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): **May 9, 2023**

Eagle Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36306**	**20-8179278**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

50 Tice Boulevard, Suite 315 **Woodcliff Lake, NJ** (Address of principal executive offices)	**07677** (Zip Code)

Registrant's telephone number, including area code: **(201) 326-5300**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations 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**	**Name of each exchange on which registered**
Common Stock (par value $0.001 per share)	EGRX	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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

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 May 9, 2023, Eagle Pharmaceuticals, Inc., or the Company, issued a press release announcing its financial results for the fiscal first quarter ended March 31, 2023.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The information contained in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section, and shall not be deemed incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release of the Company, dated May 9, 2023
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.

Dated: May 9, 2023

EAGLE PHARMACEUTICALS, INC.

By: /s/ Scott Tarriff
Scott Tarriff
Chief Executive Officer

Exhibit 99.1

For Immediate Release

Eagle Pharmaceuticals Reports First Quarter 2023 Results

- Total revenue for Q1 2023 was $66.3 million, compared to $115.9 million in Q1 2022
- Q1 2023 net income was $0.44 per basic and diluted share and adjusted non-GAAP net income[1] was $1.27 per basic and $1.26 per diluted share
- Q1 2023 adjusted non-GAAP EBITDA of $22.3 million
- Q1 2023 net sales of PEMFEXY® totaled $22.9 million; Eagle estimates that it has an approximate 15% share in commercial (non-340B) pemetrexed market for the second quarter of 2023 to date[2]
- BENDEKA®[3] and BELRAPZO®[4] - both ready-to-dilute ("RTD") products — combined maintained approximately 89% share of the bendamustine U.S. market for the first quarter of 2023 compared to approximately 90% historically[5]
- Company reaffirms full year guidance; adjusted EBITDA[1] of $74.0 - $80.0 million and adjusted non-GAAP earnings per share[1] of $4.20 - $4.53
- The Company is also currently working with lenders to secure financing to support a potential accretive acquisition.

WOODCLIFF LAKE, NJ—May 9, 2023—Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced financial results for the three months ended March 31, 2023.

Business and Recent Highlights:

- Net product sales of PEMFEXY totaled $22.9 million in the first quarter 2023. Based on internal data and customer feedback, the Company estimates that as of the second quarter to date, its U.S. share of commercial (non-340B) pemetrexed usage has grown to 15% up from 6% exiting the fourth quarter of 2022.

[1] Adjusted non-GAAP net income, adjusted non-GAAP earnings per share, adjusted non-GAAP EBITDA, adjusted non-GAAP R&D expense and adjusted non-GAAP SG&A expense are non-GAAP financial measures. For descriptions and reconciliations of these non-GAAP financial measures to their most comparable GAAP financial measures, please see below and the tables at the end of this press release.

[2] Based on IQVIA SMART-US weekly volume data and internal data.

[3] https://www.bendekahcp.com/globalassets/bendeka-hcp/prescribinginformation.pdf

[4] https://belrapzo.com/prescribing-information.pdf

[5] IQVIA SMART-US weekly volume data for the first quarter of 2023 and 2022 historic IQVIA data.

- Centers for Medicare & Medicaid Services ("CMS") established a unique, product-specific billing code for Byfavo® (remimazolam for injection)[6], a short-acting sedative for procedures lasting 30 minutes or less. This new Healthcare Common Procedure Coding System (HCPCS) Level II code ("J-code") is J2249 "Injection, remimazolam, 1 mg." The J-code will be effective on July 1, 2023.

- Reached a settlement agreement with Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's"). Eagle had asserted its Orange Book-listed patents against Dr. Reddy's related to its new drug application referencing BENDEKA. Under the settlement agreement, Dr. Reddy's has the right to market its product beginning November 17, 2027, or earlier based on certain circumstances. The settlement with Dr. Reddy's follows Eagle's previously announced settlements with Hospira, Inc. ("Hospira") and Accord Healthcare, Inc. ("Accord") related to their new drug applications referencing BENDEKA.

    - With the Dr. Reddy's settlement, all the existing challenges, except for one, which is for a proposed powder, not liquid, formulation have been settled. The Company expects bendamustine to be a significant contributor for several more years.

- Reaffirms full-year Company guidance.

- The Company is also currently working with lenders to secure financing to support a potential accretive acquisition.

