Eagle Pharmaceuticals Reports Third Quarter 2019 Results

November 12, 2019

-- Net loss of $0.17 per basic and diluted share and adjusted non-GAAP net income of $0.27 per basic and $0.26 per diluted share in Q3 2019 --

-- Plan to initiate a clinical trial in December for Eagle's innovative fulvestrant program, which has the potential to result in greater inhibition of estrogen receptors and better outcomes for patients with estrogen receptor-positive breast cancer --

-- Company returned to 2019 Hajj and enrolled additional EHS patients in its controlled clinical study --

-- Eagle expects to file a supplement to the current NDA for the treatment of brain damage secondary to nerve agent exposure in the second half of 2020 --

WOODCLIFF LAKE, N.J--(BUSINESS WIRE)--Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced financial results for the three- and nine-month periods ended September 30, 2019. Third quarter and recent highlights include:

- Invested $12 million in research and development and external legal costs to advance Eagle's pipeline.
- Eagle's Japanese marketing partner, SymBio Pharmaceuticals Limited, submitted a New Drug Application ("NDA") for TREAKISYM, bendamustine ready-to-dilute liquid formulation, in Japan in September. Approval is expected in Q4 2020, which would trigger a $5 million milestone payment to Eagle. Potential payments to Eagle could reach $10 to $25 million per year in royalties and milestones.
- Advanced clinical development plans for Eagle's innovative fulvestrant program, which has the potential to change the treatment of estrogen receptor-positive breast cancer. The program aims to determine if the unique properties of Eagle's product will result in greater inhibition of estrogen receptors and better patient outcomes compared to currently available treatment options. The Company expects to dose the first subject in December.
- Enrolled additional patients in its controlled clinical study of RYANODEX® (dantrolene sodium for injectable suspension) for the treatment of exertional heat stroke ("EHS") patients during the 2019 Hajj pilgrimage held from August 9-14 in Saudi Arabia. The Company has recruited a total of 41 patients at the 2015, 2018 and 2019 Hajj pilgrimages. Eagle has submitted a plan to the U.S. Food and Drug Administration ("FDA") that proposes reviewing the data collectively for all 41 patients. If FDA agrees with this plan, Eagle plans to resubmit the NDA for EHS in response to the Complete Response Letter received in 2017.
- The Company, in dialogue with FDA, has received further clarity regarding RYANODEX for the treatment of brain damage secondary to nerve agent exposure. FDA has recommended that, under the animal rule, an additional study be conducted in a second species. Eagle expects to file a supplement to the current NDA in the second half of 2020.
- Total revenue for Q3 2019 was $41.1 million, compared to $51.3 million in Q3 2018, primarily reflecting lower BENDEKA® royalty revenue and lower product sales of BELRAPZO® and RYANODEX, partially offset by higher product sales of BENDEKA.
- Q3 2019 net loss was $2.4 million, or $0.17 per basic and diluted share, compared to net income of $14.0 million, or $0.94 per basic and $0.91 per diluted share in Q3 2018.
- Q3 2019 adjusted non-GAAP net income was $3.7 million, or $0.27 per basic and $0.26 per diluted share, compared to adjusted non-GAAP net income of $18.3 million, or $1.22 per basic and $1.18 per diluted share, in Q3 2018.
- Cash and cash equivalents were $117.2 million, net accounts receivable was $44.8 million, and debt was $40.0 million as of September 30, 2019.

"In the third quarter, we invested over $12 million to further advance our pipeline. This includes $9 million in non-GAAP R&D expense as well as $3 million in external legal expense related to the pemetrexed and vasopressin litigations. We are advancing our pipeline, as evidenced by the news today on EHS, nerve agent and the planned initiation of our next clinical trial for fulvestrant. We are also pleased that our bendamustine program is expanding to Japan, and we are expecting $10-$25 million in annual royalty and milestone payments beginning in 2021. This is an exciting time for Eagle as we move closer to realizing the full potential of many of our late-stage products," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

Third Quarter 2019 Financial Results

Total revenue for the three months ended September 30, 2019 was $41.1 million, as compared to $51.3 million for the three months ended September 30, 2018.

