



Eagle Pharmaceuticals Reports Second Quarter 2020 Results

August 10, 2020

- Q2 2020 net loss was (\$0.02) per basic and diluted share and adjusted non-GAAP net income was \$0.59 per basic and \$0.57 per diluted share--
- Anticipate launch of vasopressin, maintaining our 180-day market exclusivity --
- CMS establishes unique J-code for PEMFEXY™ (pemetrexed for injection); FDA granted supplement approval for 500mg multiple-dose vial --
- Received positive additional data for the Company's fulvestrant product candidate, EA-114, for HR-positive advanced breast cancer --
- Received a Complete Response Letter for NDA for RYANODEX for EHS --

WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)-- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced financial results for the three and six months ended June 30, 2020.

Business and Recent Highlights:

- Centers for Medicare & Medicaid Services ("CMS") established unique Healthcare Common Procedure Coding System ("HCPCS") code, or J-code, for PEMFEXY™ (Pemetrexed for Injection, 10 mg), a branded alternative to ALIMTA® effective October 1, 2020;
- Granted a supplement approval by U.S. Food and Drug Administration ("FDA") for 500mg multiple-dose vial of PEMFEXY. The Company has initial market entry (equivalent to approximately a three-week supply of current ALIMTA utilization) on February 1, 2022, and a subsequent uncapped entry on April 1, 2022;
- The Company's strategic collaboration partner, Tyme Technologies, Inc. ("Tyme"), announced that FDA granted Orphan Drug Designation for its lead product candidate, SM-88, a treatment for patients with pancreatic cancer;
- On August 7, 2020, the Company received a Complete Response Letter for its New Drug Application ("NDA") for RYANODEX® for the treatment of exertional heat stroke ("EHS"); Eagle has decided that it will no longer pursue this indication;
- Received encouraging recent additional data for the Company's fulvestrant product candidate, EA-114, for HR-positive advanced breast cancer; next steps are to meet with FDA to finalize clinical trial plans; product could potentially represent cornerstone of Eagle's oncology franchise treating HR positive breast cancer patients;
- Favorable patent litigation decision issued by the U.S. District Court for the District of Delaware for Eagle and Teva Pharmaceutical Industries Ltd. for BENDEKA® upholding the asserted patent claims as valid and infringed by the defendants' proposed Abbreviated New Drug Application ("ANDA") products. Under this decision, defendants are enjoined from launching their ANDA products before 2031;
- Symbio, the Company's Japanese licensing partner, announced that it expects regulatory approval of its TREAKISYM Ready-to-Dilute ("RTD") formulation late this year. Eagle is entitled to receive a \$5 million milestone payment upon approval of either TREAKISYM Ready-to-Dilute or TREAKISYM Rapid Infusion, as well as royalties and milestones that could total \$10 to \$25 million per year if Symbio first launches TREAKISYM RTD and then its Rapid Infusion product; and
- Despite the ongoing COVID-19 pandemic, the Company has not experienced significant disruptions to its supply chain to date, and believes it has sufficient supply chain inventory to continue manufacturing and to provide product without interruption consistent with its current business plan; the Company has experienced limited impacts on the timing of its pre-clinical programs due to the COVID-19 pandemic; the Company continues to monitor the ongoing pandemic and evaluate and evolve its business plans and response strategy thereto.

Second Quarter 2020 Financial Highlights

- Total revenue for Q2 2020 was \$41.9 million, compared to \$56.7 million in Q2 2019, primarily reflecting lower product sales of BELRAPZO® and BENDEKA, partially offset by higher product sales of RYANODEX.
- Net loss for Q2 2020 was \$0.3 million, or (\$0.02) per basic and diluted share, compared to net income for Q2 2019 of \$6.7 million, or \$0.49 per basic and \$0.48 per diluted share.
- Adjusted non-GAAP net income for Q2 2020 was \$8.0 million, or \$0.59 per basic and \$0.57 per diluted share, compared to adjusted non-GAAP net income for Q2 2019 of \$11.8 million, or \$0.86 per basic and \$0.84 per diluted share.
- Cash and cash equivalents were \$108.2 million, net accounts receivable was \$46.8 million, and debt was \$37.0 million as of June 30, 2020.

