Eagle Pharmaceuticals Reports Third Quarter 2021 Results

November 9, 2021

- Q3 2021 net loss was $0.43 per basic and diluted share and adjusted non-GAAP net income was $0.57 per basic and $0.56 per diluted share
- Expect to receive approval for Abbreviated New Drug Application (“ANDA”) for vasopressin; December 15, 2021 GDUFA date
- Received favorable district court decision that Eagle’s proposed vasopressin product does not infringe any of the patents Par asserted against Eagle
- Entered into worldwide licensing agreement for CAL02, a novel first-in-class antitoxin agent ready for Phase 2b/3 development for the treatment of severe bacterial pneumonia
- Licensed U.S. commercial rights to landiolol, a beta-1 adrenergic blocker, a leading hospital emergency use product in Europe and Japan

WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)-- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) (“Eagle” or the “Company”) today announced financial results for the three and nine months ended September 30, 2021.

Business and Recent Highlights:

- Entered into a worldwide licensing agreement for the commercial rights to CAL02, a novel first-in-class antitoxin agent ready for Phase 2b/3 development for the treatment of severe bacterial pneumonia in combination with traditional antibacterial drugs.

- Vasopressin updates:
  - In August 2021, received favorable decision from the U.S. District Court for the District of Delaware that Eagle’s proposed vasopressin product does not infringe any of the patents Par Pharmaceutical, Inc. asserted against Eagle.
  - U.S. Food and Drug Administration (“FDA”) maintained Priority Review for the Company’s ANDA with December 15, 2021 GDUFA date.
  - Received a 30-day information request from the FDA; Eagle fully responded to the request on September 20, 2021, and there are no other review requests outstanding.

- Granted U.S. Patent No. 11,103,483, “Formulations of Bendamustine,” which has been listed in the FDA Orange Book for BENDEKA® and BELRAPZO®.
- Entered into a licensing agreement for the U.S. commercial rights to landiolol, a leading hospital emergency use product in Europe and Japan. Landiolol is currently approved in Europe for the treatment of non-compensatory sinus tachycardia and tachycardic supraventricular arrhythmias. Eagle will support the submission of a new drug application to the FDA seeking approval for landiolol for the short-term reduction of ventricular rate in patients with supraventricular tachycardia, including atrial fibrillation and atrial flutter.

Financial Highlights

Third Quarter 2021

- Total revenue for Q3 2021 was $39.9 million, compared to $49.9 million in Q3 2020, primarily reflecting lower product sales of BELRAPZO and BENDEKA, partially offset by higher product sales of TREAKISYM.
- Q3 2021 net loss was $5.6 million, or $0.43 per basic and diluted share, compared to net income of $7.1 million, or $0.52 per basic and $0.51 diluted share in Q3 2020.
- Q3 2021 adjusted non-GAAP net income was $7.5 million, or $0.57 per basic and $0.56 per diluted share, compared to adjusted non-GAAP net income of $16.1 million, or $1.19 per basic and $1.17 per diluted share, in Q3 2020.
- Cash and cash equivalents were $99.7 million, net accounts receivable was $45.3 million, and debt was $28.0 million as of September 30, 2021.

“We are preparing for two significant product launches, vasopressin and PEMFEXY™, expected within the next ninety days that we believe will meaningfully increase the revenue and profitability of Eagle. With the recent licensing of CAL02 and landiolol, our expectation going forward is that we will utilize our cash and possibly the balance sheet to further strengthen the pipeline and portfolio,” stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

Third Quarter 2021 Financial Results

Total revenue for the three months ended September 30, 2021 was $39.9 million, as compared to $49.9 million for the three months ended September 30, 2020.

Q3 2021 BELRAPZO product sales were $4.9 million, compared to $8.7 million in Q3 2020.

Q3 2021 RYANODEX® product sales were $4.5 million, compared to $4.2 million in Q3 2020.

Royalty revenue was $27.7 million in the third quarter of 2021, compared to $27.6 million in the third quarter of 2020. BENDEKA royalties were $26.5 million in the third quarter of 2021, compared to $27.6 million in the third quarter of 2020. A summary of total revenue is outlined below:

	Three Months Ended September 30,	
	2021	2020
	(unaudited)	(unaudited)
Revenue (in thousands):		
Product sales, net	$ 12,124	$ 17,317
Royalty revenue	27,729	27,611
License and other revenue	—	5,000
Total revenue	$ 39,853	$ 49,928

Gross Margin was 79% during the third quarter of 2021, as compared to 76% in the third quarter of 2020. The increase in gross margin for the third quarter of 2021 was driven by revenue mix.