Royalty revenue was $26.5 million in the third quarter of 2019, compared to $35.2 million in the third quarter of 2018. BENDEKA royalties were $26.2 million in the third quarter of 2019, compared to $33.8 million in the third quarter of 2018. A summary of total revenue is outlined below:

Three Months Ended September 30,	
2019	2018
(unaudited)	(unaudited)

Revenue (in thousands):		
Product sales	14,659	16,163
Royalty revenue	26,488	35,174
Total revenue	41,147	51,337

Gross Margin was 64% during the third quarter of 2019, as compared to 75% in the third quarter of 2018. The compression in gross margin in the third quarter of 2019 was primarily driven by an increase in BENDEKA product sales to our marketing partner, on which Eagle earns no profit, and the decrease in BENDEKA royalty revenue.

R&D expense was $10.2 million for the third quarter of 2019, compared to $6.0 million in the third quarter of 2018. The increase is largely attributable to spending on fulvestrant and vasopressin. Excluding stock-based compensation and other non-cash and non-recurring items, R&D expense during the third quarter of 2019 was $9.0 million.

SG&A expense in the third quarter of 2019 increased to $18.5 million compared to $13.9 million in the third quarter of 2018. External legal spend associated with litigation on pemetrexed and vasopressin as well as higher stock compensation expense account for the year-over-year increase. Excluding stock-based compensation and other non-cash and non-recurring items, third quarter 2019 SG&A expense was $13.4 million.

Net loss for the third quarter of 2019 was $2.4 million, or $0.17 per basic and diluted share, compared to net income of $14.0 million, or $0.94 per basic and $0.91 per diluted share, in the third quarter of 2018, due to the factors discussed above.

Adjusted non-GAAP net income for the third quarter of 2019 was $3.7 million, or $0.27 per basic and $0.26 per diluted share, compared to adjusted non-GAAP net income of $18.3 million or $1.22 per basic and $1.18 per diluted share in the third quarter of 2018. 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.

2019 Expense Guidance

- R&D spend in 2019, on a non-GAAP basis, is expected to be $32.0-$36.0 million, as compared to $38.0 million in 2018.
- SG&A spend in 2019, on a non-GAAP basis, is expected to be $51.0-$54.0 million, as compared to $43.0 million in 2018.

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, 2019, the Company had $117.2 million in cash and cash equivalents plus $44.8 million in net accounts receivable, $34.4 million of which was due from Teva Pharmaceutical Industries Ltd. The Company had $40.0 million in outstanding debt. Therefore, at September 30, 2019, the Company had net cash plus receivables of $122.0 million.

Conference Call

As previously announced, Eagle management will host its third quarter 2019 conference call as follows:

Date	Tuesday, November 12, 2019
Time	8:30 A.M. EST
Toll free (U.S.)	866-342-8591
International	203-518-9713
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 800-839-4577 (US) or 402-220-2682 (International) and entering conference call ID EGRXQ319. 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,” “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 including, but not limited to: the Company’s clinical development plan for its fulvestrant formulation, as well as the development efforts for the other product candidates in its portfolio; the Company’s expense guidance for fiscal year 2019; the Company's ability to deliver value in 2019 and over the long term; 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 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 Eagle will successfully implement its development plan for its fulvestrant formulation or other product candidates; whether the FDA will ultimately approve the products in its pipeline for any indications; whether the Company can successfully market and commercialize its product candidates, including RYANODEX, BENDEKA and BELRAPZO, in the treatment of any indications; whether SymBio Pharmaceuticals Limited can successfully launch and commercialize TREAKISYM in Japan; 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; the success of our commercial relationships

with Teva and SymBio and the parties' ability to work effectively together; whether Eagle and its commercial partners will successfully perform their respective obligations under their respective agreements; 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 the 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; that Eagle's redirection of resources to other products in its pipeline may not be successful; and other factors that are discussed in Eagle's 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.

