

Eagle Pharmaceuticals Reports First Quarter 2020 Results

May 11, 2020

-- Q1 2020 net loss was (\$0.21) per basic and diluted share and adjusted non-GAAP net income was \$0.86 per basic and \$0.84 per diluted share---

-- Advanced novel fulvestrant product candidate, EA-114, which has the potential to enhance estrogen receptor ("ER") inhibition in advanced hormonereceptor ("HR")-positive breast cancer --

- -- Received favorable patent litigation decision for BENDEKA® (bendamustine hydrochloride injection); ANDA holders to be enjoined from launching prior to 2031 --
 - -- Preparing for multiple potential product launches in the next three years; 13 ongoing initiatives underway including six additional potential new indications for RYANODEX --

WOODCLIFF LAKE, N.J--(BUSINESS WIRE)-- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced financial results for the three months ended March 31, 2020.

Business and Recent Highlights:

- Despite the ongoing COVID-19 pandemic, the Company has not experienced any impact 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;
- Advanced pilot work on proprietary formulation of fulvestrant product candidate, EA-114, for HR-positive advanced breast cancer, met internal objectives, and requested additional meeting with U.S. Food and Drug Administration ("FDA") to discuss regulatory path forward;
- Submitted Investigational New Drug ("IND") application to FDA for a Phase 2 clinical trial in partnership with Hackensack University Medical Center to evaluate the efficacy of RYANODEX (dantrolene sodium) in patients infected with SARS-CoV-2, the virus causing the COVID-19 pandemic;
- 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 ANDA products. Defendants will be enjoined from launching their ANDA products before 2031;
- Received United States Court of Appeals for the D.C. Circuit affirmation of district court decision requiring FDA to recognize seven years of orphan drug exclusivity for BENDEKA. Accordingly, the Company does not believe other bendamustine products to treat the same indication, unless clinically superior to BENDEKA, will enter the market before 2022;
- July 8, 2020 Prescription Drug User Fee Act ("PDUFA") date for the Company's resubmitted New Drug Application ("NDA") for RYANODEX for the treatment of exertional heat stroke ("EHS"), in conjunction with body cooling;
- Letter requesting summary judgment of non-infringement related to vasopressin filed with the United States District Court for the District of Delaware on April 17, after May trial date was postponed due to the COVID pandemic. Eagle is the first to file an ANDA referencing VASOSTRICT, 20 units/1mL;
- SymBio, the Company's Japanese licensing partner, announced completion of patient enrollment in its clinical trial for TREAKISYM Rapid Infusion ("RI"), a liquid bendamustine injection with a ten-minute administration time, with expected regulatory approval in the second half of 2022. Eagle is entitled to a \$5 million milestone payment upon approval of either TREAKISYM Ready-to-Dilute, filed on October 7, 2019, or RI, as well as royalties and milestones that could total \$10 to \$25 million per year if SymBio first launches TREAKISYM RTD and then its RI product;
- Received final approval from FDA for PEMFEXY[™], a branded alternative to ALIMT[®], following settlement of patent litigation with Eli Lilly and Company. This allows for 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;
- Announced collaboration and agreement on terms for an exclusive worldwide license with the University of Pennsylvania to develop dantrolene sodium for the potential treatment of people living with Alzheimer's disease;
- Entered into strategic collaboration with Tyme Technologies, Inc. ("Tyme") to advance SM-88, a modified tyrosine derivative, for the treatment of cancer patients. Eagle made an initial investment of \$20 million and will be responsible for 25% of the promotional sales efforts of SM-88 and will receive 15% royalty on net revenues of SM-88 in the United States. Tyme retains all commercial rights to SM-88 outside the U.S. and reserves the right to repurchase Eagle's U.S. co-promotion right for \$200 million; and
- Entered into a research agreement with NorthShore University HealthSystem to study RYANODEX for the treatment of traumatic brain injury, including concussion, for which there are currently no drug treatments.

