Eagle Pharmaceuticals Reports Fourth Quarter and Full Year 2022 Results

March 13, 2023

• Q4 2022 net income was $0.63 per basic and $0.62 per diluted share and adjusted non-GAAP net income was $1.11 per basic and $1.10 per diluted share[1]

• Total revenue for Q4 2022 was $60.7 million, compared to $42.3 million in Q4 2021

• FY 2022 net income was $2.76 per basic and $2.73 per diluted share and adjusted non-GAAP net income was $7.87 per basic and $7.79 per diluted share[1]

• FY 2022 revenue was $316.6 million compared to $171.5 million in FY 2021

• FY 2022 net sales of PEMFEXY® totaled $67.5 million, and were $12.1 million in Q4 2022, representing a 6% U.S. market share in community oncology at the end of Q4 2022; already captured a 10% share through February 2023; anticipate exiting Q1 2023 with 12% share[2]

• BENDEKA®[3] and BELRAPZO®[4] - both ready-to-dilute ("RTD") products — combined maintained approximately 88% share of the bendamustine U.S. market for the most recent four-week period according to IQVIA compared to approximately 90% historically[5]

• Q4 2022 gross profit from the U.S. bendamustine franchise increased $2.7 million or 11% compared to Q4 2021[6]

• As of December 31, 2022, Eagle had $55.3 million in cash and cash equivalents, which is almost entirely held at JPMorgan Chase Bank, N.A. ("JPMorgan"); as of today, the Company holds less than $1.0 million in cash and cash equivalents at Silicon Valley Bank with no individual account in excess of the Federal Deposit Insurance Corporation ("FDIC") set coverage limit

• Received U.S. Food and Drug Administration ("FDA") approval for additional indication for PEMFEXY in combination with pembrolizumab and platinum chemotherapy and bought down future royalties on PEMFEXY profits for $15 million, eliminating royalty on first $85 million of profit and reduce royalty thereafter

• Reached settlement agreement with Accord Healthcare, Inc. related to BENDEKA (bendamustine hydrochloride)

• Announced FDA acceptance of Investigational New Drug Application ("IND") for CAL02, a novel first-in-class broad-spectrum anti-virulence agent for the adjunct treatment of severe community-acquired bacterial pneumonia

WOODCLIFF LAKE, N.J., March 13, 2023 (GLOBE NEWSWIRE) -- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced financial results for the three and 12 months ended December 31, 2022.

Business and Recent Highlights:

- Received approval from the U.S. Food and Drug Administration ("FDA") for an additional indication for PEMFEXY ® (pemetrexed injection) in combination with pembrolizumab and platinum chemotherapy for the initial treatment of patients with metastatic, non-squamous, non-small cell lung cancer ("NSCLC") with no EGFR or ALK genomic tumor aberrations. Eagle's approved PEMFEXY (pemetrexed injection) is a ready-to-dilute ("RTD") novel liquid intravenous formulation developed to eliminate the reconstitution step of the Listed Drug ("LD"), ALIMTA ®.
    - Bought down future royalties on PEMFEXY profits through a one-time payment of $15 million to eliminate the royalty on the first $85 million of profit beginning October 1, 2022, and to reduce the royalty thereafter.

- During the fourth quarter of 2022, the Company reached the contractual limit for royalties paid to development partner on worldwide bendamustine profits.

- Reached a settlement agreement with Accord Healthcare, Inc. ("Accord"). Eagle had asserted its Orange Book-listed patents against Accord related to Accord's new drug application ("NDA") referencing BENDEKA ®. The settlement agreement provides that Accord has the right to market its product beginning January 17, 2028, or earlier based on certain circumstances. The settlement agreement is confidential and subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice.

- FDA accepted the Company's investigational new drug ("IND") application for CAL02, a novel first-in-class broad-spectrum anti-virulence agent for the adjunct treatment of severe community-acquired bacterial pneumonia ("SCABP"). The Phase 2 study is expected to begin enrollment of approximately 276 patients with severe community-acquired pneumonia at approximately 120 sites worldwide in early 2023.