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 share-based compensation expense, depreciation, amortization of acquired intangible assets, changes in fair value of contingent consideration, severance, non-cash interest expense, expense of acquired in-process research and development, asset impairment charge, restructuring charge and the tax impact 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, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 117,211	$ 78,791
Accounts receivable, net	44,812	66,486
Inventories	7,247	8,304
Prepaid expenses and other current assets	10,516	10,263
Total current assets	179,786	163,844
Property and equipment, net	2,319	2,397
Intangible assets, net	16,213	18,103
Goodwill	39,743	39,743
Deferred tax asset, net	13,997	13,822
Other assets	4,980	694
Total assets	$ 257,038	$ 238,603
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 11,232	$ 9,917
Accrued expenses and other liabilities	27,127	23,519
Current portion of long-term debt	4,000	6,250
Total current liabilities	42,359	39,686
Other long-term liabilities	3,227	—
Long-term debt, less current portion	35,687	38,155
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of September 30, 2019 and December 31, 2018	—	—

Common stock, $0.001 par value; 50,000,000 shares authorized; 16,524,848 and 16,504,283 shares issued as of September 30, 2019 and December 31, 2018, respectively	17	17
Additional paid in capital	273,153	256,458
Retained earnings	71,495	58,187
Treasury stock, at cost, 2,855,316 and 2,590,258 shares as of September 30, 2019 and December 31, 2018, respectively	(168,900)	(153,900)
Total stockholders' equity	175,765	160,762
Total liabilities and stockholders' equity	$ 257,038	$ 238,603

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue:				
Product sales	$ 14,659	$ 16,163	$ 58,568	$ 50,042
Royalty revenue	26,488	35,174	80,066	107,216
License and other revenue	—	—	9,000	—
Total revenue	41,147	51,337	147,634	157,258
Operating expenses:				
Cost of product sales	12,137	8,621	39,866	29,919
Cost of royalty revenue	2,785	4,370	9,440	13,440
Research and development	10,172	5,975	25,504	38,560
Selling, general and administrative	18,537	13,878	53,906	45,033
Restructuring charge	—	91	—	7,479
Asset impairment charge	—	—	—	2,704
Change in fair value of contingent consideration	—	—	—	(763)
Total operating expenses	43,631	32,935	128,716	136,372
(Loss) Income from operations	(2,484)	18,402	18,918	20,886
Interest income	570	9	1,701	36
Interest expense	(628)	(743)	(1,979)	(2,118)
Total other expense, net	(58)	(734)	(278)	(2,082)
(Loss) Income before income tax benefit (provision)	(2,542)	17,668	18,640	18,804
Income tax benefit (provision)	152	(3,628)	(5,332)	509
Net (Loss) Income	$ (2,390)	$ 14,040	$ 13,308	$ 19,313
(Loss) Earnings per share attributable to common stockholders:				
Basic	$ (0.17)	$ 0.94	$ 0.96	$ 1.30
Diluted	$ (0.17)	$ 0.91	$ 0.94	$ 1.25
Weighted average number of common shares outstanding:				
Basic	13,668,091	15,011,159	13,791,071	14,903,945
Diluted	13,668,091	15,483,037	14,147,658	15,482,768

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

	Nine Months Ended September 30,	
	2019	2018
Cash flows from operating activities:		
Net income	$ 13,308	$ 19,313
Adjustments to reconcile net income to net cash provided by operating activities:		
Deferred income taxes	(175)	2,040
Depreciation expense	1,479	918
Amortization expense	1,890	1,916
Stock-based compensation expense	16,815	14,512

