Eagle Pharmaceuticals, Inc. Reports Third Quarter 2017 Results

November 8, 2017

-- Bendeka market share of 97% with record royalty revenue of $41.4 million --

-- Revenue grows 67% year-over-year to $63.0 million --

-- New patent related to RYANODEX granted --

-- Tentative FDA approval for PEMFEXY (pemetrexed injection) --

-- Net income was $0.98 per diluted share and Adjusted Non-GAAP net income was $1.22 per diluted share --

Eagle Pharmaceuticals, Inc. (“Eagle” or “the Company”) (Nasdaq: EGRX) today announced its financial results for the three- and nine-months ended September 30, 2017. Highlights of and subsequent to the third quarter of 2017 include:

Financial Highlights:

- Total revenue for the third quarter of 2017 grew 67% to $63.0 million compared to $37.8 million in the third quarter of 2016;
  - Royalty revenue increased to $43.6 million compared to $26.2 million in Q3 2016;
  - Product sales decreased to $6.9 million compared to $7.8 million in Q3 2016;
- Q3 2017 income before income tax provision was $24.5 million;
- Q3 2017 net income was $15.4 million, or $1.03 per basic and $0.98 per diluted share, compared to a net income of $12.0 million, or $0.77 per basic and $0.73 per diluted share in Q3 2016;
- Q3 2017 Adjusted Non-GAAP net income was $19.2 million, or $1.27 per basic and $1.22 per diluted share, compared to Adjusted Non-GAAP net income of $14.7 million, or $0.95 per basic and $0.89 per diluted share in the prior year quarter. 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; and,
- Cash and cash equivalents were $97.5 million and accounts receivable were $71.6 million as of September 30, 2017.

Business and Recent Highlights:

- BENDEKA® total market share of 97%, as of September 30, 2017;
- Sales of RYANODEX® grew 29% to $3.3 million during the third quarter of 2017 compared to $2.5 million in Q3 2016;
- Received tentative U.S. Food and Drug Administration (FDA) approval for PEMFEXY™ (pemetrexed injection) ready-to-dilute formulation;
- Granted a new patent related to RYANODEX formulation (dantrolene sodium) by the United States Patent and Trademark Office, expiring June 2022;
- Licensed Japanese rights for bendamustine hydrochloride ready-to-dilute and rapid infusion injection products to SymBio Pharmaceuticals Limited and received a $12.5 million upfront payment;
- Announced positive results of an initial study in over 50 rodents to evaluate the neuroprotective effects of RYANODEX in an established rodent model of Nerve Agent-induced seizures and seizure-related brain damage;
- Filed for a second source drug product manufacturing site for BENDEKA;
- 2017 R&D and SG&A guidance updated:
  - We expect our full year 2017 R&D expense will be consistent with the upper end of the $31-$35 million range. This reflects ongoing expenses for the enrollment of the fulvestrant and RYANODEX for Ecstasy and methamphetamine intoxication clinical trials. Excluding stock based compensation, the R&D expense would be in the range of $27 - $31 million.
  - We expect our full year SG&A expense to be in the range of $67 - $70 million, slightly higher than previous guidance. Excluding stock based compensation and other non-cash items, SG&A expense would be in the range of $53 - $56 million.

“This was another strong quarter for Eagle with record revenue driven by BENDEKA, a growing cash position and significant movement in our pipeline,” stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

“During the quarter, we advanced multiple pipeline candidates. We plan to begin dosing patients in our fulvestrant study in a few weeks and expect to file an NDA in the fourth quarter of 2018. With one dose, our formulation will deliver a 5mL solution, using a smaller needle and in less time than the current commercially available product. In addition, we received tentative approval from the FDA for PEMFEXY, our ready-to-dilute pemetrexed IV formulation. As the first company to receive tentative approval for this product using the 505(b)2 pathway, we hope to find a way to market as soon as possible, once our litigation with Eli Lilly is resolved,” added Tarriff.

“We remain confident in our RYANODEX portfolio. We are continuing our dialogue with the FDA regarding EHS, while advancing our clinical work for the Ecstasy and methamphetamine, and nerve agent programs. We have also made progress on an intramuscular delivery formulation for RYANODEX, which we believe will provide patients and healthcare professionals with a valuable delivery option,” Tarriff added.

“Eagle continues to generate strong cash flow, which allows us to invest in our pipeline, evaluate additional strategic opportunities and return capital to shareholders when it maximizes value. We have completed the first $75 million share repurchase program and will continue purchasing up to an additional $100 million shares under our current share repurchase plan, reflecting our belief in the potential of our products and pipeline,” concluded Tarriff.