"We had an excellent start to the first half of the year, advancing our exciting pipeline of oncology and critical care products. Our ANDA and orphan drug exclusivity legal wins for BENDEKA, CMS' decision to establish a separate J-Code and supplement approval for the 500mg dose for PEMFEXY, along with continued progress on our fulvestrant product candidate and the opportunity for vasopressin, supports the diversification and acceleration of Eagle's earnings power," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

"We're also pleased with our collaborations with Tyme, NorthShore University HealthSystem, and UPenn to advance important products. Furthermore, we have made progress on the study of RYANODEX for the treatment of brain damage secondary to Nerve Agent exposure, as we continue to pursue expanded indications. We have important work ahead in the second half of the year, regardless of EHS, and we will continue to identify opportunities that fulfill our strategic vision and bring innovative therapeutics to the patients who can benefit," concluded Tarriff.

Second Quarter 2020 Financial Results

Total revenue for Q2 2020 was \$41.9 million, as compared to \$56.7 million for Q2 2019.

Q2 2020 BELRAPZO product sales were \$4.1 million, compared to \$15.4 million in Q2 2019. Second quarter 2019 BELRAPZO revenue reflected wholesaler stocking occasioned by the June 2019 transition to the branded name.

Q2 2020 RYANODEX product sales were \$4.7 million, compared to \$2.9 million in Q2 2019.

Royalty revenue was \$27.6 million in the second quarter of 2020, compared to \$27.3 million in the second quarter of 2019. BENDEKA royalties were \$27.5 million in the second quarter of 2020, compared to \$26.5 million in the second quarter of 2019. A summary of total revenue is outlined below:

	Three Months Ended March 31,	
	2020 (unaudited)	2019 (unaudited)
Revenue (in thousands):		
Product sales	\$14,376	\$29,437
Royalty revenue	27,562	27,265
Total revenue	\$41,938	\$56,702

Gross margin was 69% during the second quarter of 2020, as compared to 62% in the second quarter of 2019. The expansion in gross margin in the second quarter of 2020 was driven by an increase in RYANODEX product sales, lower BENDEKA product sales in the period to the Company's marketing partner, on which Eagle earns no profit, and the increase in BENDEKA royalty revenue.

R&D expense was \$7.1 million for the second quarter of 2020, compared to \$9.0 million in the second quarter of 2019. The change primarily resulted from a decrease in spending for vasopressin, partly offset by an increase in spending for the Company's fulvestrant product candidate. Excluding stock-based compensation and other non-cash and non-recurring items, R&D expense during the second quarter of 2020 was \$6.0 million.

SG&A expense in the second quarter of 2020 increased to \$18.0 million compared to \$17.2 million in the second quarter of 2019. The change primarily resulted from an increase in stock compensation expense, partially offset by decreases in T&E, trade show costs, and external legal expenses. Excluding stock-based compensation and other non-cash and non-recurring items, second quarter 2020 SG&A expense was \$12.2 million.

Net loss for the second quarter of 2020 was \$0.3 million, or (\$0.02) per basic and diluted share, compared to net income of \$6.7 million, or \$0.49 per basic and \$0.48 per diluted share, in the second quarter of 2019.

Adjusted non-GAAP net income for the second quarter of 2020 was \$8.0 million, or \$0.59 per basic and \$0.57 per diluted share, compared to adjusted non-GAAP net income of \$11.8 million or \$0.86 per basic and \$0.84 per diluted share in the second quarter of 2019. 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.

2020 Expense Guidance

- As a result of COVID-related delays, with respect to our pre-clinical programs, we are lowering our previously reported 2020 R&D Non-GAAP expense guidance to \$40 million-\$44 million, as compared to \$31 million in 2019.
- SG&A spend in 2020, on a non-GAAP basis, is expected to be \$61-\$64 million, as compared to \$56 million in 2019.

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 June 30, 2020, the Company had \$108.2 million in cash and cash equivalents plus \$46.8 million in net accounts receivable, \$35.7 million of which was due from Teva. The Company had \$37.0 million in outstanding debt. Therefore, at June 30, 2020, the Company had net cash plus receivables of \$118.0 million. In the second quarter of 2020, the Company repaid the full \$110.0 million amount borrowed under its revolving credit facility.

In the second quarter of 2020, the Company repurchased \$4.0 million of Eagle's common stock as part of the share repurchase program. From August 2016 through June 30, 2020, the Company repurchased \$176.9 million of its common stock.

Conference Call

As previously announced, Eagle management will host its second quarter 2020 conference call as follows:

Date	Monday, August 10, 2020
Time	8:30 A.M. ET
Toll free (U.S.)	877-876-9173
International	785-424-1667
Webcast (live and replay)	www.eagleus.com , under the "Investor + News" section

Participants should dial in 15 minutes prior to the start of the call to ensure timely access.

