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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

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**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 11, 2023**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**EIGER BIOPHARMACEUTICALS, INC.**

**(Exact name of registrant as specified in its charter)**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **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:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
| o | | | Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425) | | |
|  | | |  | | |
| o | | | Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12) | | |
|  | | |  | | |
| o | | | Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)) | | |
|  | | |  | | |
| o | | | 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:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **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 o

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. o

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**Item 2.02.**    **Results of Operations and Financial Condition.**

On May 11, 2023, Eiger BioPharmaceuticals, Inc. reported its financial results for the quarter ended March 31, 2023. A copy of the press release titled “Eiger BioPharmaceuticals Reports First Quarter 2023 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.**

|  |  |  |  |  |  |
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| **Exhibit**  **No.** | | | **Description** | | |
| 99.1 | | | [Press release, dated May 11, 2023, titled “Eiger BioPharmaceuticals Reports First Quarter 2023 Financial Results and Provides Business Update”](#eigr-2023_mayx11xexx991.htm) | | |
| 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.

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|  | | | **Eiger BioPharmaceuticals, Inc.** | | | | | |
|  | | |  | | |  | | |
| Dated: May 11, 2023 | | |  | | |  | | |
|  | | |  | | |  | | |
|  | | | By: | | | /s/ David Apelian | | |
|  | | |  | | | David Apelian Interim Chief Executive Officer | | |



**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.

Investors:

Sylvia Wheeler

Wheelhouse Life Science Advisors

swheeler@wheelhouselsa.com

Media:

Aljanae Reynolds

Wheelhouse Life Science Advisors

areynolds@wheelhouselsa.com



**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)

|  |  |  |  |  |  |  |  |  |  |  |  |
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|  | | | **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:

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
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|  | | | **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 |  |