Eiger BioPharmaceuticals Reports First Quarter 2023 Financial Results and Provides Business Update

- Phase 3 HDV *D-LIVR* (lonafarnib/ritonavir) Study: Pre-NDA Meeting with FDA in Q2 2023
- Phase 3 HDV *LIMT-2* (peginterferon lambda) Study: Complete Randomization in Q2 2023
- Phase 3 HI *AVANT* (avexitide) Program: Startup Activities Initiated
- Cash Position: $75.3 million in Cash, Cash Equivalents, and Short-Term Debt Securities as of March 31, 2023

Palo Alto, Calif., May 11, 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 first quarter 2023 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 our pre-NDA meeting with the FDA in the second quarter, which will inform our strategy for the lonafarnib HDV program," said David Apelian, MD, PhD, Interim CEO, Eiger.

Dr. Apelian continued, "On the corporate front, we strengthened our management team with the appointments of our new Chief Financial Officer and our new General Counsel, Chief Compliance Officer and Corporate Secretary, both of which come during a pivotal time as we complete our program prioritization analyses this quarter to determine the most promising drivers for shareholder value."

Business Highlights

Hepatitis Delta Virus Platform

Lonafarnib-Based Regimens for HDV

- First-in-class, oral prenylation inhibitor
- Pre-NDA meeting with FDA in Q2 2023
- *D-LIVR* Week 72 data to be presented at EASL in June

Peginterferon Lambda for HDV

- First-in-class, well-characterized interferon
- Phase 3 *LIMT-2* study to complete randomization by end of Q2 2023 (N=150)

Combination of Peginterferon Lambda and Lonafarnib/Ritonavir for HDV

- 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

Avexitide for Rare Metabolic Disorders

- Well-characterized GLP-1 antagonist
- Phase 3 readiness activities initiated in *AVANT* congenital hyperinsulinism (HI) program

Zokinvy® (lonafarnib) for Progeria and Processing-Deficient Progeroid Laminopathies

- Granted marketing authorization approval in EU and U.K.
- Achieved net revenue of $4.1 million in Q1 2023

Corporate

- William G. Kachioff appointed as Chief Financial Officer
- James A. Vollins appointed as General Counsel, Chief Compliance Officer and Corporate Secretary

Financial Guidance

- $75.3 million in cash, cash equivalents, and short-term debt securities as of March 31, 2023

First Quarter 2023 Financial Results

Product revenue, net was $4.1 million for the first quarter of 2023, as compared to $2.7 million for the same period in 2022. The increase in product revenue was primarily due to higher sales in Germany, France ATU, and U.S during the quarter.

Cost of sales was flat for the three months ended March 31, 2023 compared to the same period in 2022.

Research and Development expenses was $16.7 million for the first quarter of 2023, as compared to $17.6 million for the same period in 2022. The decrease was primarily driven by a decrease in milestone expense related to the Phase 3 *LIMT-2* study of peginterferon lambda for HDV under the BMS License Agreement, which occurred in March 2022, and a decrease in outside services across programs including consulting and advisory services. These decreases were partially offset by an increase in clinical and contract manufacturing expenditures, an increase in headcount related expenses, including stock-based compensation, and an increase in operational overhead costs.

Selling, General and Administrative expenses was $9.5 million for the first quarter of 2023, as compared to $6.8 million for the same period in 2022. The increase primarily relates to an increase in outside services, including consulting, advisory and accounting services, an increase in compensation and personnel related expenses, including stock-based compensation, and an increase in other operating expenses, all to support Company operations.

Total operating expenses include non-cash expenses of $2.7 million for the first quarter of 2023, as compared to $2.8 million for the same period in 2022.

The Company reported a net loss of $22.8 million, or $0.52 per share basis for the first quarter of 2023. This compares to a net loss of $22.6 million, or $0.64 per share basis for the same period in 2022.

Cash, cash equivalents, and short-term debt securities as of March 31, 2023 totaled $75.3 million compared to $98.9 million as of December 31, 2022.

As of March 31, 2023, the Company had 44,296,417 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 March 31, 2023 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)

	March 31, 2023	December 31, 2022[1]
	(Unaudited)	
ASSETS		
Cash and cash equivalents	$ 15,181	$ 25,798
Short-term debt securities	60,091	73,150
Accounts receivable	3,891	1,749
Inventories	5,338	2,853
Prepaid expenses and other current assets	12,410	13,985
Total current assets	96,911	117,535
Long-term debt securities	—	—
Property and equipment, net	804	696
Operating lease right-of-use assets	446	561
Other assets	1,067	1,347
Total assets	$ 99,228	$ 120,139
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	23,999	$ 25,121
Other liabilities	39,990	39,708
Stockholders' equity	35,239	55,310
Total liabilities and stockholders' equity	$ 99,228	$ 120,139

(1) Derived from the audited financial statements, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

Eiger BioPharmaceuticals Inc.
Condensed Consolidated Statements of Operations Financial Data
(in thousands, except per share and share amounts)

	Three Months Ended March 31, (unaudited)	
	2023	2022
Product revenue, net	$ 4,118	$ 2,673
Costs and operating expenses:		
Cost of sales	118	110
Research and development[(1)]	16,748	17,570
Selling, general and administrative[(1)]	9,515	6,813
Total operating expenses	26,381	24,493
Loss from operations	(22,263)	(21,820)
Interest expense	(1,285)	(886)
Interest income	711	45
Other income (expense), net	55	27
Income (loss) before provision for taxes	(22,782)	(22,634)
Provision for income taxes	2	9
Net loss	$ (22,784)	$ (22,643)
Net income (loss) per common share:		
Basic and diluted	$ (0.52)	$ (0.64)
Weighted-average common shares outstanding:		
Basic and diluted	44,145,635	35,253,147

(1) Includes stock-based compensation expense of:

	Three Months Ended March 31,	
	2023	2022
Research and development	$ 834	$ 625
General and administrative	1,709	1,422
Total stock-based compensation expense	$ 2,543	$ 2,047