- Total revenue for Q1 2020 was \$46.0 million, compared to \$49.8 million in Q1 2019, primarily reflecting lower product sales of BENDEKA, partially offset by higher product sales of RYANODEX and BELRAPZO[®].
- Net loss for Q1 2020 was \$2.9 million, or (\$0.21) per basic and diluted share, compared to net income for Q1 2019 of \$9.0 million, or \$0.64 per basic and \$0.62 per diluted share.
- Adjusted non-GAAP net income for Q1 2020 was \$11.7 million, or \$0.86 per basic and \$0.84 per diluted share, compared to adjusted non-GAAP net income for Q1 2019 of \$14.6 million, or \$1.05 per basic and \$1.01 per diluted share.
- Cash and cash equivalents were \$202.0 million, net accounts receivable was \$54.5 million, and debt was \$148.0 million as of March 31, 2020.
- Approved a new share repurchase program, which replaced the Company's existing share repurchase program, providing for the repurchase of up to an aggregate of \$160.0 million of the Company's outstanding common stock.

"The momentum from late last year has continued into the first quarter of 2020, including advancing fulvestrant, receiving extended patent protection and orphan drug exclusivity affirmation for BENDEKA, and proceeding with other initiatives for RYANODEX. We believe that we are well positioned to realize the full potential of our robust portfolio of oncology and CNS/metabolic critical care products and pipeline candidates, given our strong cash flow and several potential near-term catalysts," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

First Quarter 2020 Financial Results

Total revenue for Q1 2020 was \$46.0 million, as compared to \$49.8 million for Q1 2019.

Q1 2020 BELRAPZO product sales were \$4.6 million, compared to \$3.2 million in Q1 2019.

Q1 2020 RYANODEX product sales were \$11.4 million, compared to \$4.0 million in Q1 2019.

Royalty revenue was \$28.3 million in the first quarter of 2020, compared to \$26.3 million in the first quarter of 2019. BENDEKA royalties were \$28.0 million in the first quarter of 2020, compared to \$26.0 million in the first quarter of 2019. A summary of total revenue is outlined below:

	Three Months End	ed March 31,
	2020	2019
	(unaudited)	(unaudited)
Revenue (in thousands):		
Product sales	\$17,694	\$14,472
Royalty revenue	28,326	26,313
License and other revenue	-	9,000
Total revenue	\$46,020	\$49,785

Gross margin was 83% during the first quarter of 2020, as compared to 74% in the first quarter of 2019. The expansion in gross margin in the first 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 \$9.4 million for the first quarter of 2020, compared to \$6.4 million in the first quarter of 2019. The year-over-year increase is largely attributable to spending related to its fulvestrant product candidate as well as payroll expenses. Excluding stock-based compensation and other non-cash and non-recurring items, R&D expense during the first quarter of 2020 was \$7.8 million.

SG&A expense in the first quarter of 2020 increased to \$24.8 million compared to \$18.1 million in the first quarter of 2019. External legal spend, external sales and marketing spend, and stock-based compensation expense, as well as a \$2.5 million expense related to the collaboration with Tyme, account for most of the year-over-year increase. Excluding stock-based compensation and other non-cash and non-recurring items, first quarter 2020 SG&A expense was \$15.5 million.

Net loss for the first quarter of 2020 was \$2.9 million, or (\$0.21) per basic and diluted share, compared to net income of \$9.0 million, or \$0.64 per basic and \$0.62 per diluted share, in the first quarter of 2019.

Adjusted non-GAAP net income for the first quarter of 2020 was \$11.7 million, or \$0.86 per basic and \$0.84 per diluted share, compared to adjusted non-GAAP net income of \$14.6 million or \$1.05 per basic and \$1.01 per diluted share in the first 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

- R&D spend in 2020, on a non-GAAP basis, is expected to be \$46-\$50 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 March 31, 2020, the Company had \$202.0 million in cash and cash equivalents plus \$54.5 million in net accounts receivable, \$34.5 million of which was due from Teva. The Company had \$148 million in outstanding debt, including \$110.0 million drawn on its revolving credit facility. Therefore, at March 31, 2020, the Company had net cash plus receivables of \$108.5 million. Since March 31, the Company has re-paid the full \$110.0 million drawn under its revolving credit facility.