A replay of the conference call will be available for one week after the call's completion by dialing 800-839-4014 (US) or 402-220-2983 (International) and entering conference call ID EGRXQ220. 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 Company's expectations regarding the current and anticipated impact of the ongoing COVID-19 pandemic on the Company's business and operations, including sales, marketing, manufacturing and supply chain interruptions; the number and timing of potential product launches, development initiatives and new indications for RYANODEX, including for the treatment of brain damage secondary to Nerve Agent exposure; the Company's clinical development plan for its fulvestrant product candidate, EA-114, as well as the development efforts for the other product candidates in its portfolio; the timing of the Company's PEMFEXY and vasopressin launches, if ever; the period of market exclusivity for vasopressin; the success of the Company's collaborations with its strategic partners; the Company's expense guidance for fiscal year 2020; the Company's expectations with respect to earnings power, including statements regarding the Company's ability to diversify and accelerate earnings power; the Company's ability to deliver value in 2020 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 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 ongoing 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 continued 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 fulvestrant product candidate, EA-114, or other 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, including RYANODEX, BENDEKA and BELRAPZO; the success of the Company's relationships with its partners, including the University of Pennsylvania, Teva, Tyme and NorthShore University HealthSystem and the parties' ability to work effectively together; 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" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed with the Securities and Exchange Commission on March 2, 2020 and its other subsequent filings with the Securities and Exchange Commission. 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 stock-based compensation expense, depreciation expense, amortization expense, severance, non-cash interest expense, expense related to collaboration with Tyme, fair value adjustments on equity investment, 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 --

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

	June 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 108,213	\$ 109,775
Accounts receivable, net	46,781	48,004
Inventories	7,891	6,566
Prepaid expenses and other current assets	5,551	15,104
Total current assets	168,436	179,449
Property and equipment, net	2,118	2,202
Intangible assets, net	14,250	15,583
Goodwill	39,743	39,743
Deferred tax asset, net	14,585	13,669
Other assets	17,578	3,908
Total assets	\$ 256,710	\$ 254,554
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 13,708	\$ 5,462
Accrued expenses and other liabilities	19,778	28,361
Current portion of long-term debt	7,000	5,000
Total current liabilities	40,486	38,823
Other long-term liabilities	3,361	3,000
Long-term debt, less current portion	28,899	33,557
Total liabilities	72,746	75,380
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of June 30, 2020 and December 31, 2019	—	—
Common stock, \$0.001 par value; 50,000,000 shares authorized; 16,621,681 and 16,537,846 shares issued as of June 30, 2020 and December 31, 2019, respectively	17	17
Additional paid in capital	291,434	278,518
Retained earnings	69,373	72,500
Treasury stock, at cost, 3,017,710 and 2,907,687 shares as of June 30, 2020 and December 31, 2019, respectively	(176,860)	(171,861)
Total stockholders' equity	183,964	179,174
Total liabilities and stockholders' equity	\$ 256,710	\$ 254,554

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue:				
Product sales	\$ 14,376	\$ 29,437	\$ 32,070	\$ 43,909
Royalty revenue	27,562	27,265	55,888	53,578
License and other revenue	—	—	—	9,000
Total revenue	41,938	56,702	87,958	106,487
Operating expenses:				
Cost of product sales	10,313	18,175	15,078	27,729
Cost of royalty revenue	2,822	3,109	5,860	6,655
Research and development	7,135	8,957	16,562	15,332
Selling, general and administrative	17,959	17,228	42,714	35,369
Total operating expenses	38,229	47,469	80,214	85,085
Income from operations	3,709	9,233	7,744	21,402

Interest income	150	637	496	1,131
Interest expense	(786)	(665)	(1,675)	(1,351)
Other income (expense)	2,300	—	(4,200)	—
Total other income (expense), net	1,664	(28)	(5,379)	(220)
Income before income tax provision	5,373	9,205	2,365	21,182
Income tax provision	(5,629)	(2,480)	(5,492)	(5,484)
Net (Loss) Income	\$ (256)	\$ 6,725	\$ (3,127)	\$ 15,698
(Loss) Earnings per share attributable to common stockholders:				
Basic	\$ (0.02)	\$ 0.49	\$ (0.23)	\$ 1.13
Diluted	\$ (0.02)	\$ 0.48	\$ (0.23)	\$ 1.11
Weighted average number of common shares outstanding:				
Basic	13,664,951	13,782,720	13,666,279	13,853,580
Diluted	13,664,951	14,156,627	13,666,279	14,176,297