R&D expense was $23.3 million for the third quarter of 2021, compared to $4.8 million in the third quarter of 2020. The increase includes a $10.0 million upfront payment related to our license agreement with Combioxin for CAL02, a $5.0 million upfront expense related to our licensing agreement with AOP Orphan for landiolol, a $0.8 million increase in development and pre-launch inventory costs for vasopressin and a $1.1 million increase related to PEMFEXY. Excluding stock-based compensation and other non-cash and non-recurring items, R&D expense during the third quarter of 2021 was $7.6 million.

SG&A expenses in the third quarter of 2021 totaled $18.5 million compared to $17.7 million in the third quarter of 2020. This increase is primarily related to higher external legal costs partially offset by a decrease in stock-based compensation expense. Excluding stock-based compensation and other non-cash and non-recurring items, third quarter 2021 SG&A expense was $14.5 million.

Net loss for the third quarter of 2021 was $5.6 million, or $0.43 per basic and diluted share, compared to net income of $7.1 million, or $0.52 per basic and $0.51 per diluted share, in the third quarter of 2020, due to the factors discussed above.

Adjusted non-GAAP net income for the third quarter of 2021 was $7.5 million, or $0.57 per basic and $0.56 per diluted share, compared to adjusted non-GAAP net income of $16.1 million or $1.19 per basic and $1.17 per diluted share in the third quarter of 2020. For a full reconciliation of adjusted non-GAAP net income to the most comparable GAAP financial measures, please see the tables at the end of this press release.

2021 Expense Guidance

- R&D spend in 2021, on a non-GAAP basis, is expected to be $34-$38 million, as compared to $27.8 million in 2020.
- SG&A spend in 2021, on a non-GAAP basis, is expected to be $52-$56 million, as compared to $50.9 million in 2020.
- The guidance provided in this section represents forward-looking information, and actual results may vary. Please see the risks and assumptions referred to in the Forward-Looking Statements section of this press release.

Liquidity

As of September 30, 2021, the Company had $99.7 million in cash and cash equivalents plus $45.3 million in net accounts receivable. The Company had $28.0 million in outstanding debt. Therefore, as of September 30, 2021, the Company had net cash plus receivables of $117.0 million.

In the third quarter of 2021, the Company purchased $8.3 million of its common stock as part of its $160.0 million Share Repurchase Program. From August 2016 through September 30, 2021, the Company has repurchased $219.4 million of its common stock.

Conference Call

As previously announced, Eagle management will host its third quarter 2021 conference call as follows:

Date	Tuesday, November 9, 2021
Time	8:30 A.M. EDT
Toll free (U.S.)	866-342-8591
International	203-518-9822
Webcast (live and replay)	www.eagleus.com, under the “Investor + News” section

A replay of the conference call will be available for one week after the call's completion by dialing 800-839-8292 (US) or 402-220-6069 (International) and entering conference call ID EGRXQ321. 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 RYANODEX®, BENDEKA®, BELRAPZO®, and its 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 information within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other securities laws. Forward-looking statements are statements that are not historical facts. Words and phrases such as “anticipated,” “forward,” “will,” “would,” “may,” “remain,” “potential,” “prepare,” “expected,” “believe,” “plan,” “near future,” “belief,” “guidance,” and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding future events such as: the number and timing of potential product launches, development initiatives or new indications for the Company’s product candidates; the period of market exclusivity for any of the Company’s product candidates; potential future revenue or earnings of the Company, including resulting from potential product launches of vasopressin and PEMFEXY; the Company's clinical development plan for the product candidates in its portfolio; the ability of the Company’s executive team to execute on the Company’s strategy and build stockholder value; 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 potential timing of the Company’s commercial launch of PEMFEXY, vasopressin or landiolol, if ever; the Company’s plans for and ability to support the commercial launch of landiolol in the United States, if approved; the ability of the Company’s product candidates, including landiolol, vasopressin and PEMFEXY, to deliver value to stockholders; ; the success of the Company's collaborations with its strategic partners and the timing and results of these partners’ preclinical studies and clinical trials; the Company’s timing and ability to enroll patients in ongoing and upcoming clinical trials; the ability of the Company to obtain and maintain coverage and adequate reimbursement for its products; the implementation of certain healthcare reform measures; the Company's timing and ability to repurchase additional shares of the Company's common stock, if any, under its Share Repurchase Program; the Company's ability to deliver value in 2021 and over the long term; 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. 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 impacts of the COVID-19 pandemic, 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 on the Company's business, financial condition and results of operations; risks that the Company's business, financial condition and results of operations will be impacted by the spread of COVID-19 in the geographies where the Company's third-party partners operate; 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 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 our 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, 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 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, 2020 filed with the Securities and Exchange Commission (the “SEC”) on March 5, 2021, as updated by the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, which the Company expects to file with the SEC on November 9, 2021, and its other subsequent filings with the SEC. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and the Company does not undertake any obligation to revise and disseminate forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of or non-occurrence of any events, except as required by law.