Financial Highlights

First Quarter 2023

- Total revenue for Q1 2023 was $66.3 million, compared to $115.9 million in Q1 2022.
- Q1 2023 net income was $5.8 million, or $0.44 per basic and diluted share, compared to net income of $44.1 million, or $3.47 per basic and $3.41 per diluted share, in Q1 2022.
- Q1 2023 adjusted non-GAAP net income was $16.5 million, or $1.27 per basic and $1.26 per diluted share, compared to adjusted non-GAAP net income of $52.2 million, or $4.10 per basic and $4.04 per diluted share, in Q1 2022.
- Cash and cash equivalents were $21.9 million, net accounts receivable was $115.0 million, and total debt was $77.5 million, as of March 31, 2023.

"Following on from our outstanding performance in 2022, we believe Eagle remains well positioned for another strong year, and therefore we are reiterating our 2023 guidance. Our products continue to track well, and we are on pace to surpass our 2022 net product sales for the full year 2023 for PEMFEXY, which continues to gain share in commercial (non-340B) pemetrexed usage in the U.S.," stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

"To be clear, the investments we are making for the future account for much of the expected difference of our earnings in 2023 versus 2022. We are investing to support our products and advance our pipeline, notably CAL02, which bridges much of the year-over-year gap. We believe the expansion of our commercial team will enable us to capture synergies with an acquisition target and are currently working with lenders to secure financing to support a potentially accretive transaction," concluded Tarriff.

[6] https://bynder.acaciapharma.com/m/5d7c2cd0d58865f7/original/Barhemsys-Prescribing-Information.pdf

First Quarter 2023 Financial Results

Total revenue for the three months ended March 31, 2023 was $66.3 million, as compared to $115.9 million for the three months ended March 31, 2022.

Q1 2023 RYANODEX® net product sales were $8.8 million, compared to $6.6 million in the first quarter of 2022.

Q1 2023 BELRAPZO net product sales were $6.4 million, compared to $5.9 million in the first quarter of 2022.

Q1 2023 PEMFEXY net product sales were $22.9 million, compared to $37.2 million in the first quarter of 2022.

Q1 2023 vasopressin net product sales were $3.5 million, compared to $34.3 million in the first quarter of 2022. During the first quarter of 2023, the Company gave notice to customers and the FDA that it was withdrawing from the vasopressin market. Inventory on hand is expected to be depleted by the end of the second quarter of 2023.

Q1 2023 royalty revenue was $20.1 million, compared to $25.8 million in the prior year quarter.

A summary of total revenue is outlined below:

	Three Months Ended March 31,	
	2023	2022
	(unaudited)	(unaudited)
Revenue (in thousands):		
Product sales, net	$ 46,221	$ 90,088
Royalty revenue	20,084	25,786
Total revenue	$ 66,305	$ 115,874

Gross margin was 74% during the first quarter of 2023, compared to 76% in the first quarter of 2022. The decrease in gross margin was primarily the result of the inclusion of amortization of intangible assets related to the newly acquired products, which we expect to continue going forward.

R&D expense was $9.3 million for the first quarter of 2023, compared to $6.1 million for the first quarter of 2022. The increase was primarily due to higher spend of $2.0 million on CAL02 and $1.0 million on Byfavo and Barhemsys pediatric studies.

SG&A expenses in the first quarter of 2023 were $28.0 million compared to $22.2 million in the first quarter of 2022. This increase was driven by $3.3 million in salary and other personnel-related costs, $2.0 million in external sales and marketing spend, partially offset by $2.0 million in lower legal-related costs.

Net income for the first quarter of 2023 was $5.8 million, or $0.44 per basic and diluted share, compared to net income of $44.1 million, or $3.47 per basic and $3.41 per diluted share, in the first quarter of 2022, primarily as a result of the factors discussed above.

Adjusted non-GAAP net income for the first quarter of 2023 was $16.5 million, or $1.27 per basic and $1.26 per diluted share, compared to adjusted non-GAAP net income of $52.2 million, or $4.10 per basic and $4.04 per diluted share, in the first quarter of 2022.

Adjusted non-GAAP EBITDA for the first quarter of 2023 was $22.3 million, compared to adjusted non-GAAP EBITDA of $66.9 million in the first quarter of 2022.

2023 Full-Year Guidance

The Company continues to expect:

- Adjusted EBITDA of $74.0-$80.0 million
- Adjusted non-GAAP earnings per share of $4.20-$4.53
- Adjusted non-GAAP R&D expense of $41.0-$45.0 million
- Adjusted non-GAAP SG&A expense of $86.0-$90.0 million

Liquidity

As of March 31, 2023, Eagle had $21.9 million in cash and cash equivalents, $115.0 million in accounts receivable, net, and $77.5 million in outstanding debt on the Company's $150 million credit facility with JPMorgan. As of March 31, 2023, Eagle had a working capital surplus of $94.7 million.