On March 17, 2020, the Company announced that Eagle's Board of Directors approved a new share repurchase program, which replaced the Company's existing share repurchase program providing for the repurchase of up to an aggregate of \$160.0 million of the Company's outstanding common stock. In the first quarter of 2020, the Company repurchased \$1.0 million of Eagle's common stock as part of the share repurchase program. From August 2016 through March 31, 2020, the Company repurchased \$172.9 million of its common stock.

Conference Call

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

Date	Monday, May 11, 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 800-839-6803 (US) or 402-220-6056 (International) and entering conference call ID EGRXQ120. 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 <u>www.eagleus.com</u>.

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 anticipated and potential 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; 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 potential benefits and efficacy of RYANODEX, including the potential for RYANODEX to be a possible therapeutic option for patients with SARS-CoV-2 infection and expansion into other potential indications; preclinical data of RYANODEX for the treatment of patients with SARS-CoV-2 infection and the progress and development of RYANODEX in a Phase 2 clinical trial evaluating RYANODEX as a treatment for patients with SARS-CoV-2 infection; the potential for other products treating the same indication as BENDEKA entering the market before 2022; the potential of dantrolene sodium as a treatment for Alzheimer's disease; the timing of the Company's PEMFEXY launch, if ever; the success of the Company's collaborations with its strategic partners; 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 expense guidance for fiscal year 2020; 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 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; risks that results from in vitro laboratory tests of RYANODEX are not necessarily predictive of future clinical trial and in vivo results; 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 Hackensack University Medical Center, 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 --

EAGLE PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (In thousands, except share amounts)

		ch 31, 2020 naudited)	De	cember 31, 2019
ASSETS				
Current assets:				
Cash and cash equivalents	\$	202,016	\$	109,775
Accounts receivable, net		54,491		48,004
Inventories		8,434		6,566
Prepaid expenses and other current assets		10,631		15,104
Total current assets		275,572		179,449
Property and equipment, net		2,423		2,202
Intangible assets, net		14,917		15,583
Goodwill		39,743		39,743
Deferred tax asset, net		13,759		13,669
Other assets	,	15,530		3,908
Total assets	\$	361,944	\$	254,554
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	9,756	\$	5,462
Accrued expenses and other liabilities		20,123		28,361
Current portion of long-term debt		116,000		5,000
Total current liabilities		145,879		38,823
Other long-term liabilities		3,454		3,000
Long-term debt, less current portion		30,781		33,557
Total liabilities		180,114		75,380
Commitments and Contingencies				
Stockholders' equity:				
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of March 31, 2020 and December 31, 2019				_
Common stock, \$0.001 par value; 50,000,000 shares authorized; 16,597,814 and 16,537,846 shares issued as of March 31, 2020 and December 31, 2019, respectively		17		17
Additional paid in capital		285,044		278,518
Retained earnings		69,629		72,500
Treasury stock, at cost, 2,933,320 and 2,907,687 shares as of March 31, 2020 and December 31, 2019, respectively		(172,860)		(171,861)
Total stockholders' equity		181,830		179,174
Total liabilities and stockholders' equity	\$	361,944	\$	254,554

EAGLE PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts) (unaudited)

	Th	Three Months Ended March 31,			
	_	2020		2019	
Revenue:					
Product sales	\$	17.694	\$	14,472	
Royalty revenue	•	28,326		26,313	
License and other revenue				9,000	
Total revenue		46,020		49,785	
Operating expenses:					
Cost of product sales		4,765		9,554	
Cost of royalty revenue		3,038		3,546	
Research and development		9,427		6,375	
Selling, general and administrative		24,755		18,141	
Total operating expenses		41,985		37,616	
Income from operations		4,035	_	12,169	
Interest income		346		494	
Interest expense		(889)		(686)	
Other expense		(6,500)			
Total other expense, net		(7,043)		(192)	
(Loss) Income before income tax benefit (provision)		(3,008)		11,977	
Income tax benefit (provision)		137		(3,004)	
Net (Loss) Income	\$	(2,871)	\$	8,973	
(Loss) Earnings per share attributable to common stockholder	s:				
Basic	\$	(0.21)	\$	0.64	
Diluted	\$	(0.21)	\$	0.62	
Weighted average number of common shares outstanding:					
Basic		13,667,606		13,925,227	
Diluted		13,667,606		14,418,211	

