Eagle Pharmaceuticals Reports First Quarter 2021 Results

May 10, 2021

Q1 2021 net loss was $0.03 per basic and diluted share and adjusted non-GAAP net income was $0.24 per basic and diluted share

Anticipate vasopressin approval and launch this year; completed last required study; expect to respond to vasopressin Complete Response Letter ("CRL") in full by mid-year

Expects approximately $20-$25 million from combined royalty and milestone revenue in 2022 for TREAKISYM (bendamustine) Ready-to-Dilute ("RTD") and Rapid Infusion ("RI") formulations

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, 2021.

Business and Recent Highlights:

- Completed the last study required by FDA for the Company's vasopressin product and expect to have the results shortly. Eagle plans to respond to the CRL issued for its first-to-file Abbreviated New Drug Applicable ("ANDA") for vasopressin in full by mid-year. The Company's patent trial against Endo Par Innovation Company, LLC was postponed and is now scheduled to begin on July 7, 2021. The Company believes it will have first-to-file 180 day exclusivity for vasopressin;
- Approval of TREAKISYM (bendamustine) RTD formulation, in combination with rituximab for treatment of relapsed or refractory diffuse large B-cell lymphoma ("r/r DLBCL") received from the Pharmaceuticals and Medical Devices Agency ("PMDA") in Japan. This represents a meaningful extension of Eagle's bendamustine franchise and is expected to significantly increase the market opportunity;
- Filing of TREAKISYM RI (50ml) liquid formulation with the PMDA in Japan. Eagle expects approximately $20-$25 million from combined royalty and milestone revenue in 2022 for TREAKISYM (bendamustine) RTD and RI formulations;
- Appointed former FDA Official and Public Health Expert Dr. Luciana Borio to its Board of Directors; and
- In active discussions for several promising in-licensing and acquisition candidates that the Company believes will strengthen its portfolio and pipeline going forward.

Financial Highlights

First Quarter 2021

Total revenue for Q1 2021 was $41.2 million, compared to $46.0 million in Q1 2020, primarily reflecting decreased product sales of RYANODEX® and royalty revenue of BENDEKA®.

- Q1 2021 net loss was $0.4 million, or $0.03 per basic and diluted share, compared to net loss of $2.9 million, or $0.21 per basic and diluted share in Q1 2020.
- Q1 2021 adjusted non-GAAP net income was $3.2 million, or $0.24 per basic and diluted share, compared to adjusted non-GAAP net income of $11.7 million, or $0.86 per basic and $0.84 per diluted share, in Q1 2020.
- Cash and cash equivalents were $105.2 million, net accounts receivable was $44.9 million, and debt was $32.0 million as of March 31, 2021.

"Vasopressin is tracking as expected. The trial is now less than two months away and we have now completed the last study required to submit our response to the CRL to the FDA. Our expectation remains that we will receive final approval in time to bring the product to market this year. We believe we also have an outstanding and large opportunity with TREAKISYM in Japan representing another extension of our bendamustine franchise. Equally important and exciting is the PEMFEXY ™ launch early next year, which gives us four months of initial exclusivity," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

"We are now in late-stage diligence for several in-licensing opportunities that would leverage our capabilities, meet our criteria and broaden our portfolio and pipeline. We will aim to finalize a few such transactions that have the potential to bolster our earnings both in the short and longer term," concluded Tarriff.

First Quarter 2021 Financial Results

Total revenue for the three months ended March 31, 2021 was $41.2 million, as compared to $46.0 million for the three months ended March 31, 2020.

Q1 2021 BELRAPZO® product sales were $5.7 million, compared to $4.6 million in Q1 2020.

Q1 2021 RYANODEX product sales were $6.8 million, compared to $11.4 million in Q1 2020.

Royalty revenue was $24.1 million in the first quarter of 2021, compared to $28.3 million in the first quarter of 2020. BENDEKA royalties were $23.8 million in the first quarter of 2021, compared to $28.0 million in the first quarter of 2020. A summary of total revenue is outlined below:

	Three Months Ended March 31,	
	2021	2020
	(unaudited)	(unaudited)
Revenue (in thousands):		
Product sales, net	$17,120	$17,694
Royalty revenue	24,129	28,326
Total revenue	$41,249	$46,020

Gross Margin was 74% during the first quarter of 2021, as compared to 83% in the first quarter of 2020. The compression in gross margin for the first quarter of 2021 was driven by revenue mix including the launch of TREAKISYM product sales to our partner in the first quarter of 2021, on which we earn no profit.

R&D expense was $14.3 million for the first quarter of 2021, compared to $9.4 million in the first quarter of 2020. The increase is largely attributable to $2.6 million in development costs for vasopressin, a $0.9 million increase in the cost for fulvestrant, and a $0.9 million increase in development costs for RYANODEX related projects. Excluding stock-based compensation and other non-cash and non-recurring items, R&D expense during the first quarter of 2021 was $13.1 million.