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

	Six Months Ended June 30,	
	2020	2019
Cash flows from operating activities:		
Net (loss) income	\$ (3,127)	\$ 15,698
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Deferred income taxes	(916)	(127)
Depreciation expense	931	1,005
Amortization expense	1,333	1,260
Fair value adjustments on equity investment	4,200	—
Stock-based compensation expense	13,713	11,164
Amortization of debt issuance costs	183	188
Changes in operating assets and liabilities which provided (used) cash:		
Accounts receivable	1,223	6,147
Inventories	(1,325)	(3,290)
Prepaid expenses and other current assets	9,553	4,665
Accounts payable	8,246	7,379
Accrued expenses and other liabilities	(8,583)	4,880
Other assets and other long-term liabilities, net	(1,321)	(396)
Net cash provided by operating activities	<u>24,110</u>	<u>48,573</u>
Cash flows from investing activities:		
Purchase of equity investment security	(17,500)	—
Purchase of property and equipment	(376)	(343)
Net cash used in investing activities	<u>(17,876)</u>	<u>(343)</u>
Cash flows from financing activities:		
Proceeds from common stock option exercises	513	55
Employee withholding taxes related to stock-based awards	(1,310)	(198)
Proceeds from existing revolving credit facility	110,000	—
Repayment of existing revolving credit facility	(110,000)	—
Payment of debt	(2,000)	(3,750)
Repurchases of common stock	(4,999)	(15,000)
Net cash used in financing activities	<u>(7,796)</u>	<u>(18,893)</u>
Net (decrease) increase in cash and cash equivalents	(1,562)	29,337
Cash and cash equivalents at beginning of period	109,775	78,791
Cash and cash equivalents at end of period	\$ 108,213	\$ 108,128
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Income taxes, net	\$ 502	\$ 2,874
Interest	1,458	1,221
Right-of-use asset obtained in exchange for lease obligation - lease amendment	842	2,871

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net (loss) income - GAAP	\$ (256)	\$ 6,725	\$ (3,127)	\$ 15,698
Adjustments:				
Cost of product revenues:				
Amortization expense	262	225	523	450
Research and development:				
Stock-based compensation expense	1,034	1,096	2,584	2,239
Depreciation expense	60	70	134	139
Selling, general and administrative:				
Stock-based compensation expense	5,207	4,286	11,129	8,925
Expense related to collaboration with Tyme	-	-	2,500	-
Amortization expense	405	405	810	810
Depreciation expense	149	172	326	344
Severance	-	-	245	-
Other:				
Non-cash interest expense	118	94	236	188
Fair value adjustments on equity investment	(2,300)	-	4,200	-
Tax effect of the non-GAAP adjustments	3,344	(1,228)	(3,457)	(2,319)
Adjusted non-GAAP net income	\$ 8,023	\$ 11,845	\$ 16,103	\$ 26,474
Adjusted non-GAAP earnings per share:				
Basic	\$ 0.59	\$ 0.86	\$ 1.18	\$ 1.91
Diluted	\$ 0.57	\$ 0.84	\$ 1.15	\$ 1.87
Weighted number of common shares outstanding:				
Basic	13,664,951	13,782,720	13,666,279	13,853,580
Diluted	13,971,725	14,156,627	13,983,093	14,176,297

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

	Three Months Ended June 30,		Six Months Ended June 30,		Twelve Months Ended June 30,	Twelve Months Ended December 31,
	2020	2019	2020	2019	2020	2019
Net (loss) income - GAAP	\$ (256)	\$ 6,725	\$ (3,127)	\$ 15,698	\$ (4,512)	\$ 14,313
Add back:						
Interest expense, net of interest income	636	28	1,179	220	1,476	517
Income tax provision	5,629	2,480	5,492	5,484	7,693	7,685
Depreciation and amortization expense	876	872	1,793	1,743	3,542	3,492
Add back:						
Stock-based compensation expense	6,241	5,382	13,713	11,164	24,547	21,998
Debt issuance cost	-	-	-	-	88	88
Fair value adjustments on equity investment	(2,300)	-	4,200	-	4,200	-

Expense of acquired in-process research & development	-	-	-	-	500	500
Expense related to collaboration with Tyme	-	-	2,500	-	2,500	-
Severance	-	-	245	-	700	455
Adjusted Non-GAAP EBITDA	\$ 10,826	\$ 15,487	\$ 25,995	\$ 34,309	\$ 40,734	\$ 49,048

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