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 and adjusted non-GAAP earnings per share attributable to Eagle. 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 excludes stock-based compensation expense, depreciation expense, expense of acquired in-process research and development expense, amortization expense, severance, non-cash interest expense, expense related to collaboration with Tyme, fair value adjustments on equity investment, fair value adjustments related to derivative instrument, convertible promissory note related credit losses, accretion of discount on convertible promissory note and the tax effect of these adjustments. The Company believes these non-GAAP financial measures help 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 of GAAP to Adjusted Non-GAAP Net Income and Adjusted Non-GAAP Earnings per Share and Reconciliation of GAAP to Adjusted Non-GAAP EBITDA for details of the amounts excluded and included to arrive at adjusted non-GAAP net income, adjusted non-GAAP earnings per share amounts, and adjusted non-GAAP EBITDA amounts, respectively.

These adjusted measures are non-GAAP and 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 measures used by the Company may differ from similar measures used by other companies, even when similar terms are used to identify such measures.

-- Financial tables follow --

EAGLE PHARMACEUTICALS, INC.

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

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 99,741	$ 103,155
Accounts receivable, net	45,335	50,678
Inventories	9,315	8,075
Prepaid expenses and other current assets	17,303	4,157
Total current assets	171,694	166,065
Property and equipment, net	1,775	2,077
Intangible assets, net	10,799	12,917
Goodwill	39,743	39,743
Deferred tax asset, net	17,713	15,180
Other assets	14,537	17,208
Total assets	$ 256,261	$ 253,190
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 12,717	$ 6,268
Accrued expenses and other liabilities	27,714	23,817
Current portion of long-term debt	8,000	8,000
Total current liabilities	48,431	38,085
Other long-term liabilities	3,048	3,959
Long-term debt, less current portion	19,489	25,135
Total liabilities	70,968	67,179
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of September 30, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value; 50,000,000 shares authorized; 16,886,123 and 16,739,203 shares issued as of September 30, 2021 and December 31, 2020, respectively	17	17
Additional paid in capital	320,566	305,403
Accumulated other comprehensive loss	(882)	—
Retained earnings	82,058	84,489
Treasury stock, at cost, 3,941,541 and 3,682,176 shares as of September 30, 2021 and December 31, 2020, respectively	(216,466)	(203,898)
Total stockholders' equity	185,293	186,011
Total liabilities and stockholders' equity	$ 256,261	$ 253,190

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,	
	2021	2020	2021	2020
Revenue:				
Product sales, net	$ 12,124	$ 17,317	$ 48,865	$ 49,387
Royalty revenue	27,729	27,611	80,361	83,499
License and other revenue	—	5,000	—	5,000
Total revenue	39,853	49,928	129,226	137,886
Operating expenses:				
Cost of product sales	5,486	8,726	21,835	23,804
Cost of royalty revenue	2,773	3,260	8,036	9,120
Research and development	23,289	4,828	47,488	21,390
Selling, general and administrative	18,482	17,697	54,997	60,411
Total operating expenses	50,030	34,511	132,356	114,725
(Loss) income from operations	(10,177)	15,417	(3,130)	23,161
Interest income	197	46	395	542

Interest expense	(396)	(489)	(1,240)	(2,164)
Other expense	(2,284)	(6,049)	(1,797)	(10,249)
Total other expense, net	(2,483)	(6,492)	(2,642)	(11,871)
(Loss) income before income tax benefit (provision)	(12,660)	8,925	(5,772)	11,290
Income tax benefit (provision)	7,038	(1,866)	3,341	(7,358)
Net (loss) income	$ (5,622)	$ 7,059	$ (2,431)	$ 3,932
(Loss) earnings per share attributable to common stockholders:				
Basic	$ (0.43)	$ 0.52	$ (0.19)	$ 0.29
Diluted	$ (0.43)	$ 0.51	$ (0.19)	$ 0.28
Weighted average number of common shares outstanding:				
Basic	13,077,298	13,531,372	13,103,203	13,620,981
Diluted	13,077,298	13,786,803	13,103,203	13,917,800

