Correcting & Replacing: Eagle Pharmaceuticals Reports Third Quarter 2022 Results

November 9, 2022

WOODCLIFF LAKE, N.J., Nov. 09, 2022 (GLOBE NEWSWIRE) -- **Eagle Pharmaceuticals, Inc. is re-issuing in its entirety its earnings press release for the third quarter ended September 30, 2022, originally issued on November 7, 2022 at 6:50 am ET, to correct errors in the presentation of certain line items in the financial statements included therein and corresponding references to such items in the narrative disclosure as described in the Company's Form 8-K/A filed on November 9, 2022. All other information in the earnings press release remains unchanged, including adjusted non-GAAP net income, adjusted non-GAAP basic and diluted earnings per share and adjusted non-GAAP EBITDA.**

The corrected release reads:

- Q3 2022 net loss was $(0.54) per basic and diluted share and adjusted non-GAAP net income was $1.13 per basic and $1.12 per diluted share[1]
- Total revenue for Q3 2022 was $65.9 million, compared to $39.9 million in Q3 2021
- Nine-month 2022 net income was $2.13 per basic and $2.11 per diluted share
- Nine-month 2022 adjusted non-GAAP earnings per diluted share[1] more than doubled to $6.69 from full year 2021 adjusted non-GAAP earnings per diluted share, outperforming any full year in the Company's history
- Nine-month 2022 revenue of $255.9 million exceeds full year 2021 revenue of $171.5 million
- Nine-month 2022 net sales of vasopressin and PEMFEXY combined totaled $114.9 million
- BENDEKA®[2] and BELRAPZO®[3] - both ready-to-dilute ("RTD") products — combined currently have 91% share of the bendamustine market, up from 85% at the beginning of the year. TREANDA®[4], which is not an RTD product, has just 9%[5]
- Q3 2022 gross profit from bendamustine franchise increased 9% compared to Q3 2021[6]
- Submitted an investigational new drug ("IND") application to the U.S. Food and Drug Administration ("FDA") for CAL02, a novel first-in-class broad-spectrum anti-virulence agent for the treatment of severe community-acquired bacterial pneumonia
- Strengthened hospital pipeline through equity stake in and an option to acquire Enalare Therapeutics Inc ("Enalare") [7]. Enalare's lead pipeline compound, ENA-001, a novel agnostic respiratory stimulant with strong patent protection, has three target indications: post-operative respiratory depression; community drug overdose; and Apnea of Prematurity, a common condition in preterm infants
- Company to host Investor Day in New York City on December 6, 2022

WOODCLIFF LAKE, NJ - Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced financial results for the three and nine months ended September 30, 2022.

Business and Recent Highlights:

- Submitted an IND application to FDA for CAL02, a novel first-in-class broad-spectrum anti-virulence agent for the treatment of severe community-acquired bacterial pneumonia ("SCABP"). The IND filing includes a protocol for an adequately powered global Phase 2 study to evaluate the efficacy and safety of CAL02 when added to standard of care therapy in patients with SCABP.
- Acquired an equity stake in, with an option to purchase, Enalare Therapeutics Inc. ("Enalare"), adding a portfolio of novel NCEs with strong intellectual property protection, from the mid-2030s into the 2040s, including composition of matter patents. 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. The initial targeted indications include post-operative respiratory depression; community drug overdose; and Apnea of Prematurity, a common

condition in preterm infants. The Company believes this investment strengthens Eagle's position as a diversified pharmaceutical company and a leader in hospital/anesthesia.

- Enalare secured a contract for up to $50.3 million from the Biomedical Advanced Research and Development Authority ("BARDA"), part of the Administration for Strategic Preparedness and Response in the U.S. Department of Health and Human Services (contract number 75A50122C00072). In partnership with BARDA, ENA-001 is being developed in an intramuscular ("IM") formulation for potential use in patients experiencing community drug overdose and as a potential medical countermeasure for mass casualty events.

- FDA granted Orphan Drug Designation ("ODD") to ENA-001 for the treatment of Apnea of Prematurity ("AoP"). AoP is a development disorder attributed to immaturity of the pulmonary system characterized by either cessation of breathing for more than 20 seconds or cessation of breathing that lasts less than 20 seconds but is accompanied by either bradycardia or hypoxemia.

- Received favorable ruling in vasopressin litigation. The U.S. Court of Appeals for the Federal Circuit affirmed the U.S. District Court for the District of Delaware's decision that Eagle's vasopressin product does not infringe on any of the patents asserted by Par Pharmaceutical, Inc.