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

	Three Months Ende			ded March 31,	
	2020			2019	
Cash flows from operating activities:					
Net (loss) income	\$	(2,871)	\$	8,973	
Adjustments to reconcile net (loss) income to net cash provided by operating activities	:				
Deferred income taxes		(90)		(287)	
Depreciation expense		472		503	
Amortization expense		666		630	
Fair value adjustments on equity investment		6,500		_	
Stock-based compensation expense		7,472		5,782	
Amortization of debt issuance costs		65		94	
Changes in operating assets and liabilities which provided (used) cash:					
Accounts receivable		(6,487)		2,556	
Inventories		(1,868)		(1,961)	
Prepaid expenses and other current assets		4,473		4,368	
Accounts payable		4,294		6,869	
Accrued expenses and other liabilities		(8,238)		(1,083)	
Other assets and other long-term liabilities, net		(1,230)		(263)	
Net cash provided by operating activities		3,158		26,181	
Cash flows from investing activities:					
Purchase of equity investment security		(17,500)			
Purchase of property and equipment		(472)		(177)	
Net cash used in investing activities		(17,972)		(177)	

Cash flows from financing activities:		
Proceeds from common stock option exercises	330	42
Employee withholding taxes related to stock-based awards	(1,276)	(198)
Proceeds from existing revolving credit facility	110,000	_
Payment of debt	(1,000)	(2,500)
Repurchases of common stock	 (999)	
Net cash provided by (used in) financing activities	 107,055	 (2,656)
Net increase in cash and cash equivalents	92,241	23,348
Cash and cash equivalents at beginning of period	 109,775	 78,791
Cash and cash equivalents at end of period	\$ 202,016	\$ 102,139
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Income taxes, net	\$ 24	\$ (6,490)

576

842

625

2,871

EAGLE PHARMACEUTICALS, INC.

Right-of-use asset obtained in exchange for lease obligation - lease amendment

Interest

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 March 3				
		2020		2019	
Net (loss) income - GAAP	\$	(2,871)	\$	8,973	
Adjustments:					
Cost of product revenues:					
Amortization expense		261		225	
Research and development:					
Stock-based compensation expense		1,550		1,143	
Depreciation expense		177		69	
Selling, general and administrative:					
Stock-based compensation expense		5,922		4,639	
Expense related to collaboration with Tyme		2,500		-	
Amortization expense		405		405	
Depreciation expense		74		172	
Severance		245		-	
Other:					
Non-cash interest expense		118		94	
Fair value adjustments on equity investment	t	6,500		-	
Tax effect of the non-GAAP adjustments		(3,179)		(1,091)	
Adjusted non-GAAP net income	\$	11,702	\$	14,629	
			-		
Adjusted non-GAAP earnings per share:					
Basic	\$	0.86	\$	1.05	
Diluted	\$	0.84	\$	1.01	
Weighted number of common shares outstanding:					
Basic		13,667,606		13,925,227	
Diluted		14,000,932		14,418,211	

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

	Three Months Ended March 31,			Twelve Months Ended March 31,				
		2020		2019		2020		2019
Net (loss) income - GAAP	\$	(2 971)	¢	8,973	¢	2,469	\$	14,313
Net (IUSS) Income - GAAF	φ	(2,871)	\$	0,973	φ	2,409	φ	14,313
Add back:								
Interest expense, net of interest income		543		192		868		517
Income tax (benefit) provision		(137)		3,004		4,544		7,685
Depreciation and amortization expense		917		871		3,538		3,492
Add back:								
Stock-based compensation expense		7,472		5,782		23,688		21,998
Debt issuance cost		-		-		88		88
Fair value adjustments on equity investment		6,500		-		6,500		-
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	\$	15,169	\$	18,822	\$	45,395	\$	49,048

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