SG&A expenses in the first quarter of 2021 totaled $19.9 million compared to $24.8 million in the first quarter of 2020. The decrease is primarily related to the non-recurrence of a $2.5 million charge for the Tyme transaction, and lower marketing, travel, entertainment, and trade show expenses as a result of reduced travel due to the COVID-19 pandemic. Excluding stock-based compensation and other non-cash and non-recurring items, first quarter 2021 SG&A expense was $13.4 million.

Net loss for the first quarter of 2021 was $0.4 million, or $0.03 per basic and diluted share, compared to net loss of $2.9 million, or $0.21 per basic and diluted share, in the first quarter of 2020, due to the factors discussed above.

Adjusted non-GAAP net income for the first quarter of 2021 was $3.2 million, or $0.24 per basic and diluted share, compared to adjusted non-GAAP net income of $11.7 million or $0.86 per basic and $0.84 per diluted share in the first quarter of 2020. For a full reconciliation of adjusted non-GAAP net income to the most comparable GAAP financial measures, please see the tables at the end of this press release.

2021 Expense Guidance

- R&D spend in 2021, on a non-GAAP basis, is expected to be $26-$30 million, as compared to $27.8 million in 2020.
- SG&A spend in 2021, on a non-GAAP basis, is expected to be $52-$56 million, as compared to $50.9 million in 2020. This represents a reduction from earlier guidance for 2021 SG&A spend of $56-60 million.

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, 2021, the Company had $105.2 million in cash and cash equivalents plus $44.9 million in net accounts receivable. The Company had $32.0 million in outstanding debt. Therefore, as of March 31, 2021, the Company had net cash plus receivables of $118.1 million.

In the first quarter of 2021, the Company purchased $1.4 million of its common stock as part of its $160.0 million Share Repurchase Program. From August 2016 through March 31, 2021, the Company has repurchased $208.3 million of its common stock.

Conference Call

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

Date	Monday, May 10, 2021
Time	8:30 A.M. EDT
Toll free (U.S.)	877-876-9173
International	785-424-1667
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 800-839-6980 (US) or 402-220-6062 (International) and entering conference call ID EGRXQ121. The webcast will be archived for 30 days at the aforementioned URL.

About Eagle Pharmaceuticals, Inc.

Eagle is a fully integrated pharmaceutical company with research and development, clinical, manufacturing and commercial expertise. Eagle is committed to developing innovative medicines that result in meaningful improvements in patients’ lives. Eagle’s commercialized products include RYANODEX®, BENDEKA®, BELRAPZO®, and its oncology and CNS/metabolic critical care pipeline includes product candidates with the potential to address underserved therapeutic areas across multiple disease states. Additional information is available on Eagle’s website at www.eagleus.com.

Forward-Looking Statements

This press release contains forward-looking information within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other securities laws. Forward-looking statements are statements that are not historical facts. Words and phrases such as “anticipated,” “forward,” “will,” “would,” “may,” “remain,” “potential,” “prepare,” “expected,” “believe,” “plan,” “near future,” “belief,” “guidance,” and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding future events such as: the

number and timing of potential product launches, development initiatives or new indications for the Company's product candidates; the period of market exclusivity for any of the Company's product candidates; the Company's clinical development plan for the product candidates in its portfolio; the potential benefits and efficacy of RYANODEX, including the potential for RYANODEX as a treatment for additional indications; the ability of the Company's executive team to execute on the Company's strategy and build stockholder value; the timing, scope or likelihood and timing of regulatory filings and approvals from the FDA for the Company's product candidates; the timing of the Company's PEMFEXY launch, if ever; the success of the Company's collaborations with its strategic partners and the timing and results of these partners' preclinical studies and clinical trials, including the Company's collaboration with its Japanese licensing partner, SymBio, with respect to the commercialization of SymBio's product TREAKISYM; the future commercial success of TREAKISYM RTD and, if approved, TREAKISYM RI, including anticipated royalty and milestone revenue and potential market opportunity; the Company's timing and ability to enroll patients in ongoing and upcoming clinical trials; the ability of the Company to obtain and maintain coverage and adequate reimbursement for its products; the implementation of certain healthcare reform measures; the Company's timing and ability to repurchase additional shares of the Company's common stock, if any, under its Share Repurchase Program; the Company's ability to deliver value in 2021 and over the long term; the Company's ability to utilize its cash and other assets to increase shareholder value; the Company's ability to effectively manage and control expenses in line with its budget; and the Company's plans and ability to advance the products in its pipeline. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the Company's control, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. Such risks and uncertainties include, but are not limited to: the impacts of the COVID-19 pandemic, including disruption or impact in the sales of the Company's marketed products, interruptions or other adverse effects to clinical trials, delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems, disruption in the operations of the Company's third party partners and disruption of the global economy, and the overall impact of the COVID-19 pandemic on the Company's business, financial condition and results of operations; risks that the Company's business, financial condition and results of operations will be impacted by the spread of COVID-19 in the geographies where the Company's third-party partners operate; whether the Company will incur unforeseen expenses or liabilities or other market factors; whether the Company will successfully implement its development plan for its product candidates; delay in or failure to obtain regulatory approval of the Company's product candidates; whether the Company can successfully market and commercialize its product candidates; the success of the Company's relationships with its partners; the availability and pricing of third party sourced products and materials; the outcome of litigation involving any of our products or that may have an impact on any of our products; successful compliance with the FDA and other governmental regulations applicable to product approvals, manufacturing facilities, products and/or businesses; general economic conditions, including the potential adverse effects of public health issues, including the COVID-19 pandemic, on economic activity and the performance of the financial markets generally; the strength and enforceability of the Company's intellectual property rights or the rights of third parties; competition from other pharmaceutical and biotechnology companies and the potential for competition from generic entrants into the market; the risks inherent in the early stages of drug development and in conducting clinical trials; and those risks and uncertainties identified in the "Risk Factors" sections of the Company's Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission (the "SEC") on March 5, 2021, as updated by the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, which the Company expects to file with the SEC on May 10, 2021, and its other subsequent filings with the SEC. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and the Company does not undertake any obligation to revise and disseminate forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of or non-occurrence of any events.