- Appointed pharmaceutical industry veteran, Debra M. Hussain, as Senior Vice President, Head of Commercial, with responsibility for FDA-approved new chemical entities, BARHEMSYS® and BYFAVO®, acquired as part of the acquisition of Acacia Pharma Group plc ("Acacia").

- Amended and restated its credit agreement providing for a three-year $100 million revolving credit facility and $50 million term loan facility and repaid all other debt.

Financial Highlights

Third Quarter 2022

- Total revenue for Q3 2022 was $65.9 million, compared to $39.9 million in Q3 2021.

- Q3 2022 net loss was $(7.1) million, or $(0.54) per basic and diluted share, compared to net loss of $(5.6) million, or $(0.43) per basic and diluted share, in Q3 2021.

- Q3 2022 adjusted non-GAAP net income was $14.9 million, or $1.13 per basic and $1.12 per diluted share, compared to adjusted non-GAAP net income of $7.5 million, or $0.57 per basic and $0.56 per diluted share, in Q3 2021.

- Cash and cash equivalents were $15.4 million, net accounts receivable was $96.9 million, and debt was $59.3 million, as of September 30, 2022.

- Recorded a $3.8 million milestone payment from SymBio on TREAKISYM® in Q3 2022, $1.2 million ($0.07 per basic and diluted share) less than anticipated due to currency declines of the Japanese Yen.

"It was another strong quarter for Eagle, and we are pleased that the earnings growth has continued. We are posting record earnings this year, as evidenced by the fact that in the first nine months of the year, we have already earned $6.69 per share, topping our previous best full year ever," stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

"We expect another strong year in 2023 and anticipate deploying the cash from our earnings and strong balance sheet not only to fund our key clinical initiatives but also to potentially make an accretive acquisition to round out our portfolio. Between business development activities and our own R&D engine, we believe Eagle can grow significantly larger as it transitions into a branded pharmaceutical company with a diversified portfolio of assets," concluded Tarriff.

Third Quarter 2022 Financial Results

Total revenue for the three months ended September 30, 2022 was $65.9 million, as compared to $39.9 million for the three months ended September 30, 2021.

Q3 2022 RYANODEX® net product sales were $7.6 million, compared to $4.5 million in the third quarter of 2021.

Q3 2022 BELRAPZO net product sales were $8.5 million, compared to $4.9 million in the third quarter of 2021.

Q3 2022 PEMFEXY® net product sales were $1.7 million and vasopressin net product sales were $13.8 million.

A summary of total revenue is outlined below:

	Three Months Ended September 30,	
	2022	2021
	(unaudited)	(unaudited)

Revenue (in thousands):				
Product sales, net	$	38,086	$	12,124
Royalty revenue		24,007		27,729
License and other revenue		3,808		-
Total revenue	**$**	**65,901**	**$**	**39,853**

Gross margin was 64% during the third quarter of 2022, as compared to 79% in the third 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 BARHEMSYS and BYFAVO.

R&D expense was $9.3 million for the third quarter of 2022, compared to $23.3 million for the third quarter of 2021. The decrease was primarily due to lower spend of $6.6 million on CAL02 and $4.8 million on landiolol due to the upfront license fees paid in Q3 2021 and non-recurrence of development costs of $2.1 million on vasopressin and $1.4 million on PEMFEXY. This was partially offset by an increase in spend on fulvestrant of $0.9 million compared to Q3 2021.

SG&A expenses in the third quarter of 2022 totaled $23.5 million compared to $18.5 million in the third quarter of 2021. This increase was primarily related to $1.1 million of external sales and marketing and $1.2 million of headcount costs for BARHEMSYS and BYFAVO re-launches, $1.1 million of financial and other professional fees, $0.6 million of severance related to the integration of Acacia, $0.5 million of external legal costs, and $0.2 million of sales and marketing costs for PEMFEXY, partially offset by lower general and administrative head count costs.

Net loss for the third quarter of 2022 was $(7.1) million, or $(0.54) per basic and diluted share, compared to net loss of $(5.6) million, or $(0.43) per basic and diluted share, in the third quarter of 2021, primarily as a result of the factors discussed above.

Adjusted non-GAAP net income for the third quarter of 2022 was $14.9 million, or $1.13 per basic and $1.12 per diluted share, compared to adjusted non-GAAP net income of $7.5 million, or $0.57 per basic and $0.56 per diluted share, in the third quarter of 2021.

2022 Full Year Expense Guidance

- Adjusted non-GAAP R&D expense for the full year 2022 is expected to be less than $40 million, as compared to $32.5 million in 2021.
- Adjusted non-GAAP SG&A expense for the full year 2022 is expected to be in the range of $64 million to $68 million, as compared to $54.9 million in 2021.