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

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net (loss) income	$ (2,431)	$ 3,932
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Deferred income taxes	(2,533)	(1,671)
Depreciation expense	575	656
Noncash operating lease expense related to right-of-use assets	768	980
Amortization expense of intangible assets	2,118	1,999
Fair value adjustments on equity investment	1,900	7,700
Stock-based compensation expense	14,873	18,435
Convertible promissory note related credit losses	150	—
Amortization of debt issuance costs	354	301
Fair value adjustments related to derivative instrument	(254)	2,549
Accretion of discount on convertible promissory note	(102)	—
Changes in operating assets and liabilities which provided (used) cash:		
Accounts receivable	5,343	(4,195)
Inventories	(1,240)	(20
Prepaid expenses and other current assets	(8,821)	(2,774)
Accounts payable	6,449	7,606
Accrued expenses and other liabilities	3,897	(3,916)
Other assets and other long-term liabilities, net	(908)	(1,845)
Net cash provided by operating activities	20,138	29,737
Cash flows from investing activities:		
Purchase of equity investment security	—	(17,500)
Purchase of property and equipment	(274)	(577)
Purchase of convertible promissory note	(5,000)	—
Net cash used in investing activities	(5,274)	(18,077)
Cash flows from financing activities:		
Proceeds from common stock option exercises	1,841	555
Employee withholding taxes related to stock-based awards	(1,551)	(1,310)
Proceeds from existing revolving credit facility	—	110,000
Repayment of existing revolving credit facility	—	(110,000)
Payment of debt	(6,000)	(3,000)
Repurchases of common stock	(12,568)	(27,999)
Net cash used in financing activities	(18,278)	(31,754)
Net decrease in cash and cash equivalents	(3,414)	(20,094)
Cash and cash equivalents at beginning of period	103,155	109,775
Cash and cash equivalents at end of period	$ 99,741	$ 89,681
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Income taxes, net	$ 6,303	$ 3,036

Interest	917	1,878
Right-of-use asset obtained in exchange for lease obligation - lease amendment	—	842

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,	
	2021	2020	2021	2020
Net (loss) income - GAAP	$ (5,622)	$ 7,059	$ (2,431)	$ 3,932
Adjustments:				
Cost of product revenues:				
Amortization expense	301	261	903	784
Research and development:				
Stock-based compensation expense	641	(514)	2,177	2,070
Depreciation expense	57	72	164	206
Expense of acquired in-process research & development	15,000	-	15,000	-
Severance	-	-	274	-
Selling, general and administrative:				
Stock-based compensation expense	3,443	5,236	12,696	16,365
Expense related to collaboration with Tyme	-	-	-	2,500
Amortization expense	405	405	1,215	1,215
Depreciation expense	140	124	411	450
Severance	-	-	334	245
Other:				
Non-cash interest expense	118	118	354	354
Fair value adjustments on equity investment	2,300	3,500	1,900	7,700
Convertible promissory note related credit losses	50	-	150	-
Fair value adjustments related to derivative instrument	(66)	2,549	(254)	2,549
Accretion of discount on convertible promissory note	(46)	-	(102)	-
Tax effect of the non-GAAP adjustments	(9,205)	(2,663)	(9,608)	(2,466)
Adjusted non-GAAP net income	$ 7,516	$ 16,147	$ 23,183	$ 35,904
Adjusted non-GAAP earnings per share:				
Basic	$ 0.57	$ 1.19	$ 1.77	$ 2.64
Diluted	$ 0.56	$ 1.17	$ 1.74	$ 2.58
Weighted average number of common shares outstanding:				
Basic	13,077,298	13,531,372	13,103,203	13,620,981
Diluted	13,307,559	13,786,803	13,290,677	13,917,800

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,
	2021	2020	2021	2020	2021	2020
Net (loss) income - GAAP	$ (5,622)	$ 7,059	$ (2,431)	$ 3,932	$ 5,626	$ 11,989
Add back:						

Interest expense, net of interest income	199	443	845	1,622	1,238	2,015
Income tax (benefit) provision	(7,038)	1,866	(3,341)	7,358	(11)	10,688
Depreciation and amortization expense	903	862	2,693	2,655	3,576	3,538
Add back:						
Stock-based compensation expense	4,084	4,722	14,873	18,435	21,194	24,756
Fair value adjustments on equity investment	2,300	3,500	1,900	7,700	(500)	5,300
Expense of acquired in-process research & development	15,000	-	15,000	-	15,000	-
Convertible promissory note related credit losses	50	-	150	-	150	-
Fair value adjustments related to derivative instrument	(66)	2,549	(254)	2,549	159	2,962
Expense related to collaboration with Tyme	-	-	-	2,500	-	2,500
Severance	-	-	608	245	1,287	924
Adjusted Non-GAAP EBITDA	$ 9,810	$ 21,001	$ 30,043	$ 46,996	$ 47,719	$ 64,672

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

Source: Eagle Pharmaceuticals, Inc.