Study Topline Data Planned by End of 2022
- Phase 3 HDV LIMT-2 (Lambda) Study Enrolling
- Strong Cash Position of Approximately \$106 Million as of 12/31/21
- Company to Host Conference Call Today at 4:30 PM ET

Palo Alto, Calif., March 10, 2022 /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 diseases, today reported financial results for fourth quarter and full year 2021 and provided a business update.

"We expect 2022 to be a transformational year for Eiger with topline data planned from two Phase 3 studies," said David Cory, President and CEO of Eiger. "The Phase 3 *TOGETHER* study of Peginterferon Lambda for COVID-19 is expected to readout later this month and the Phase 3 *D-LIVR* study of Lonafarnib for HDV is planned to readout by end of year. We look forward to reporting results from these potentially registration enabling studies as well as progress across our other late-stage pipeline programs with multiple catalysts this year."

# **Program Highlights**

#### Lonafarnib: Oral Prenylation Inhibitor for HDV

- *D-LIVR* Phase 3 multi-center, global study
  - Two Lonafarnib-based regimens, both with potential for registration
    - Lonafarnib oral and Lonafarnib / peginterferon alfa combination
  - Fully enrolled N=407, with topline data planned by end of 2022
  - *D-LIVR* study design includes conservative powering assumptions, modeling response rates well below what was demonstrated in Phase 2
  - Ukraine and Russia Update
    - Ukraine:
      - Eiger continues to closely assess this evolving situation, prioritizing patient care and patient monitoring to ensure continuity in the study
      - Eiger believes the study remains more than adequately powered to demonstrate statistical significance over placebo even if these patients discontinue from study
    - Russia:
      - To date, no interruption to patient visits, safety monitoring, or drug supply; contingency plans in place to ensure continuity of drug supply, sample storage and analysis to preserve integrity of results

## Peginterferon Lambda: Well-tolerated Interferon for HDV

- LIMT-2 Phase 3 multi-center, global study
  - Peginterferon Lambda monotherapy for registration
  - Enrolling patients, targeting N=150

#### Peginterferon Lambda and Lonafarnib Combination for HDV

- *LIFT-2* Phase 2 study at National Institutes of Health
  - Initiating 1H22, targeting N=30
- Potential to be interferon of choice in HDV combination therapies

# Peginterferon Lambda for Non-hospitalized COVID-19 Infection

- Novel mechanism of action, agnostic to variants and mutations
- TOGETHER Phase 3 study fully enrolled, N>1,800
  - Includes unvaccinated and vaccinated patients across multiple variants
  - Topline data planned in March 2022

#### Avexitide for Rare Metabolic Disorders

- Granted Breakthrough Therapy Designation for Congenital Hyperinsulinism (HI)
- Granted Rare Pediatric Disease Designation for HI; PRV eligible
- Phase 3 ready in 2022

## Zokinvy® for Progeria and Processing-Deficient Progeroid Laminopathies

- Successful U.S. commercial launch
  - Approximately 80% of identified U.S. patients converted to commercial supply
- EMA review of MAA
  - CHMP opinion expected in first half of 2022

#### **Corporate**

• Cash, cash equivalents and investments of \$106.1 million to begin 2022 expected to fund planned operations through Q3 2023

# Fourth Quarter and Full Year 2021 Financial Results

Cash, cash equivalents, and total investments as of December 31, 2021 totaled \$106.1 million compared to \$128.8 million on December 31, 2020.

Net product sales of Zokinvy were \$3.4 million for fourth quarter 2021, as compared to \$3.0 million for third quarter 2021. The increase reflects shipment of product under a reimbursed early access program approved in France, partially offset by fewer shipments to the U.S. specialty pharmacy due to timing of patient refills. The Company commercially launched Zokinvy in the U.S. in January 2021 and reported full year 2021 net sales of \$12.1 million.

Cost of Sales was \$0.1 million and \$0.7 million for fourth quarter and full year 2021, respectively, and related to certain manufacturing, shipping, and distribution costs associated with Zokinvy that were incurred after FDA approval.