- With Enalare Therapeutics Inc. ("Enalare"), announced that the FDA granted Orphan Drug Designation ("ODD") for the treatment of Apnea of Prematurity ("AoP") to ENA-001, a new chemical entity with a novel mechanism of action as a

respiratory stimulant. Enalare's lead compound, ENA-001 is an investigational, one-of-a-kind NCE being developed as an agnostic respiratory stimulant for multiple patient populations experiencing acute respiratory depression. In August 2022, Eagle acquired a 17% equity stake in Enalare, with an option to purchase the remaining shares of Enalare upon achievement of specified milestones, presenting the potential to add to Eagle's portfolio novel NCEs with strong intellectual property protection, from the mid-2030s into the 2040s, including composition of matter patents.

- Hosted Investor Day including in-depth discussions of pipeline products, newly acquired acute care products, and perspectives from Key Opinion Leaders in each clinical area.

Financial Highlights

Fourth Quarter 2022

- Total revenue for Q4 2022 was $60.7 million, compared to $42.3 million in Q4 2021.
- Q4 2022 net income was $8.2 million, or $0.63 per basic and $0.62 per diluted share, compared to net loss of $(6.2) million, or $(0.48) per basic and diluted share, in Q4 2021.
- Q4 2022 adjusted non-GAAP net income was $14.4 million, or $1.11 per basic and $1.10 per diluted share, compared to adjusted non-GAAP net income of $11.0 million, or $0.85 per basic and $0.83 per diluted share, in Q4 2021. [1]
- Cash and cash equivalents were $55.3 million, net accounts receivable was $72.4 million, and total debt was $63.8 million, as of December 31, 2022.

Full Year 2022

- Total revenue for the 12 months ended December 31, 2022 was $316.6 million, compared to $171.5 million, in 2021, an increase of 84.6%.
- Net income for the 12 months ended December 31, 2022 was $35.6 million, or $2.76 per basic and $2.73 per diluted share, compared to net loss of $(8.6) million, or $(0.66) per basic and diluted share, in 2021.
- Adjusted non-GAAP net income for the 12 months ended December 31, 2022 was $101.8 million, or $7.87 per basic and $7.79 per diluted share, compared to $22.3 million, or $1.71 per basic and $1.68 per diluted share, in 2021.[1]
- From August 2016 through December 31, 2022, Eagle has repurchased $246.1 million of its common stock through its Share Repurchase Program.

"2022 was an outstanding year for Eagle, as we tripled our adjusted non-GAAP net income per diluted share over 2021. This is a significant achievement for a company of our size, and I am pleased that we accomplished this almost entirely through organic growth. During the final three months of 2022, we recorded $12 million of Pemfexy net sales and exited the quarter with a 6% U.S. market share in community oncology. We anticipate doubling this share to approximately 12% leaving the first quarter of 2023, and have already captured a 10% share through February[2]," stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

"Looking ahead, we anticipate growth in Barhemsys and Byfavo over time now that our sales force is scaled to plan and trained. We intend to continue to manage our U.S. bendamustine franchise, support Enalare's development of ENA-001, and advance our pipeline programs for CAL02 and landiolol. We believe our strong cash position and balance sheet provide us with the flexibility not only to support our clinical development work but also to seek a meaningful acquisition that could potentially go a long way in solidifying Eagle's position as a diversified pharmaceutical company," concluded Tarriff.

Fourth Quarter 2022 Financial Results

Total revenue for the three months ended December 31, 2022 was $60.7 million, as compared to $42.3 million for the three months ended December 31, 2021.

Q4 2022 RYANODEX® net product sales were $7.2 million, compared to $6.1 million in the fourth quarter of 2021.

Q4 2022 BELRAPZO net product sales were $11.0 million, compared to $5.5 million in the fourth quarter of 2021.

Q4 2022 PEMFEXY® net product sales were $12.1 million and vasopressin net product sales were $3.6 million.

A summary of total revenue is outlined below:

	Three Months Ended December 31,	
	2022	2021
	(unaudited)	(unaudited)
Revenue (in thousands):		
Product sales, net	$ 37,161	$ 16,158
Royalty revenue	23,538	26,162

Total revenue	$ 60,699	$ 42,320

Q4 2022 royalty revenue was $23.5 million, compared to $26.2 million in the prior year quarter. Full-year 2022 royalty revenue totaled $98.3 million compared to $106.5 million in 2021.

During the first quarter of 2023, Eagle provided notice to customers and the FDA that the Company is withdrawing from the vasopressin market; inventory is expected to be depleted by the end of the second quarter of 2023.

