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

- Peginterferon lambda COVID-19 EUA Application to be Submitted in Q2 2022
- Phase 3 HDV *D-LIVR* (lonafarnib) Study Topline Data Anticipated by Year End
- Zokinvy® (lonafarnib) CHMP Opinion Expected in Q2 2022
- Phase 3 Avexitide Congenital Hyperinsulinism Program Initiation Planned by Year End
- Strong Cash Position: $153.5M Pro Forma Cash

PALO ALTO, Calif., May 5, 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 first quarter 2022 and provided a business update.

"We are laser focused on executing our development and commercialization strategies and anticipate significant value-creating milestones this quarter, including the submission of an Emergency Use Authorization application for lambda to treat COVID-19 as well a CHMP opinion on our Zokinvy MAA for progeria," said David Cory, President and CEO, Eiger. "In parallel, we continue to advance our clinical pipeline and remain on track to announce topline data from our landmark Phase 3 *D-LIVR* study of lonafarnib for HDV this year."

Business Highlights

Peginterferon Lambda for COVID-19 Infection

- Actively engaging with FDA on Emergency Use Authorization (EUA) application
- Preparing to submit EUA application and publish full dataset
    - Gating component for EUA application is full data analyses from *TOGETHER* team which is in process and nearing completion
- Announced Phase 3 *TOGETHER* study topline data in mid-March
    - Novel mechanism of action, likely agnostic to variants
    - Second largest outpatient study to date in COVID-19 (N>1,900)
    - Single-dose peginterferon lambda for COVID-19 reduced risk of hospitalization or ER visits greater than six hours by 50% in a predominantly vaccinated population
    - Highly superior compared to placebo, with a probability of superiority of 99.91% on the primary endpoint
    - Primary endpoint of reduced risk of hospitalization or ER visits achieved across multiple SARS-CoV-2 variants

Hepatitis Delta Virus Platform

Lonafarnib for HDV

- First-in-class, oral prenylation inhibitor
- *D-LIVR* Phase 3 study with potential approval of two lonafarnib-based regimens
    - Oral lonafarnib/ritonavir and in combination with peginterferon alfa
    - Topline data planned by end of 2022

Peginterferon Lambda for HDV

- First-in-class well-tolerated interferon
- Potential to be interferon of choice in HDV combination therapies
- *LIMT-2* Phase 3 study of peginterferon lambda monotherapy
    - Enrolling patients, targeting N=150

Combination of Peginterferon Lambda and Lonafarnib 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

- CHMP opinion expected in Q2 2022

Avexitide for Rare Metabolic Disorders

- Planned Phase 3 congenital hyperinsulinism (HI) program to be initiated by end of 2022
- Granted Breakthrough Therapy designation for HI
- Granted Rare Pediatric Disease designation for HI – Priority Review Voucher eligible
- Reported positive Phase 2 data from Children's Hospital of Philadelphia (CHOP) published in *Diabetes Care*

Corporate

- Strengthened leadership team with new biopharma executive hires
    - Chris Kurtz hired as Chief Technical Officer
    - Sarah Mathieson hired as Senior Vice President, Corporate Affairs

First Quarter 2022 Financial Results

Cash, cash equivalents, and total investments as of March 31, 2022 totaled $132.7 million compared to $106.1 million on December 31, 2021. In April 2022, Eiger received $20.8 million in additional net proceeds from the sale of common stock under the Company's at-the-market facility, resulting in pro forma cash, cash equivalents and investments of $153.5 million, which is expected to fund planned operations into Q4 2024.

Net product sales of Zokinvy were $2.7 million for first quarter 2022, as compared to $3.6 million for first quarter 2021. The decrease was primarily driven by initial inventory build at the specialty pharmacy when Zokinvy was launched in the U.S. in January 2021.

Cost of sales was approximately $0.1 million for first quarter 2022, as compared to $53,000 for the same period in 2021. The increase was primarily driven by product manufacturing related costs, including product testing.

Research and Development expenses were $17.5 million for first quarter 2022, as compared to $13.8 million for the same period in 2021. The increase is primarily driven by a $5.0 million milestone to BMS expensed in the quarter related to the *LIMT-2* Phase 3 study of peginterferon lambda for HDV and an increase in personnel related costs, including stock-based compensation, from increased headcount. This increase was partially offset by lower clinical trial related costs, including contract manufacturing expenditures.

Selling, General and Administrative expenses were $6.8 million for first quarter 2022, as compared to $5.5 million for the same period in 2021. The increase was 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 first quarter 2022, as compared to $2.2 million for the same period in 2021.

The Company reported a net loss of $22.6 million, or $0.64 per share for first quarter 2022. This compares to net income of $29.2 million, or $0.85 on a fully diluted per share basis for the same period in 2021 which included a one-time gain of $46.5 million related to the sale of a priority review voucher.

As of March 31, 2022, the company had 40.5 million of common shares outstanding.

Conference Call
At 4:30 PM Eastern Time today, May 5, 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 2392544. 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. Eiger is also developing peginterferon lambda as a therapeutic for COVID-19 and is preparing to submit an emergency use authorization application to FDA based on positive results from the investigator sponsored Phase 3 *TOGETHER* study. 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, 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, 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; the likelihood of timely submitting and obtaining an Emergency Use Authorization from the FDA 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; commencing a Phase 3 study of avexitide in congenital hyperinsulinism; the approval of Zokinvy in jurisdictions outside of the U.S., including the EU; 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 the continued advancement of our development pipeline products; and the potential for 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 Annual Report on Form 10-K for the year ended December 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.

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

	Quarter Ended March 31, 2022	Year Ended December 31, 2021[1]
ASSETS		
Cash and cash equivalents	$ 46,562	$ 22,221
Short-term debt securities	86,155	66,594
Accounts receivable	2,287	2,576
Inventories	1,910	2,612
Prepaid expenses and other current assets	10,442	9,361
Total current assets	147,356	103,364
Long-term debt securities	-	17,262
Property and equipment, net	545	613
Operating lease right-of-use assets	521	653
Other assets	4,907	4,510
Total assets	$ 153,329	$ 126,402
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	$ 36,612	$ 29,901
Other liabilities	19,450	24,102
Stockholders' equity	97,267	72,399
Total liabilities and stockholders' equity	$ 153,329	$ 126,402
	-	-

(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 March 31, (unaudited)	
	2022	**2021**
Product revenue, net	$ 2,673	$ 3,646
Costs and operating expenses:		
Cost of sales	110	53
Research and development[(1)]	17,570	13,842
Selling, general and administrative[(1)]	6,813	5,564
Total operating expenses	24,493	19,459
Loss from operations	(21,820)	(15,813)
Interest expense	(886)	(885)
Interest income	45	51
Other income (expense), net	27	45,914
Income (loss) before provision for taxes	(22,634)	29,267
Provision for income taxes	9	19
Net loss	$ (22,643)	$ 29,248
Net income (loss) per common share:		
Basic	$ (0.64)	$ 0.86
Diluted	$ (0.64)	$ 0.85
Weighted-average common shares outstanding:		
Basic	35,253,147	33,886,896
Diluted	35,253,147	34,220,895

(1) Includes stock-based compensation expense of:

	Three Months Ended March 31,	
	2022	**2021**
Research and development	$ 625	$ 391
General and administrative	1,422	1,158
Total stock-based compensation expense	$ 2,047	$ 1,549

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