Third Quarter 2017 Financial Results

Total revenue for the three months ended September 30, 2017 was $63.0 million, as compared to $37.8 million for the three months ended September 30, 2016. A summary of total revenue is outlined below:

	Three Months Ended September 30,	
	2017	2016
Revenue ($ in 000’s):		
Product sales	$ 6,905	$ 7,837
Royalty revenue	43,616	26,246
License and other income	12,500	3,750
Total revenue	63,021	37,833

Product sales decreased to $6.9 million driven by lower net product sales of BENDEKA and Argatroban, partially offset by an increase in net product sales of RYANODEX. Royalty revenue increased to $43.6 million, as a result of the increased market share on Teva sales of BENDEKA, as well as an increase in the royalty rate from 20% to 25%.

Research and development expenses increased to $9.0 million in the three months ended September 30, 2017, compared to $3.2 million in the prior year quarter. The increase is due to continued spending on the Company’s pipeline, and in particular, our fulvestrant, RYANODEX for Ecstasy and methamphetamine intoxication, and pemetrexed projects.

SG&A expenses increased to $16.7 million in the third quarter of 2017 compared to $11.7 million in the three months ended September 30, 2016. Personnel-related expenses grew as a result of the expansion of our sales force in the second quarter of 2017. External legal expenses also increased, due to ongoing litigation.

An income tax provision of $9.0 million was recorded during the third quarter of 2017.

Net income for the third quarter of 2017 was $15.4 million, or $1.03 per basic share and $0.98 per diluted share, compared to net income of $12.0 million, or $0.77 per basic and $0.73 per diluted share in the three months ended September 30, 2016, due to the factors discussed above.

Adjusted Non-GAAP net income for the third quarter of 2017 was $19.2 million, or $1.27 per basic and $1.22 per diluted share, compared to Adjusted Non-GAAP net income of $14.7 million or $0.95 per basic and $0.89 per diluted share in the prior year quarter. 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.

Liquidity

As of September 30, 2017, the Company had $48 million in net cash and cash equivalents and $72 million in net accounts receivable, $46 million of which was due from Teva. For the nine months ended September 30, 2017, net cash provided by operating activities, excluding the increase in net accounts receivable, was $62 million. The Company had $50 million in outstanding debt.

As part of our stock repurchase plan, we purchased $13.5 million worth of our shares during the quarter, completing our original $75 million share repurchase plan initiated in August 2016. We expanded the program by $100 million during the second quarter of 2017.

Conference Call

As previously announced, Eagle management will host its third quarter 2017 conference call as follows:

Date	Wednesday, November 8, 2017
Time	8:30 A.M. EST
Toll free (U.S.)	866-518-6930
International	203-518-9797

Webcast (live and replay) www.eagleus.com, under the “Investor Relations” section

A replay of the conference call will be available for one week after the call's completion by dialing 800-839-8705 (US) or 402-220-6075 (International) and entering conference call ID EGRXQ317. The webcast will be archived for 30 days at the aforementioned URL.

About Eagle Pharmaceuticals, Inc.

Eagle is a specialty pharmaceutical company focused on developing and commercializing injectable products that address the shortcomings, as identified by physicians, pharmacists and other stakeholders, of existing commercially successful injectable products. Eagle’s strategy is to utilize the FDA's 505(b)(2) regulatory pathway. Additional information is available on the Company’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,” “may,” “remain,” “potential,” “prepare,” “expected,” “believe,” “plan,” “near future,” “belief,” and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding future events including, but not limited to: the Company’s plans for gaining approval of the label expansion of RYANODEX to treat EHS patients and for the treatment of Ecstasy and methamphetamine intoxication, including the ongoing discussions with FDA relating thereto and the outcome of such discussions; the Company’s plans for the development of fulvestrant; the Company's ability to continue to deliver value over the long term; and the Company’s timing and ability to repurchase additional shares of the Company's common stock, if any, under its share repurchase program. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond Eagle’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 include, but are not limited to: whether the Company will incur unforeseen expenses or liabilities or other market factors; whether the FDA will ultimately approve RYANODEX for the treatment of EHS and Ecstasy and methamphetamine intoxication; the ability of Eagle to manufacture and commercialize its PEMFEXY product upon final approval; the formation of a market for Eagle’s PEMFEXY product; whether the Company can continue to make progress with the development of fulvestrant; fluctuations in the trading volume and market price of shares of the Company's common stock, general business and market conditions and management's determination of alternative needs and uses of the Company's cash resources all of which may affect the Company's long-term performance and the share repurchase program; the success of our commercial relationship with Teva and the parties’ ability to work effectively together; whether Eagle and Teva will successfully perform their respective obligations under the license agreement; difficulties or delays in manufacturing; 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 FDA and other governmental regulations applicable to product approvals, manufacturing facilities, products and/or businesses; general economic conditions; the strength and enforceability of our 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 timing of product launches; the successful marketing of our products; the risks inherent in the early stages of drug development and in conducting clinical trials; and other factors that are discussed in Eagle’s Annual Report on Form 10-K for the year ended December 31, 2016, as filed with the U.S. Securities and Exchange Commission (SEC) on March 15, 2017 and its other 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 we do 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.