Change in fair value of contingent consideration	—	(763)
Amortization of debt issuance costs	282	282
Asset impairment charge	—	2,704
Non-cash restructuring charge	—	5,771
Changes in operating assets and liabilities which provided (used) cash:		
Accounts receivable	21,674	(24,640)
Inventories	1,057	(4,525)
Prepaid expenses and other current assets	(253)	(5,709)
Accounts payable	1,315	(4,437)
Accrued expenses and other liabilities	3,608	7,476
Other assets and other long-term liabilities, net	(1,813)	(582)
Net cash provided by operating activities	59,187	14,276
Cash flows from investing activities:		
Purchase of property and equipment	(647)	(52)
Net cash used in investing activities	(647)	(52)
Cash flows from financing activities:		
Proceeds from common stock option exercises	78	8,601
Payments related to employee net option exercises	—	(4,877)
Employee withholding taxes related to stock-based awards	(198)	—
Payment of contingent consideration	—	(15,001)
Payment of debt	(5,000)	(3,750)
Repurchases of common stock	(15,000)	(22,628)
Net cash used in financing activities	(20,120)	(37,655)
Net increase (decrease) in cash and cash equivalents	38,420	(23,431)
Cash and cash equivalents at beginning of period	78,791	114,657
Cash and cash equivalents at end of period	$ 117,211	$ 91,226
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Income taxes, net	$ 6,587	$ 1,887
Interest	1,787	1,540

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,	
	2019	2018	2019	2018
Net (loss) income - GAAP	$ (2,390)	$ 14,040	$ 13,308	$ 19,313
Adjustments:				
Cost of product revenues:				
Amortization expense	225	194	675	701
Research and development:				
Stock-based compensation expense	1,081	831	3,320	3,094
Depreciation expense	71	66	210	405
Expense of acquired in-process research & development	-	-	-	1,200
Severance	-	68	-	466
Selling, general and administrative:				
Stock-based compensation expense	4,570	3,641	13,495	11,418
Amortization expense	405	405	1,215	1,215
Depreciation expense	171	169	515	513
Other:				
Non-cash interest expense	94	94	282	282
Change in fair value of contingent consideration	-	-	-	(763)
Asset impairment charge	-	-	-	2,704
Restructuring charge	-	91	-	7,479
Tax effect of the non-GAAP adjustments	(556)	(1,334)	(2,875)	(6,868)

Adjusted non-GAAP net income	$ 3,671	$ 18,265	$ 30,145	$ 41,159
Adjusted non-GAAP earnings per share:				
Basic	$ 0.27	$ 1.22	$ 2.19	$ 2.76
Diluted	$ 0.26	$ 1.18	$ 2.13	$ 2.66
Weighted number of common shares outstanding:				
Basic	13,668,091	15,011,159	13,791,071	14,903,945
Diluted	14,120,025	15,483,037	14,147,658	15,482,768

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,
	2019	2018	2019	2018	2019	2018
Net (loss) income - GAAP	$ (2,390)	$ 14,040	$ 13,308	$ 19,313	$ 25,898	$ 31,903
Add back:						
Interest expense, net of interest income	58	734	278	2,083	774	2,579
Income tax (benefit) provision	(152)	3,628	5,332	(509)	7,976	2,135
Depreciation and amortization expense	872	834	2,615	2,834	3,451	3,670
Add back:						
Stock-based compensation expense	5,651	4,472	16,815	14,512	21,385	19,082
Change in fair value of contingent consideration	-	-	-	(763)	-	(763)
Asset impairment charge	-	-	-	2,704	-	2,704
Expense of acquired in-process research & development	-	-	-	1,200	500	1,700
Severance	-	68	-	466	-	466
Restructuring charge	-	91	-	7,479	432	7,911
Adjusted Non-GAAP EBITDA	$ 4,039	$ 23,867	$ 38,348	$ 49,319	$ 60,416	$ 71,387

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

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