Research and Development expenses were \$18.2 million and \$64.4 million for fourth quarter and full year 2021, respectively, as compared to \$12.5 million and \$41.6 million for the same periods in 2020. The increases in fourth quarter and full year 2021 expenses were primarily due to contract manufacturing and clinical trial related expenses for increased clinical development activities and personnel related expenses, including stock-based compensation, due to an increase in headcount.

Selling, General and Administrative expenses were \$6.0 million and \$23.9 million for fourth quarter and full year 2021, respectively, as compared to \$5.4 million and \$20.6 million for the same periods in 2020. The increases in fourth quarter and full year 2021 were primarily due to an increase in personnel related expenses attributed to an increase in headcount and an increase in outside services, including consulting and advisory services to support the growth of the Company.

Total operating expenses include non-cash expenses of \$2.8 million and \$10.7 million for fourth quarter and full year 2021, respectively, as compared to \$2.1 million and \$7.8 million for the same periods in 2020.

The Company reported net losses of \$21.8 million, or \$0.64 per share, and \$33.9 million, or \$1.00 per share, for fourth quarter and full year 2021, respectively, as compared to \$18.8 million, or \$0.58 per share, and \$65.1 million, or \$2.31 per share, for the same periods in 2020.

As of December 31, 2021, the company had 34.6 million of common shares outstanding.

# CONFERENCE CALL

At 4:30 PM Eastern Time today, March 10, 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, dial (844) 743-2495 (U.S.) or (661) 378-9529 (International) and enter conference ID 4338659. 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 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 fully enroll the Phase 3 LIMT-2 study; initiating a Phase 3 study for avexitide in congenital hyperinsulinism; the approval of Zokinvy in jurisdictions outside of the U.S., including the EU; and the potential of peginterferon lambda to be an effective therapy for newly diagnosed outpatients with COVID-19; and the possibility of success of any of our 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 September 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.

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

	Year Ended December 31, 2021		Year Ended December 31, 2020(1)	
ASSETS				
Cash and cash equivalents	\$	22,221	\$	28,864
Short-term debt securities		66,594		99,976
Accounts receivable		2,576		—
Inventories		2,612		93
Prepaid expenses and other current assets		9,361		8,873
Total current assets		103,364		137,806
Long-term debt securities		17,262		_
Property and equipment, net		613		709
Operating lease right-of-use assets		653		1,176
Other assets		4,510		3,903
Total assets	\$	126,402	\$	143,594
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities	\$	29,901	\$	16,627
Other liabilities		24,102		31,932
Stockholders' equity		72,399		95,035
Total liabilities and stockholders' equity	\$	126,402	\$	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 December 31, Year Ended December 31, (unaudited) 2021 2020 2021 2020 3,360 12,142 Product revenue, net \$ \$ \$ \$ Costs and operating expenses: Cost of sales 104 745 Research and development(1) 12,545 41,590 18,186 64,436 Selling, general and administrative<sup>(1)</sup> 5,984 5,418 23,900 20,559 Total operating expenses 24,274 17,963 89,081 62,149 Loss from operations (20, 914)(17, 963)(76, 939)(62,149) (900) Interest expense (913) (3, 559)(3, 594)Interest income 39 75 158 704 Other income (expense), net 25 (5) 46,487 (12) Income (loss) before provision for taxes (21,750) (18,806) (33,853) (65,051) Provision for income taxes 18 64 (21,768) (18,806) (33,917) (65,051) Net loss \$ \$ \$ \$ Net income (loss) per common share: (0.58) (1.00)Basic and diluted \$ (0.64) \$ \$ \$ (2.31)Weighted-average common shares outstanding: Basic and diluted 34,010,405 32,701,820 33,944,342 28,143,391

(1) Includes stock-based compensation expense of:

	Three Months Ended December 31,			Year Ended December 31,				
	 2021		2020		2021		2020	
Research and development	\$ 625	\$	340	\$	2,252	\$	1,494	
General and administrative	 1,339		1,097		5,649		4,479	
Total stock-based compensation expense	\$ 1,964	\$	1,437	\$	7,901	\$	5,973	