Non-GAAP Financial Performance Measures

In addition to financial information prepared in accordance with U.S. GAAP, this press release also contains adjusted net income and adjusted earnings per share from continuing operations attributable to Eagle Pharmaceuticals. 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 net income from continuing operations excludes share-based compensation expense, depreciation, amortization of acquired intangible assets, changes in contingent purchase price, non-cash interest expense and tax 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 Reconciliations of GAAP to Adjusted Net Income and Adjusted Earnings per Share for explanations of the amounts excluded and included to arrive at adjusted net income and adjusted earnings per share amounts for the three and nine month periods ended September 30, 2017 and 2016.

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
(In thousands, except per share amounts)

	September 30, 2017	December 31, 2016
	(unaudited)	

ASSETS		
Current assets:		
Cash and cash equivalents	$ 97,545	$ 52,820
Accounts receivable	71,601	42,194
Inventories	4,878	2,739
Prepaid expenses and other current assets	8,130	11,357
Total current assets	182,154	109,110
Property and equipment, net	4,365	3,316
Intangible assets, net	24,002	33,372
Goodwill	39,743	39,743
Deferred tax asset, net	16,502	28,643
Other assets	124	136
Total assets	$ 266,890	$ 214,320
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 8,902	$ 14,716
Accrued expenses	20,438	25,237
Current portion of contingent consideration	55	1,012
Current portion of long-term debt	5,000	—
Total current liabilities	34,395	40,965
Contingent consideration, less current portion	17,482	22,129
Long-term debt, less current portion	43,936	
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of September 30, 2017 and December 31, 2016	—	—
Common stock, $0.001 par value; 50,000,000 shares authorized; 16,071,435 and 15,890,862 issued as of September 30, 2017 and December 31, 2016, respectively	16	16
Additional paid in capital	229,655	213,872
Retained earnings (Accumulated deficit)	17,199	(25,659)
Treasury stock, at cost, 1,150,437 and 566,838 shares as of September 30, 2017 and December 31, 2016	(75,793)	(37,003)
Total stockholders' equity	171,077	151,226
Total liabilities and stockholders' equity	$ 266,890	$ 214,320

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue:				
Product sales	$ 6,905	$ 7,837	$ 34,895	$ 31,566
Royalty revenue	43,616	26,246	117,527	67,025
License and other income	12,500	3,750	37,500	9,750
Total revenue	63,021	37,833	189,922	108,341
Operating expenses:				
Cost of product sales	4,815	6,000	24,490	25,949
Cost of royalty revenue	6,850	4,425	18,990	10,538
Research and development	8,954	3,207	23,163	13,612
Selling, general and administrative	16,669	11,661	58,100	34,300
Gain on sale of asset	—	—	—	(1,750)
Asset impairment charges	7,235	—	7,235	—
Changes in fair value of contingent consideration	(6,452)	232	(5,604)	627
Total operating expenses	38,071	25,525	126,374	83,276
Income from operations	24,950	12,308	63,548	25,065
Interest income	35	26	52	76
Interest expense	(527)	(3)	(594)	(6)
Total other income	(492)	23	(542)	70

Income before income tax provision	24,458	12,331	63,006	25,135
Income tax provision	(9,027)	(379)	(20,148)	(983)
Net Income	$ 15,431	$ 11,952	$ 42,858	$ 24,152
Earnings per share attributable to common stockholders:				
Basic	$ 1.03	$ 0.77	$ 2.82	$ 1.55
Diluted	$ 0.98	$ 0.73	$ 2.68	$ 1.46
Weighted average number of common shares outstanding:				
Basic	15,047,917	15,570,740	15,174,426	15,614,328
Diluted	15,764,360	16,450,182	16,015,051	16,501,167