Gross margin was 67% during the fourth quarter of 2022, compared to 71% in the fourth quarter of 2021. The decrease in gross margin was driven by a change in the revenue mix, including the launch of PEMFEXY and vasopressin and amortization expense related to PEMFEXY, BARHEMSYS and BYFAVO.

R&D expense was $7.2 million for the fourth quarter of 2022, compared to $3.8 million for the fourth quarter of 2021. The increase was primarily due to higher spend of $3.9 million on CAL02.

SG&A expenses in the fourth quarter of 2022 totaled $24.2 million, compared to $20.3 million in the fourth quarter of 2021. This increase was primarily related to increased sales and marketing expense including headcount costs of $1.7 million and marketing costs of 2.1 million associated with BARHEMSYS, BYFAVO and PEMFEXY.

Net income for the fourth quarter of 2022 was $8.2 million, or $0.63 per basic and $0.62 per diluted share, compared to net loss of $(6.2) million, or $(0.48) per basic and diluted share, in the fourth quarter of 2021, primarily as a result of the factors discussed above.

Adjusted non-GAAP net income for the fourth quarter of 2022 was $14.4 million, or $1.11 per basic and $1.10 per diluted share, compared to adjusted non-GAAP net income[1] of $11.0 million, or $0.85 per basic and $0.83 per diluted share, in the fourth quarter of 2021.

Full Year 2022 Financial Results

Total revenue for the year ended December 31, 2022 was $316.6 million, as compared to $171.5 million for the year ended December 31, 2021. A summary of total revenue is outlined below:

	Twelve Months Ended December 31,	
	2022	2021
Revenue (in thousands):		
Product sales, net	$ 214,536	$ 65,023
Royalty revenue	98,266	106,523
License and other revenue	3,808	—
Total revenue	$ 316,610	$ 171,546

Net revenues increased by $145.1 million to $316.6 million in the year ended December 31, 2022 compared to $171.5 million in 2021, primarily driven by the launches of PEMFEXY and vasopressin, increases in product sales of BELRAPZO of $9.9 million and Ryanodex of $4.9 million, the acquisition of BARHEMSYS and BYFAVO, and increases in TREAKISYM royalties of $4.1 million, partially offset by a decrease in royalties of BENDEKA of $12.3 million. During 2022, we recorded $3.8 million of other revenue for a cumulative sales milestone on sales of TREAKISYM in Japan by our marketing partner, SymBio.

Gross margin was 70% for the full year 2022, as compared to 75% for 2021. The decrease in gross margin was driven by a change in the revenue mix, including the launch of PEMFEXY and vasopressin and amortization expense related to PEMFEXY, BARHEMSYS and BYFAVO.

R&D expense decreased to $34.1 million in 2022, compared to $51.3 million in 2021, primarily reflecting the non-recurrence of a $10.0 million upfront payment related to our license agreement with Combioxin SA for CAL02, a $5.0 million upfront payment related to our licensing agreement with AOP Orphan for landiolol, lower headcount cost of $1.3 million, lower spend of vasopressin of $7.6 million, RYANODEX and EA111 of $3.1 million and PEMFEXY of $2.2 million. This was partially offset by $11.0 million of CMC and clinical expenses on our CAL02 program.

Excluding stock-based compensation and other non-cash items, adjusted non-GAAP R&D expense[1] for 2022 was $31.5 million.

SG&A expenses increased by $31.3 million to $106.6 million in 2022, compared to $75.3 million in 2021. The increase primarily reflects $16.6 million of higher professional fees which primarily resulted from our Acacia Pharma Group plc (“Acacia”) and Enalare transactions, $6.9 million of severance related to the acquisition of Acacia, and increased sales and marketing expense which includes increased headcount costs of $3.8 million and increased marketing costs of 5.9 million associated with BARHEMSYS, BYFAVO and PEMFEXY. This was partially offset by $2.9 million of lower stock-based compensation expense.

Net income for the year ended December 31, 2022 was $35.6 million, or $2.76 per basic and $2.73 per diluted share, as compared to net loss of $(8.6) million or $(0.66) per basic and diluted share for the year ended December 31, 2021, as a result of the factors discussed above.