Conference Call

As previously announced, Eagle management will host its first quarter 2023 conference call as follows:

Date	May 9, 2023
Time	8:30 A.M. ET
Toll free (U.S.)	800-274-8461
International	203-518-9814
Webcast (live and replay)	www.eagleus.com, under the "Investor + News" section

A replay of the conference call will be available for two weeks after the call's completion by dialing 888-566-0151 (U.S.) or 402-220-9181 (International) and entering conference call ID EGRXQ123. The webcast will be archived for 30 days at the aforementioned URL.

About Eagle Pharmaceuticals, Inc.

Eagle is a fully integrated pharmaceutical company with research and development, clinical, manufacturing and commercial expertise. Eagle is committed to developing innovative medicines that result in meaningful improvements in patients' lives. Eagle's commercialized products include vasopressin, PEMFEXY®, RYANODEX®, BENDEKA®, BELRAPZO®, TREAKISYM® (Japan), and Byfavo® and Barhemsys® through its wholly owned subsidiary Acacia Pharma Inc. Eagle's oncology and CNS/metabolic critical care pipeline includes product candidates with the potential to address underserved therapeutic areas across multiple disease states. Additional information is available on Eagle's website at www.eagleus.com.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other securities law. Forward-looking statements are statements that are not historical facts. Words and phrases such as "anticipated," "forward," "will," "would," "could," "should," "may," "remain," "potential," "prepare," "expect," "anticipate," "believe," "plan," "future," "believe," "guidance," "project," "estimate," "intend," "advance," "continue" and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements with respect to: the effectiveness date of the J-code and potential benefits thereof; the Company's ability to manage its bendamustine franchise; the potential further investment by the Company in its development programs, products and pipeline the ability of the Company's products and product candidates to address unmet clinical needs; the Company's financial projections and guidance, including anticipated financial performance for 2023, including expected adjusted EBITDA, adjusted non-GAAP earnings per share, adjusted non-GAAP R&D and adjusted non-GAAP SG&A expense; the potential benefits and commercial opportunity of Enalare's product candidates; expected continued earnings growth and anticipated deployment of cash to fund clinical development and potential strategic transactions; the potential for the Company to transition into a diversified pharmaceutical company with a portfolio of branded, first-in-class assets and to utilize legacy products; the Company's ability to pursue additional potential transactions to further diversify its product portfolio and pipeline and broaden its footprint on favorable terms or at all and expectations that the Company's cash and balance sheet will be used for any such transaction and that any such transaction will be accretive; the Company's ability to obtain and maintain regulatory approval of its products and product candidates; the Company's clinical development plan for its product candidates, including the number and timing of development initiatives or new indications for the Company's product candidates; the timing, scope or likelihood and timing of regulatory filings and approvals from the FDA for the Company's or its partner's product candidates; the progress and success of the Company's launch of any products; the addressable market size for, and the ability of the Company to successfully commercialize, its products and product candidates, and expectations with respect to growth of market share; the period of marketing exclusivity for any of the Company's products or product candidates; the resolution of patent litigation and related settlement terms, including the date of market entry and the potential for earlier market entry under certain circumstances and submission of settlement agreements to the U.S. Federal Trade Commission and the U.S. Department of Justice for review; the strength of the Company's intellectual property rights; the expected expansion, defense and enforcement of intellectual property rights; the ability of the Company to obtain and maintain coverage and adequate reimbursement for its products; the success of the Company's collaborations with its strategic partners and the timing and results of these partners' preclinical studies and clinical trials, and the Company's potential earnings potential through such collaborations; the ability of the Company's executive team to execute on the Company's strategy and to utilize its cash and other assets to increase shareholder value; and the ability of the Company's product candidates to deliver value to stockholders; the Company's ability to deliver value in 2023 and over the long term; the Company's ability to sustain and further its growth; the Company's ability to effectively manage and control expenses in line with its budget; the sufficiency of the Company's cash flows and capital resources; and the Company's ability to achieve expected future financial performance and results. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the Company's control, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. Such risks and uncertainties include, but are not limited to: the risk that the anticipated benefits of the Company's acquisition of Acacia are not realized; the ability of Enalare to achieve milestones and deliverables and achieve successful results in the development of ENA-001 and the Company's ability to exercise its option to acquire the remaining outstanding share capital of Enalare; the impacts of the continuing effects of the COVID-19 pandemic and geopolitical events such as the conflict in Ukraine, including disruption or impact in the sales of the Company's marketed products, interruptions or other adverse effects to clinical trials, delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems, disruption in the operations of the Company's third party partners and disruption of the global economy or other events on the Company's business, financial condition and results of operations; macroeconomic conditions, including rising inflation and interest rates, uncertain credit and financial markets and recent and potential disruptions in banking systems; whether the Company will incur unforeseen expenses or liabilities or other market factors; whether the Company will successfully implement its development plan for its product candidates; delay in or failure to obtain regulatory approval of the Company's or its partners' product candidates; whether the Company can successfully market and commercialize its product candidates; the success of the Company's relationships with its partners; the availability and pricing of third party sourced products and materials; the outcome of litigation involving any of its products or that may have an impact on any of our products; successful compliance with the FDA and other governmental regulations applicable to product approvals, manufacturing facilities, products and/or businesses; general economic conditions, including the potential adverse effects of public health issues, including the COVID-19 pandemic and geopolitical events, on economic activity and the performance of the financial markets generally; the strength and enforceability of the Company's intellectual property rights or the rights of third parties; competition from other pharmaceutical and biotechnology companies and the potential for competition from generic entrants into the market; the risks inherent in the early stages of drug development and in conducting clinical trials; and any unanticipated factors in addition to the foregoing that may impact the Company's financial and business projections and guidance and may cause the Company's actual results and outcomes to materially differ from its projections and guidance; and those risks and uncertainties identified in the "Risk Factors" sections of the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission (the "SEC") on March 23, 2023, and its other subsequent filings with the SEC, including the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023. Readers are cautioned not to place undue reliance on these forward-looking statements. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Non-GAAP Financial Performance Measures