Liquidity

As of September 30, 2022, Eagle had $15.4 million in cash and cash equivalents and $96.9 million in net accounts receivable, and $59.3 million in outstanding debt. Therefore, as of September 30, 2022, Eagle had cash plus net receivables of $112.3 million.

In the third quarter of 2022, Eagle repurchased $10 million of its common stock as part of its current $160 million Share Repurchase Program. From August 2016 through September 30, 2022, Eagle has repurchased $246.1 million of its common stock.

Conference Call

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

Date	November 7, 2022
Time	8:30 A.M. ET
Toll free (U.S.)	800-343-4849
International	785-424-1699
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 800-934-4548 (U.S.) or 402-220-1175 (International) and entering conference call ID EGRXQ322. The webcast will be archived for 30 days at the aforementioned URL.

Investor Day Registration Information

Eagle will host an Investor Day on Tuesday, December 6, 2022, at the Lotte New York Palace Hotel, at 8:00am ET.

The program will provide an opportunity for an in-depth look at the Company’s hospital-based products and product candidates, including CAL02, BARHEMSYS and BYFAVO, landiolol, and Enalare’s ENA-001. Featured speakers include Scott Tarriff, President and Chief Executive Officer, senior members of Eagle’s clinical and commercial teams, and noteworthy Key Opinion Leaders, who will discuss the scientific rationale and potential unmet medical needs for each pipeline asset and commercial product.

Advance registration is required for this event. Institutional investors and analysts are kindly requested to RSVP through this link to attend.

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,” “near future,” “belief,” “guidance,” “estimate,” and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements with respect to: the development of, potential benefits of and potential FDA submission for ENA-001, including a potential IM formulation that could potentially enable more rapid deployment in emergency situations and the potential to develop an innovative and rapid treatment for respiratory depression in a variety of settings; expectations with respect to the BARDA award providing funding to Enalare to accelerate the development of ENA-001; the achievement of milestones and deliverables; the potential further investment by the Company in Enalare and the Company’s development programs, products and pipeline; 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 2022, including expected R&D and SG&A expense; any further investments in Enalare and Enalare’s development programs; the potential exercise of the Company’s option to acquire all of Enalare’s outstanding shares; the potential benefits and commercial opportunity of Enalare’s product candidates; the potential of Enalare product candidates to immediately expand the Company’s long-term growth possibilities, if acquired; expected continued earnings growth in 2023 and 2024,and anticipated deployment of cash to fund clinical development and potential strategic transactions to round out the Company's portfolio; the potential for the Company to grow significantly larger as it transitions into a diversified pharmaceutical company with a portfolio of branded, first-in-class assets; expectations for earnings to grow in 2023 and 2024; 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 Company’s timing and ability to enroll patients in upcoming clinical trials, including for CAL02; the timing, scope or likelihood and timing of regulatory filings and approvals from the FDA for the Company’s product candidates, including landiolol and its fulvestrant product; 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; the ability of vasopressin to benefit providers and patients as an alternative to Vasostrict; 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, including vasopressin; 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 2022 and over the long term; the Company’s ability to sustain and accelerate this growth; the Company’s ability to utilize its cash and other assets to increase shareholder value; 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 recently completed transaction with Acacia are not realized; the ability of Enalare to achieve milestones and deliverables under the BARDA agreement and otherwise accelerate and achieve successful results in the development of ENA-001; 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 factors in addition to the foregoing that may impact the Company’s financial projects and guidance, including among other things, any potential business development transactions, acquisitions, restructurings or legal settlements, in addition to any unanticipated factors, that 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, 2021, filed with the Securities and Exchange Commission (the “SEC”) on March 8, 2022, the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, filed with the SEC on May 9, 2022, the Company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August 9, 2022 and its other subsequent filings with the SEC, including the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 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 attributable to Eagle, adjusted non-GAAP R&D expense 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, expense of acquired in-process research & development, 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 loss, inventory step-up and the tax effect of these adjustments.

Adjusted non-GAAP R&D expense excludes stock-based compensation expense, depreciation expense, severance and expense of acquire in-process research & development.

Adjusted non-GAAP SG&A expense excludes stock-based compensation expense, amortization expense, depreciation expense, severance, legal settlement and acquisition related 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. Reconciliations of the components of projected adjusted non-GAAP R&D and adjusted non-GAAP SG&A to their most comparable GAAP financial measures is not provided because the quantification of projected GAAP R&D and SG&A and the reconciling items between projected GAAP to adjusted non-GAAP R&D and SG&A cannot be reasonably calculated or predicted at this time without unreasonable efforts. For example, with respect to GAAP R&D and SG&A, 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 R&D and SG&A would vary significantly from projected GAAP and adjusted non-GAAP R&D and adjusted non-GAAP SG&A.

