Eiger BioPharmaceuticals Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

- Phase 3 HDV *D-LIVR* (lonafarnib/ritonavir) Study: Pre-NDA Meeting Planned by End of Q2
- Phase 3 HDV *LIMT-2* (peginterferon lambda) Study: On Track to Complete Randomization by End of Q2
- Phase 3 HI *AVANT* (avexitide) Program: Startup Activities Initiated
- Cash Position: $98.9 million in Cash, Cash Equivalents, and Short-Term Debt Securities as of December 31, 2022

Palo Alto, Calif., March 16, 2023 /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 fourth quarter and full year 2022 and provided a business update.

“In December, we announced that both our lonafarnib-based treatments met the primary endpoint in our pivotal Phase 3 *D-LIVR* trial in hepatitis delta virus (HDV), and we look forward to the pre-NDA meeting with the FDA, which we expect by end of Q2,” said David Apelian, MD, PhD, Interim CEO, Eiger. “In addition, we have completed screening in our Phase 3 *LIMT-2* study and expect to complete enrollment by the end of Q2. We continue to execute on our unwavering mission to develop innovative therapies for patients with rare diseases, with a focus on maintaining a position of readiness and being thoughtful about how best to employ our resources."

Dr. Apelian continued, “On the corporate front, using both internal and external advisors, we continue our program prioritization analyses to assess the most promising drivers for shareholder value. Given the robust nature of this process, we anticipate providing an update in Q2. In addition, we remain focused on preparing for a planned pre-NDA meeting and guidance from FDA on the *D-LIVR* program in mid-2023.”

Business Highlights

Hepatitis Delta Virus Platform

Lonafarnib-Based Regimens for HDV

- First-in-class, oral prenylation inhibitor
- In December, announced Phase 3 *D-LIVR* study topline Week 48 data met the primary endpoint
  - Lonafarnib/ritonavir response rate of 10.1% (p=0.0044)
  - Lonafarnib/ritonavir in combination with peginterferon alfa response rate of 19.2% (p<0.0001)
  - Key secondary endpoint of proportion of patients with improvement in histological response rate demonstrated with statistical significance in combination arm vs placebo
- Pre-NDA meeting planned by end of Q2
- *D-LIVR* Week 72 data expected to be presented in mid-2023

Peginterferon Lambda for HDV

- Potential first-in-class, well-tolerated interferon
- Potential to be interferon of choice in HDV combination therapies
- Phase 3 *LIMT-2* study of peginterferon lambda monotherapy
    - Anticipate complete randomization by end of Q2 (N=150)

Combination of Peginterferon Lambda and Lonafarnib/Ritonavir for HDV

- Combination of Eiger's two proprietary HDV therapies in development
- Phase 2 *LIFT-2* study in collaboration with National Institutes of Health initiating in 2023
    - 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 approval in EU and U.K.

Avexitide for Rare Metabolic Disorders

- Phase 3 startup activities initiated in *AVANT* congenital hyperinsulinism (HI) program
- Optimizing product-related impurities in the finished drug product to support Phase 3 dosing
- Rare Pediatric Disease designation for HI – Priority Review Voucher eligible

Financial Guidance

- $98.9 million in cash, cash equivalents, and short-term debt securities as of December 31, 2022

Fourth Quarter and Full Year 2022 Financial Results

Net revenue was $2.7 million and $13.5 million in fourth quarter and full year 2022, respectively, as compared to $3.4 million and $12.1 million for the same periods in 2021. The decrease in fourth quarter was primarily driven by a decrease in units shipped during the quarter and the increase in full year 2022 was primarily driven by the upfront payment received from AnGes, Inc. pursuant to the Marketing and Distribution Agreement, which was executed in May 2022.

Cost of sales was $0.3 million and $1.8 million for fourth quarter and full year 2022, respectively, as compared to $0.1 million and $0.7 million for the same periods in 2021. The increase in fourth quarter was primarily driven by a minimum purchase commitment by our contract manufacturer. The increase in full year was primarily driven by a one-time write-off of a non-conforming batch of inventory.