In addition to financial information prepared in accordance with U.S. GAAP, this press release also contains adjusted non-GAAP net income, adjusted non-GAAP earnings per share, adjusted non-GAAP R&D expense and adjusted non-GAAP SG&A expense and projected adjusted non-GAAP R&D expense, adjusted EBITDA, adjusted non-GAAP earnings per share and adjusted non-GAAP SG&A expense. The Company believes these measures provide investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information.

Adjusted non-GAAP net income and related earnings per share information excludes amortization expense, stock-based compensation expense, depreciation expense, severance, acquisition related costs, legal settlement, non-cash interest expense, fair value adjustments on equity investment, convertible promissory note related adjustments, fair value adjustments related to derivative instruments, foreign currency exchange gain, inventory step-up, and the tax effect of these adjustments.

Adjusted EBITDA excludes interest expense net of interest income, income tax provision, depreciation and amortization expense, stock-based compensation expense, fair value adjustments on equity investment, convertible promissory note related adjustments, fair value adjustments related to derivative instruments, foreign currency exchange gain, gain on euro debt, legal settlement, acquisition related costs, inventory step-up, debt issuance cost and severance.

Adjusted non-GAAP R&D expense excludes stock-based compensation expense and depreciation expense.

Adjusted non-GAAP SG&A expense excludes stock-based compensation expense, depreciation expense, severance, acquisition related costs and legal settlement.

The Company believes the use of non-GAAP financial measures helps indicate underlying trends in the Company's business and are important in comparing current results with prior period results and understanding projected operating performance. Non-GAAP financial measures provide the Company and its investors with an indication of the Company's baseline performance before items that are considered by the Company not to be reflective of the Company's ongoing results. See the attached reconciliation tables for details of the amounts excluded and included to arrive at certain of the non-GAAP financial measures.

Investors should note that reconciliations of the forward-looking or projected non-GAAP financial measures included in this press release to their most comparable GAAP financial measures cannot be provided because the Company cannot do so without unreasonable efforts due to the unavailability of information needed to calculate the reconciling items and the variability, complexity, and limited visibility of comparable GAAP measures, and the reconciling items that would be excluded from the non-GAAP financial measures in the future. Likewise, the Company is unable to provide projected GAAP financial measures. GAAP projections and reconciliations of the components of projected adjusted EBITDA, adjusted non-GAAP R&D expenses, adjusted non-GAAP SG&A expense, and adjusted non-GAAP earning per share to their most comparable GAAP financial measures are not provided because the quantification of projected GAAP R&D expenses, adjusted non-GAAP SG&A expense, net income and earnings per share and the reconciling items between projected GAAP to adjusted EBITDA, adjusted non-GAAP R&D expenses, adjusted non-GAAP SG&A expense and adjusted non-GAAP earnings per share cannot be reasonably calculated or predicted at this time without unreasonable efforts. For example, with respect to GAAP net income, R&D expenses and SG&A expenses, the Company is not able to calculate the favorable or unfavorable expenses related to the fair value adjustments on equity investments and derivative instruments primarily due to nature of these items. Such unavailable information could be significant such that actual GAAP net income, R&D expenses, SG&A expenses and earnings per share would vary significantly from projected adjusted EBITDA, adjusted non-GAAP R&D expenses, adjusted non-GAAP SG&A expense and adjusted non-GAAP earnings per share.