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

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,384	$ 97,659
Accounts receivable, net	96,932	41,149
Inventories	63,855	21,908
Prepaid expenses and other current assets	8,875	11,890
Total current assets	185,046	172,606
Property and equipment, net	1,297	1,636
Intangible assets, net	108,785	10,671
Goodwill	41,794	39,743
Deferred tax asset, net	23,541	18,798
Other assets	25,986	10,278
Total assets	$ 386,449	$ 253,732
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		

Accounts payable	$ 13,215	$ 16,431
Accrued expenses and other liabilities	73,652	32,338
Current debt	34,961	25,607
Total current liabilities	121,828	74,376
Long-term debt	26,431	—
Deferred tax liability	4,536	—
Other long-term liabilities	1,874	2,903
Total liabilities	154,669	77,279
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of September 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 50,000,000 shares authorized; 17,568,586 and 16,903,034 shares issued as of September 30, 2022 and December 31, 2021, respectively	18	17
Additional paid in capital	362,161	325,779
Accumulated other comprehensive income (loss)	9,377	(94)
Retained earnings	103,339	75,862
Treasury stock, at cost, 4,552,730 and 4,111,622 shares as of September 30, 2022 and December 31, 2021, respectively	(243,115)	(225,111)
Total stockholders' equity	231,780	176,453
Total liabilities and stockholders' equity	$ 386,449	$ 253,732

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue:				
Product sales, net	$ 38,086	$ 12,124	$ 177,375	$ 48,865
Royalty revenue	24,007	27,729	74,728	80,361
License and other revenue	3,808	—	3,808	—
Total revenue	65,901	39,853	255,911	129,226
Operating expenses:				
Cost of product sales	20,869	5,486	67,216	21,835
Cost of royalty revenue	2,782	2,773	7,854	8,036
Research and development	9,326	23,289	26,871	47,488
Selling, general and administrative	23,462	18,482	82,476	54,997
Total operating expenses	56,439	50,030	184,417	132,356
Income (loss) from operations	9,462	(10,177)	71,494	(3,130)
Interest income	(444)	197	(46)	395
Interest expense	(1,147)	(396)	(2,065)	(1,240)
Other expense	(11,534)	(2,284)	(21,254)	(1,797)
Total other expense, net	(13,125)	(2,483)	(23,365)	(2,642)
(Loss) income before income tax (provision) benefit	(3,663)	(12,660)	48,129	(5,772)
Income tax (provision) benefit	(3,468)	7,038	(20,652)	3,341
Net (loss) income	$ (7,131)	$ (5,622)	$ 27,477	$ (2,431)
(Loss) earnings per share attributable to common stockholders:				
Basic	$ (0.54)	$ (0.43)	$ 2.13	$ (0.19)
Diluted	$ (0.54)	$ (0.43)	$ 2.11	$ (0.19)
Weighted average number of common shares outstanding:				
Basic	13,166,931	13,077,298	12,906,235	13,103,203
Diluted	13,166,931	13,077,298	13,051,311	13,103,203

EAGLE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)
(In thousands)

	Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net income (loss)	$ 27,477	$ (2,431)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Deferred income taxes	(4,743)	(2,533)
Depreciation expense	508	575
Non-cash operating lease expense related to right-of-use assets	917	768
Amortization expense of intangible assets	5,886	2,118
Fair value adjustments on equity investment	3,208	1,900
Stock-based compensation expense	12,332	14,873
Convertible promissory note related credit losses	—	150
Amortization of debt issuance costs	354	354
Fair value adjustments related to derivative instruments	962	(254)
Accretion of discount on convertible promissory note	—	(102)
Loss on foreign currency exchange rates	7,309	—
Loss on write-off of convertible promissory note	4,444	—
Changes in operating assets and liabilities which provided (used) cash:		
Accounts receivable	(55,325)	5,343
Inventories	(15,006)	(1,240)
Prepaid expenses and other current assets	(831)	(8,821)
Accounts payable	(3,824)	6,449
Accrued expenses and other liabilities	33,888	3,897
Other assets and other long-term liabilities, net	(4,412)	(908)
Net cash provided by operating activities	13,144	20,138
Cash flows from investing activities:		
Purchase of Acacia, net of cash acquired	(74,153)	—
Purchase of equity investment security	(12,500)	—
Purchase of property and equipment	(168)	(274)
Purchase of convertible promissory note	—	(5,000)
Net cash used in investing activities	(86,821)	(5,274)
Cash flows from financing activities:		
Proceeds from common stock option exercises	1,747	1,841
Proceeds from existing revolving credit facility	15,000	—
Employee withholding taxes related to stock-based awards	(1,341)	(1,551)
Payment of debt	(6,000)	(6,000)
Repurchases of common stock	(18,004)	(12,568)
Net cash used in financing activities	(8,598)	(18,278)
Net decrease in cash and cash equivalents	(82,275)	(3,414)
Cash and cash equivalents at beginning of period	97,659	103,155
Cash and cash equivalents at end of period	$ 15,384	$ 99,741
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Income taxes, net	$ 18,855	$ 6,303
Interest	894	917