Adjusted non-GAAP net income for the year ended December 31, 2022 was $101.8 million, or $7.87 per basic and $7.79 per diluted share, compared to adjusted non-GAAP net income[1] of $22.3 million, or $1.71 per basic and $1.68 per diluted share, for 2021.[1]

2023 Guidance

- Adjusted EBITDA of $74.0-$80.0 million[1]
- Adjusted non-GAAP earnings per share of $4.20-$4.53[1]

- Adjusted non-GAAP R&D expense of $41.0-$45.0 million[1]
- Adjusted non-GAAP SG&A expense of $86.0-$90.0 million[1]

Liquidity

As of December 31, 2022, Eagle had $55.3 million in cash and cash equivalents, $72.4 million in accounts receivable, net, and $63.8 million in outstanding debt on the Company's $150 million credit facility with JPMorgan. Therefore, as of December 31, 2022, Eagle had cash and cash equivalents plus accounts receivables, net of $127.7 million.

In 2022, Eagle repurchased $18.0 million of its common stock as part of its Share Repurchase Program. From August 2016 through December 31, 2022, Eagle has repurchased $246.1 million of its common stock.

Conference Call

As previously announced, Eagle management will host its fourth quarter 2022 conference call as follows:

Date	March 13, 2023
Time	8:30 A.M. ET
Toll free (U.S.)	800-445-7795
International	785-424-1789
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 800-839-4199 (U.S.) or 402-220-2989 (International) and entering conference call ID EGRXQ422. 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," "expected," "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 potential benefits of FDA approval of an additional indication for PEMFEXY® in combination with pembrolizumab and platinum chemotherapy; the potential benefits of reduced royalty payments on PEMFEXY; the development of, potential benefits of and potential FDA submission for ENA-001; the achievement of milestones and deliverables; the Company's ability to manage its bendamustine franchise; the potential further investment by the Company in Enalare and the Company's development programs, products and pipeline and the potential exercise of the Company's option to acquire all of Enalare's outstanding shares; the potential use of ENA-001 to help preterm infants with respiratory conditions; the ability of ENA-001 and other products and product candidates to address unmet clinical needs, including for patients with post-operative respiratory depression and in combatting community drug overdose; the Company's financial projections and guidance, including anticipated financial performance for 2023, including expected adjusted EBITDA, adjusted non-GAAP earnings per share and 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 transaction; 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 potential of CAL02 to be a first-in-class broad-spectrum anti-virulence agent for the treatment of severe community-acquired bacterial pneumonia; the Company's ability to pursue additional potential transactions to further diversify its product portfolio and pipeline on favorable terms or at all; 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 design, timing and ability to enroll patients in clinical trials, including for CAL02; 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, including landiolol, CAL02 and Enalare's ENA-001; the progress and success of the Company's launch of any products, including vasopressin and PEMFEXY; the addressable market size for, and the ability of the Company to successfully commercialize, its product candidates, including vasopressin and PEMFEXY, and expectations with respect to growth of market share; the ability of BARHEMSYS, BYFAVO, landiolol and other products and product candidates to address unmet clinical needs; the potential market opportunity for the Company's products or product candidates, including for BARHEMSYS, BYFAVO and landiolol; the period of marketing exclusivity for any of the Company's products or product candidates; the resolution of patent litigation and all related settlement terms, including the date of market entry and the potential for earlier market entry under certain circumstances; the timing, scope or likelihood and timing of regulatory filings and approvals from the FDA for the Company's product candidates and the Company's ability to maintain regulatory approval of its products and product candidates; the Company's clinical development plan for the product candidates in its portfolio; the implementation of certain healthcare reform measures; 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; and the Company's plans and ability to advance the products in its pipeline; potential opportunities for, and the Company's ability to complete, business development transactions, in a timely manner, on favorable terms to the Company, or at all; 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 under the BARDA agreement 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 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, and the overall impact of the COVID-19 pandemic or other events on the Company's business, financial condition and results of operations; macroeconomic conditions, including rising inflation and uncertain credit and financial markets; 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, filed with the Securities and Exchange Commission (the "SEC") on November 9, 2022, and its other subsequent filings with the SEC, including the Company's Annual Report on Form 10-K for the year ended December 31, 2022. 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 and adjusted non-GAAP earnings per share. 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.

Beginning in the fourth quarter of 2022, Eagle no longer excludes expense for In-Process Research & Development from its non-GAAP results. Historically, the company excluded these charges. These changes have been made to align with views expressed by the U.S. Securities and Exchange Commission. Prior periods have been recast to reflect these changes.