These non-GAAP financial measures should be considered in addition to, but not as a substitute for, the information prepared in accordance with U.S. GAAP. In addition, from time to time in the future there may be other items that the Company may exclude for purposes of its non-GAAP financial measures; and the Company has ceased, and may in the future cease, to exclude items that it has historically excluded for purposes of its non-GAAP financial measures. For example, beginning in the fourth quarter of 2022, the Company no longer excludes expense of acquired in-process research & development from the Company's adjusted non-GAAP net income or adjusted EBITDA, their line item components, and non-GAAP earnings per share. For purposes of comparability, non-GAAP adjusted financial measures for the three ended March 31, 2022 have been updated to reflect this change. Accordingly, such expenses are not excluded from its non-GAAP financial measures for the three months ended March 31, 2023 and 2022, as detailed in the reconciliation tables that follow, or from 2023 non-GAAP adjusted net income and adjusted non-GAAP earnings per share guidance. Likewise, the Company may determine to modify the nature of its adjustments to arrive at its non-GAAP financial measures. The Company strongly encourages investors to review its consolidated financial statements and publicly-filed reports in their entirety and cautions investors that the non-GAAP financial measures used by the Company may differ from similar measures used by other companies, even when similar terms are used to identify such measures.

Investor Relations for Eagle Pharmaceuticals, Inc.:

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-- Financial tables follow --

EAGLE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)
(In thousands, except share amounts)

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,897	$ 55,321
Accounts receivable, net	114,953	72,439
Inventories	44,140	47,794
Prepaid expenses and other current assets	11,501	13,200
Total current assets	192,491	188,754
Property and equipment, net	1,116	1,168
Intangible assets, net	112,875	118,327
Goodwill	45,033	45,033
Deferred tax asset, net	29,150	27,146
Other assets	33,510	25,732
Total assets	$ 414,175	$ 406,160
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 17,108	$ 18,993
Accrued expenses and other liabilities	73,201	85,844
Short-term debt	7,500	6,250
Total current liabilities	97,809	111,087
Long-term debt	68,829	56,216
Other long-term liabilities	4,692	5,297
Total liabilities	171,330	172,600
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of March 31, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value; 50,000,000 shares authorized; 17,636,973 and 17,569,375 shares issued as of March 31, 2023 and December 31, 2022, respectively	18	18
Additional paid in capital	369,800	366,265
Accumulated other comprehensive loss	(1,112)	(1,112)
Retained earnings	117,254	111,504
Treasury stock, at cost, 4,552,730 and 4,552,730 shares as of March 31, 2023 and December 31, 2022, respectively	(243,115)	(243,115)
Total stockholders' equity	242,845	233,560
Total liabilities and stockholders' equity	$ 414,175	$ 406,160

EAGLE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2023	**2022**
Revenue:		
Product sales, net	$ 46,221	$ 90,088
Royalty revenue	20,084	25,786
Total revenue	66,305	115,874
Operating expenses:		
Cost of product sales	17,300	25,176
Cost of royalty revenue	—	2,579
Research and development	9,272	6,108
Selling, general and administrative	27,960	22,182
Total operating expenses	54,532	56,045
Income from operations	11,773	59,829
Interest income	212	154
Interest expense	(1,516)	(366)
Other expense	(238)	(1,957)
Total other expense, net	(1,542)	(2,169)
Income before income tax provision	10,231	57,660
Income tax provision	(4,481)	(13,602)
Net income	$ 5,750	$ 44,058
Earnings per share:		
Basic	$ 0.44	$ 3.47
Diluted	$ 0.44	$ 3.41
Weighted average number of common shares outstanding:		
Basic	13,059,153	12,710,646
Diluted	13,153,271	12,906,811