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net (loss) income - GAAP	$ (7,131)	$ (5,622)	$ 27,477	$ (2,431)
Adjustments:				
Cost of product revenues:				
Amortization expense	3,689	301	5,886	903
Research and development:				
Stock-based compensation expense	600	641	1,844	2,177
Depreciation expense	42	57	134	164
Expense of acquired in-process research & development	-	15,000	-	15,000
Severance	-	-	-	274
Selling, general and administrative:				
Stock-based compensation expense	2,937	3,443	10,488	12,696
Depreciation expense	121	140	374	411
Severance	587	-	8,378	334
Acquisition related costs	1,498	-	12,837	-
Amortization expense	-	405	-	1,215
Legal settlement	-	-	300	-
Other:				
Non-cash interest expense	756	118	1,152	354
Fair value adjustments on equity investment	(22)	2,300	3,208	1,900
Convertible promissory note related adjustments	4,674	4	4,646	48
Fair value adjustments related to derivative instruments	1,624	(66)	7,255	(254)
Foreign currency exchange loss	5,751	-	6,549	-
Inventory step-up	392	-	392	-
Tax effect of the non-GAAP adjustments	(624)	(9,205)	(3,559)	(9,608)
Adjusted non-GAAP net income	$ 14,894	$ 7,516	$ 87,361	$ 23,183
Adjusted non-GAAP earnings per share:				
Basic	$ 1.13	$ 0.57	$ 6.77	$ 1.77
Diluted	$ 1.12	$ 0.56	$ 6.69	$ 1.74
Weighted average number of common shares outstanding:				
Basic	13,166,931	13,077,298	12,906,235	13,103,203
Diluted	13,280,811	13,307,559	13,051,311	13,290,677

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

	Three Months Ended September 30,		Nine Months Ended September 30,		Twelve Months Ended September 30,	Twelve Months Ended December 31,
	2022	2021	2022	2021	2022	2021
Net (loss) income - GAAP	$ (7,131)	$ (5,622)	$ 27,477	$ (2,431)	$ 21,281	$ (8,627)
Add back:						
Interest expense, net of interest income	1,591	199	2,111	845	2,341	1,075
Income tax provision	3,468	(7,038)	20,652	(3,341)	28,072	4,079
Depreciation and amortization expense	3,852	903	6,394	2,693	7,461	3,760
Add back:						
Stock-based compensation expense	3,537	4,084	12,332	14,873	17,014	19,555
Fair value adjustments on equity investment	(22)	2,300	3,208	1,900	7,478	6,170

Expense of acquired in-process research & development	-	15,000	-	15,000	339	15,339
Convertible promissory note related adjustments	4,180	50	4,242	150	4,850	758
Fair value adjustments related to derivative instrument	1,624	(66)	7,255	(254)	6,823	(686)
Foreign currency exchange loss	5,751	-	6,549	-	6,549	-
Legal Settlement	-	-	300	-	300	-
Acquisition related costs	1,498	-	12,837	-	12,837	-
Inventory step-up	392	-	392	-	392	-
Severance	587	-	8,378	608	9,854	2,084
Adjusted Non-GAAP EBITDA	$ 19,327	$ 9,810	$ 112,127	$ 30,043	$ 125,591	$ 43,507

Important Safety Information for BARHEMSYS® (amisulpride)[8] 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)[9] 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] https://www.bendekahcp.com/globalassets/bendeka-hcp/prescribinginformation.pdf

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

[4] https://www.bendekahcp.com/globalassets/bendeka-hcp/resources-page/bendeka-treanda-product-characteristics.pdf

[5] IQVIA SMART-US monthly volume data for the months January and September 2022.

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

[7] Subject to the terms of the Company's agreement with Enalare, including achievement of specified milestones.

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

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

Source: Eagle Pharmaceuticals, Inc.