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Net income from operations - GAAP	$ 15,431	$ 11,952	$ 42,858	$ 24,152
Before tax adjustments:				
Cost of product revenues:				
Amortization of acquired intangible assets (1)	307	202	919	462
Gain on sale of asset (2)	-	-	-	(1,750)
Research and development:				
Share-based compensation expense	933	666	2,956	2,039
Selling, general and administrative:				
Share-based compensation expense	2,795	1,584	8,662	5,500
Amortization of acquired intangible assets (3)	405	-	1,216	-
Depreciation	225	164	657	461
Debt issuance costs	286	-	286	-
Other:				
Non-cash interest expense	77	3	144	3
Changes in fair value of contingent consideration (4)	(6,452)	232	(5,604)	627
Asset impairment charge	7,235	-	7,235	-
Tax adjustments (5)	(2,088)	(88)	(5,904)	(287)
Adjusted Non-GAAP net income	$ 19,154	$ 14,715	$ 53,425	$ 31,207
Adjusted Non-GAAP earnings per share				
Basic	$ 1.27	$ 0.95	$ 3.52	$ 2.00
Diluted	$ 1.22	$ 0.89	$ 3.34	$ 1.89
Weighted number of common shares outstanding:				
Basic	15,047,917	15,570,740	15,174,426	15,614,328
Diluted	15,764,360	16,450,182	16,015,051	16,501,167

Explanation of Adjustments:

(1) Amortization of intangible assets for Ryanodex and Docetaxel.
(2) Gain on divestiture of diclofenac-misoprostol.
(3) Amortization of intangible assets for Eagle Biologics.
(4) Changes in the fair value of contingent consideration (Docetaxel and Eagle Biologics).
(5) Reflects the estimated tax effect of the pretax adjustments.

EAGLE PHARMACEUTICALS
RECONCILIATION OF GAAP TO ADJUSTED NON-GAAP EBITDA
(In thousands)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Twelve Months Ended December 31,	Twelve Months Ended September 30,
	2017	2016	2017	2016	2016	2017
Net income from operations - GAAP	$ 15,431	$ 11,952	$ 42,858	$ 24,152	$ 81,453	$ 100,159
Add back:						
Interest expense (income), net	493	(23)	543	(70)	(76)	537
Provision for income taxes	9,027	379	20,148	983	(28,026)	(8,860)
Depreciation and amortization	936	366	2,790	922	1,589	3,457
Add back:			-			
Stock-based compensation	3,728	2,250	11,618	7,539	9,768	13,849
Changes in fair value of contingent consideration	(6,452)	232	(5,604)	627	957	(5,274)
Debt issuance costs	286	-	286	-	-	286
Asset impairment charges	7,235	-	7,235	-	-	7,235
Gain on sale of asset	-	-	-	(1,750)	(1,750)	-
Adjusted Non-GAAP EBITDA	$ 30,684	$ 15,156	$ 79,874	$ 32,403	$ 63,915	$ 111,389

EAGLE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands, except share and per share amounts)
(unaudited)

	Nine Months Ended September 30,	
	2017	2016
Cash flows from operating activities:		
Net income	$ 42,858	$ 24,152
Adjustments to reconcile net income to net cash provided by operating activities:		
Deferred income taxes	12,141	—
Depreciation expense	657	461
Amortization of intangible assets	2,135	461
Stock-based compensation	11,618	7,539
Change in fair value of contingent consideration	(5,604)	627
Amortization of debt issuance costs	128	—
Gain on sale of diclofenac-misoprostol	—	(1,750)
Asset impairment charge	7,235	—
Changes in operating assets and liabilities:		
Increase in accounts receivable	(29,407)	(20,783)
(Increase) decrease in inventories	(2,139)	7,936
Decrease (increase) in prepaid expenses and other current assets	3,227	(3,713)
Decrease in other assets	12	49
(Decrease) increase in accounts payable	(5,814)	7,747
Decrease in deferred revenue	—	(6,000)
Decrease in accrued expenses and other liabilities	(4,049)	(3,074)
Net cash provided by operating activities	32,998	13,652
Cash flows from investing activities:		
Purchase of property and equipment	(1,706)	(1,083)
Purchase of short term investments	—	(62,000)
Maturities of short term investments	—	62,000
Payment for business acquisition	—	(4,850)
Payment for intangible asset	(750)	(14,000)
Proceeds from sale of diclofenac-misoprostol	—	1,750
Net cash used in investing activities	(2,456)	(18,183)
Cash flows from financing activities:		

Proceeds from common stock option exercise	4,165	1,486
Payment of debt financing costs	(1,192)	—
Payment of contingent consideration	—	(230)
Proceeds from long-term debt	50,000	
Repurchases of common stock	(38,790)	(16,497)
Net cash provided by (used in) financing activities	14,183	(15,241)
Net increase (decrease) in cash	44,725	(19,772)
Cash and cash equivalents at beginning of period	52,820	79,083
Cash and cash equivalents at end of period	$ 97,545	$ 59,311
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Income taxes	$ 8,845	$ 2,800
Non-cash investing activities		
Non-cash financing activities		
Common stock repurchase not yet paid	—	1,500
Contingent consideration - business acquisition	—	6,370

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