EAGLE PHARMACEUTICALS, INC.
RECONCILIATION OF GAAP NET INCOME TO ADJUSTED NON-GAAP NET INCOME AND GAAP EARNINGS PER SHARE TO ADJUSTED NON-GAAP EARNINGS PER SHARE (UNAUDITED)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2023	**2022**
Net income - GAAP	$ 5,750	$ 44,058
Adjustments:		
Cost of product revenues:		
Amortization expense	5,442	731
Research and development:		
Stock-based compensation expense	687	643
Depreciation expense	30	48
Selling, general and administrative:		
Stock-based compensation expense	3,952	3,652
Depreciation expense	80	129
Severance	43	49
Acquisition related costs	—	1,490
Legal settlement	—	300
Other:		
Non-cash interest expense	122	118
Fair value adjustments on equity investment	403	2,530
Convertible promissory note related adjustments	—	(9)
Fair value adjustments related to derivative instruments	(77)	(608)
Foreign currency exchange gain	(90)	—
Inventory step-up	320	—
Tax effect of the non-GAAP adjustments	(126)	(979)
Adjusted non-GAAP net income	$ 16,536	$ 52,152
Earnings per share:		
Basic	$ 0.44	$ 3.47
Diluted	$ 0.44	$ 3.41
Weighted average number of common shares outstanding:		
Basic	13,059,153	12,710,646
Diluted	13,153,271	12,906,811
Adjusted non-GAAP earnings per share:		
Basic	$ 1.27	$ 4.10
Diluted	$ 1.26	$ 4.04
Weighted average number of common shares outstanding:		
Basic	13,059,153	12,710,646
Diluted	13,153,271	12,906,811

EAGLE PHARMACEUTICALS, INC.
RECONCILIATION OF GAAP NET INCOME (LOSS) TO ADJUSTED NON-GAAP EBITDA (UNAUDITED)
(In thousands)

	Three Months Ended March 31,		Twelve Months Ended March 31,	Twelve Months Ended December 31,
	2023	2022	2023	2022
Net income (loss) - GAAP	$ 5,750	$ 44,058	$ (2,666)	$ 35,642
Add back:				
Interest expense, net of interest income	1,304	212	4,866	3,774
Income tax provision	4,481	13,602	16,670	25,791
Depreciation and amortization expense	5,552	908	16,668	12,024
Add back:				
Stock-based compensation expense	4,639	4,295	16,795	16,451
Fair value adjustments on equity investment	403	2,530	2,330	4,457
Convertible promissory note related adjustments	—	36	4,206	4,242
Fair value adjustments related to derivative instruments	(77)	(608)	8,496	7,965
Foreign currency exchange gain	(90)	—	(737)	(647)
Gain on euro debt	—	—	(264)	(264)
Legal Settlement	—	300	—	300
Acquisition related costs	—	1,490	11,632	13,122
Inventory step-up	320	—	866	546
Debt issuance cost	—	—	258	258
Severance	43	49	8,445	8,451
Adjusted Non-GAAP EBITDA	$ 22,325	$ 66,872	$ 87,565	$ 132,112

EAGLE PHARMACEUTICALS, INC.
RECONCILIATION OF GAAP RESEARCH AND DEVELOPMENT AND SELLING, GENERAL AND ADMINISTRATIVE TO ADJUSTED NON-GAAP RESEARCH AND DEVELOPMENT AND SELLING, GENERAL AND ADMINISTRATIVE (UNAUDITED)
(In thousands)

	Three Months Ended March 31,	
	2023	**2022**
Research and development - GAAP	$ 9,272	$ 6,108
Add back:		
Stock-based compensation expense	687	643
Depreciation expense	30	48
Research and development - Non-GAAP	$ 8,555	$ 5,417

	Three Months Ended March 31,	
	2023	**2022**
Selling, general and administrative - GAAP	$ 27,960	$ 22,182
Add back:		
Stock-based compensation expense	3,952	3,652
Depreciation expense	80	129
Severance	43	49
Acquisition related costs	—	1,490
Legal settlement	—	300
Selling, general and administrative - Non-GAAP	$ 23,885	$ 16,562

Important Safety Information for BARHEMSYS® (amisulpride)[7] Injection

Contraindication

BARHEMSYS is contraindicated in patients with known hypersensitivity to amisulpride.

QT Prolongation

BARHEMSYS causes dose- and concentration-dependent prolongation of the QT interval. The recommended dosage is 5 mg or 10 mg as a single intravenous (IV) dose infused over 1 to 2 minutes.

Avoid BARHEMSYS in patients with congenital long QT syndrome and in patients taking droperidol.

Electrocardiogram (ECG) monitoring is recommended in patients with pre-existing arrhythmias/cardiac conduction disorders, electrolyte abnormalities (e.g., hypokalemia or hypomagnesemia), congestive heart failure, and in patients taking other medicinal products (e.g., ondansetron) or with other medical conditions known to prolong the QT interval.