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, debt issuance costs, 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 loss, gain on euro debt, 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 credit losses, fair value adjustments related to derivative instruments, foreign currency exchange loss, gain on euro debt, legal settlement, acquisition related costs, inventory step-up and debt issuance cost and severance.

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

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

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, 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, net income and earnings per share and the reconciling items between projected GAAP to adjusted EBITDA, adjusted non-GAAP R&D expenses, 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 and R&D Expense, 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 transactions. Such unavailable information could be significant such that actual GAAP net income, R&D expenses, and earnings per share would vary significantly from projected GAAP and adjusted EBITDA, adjusted non-GAAP R&D expenses, 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, commencing in 2023, 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 and twelve months ended December 31, 2021 have been updated to reflect this change. Accordingly, such expenses are not excluded from its non-GAAP financial measures for the three and twelve months ended December 31, 2022 and 2021, 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.:

Lisa M. Wilson
In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

-- Financial tables follow --

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

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 55,321	$ 97,659
Accounts receivable, net	72,439	41,149
Inventories	47,794	21,908
Prepaid expenses and other current assets	13,200	11,890
Total current assets	188,754	172,606
Property and equipment, net	1,168	1,636
Intangible assets, net	118,327	10,671
Goodwill	45,033	39,743
Deferred tax asset, net	27,146	18,798
Other assets	25,732	10,278
Total assets	$ 406,160	$ 253,732
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 18,993	$ 16,431
Accrued expenses and other liabilities	85,844	32,338
Short-term debt	6,250	25,607
Total current liabilities	111,087	74,376
Other long-term liabilities	5,297	2,903
Long-term debt	56,216	—
Total liabilities	172,600	77,279
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as December 31, 2022 and 2021	—	—
Common stock, $0.001 par value; 50,000,000 shares authorized; 17,569,375 and 16,903,034 shares issued as of December 31, 2022 and 2021, respectively	18	17
Additional paid in capital	366,265	325,779
Accumulated other comprehensive loss	(1,112)	(94)
Retained earnings	111,504	75,862
Treasury stock, at cost, 4,552,730 and 4,111,622 shares as of December 31, 2022 and 2021, respectively	(243,115)	(225,111)
Total stockholders' equity	233,560	176,453

Total liabilities and stockholders' equity	$ 406,160	$ 253,732

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
	(unaudited)	(unaudited)		
Revenue:				
Product sales, net	$ 37,161	$ 16,158	$ 214,536	$ 65,023
Royalty revenue	23,538	26,162	98,266	106,523
License and other revenue	—	—	3,808	—
Total revenue	60,699	42,320	316,610	171,546
Operating expenses:				
Cost of product sales	18,242	9,693	85,458	31,528
Cost of royalty revenue	1,624	2,616	9,478	10,652
Research and development	7,217	3,787	34,088	51,275
Selling, general and administrative	24,150	20,325	106,626	75,322
Total operating expenses	51,233	36,421	235,650	168,777
Income from operations	9,466	5,899	80,960	2,769
Interest income	317	165	271	560
Interest expense	(1,980)	(395)	(4,045)	(1,635)
Other income (expense)	5,501	(4,445)	(15,753)	(6,242)
Total other income (expense), net	3,838	(4,675)	(19,527)	(7,317)
Income (loss) before income tax provision	13,304	1,224	61,433	(4,548)
Income tax provision	(5,139)	(7,420)	(25,791)	(4,079)
Net income (loss)	$ 8,165	$ (6,196)	$ 35,642	$ (8,627)
Earnings (loss) per common share:				
Basic	$ 0.63	$ (0.48)	$ 2.76	$ (0.66)
Diluted	$ 0.62	$ (0.48)	$ 2.73	$ (0.66)
Weighted average number of common shares outstanding:				
Basic	13,015,976	12,896,471	12,933,896	13,051,095
Diluted	13,124,218	12,896,471	13,065,494	13,051,095

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Net income (loss) - GAAP	$ 8,165	$ (6,196)	$ 35,642	$ (8,627)
Adjustments:				
Cost of product revenues:				
Amortization expense	5,492	675	11,378	1,578
Research and development:				
Stock-based compensation expense	606	505	2,450	2,682
Depreciation expense	33	56	167	220