Research and Development expenses were $18.5 million and $75.3 million for fourth quarter and full year 2022, respectively, as compared to $18.2 million and $64.4 million for the same periods in 2021. Net change in the fourth quarter was relatively flat. The increase in full year was primarily driven by an increase in headcount related expenses, including stock-based compensation expense and travel expenses related to participation in scientific conferences, an increase in clinical and manufacturing expenditures related to avexitide Phase 3 readiness, and a milestone related to the Phase 3 LIMT-2 study of peginterferon lambda. This increase was primarily offset by a decrease in contract manufacturing expenditures on lonafarnib.

Selling, General and Administrative expenses were $8.3 million and $29.1 million for fourth quarter and full year 2022, respectively, as compared to $6.0 million and $23.9 million for the same periods in 2021. The increase in fourth quarter and full year primarily relate to outside services, including consulting and advisory services to support the Company's growth.

Total operating expenses include non-cash expenses of $2.4 million and $13.3 million for fourth quarter and full year 2022, respectively, as compared to $2.8 million and $10.7 million for the same periods in 2021.

The Company reported a net loss of $25.1 million, or $0.57 per share basis and $96.8 million, or $2.32 per share basis for fourth quarter and full year 2022, respectively. This compares to a net loss of $21.8 million, or $0.64 per share basis and $33.9 million, or $1.00 per share basis for the same periods in 2021.

Cash, cash equivalents, and short-term debt securities as of December 31, 2022 totaled $98.9 million compared to $106.1 million as of December 31, 2021.

As of December 31, 2022, the Company had 44,074,284 common shares outstanding.

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 short-term debt securities to fund our operations; expectations regarding the timing and availability of topline data from our Phase 3 D-LIVR study in HDV; the timing of interactions with the FDA; 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 products or product candidates, including peginterferon lambda, for studies or 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 September 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.

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

	Year Ended December 31, 2022	Year Ended December 31, 2021[1]
ASSETS		
Cash and cash equivalents	$ 25,798	$ 22,221
Short-term debt securities	73,150	66,594
Accounts receivable	1,749	2,576
Inventories	2,853	2,612
Prepaid expenses and other current assets	13,985	9,361
Total current assets	117,535	103,364
Long-term debt securities	—	17,262
Property and equipment, net	696	613
Operating lease right-of-use assets	561	653
Other assets	1,347	4,510
Total assets	$ 120,139	$ 126,402
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	$ 25,121	$ 29,901
Other liabilities	39,708	24,102
Stockholders' equity	55,310	72,399
Total liabilities and stockholders' equity	$ 120,139	$ 126,402
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(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 December 31, (unaudited)		Year Ended December 31,	
	2022	2021	2022	2021
Product revenue, net	$ 2,696	$ 3,360	$ 12,734	$ 12,142
Other revenue	—	—	750	—
Total revenue	2,696	3,360	13,484	12,142
Costs and operating expenses:				
Cost of sales	345	104	1,837	745
Research and development[(1)]	18,521	18,186	75,282	64,436
Selling, general and administrative[(1)]	8,301	5,984	29,105	23,900
Total operating expenses	27,167	24,274	106,224	89,081
Loss from operations	(24,471)	(20,914)	(92,740)	(76,939)
Interest expense	(1,220)	(900)	(4,132)	(3,559)
Interest income	469	39	1,082	158
Other income (expense), net	81	25	(963)	46,487
Income (loss) before provision for taxes	(25,141)	(21,750)	(96,753)	(33,853)
Provision for income taxes	(3)	18	23	64
Net loss	$ (25,138)	$ (21,768)	$ (96,776)	$ (33,917)
Net income (loss) per common share:				
Basic and diluted	$ (0.57)	$ (0.64)	$ (2.32)	$ (1.00)
Weighted-average common shares outstanding:				
Basic and diluted	44,066,293	34,010,405	41,628,207	33,944,342

(1) Includes stock-based compensation expense of:

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Research and development	$ 858	$ 625	$ 3,159	$ 2,252
General and administrative	982	1,339	5,158	5,649
Total stock-based compensation expense	$ 1,840	$ 1,964	$ 8,317	$ 7,901