Adverse Reactions

Common adverse reactions reported in ≥ 2% of adult patients who received BARHEMSYS 5 mg (n=748) and at a higher rate than placebo (n=741) in clinical trials for the prevention of PONV were: chills (4% vs. 3%), hypokalemia (4% vs. 2%), procedural hypotension (3% vs. 2%), and abdominal distention (2% vs. 1%).

Serum prolactin concentrations were measured in one prophylaxis study where 5% (9/176) of BARHEMSYS-treated patients had increased blood prolactin reported as an adverse reaction compared with 1% (1/166) of placebo-treated patients.

The most common adverse reaction, reported in ≥ 2% of adult patients who received BARHEMSYS 10 mg (n=418) and at a higher rate than placebo (n=416), in clinical trials for the treatment of PONV was infusion site pain (6% vs. 4%).

[7] https://bynder.acaciapharma.com/m/5d7c2cd0d58865f7/original/Barhemsys-Prescribing-Information.pdf

Use in Specific Populations

Lactation

Amisulpride is present in human milk. There are no reports of adverse effects on the breastfed child and no information on the effects of amisulpride on milk production.

BARHEMSYS may result in an increase in serum prolactin levels, which may lead to a reversible increase in maternal milk production. In a clinical trial, serum prolactin concentrations in females (n=112) increased from a mean of 10 ng/mL at baseline to 32 ng/mL after BARHEMSYS treatment and from 10 ng/mL to 19 ng/mL in males (n=61). No clinical consequences due to elevated prolactin levels were reported.

To minimize exposure to a breastfed infant, lactating women may consider interrupting breastfeeding and pumping and discarding breast milk for 48 hours after receiving a dose of BARHEMSYS.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Renal Impairment

Avoid BARHEMSYS in patients with severe renal impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min/1.73 m2). The pharmacokinetics of amisulpride in patients with severe renal impairment have not been adequately studied in clinical trials. Amisulpride is known to be substantially excreted by the kidneys, and patients with severe renal impairment may have increased systemic exposure and an increased risk of adverse reactions.

No dosage adjustment is necessary in patients with mild to moderate renal impairment

(eGFR ≥ 30 mL/min/1.73 m2).

Drug Interactions

- BARHEMSYS causes dose- and concentration-dependent QT prolongation. To avoid potential additive effects, avoid use of BARHEMSYS in patients taking droperidol.
- ECG monitoring is recommended in patients taking other drugs known to prolong the QT interval (e.g., ondansetron).
- Reciprocal antagonism of effects occurs between dopamine agonists (e.g., levodopa) and BARHEMSYS. Avoid using levodopa with BARHEMSYS.

Important Safety Information for BYFAVO™ (remimazolam)[8] Injection

Indications

BYFAVO is a benzodiazepine indicated for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less.

Important Safety Information

WARNING: PERSONNEL AND EQUIPMENT FOR MONITORING AND RESUSCITATION AND RISKS FROM CONCOMITANT USE WITH OPIOID ANALGESICS

Personnel and Equipment for Monitoring and Resuscitation

- **Only personnel trained in the administration of procedural sedation, and not involved in the conduct of the diagnostic or therapeutic procedure, should administer BYFAVO.**
- **Administering personnel must be trained in the detection and management of airway obstruction, hypoventilation, and apnea, including the maintenance of a patent airway, supportive ventilation, and cardiovascular resuscitation.**
- **BYFAVO has been associated with hypoxia, bradycardia, and hypotension. Continuously monitor vital signs during sedation and during the recovery period.**
- **Resuscitative drugs, and age- and size-appropriate equipment for bag-valve-mask–assisted ventilation must be immediately available during administration of BYFAVO.**

Risks From Concomitant Use With Opioid Analgesics and Other Sedative-Hypnotics

Concomitant use of benzodiazepines, including BYFAVO, and opioid analgesics may result in profound sedation, respiratory depression, coma, and death. The sedative effect of intravenous BYFAVO can be accentuated by concomitantly administered CNS depressant medications, including other benzodiazepines and propofol. Continuously monitor patients for respiratory depression and depth of sedation.

[8] https://bynder.acaciapharma.com/m/403e8c343b2922de/original/Byfavo-PI.pdf

Contraindication

BYFAVO is contraindicated in patients with a history of severe hypersensitivity reaction to dextran 40 or products containing dextran 40.