Severance	—	260	—	534
Selling, general and administrative:				
Stock-based compensation expense	3,513	4,177	14,001	16,873
Depreciation expense	105	133	479	544
Severance	73	1,216	8,451	1,550
Aquisition related costs	285	—	13,122	—
Amortization expense	—	203	—	1,418
Legal settlement	—	—	300	—
Debt issuance costs	258	—	258	—
Other:				
Non-cash interest expense	926	118	2,078	472
Fair value adjustments on equity investment	1,249	4,270	4,457	6,170
Convertible promissory note related adjustments	—	562	4,646	610
Fair value adjustments related to derivative instruments	710	(432)	7,965	(686)
Foreign currency exchange loss	(7,196)	—	(647)	—
Gain on euro debt	(264)	—	(264)	—
Inventory step-up	154	—	546	—
Tax effect of the non-GAAP adjustments	322	5,403	(3,237)	(1,054)
Adjusted non-GAAP net income	$ 14,431	$ 10,950	$ 101,792	$ 22,284
Earnings (loss) per share:				
Basic	$ 0.63	$ (0.48)	$ 2.76	$ (0.66)
Diluted	$ 0.62	$ (0.48)	$ 2.73	$ (0.66)
Weighted average number of common shares outstanding:				
Basic	13,015,976	12,896,471	12,933,896	13,051,095
Diluted	13,124,218	12,896,471	13,065,494	13,051,095
Adjusted non-GAAP earnings per share:				
Basic	$ 1.11	$ 0.85	$ 7.87	$ 1.71
Diluted	$ 1.10	$ 0.83	$ 7.79	$ 1.68
Weighted average number of common shares outstanding:				
Basic	13,015,976	12,896,471	12,933,896	13,051,095
Diluted	13,124,218	13,203,666	13,065,494	13,265,181

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	**2021**	**2022**	**2021**
Net income (loss) - GAAP	$ 8,165	$ (6,196)	$ 35,642	$ (8,627)
Add back:				
Interest expense, net of interest income	1,663	230	3,774	1,075
Income tax provision	5,139	7,420	25,791	4,079
Depreciation and amortization expense	5,630	1,067	12,024	3,760
Add back:				
Stock-based compensation expense	4,119	4,682	16,451	19,555
Fair value adjustments on equity investment	1,249	4,270	4,457	6,170
Convertible promissory note related adjustments	—	608	4,242	758
Fair value adjustments related to derivative instruments	710	(432)	7,965	(686)
Foreign currency exchange loss	(7,196)	—	(647)	—
Gain on euro debt	(264)	—	(264)	—

Legal Settlement	—	—	300	—
Aquisition related costs	285	—	13,122	—
Inventory step-up	154	—	546	—
Debt issuance cost	258	—	258	—
Severance	73	1,476	8,451	2,084
Adjusted Non-GAAP EBITDA	$ 19,985	$ 13,125	$ 132,112	$ 28,168

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	**2021**	**2022**	**2021**
Research and development - GAAP	$ 7,217	$ 3,787	$ 34,088	$ 51,275
Add back:				
Stock-based compensation expense	606	505	2,450	2,682
Depreciation expense	33	56	167	220
Severance	—	260	—	534
Research and development - Non-GAAP	$ 6,578	$ 2,966	$ 31,471	$ 47,839

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	**2021**	**2022**	**2021**
Selling, general and administrative - GAAP	$ 24,150	$ 20,325	$ 106,626	$ 75,322
Add back:				
Stock-based compensation expense	3,513	4,177	14,001	16,873
Depreciation expense	105	133	479	544
Severance	73	1,216	8,451	1,550
Aquisition related costs	285	—	13,122	—
Amortization expense	—	203	—	1,418
Legal settlement	—	—	300	—
Debt issuance costs	258	—	258	—
Selling, general and administrative - Non-GAAP	$ 19,916	$ 14,596	$ 70,015	$ 54,937

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%).

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) 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.

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.

[1] Adjusted non-GAAP net income, adjusted non-GAAP earnings per share, 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 2/2/23 - 2/24/23 and 2022 historic IQVIA data.

[6] Gross profit includes all U.S. revenues generated by bendamustine products and all associated costs of sales including royalty expense on a GAAP basis.

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

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