Personnel and Equipment for Monitoring and Resuscitation

Clinically notable hypoxia, bradycardia, and hypotension were observed in Phase 3 studies of BYFAVO. Continuously monitor vital signs during sedation and through the recovery period. Only personnel trained in the administration of procedural sedation, and not involved in the conduct of the diagnostic or therapeutic procedure, should administer BYFAVO. Administering personnel must be trained in the detection and management of airway obstruction, hypoventilation, and apnea, including the maintenance of a patent airway, supportive ventilation, and cardiovascular resuscitation. Resuscitative drugs, and age- and size-appropriate equipment for bag-valve-mask–assisted ventilation must be immediately available during administration of BYFAVO. Consider the potential for worsened cardiorespiratory depression prior to using BYFAVO concomitantly with other drugs that have the same potential (e.g., opioid analgesics or other sedative-hypnotics). Administer supplemental oxygen to sedated patients through the recovery period. A benzodiazepine reversal agent (flumazenil) should be immediately available during administration of BYFAVO.

Risks From Concomitant Use With Opioid Analgesics and Other Sedative-Hypnotics

Concomitant use of BYFAVO and opioid analgesics may result in profound sedation, respiratory depression, coma, and death. The sedative effect of IV BYFAVO can be accentuated when administered with other CNS depressant medications (eg, other benzodiazepines and propofol). Titrate the dose of BYFAVO when administered with opioid analgesics and sedative-hypnotics to the desired clinical response. Continuously monitor sedated patients for hypotension, airway obstruction, hypoventilation, apnea, and oxygen desaturation. These cardiorespiratory effects may be more likely to occur in patients with obstructive sleep apnea, the elderly, and ASA-PS class III or IV patients.

Hypersensitivity Reactions

BYFAVO contains dextran 40, which can cause hypersensitivity reactions, including rash, urticaria, pruritus, and anaphylaxis. BYFAVO is contraindicated in patients with a history of severe hypersensitivity reaction to dextran 40 or products containing dextran 40.

Neonatal Sedation

Use of benzodiazepines during the later stages of pregnancy can result in sedation (respiratory depression, lethargy, hypotonia) in the neonate. Observe newborns for signs of sedation and manage accordingly.

Pediatric Neurotoxicity

Published animal studies demonstrate that anesthetic and sedation drugs that block NMDA receptors and/or potentiate GABA activity increase neuronal apoptosis in the developing brain and result in long-term cognitive deficits when used for longer than 3 hours. The clinical significance of this is not clear. However, the window of vulnerability to these changes is believed to correlate with exposures in the third trimester of gestation through the first several months of life but may extend out to approximately 3 years of age in humans.

Anesthetic and sedation drugs are a necessary part of the care of children needing surgery, other procedures, or tests that cannot be delayed, and no specific medications have been shown to be safer than any other. Decisions regarding the timing of any elective procedures requiring anesthesia should take into consideration the benefits of the procedure weighed against the potential risks.

Adverse Reactions

The most common adverse reactions reported in >10% of patients (N=630) receiving BYFAVO 5-30 mg (total dose) and undergoing colonoscopy (two studies) or bronchoscopy (one study) were: hypotension, hypertension, diastolic hypertension, systolic hypertension, hypoxia, and diastolic hypotension.

Use in Specific Populations

Pregnancy

There are no data on the specific effects of BYFAVO on pregnancy. Benzodiazepines cross the placenta and may produce respiratory depression and sedation in neonates. Monitor neonates exposed to benzodiazepines during pregnancy and labor for signs of sedation and respiratory depression.

Lactation

Monitor infants exposed to BYFAVO through breast milk for sedation, respiratory depression, and feeding problems. A lactating woman may consider interrupting breastfeeding and pumping and discarding breast milk during treatment and for 5 hours after BYFAVO administration.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established. BYFAVO should not be used in patients less than 18 years of age.

Geriatric Use

No overall differences in safety or effectiveness were observed between these subjects and younger subjects. However, there is a potential for greater sensitivity (eg, faster onset, oversedation, confusion) in some older individuals. Administer supplemental doses of BYFAVO slowly to achieve the level of sedation required and monitor all patients closely for cardiorespiratory complications.

Hepatic Impairment

In patients with severe hepatic impairment, the dose of BYFAVO should be carefully titrated to effect. Depending on the overall status of the patient, lower frequency of supplemental doses may be needed to achieve the level of sedation required for the procedure. All patients should be monitored for sedation-related cardiorespiratory complications.

Abuse and Dependence

BYFAVO is a federally controlled substance (CIV) because it contains remimazolam which has the potential for abuse and physical dependence.