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 (UNAUDITED)
(In thousands, except share amounts)

	March 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 105,229	$ 103,155
Accounts receivable, net	44,868	50,678
Inventories	6,862	8,075

Prepaid expenses and other current assets	7,027	4,157
Total current assets	163,986	166,065
Property and equipment, net	2,270	2,077
Intangible assets, net	12,211	12,917
Goodwill	39,743	39,743
Deferred tax asset, net	14,278	15,180
Other assets	27,480	17,208
Total assets	$ 259,968	$ 253,190
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 12,559	$ 6,268
Accrued expenses and other liabilities	21,414	23,817
Current portion of long-term debt	8,000	8,000
Total current liabilities	41,973	38,085
Other long-term liabilities	3,664	3,959
Long-term debt, less current portion	23,253	25,135
Total liabilities	68,890	67,179
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of March 31, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value; 50,000,000 shares authorized; 16,858,031 and 16,739,203 shares issued as of March 31, 2021 and December 31, 2020, respectively	17	17
Additional paid in capital	312,323	305,403
Retained earnings	84,068	84,489
Treasury stock, at cost, 3,712,571 and 3,682,176 shares as of March 31, 2021 and December 31, 2020, respectively	(205,330)	(203,898)
Total stockholders' equity	191,078	186,011
Total liabilities and stockholders' equity	$ 259,968	$ 253,190

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

	Three Months Ended March 31,	
	2021	2020
Revenue:		
Product sales, net	$ 17,120	$ 17,694
Royalty revenue	24,129	28,326
License and other revenue	—	—
Total revenue	41,249	46,020
Operating expenses:		
Cost of product sales	8,442	4,765
Cost of royalty revenue	2,413	3,038
Research and development	14,288	9,427
Selling, general and administrative	19,879	24,755
Total operating expenses	45,022	41,985
(Loss) income from operations	(3,773)	4,035
Interest income	35	346
Interest expense	(422)	(889)
Other income (expense)	5,500	(6,500)
Total other income (expense), net	5,113	(7,043)
Income (loss) before income tax (provision) benefit	1,340	(3,008)
Income tax (provision) benefit	(1,761)	137
Net Loss	$ (421)	$ (2,871)
Loss per share attributable to common stockholders:		
Basic	$ (0.03)	$ (0.21)
Diluted	$ (0.03)	$ (0.21)
Weighted average number of common shares outstanding:		
Basic	13,069,373	13,667,606

Diluted	13,069,373	13,667,606

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

	Three Months Ended March 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (421)	$ (2,871)
Adjustments to reconcile net income to net cash provided by operating activities:		
Deferred income taxes	902	(90)
Depreciation expense	190	251
Noncash operating lease expense related to right-of-use assets	252	221
Amortization expense of intangible assets	706	666
Fair value adjustments on equity investment	(5,600)	6,500
Stock-based compensation expense	6,508	7,472
Convertible promissory note related credit losses	100	—
Amortization of debt issuance costs	118	65
Changes in operating assets and liabilities which provided (used) cash:		
Accounts receivable	5,810	(6,487)
Inventories	1,213	(1,868)
Prepaid expenses and other current assets	(2,870)	4,473
Accounts payable	6,291	4,294
Accrued expenses and other liabilities	(2,403)	(8,238)
Other assets and other long-term liabilities, net	(318)	(1,230)
Net cash provided by operating activities	10,478	3,158
Cash flows from investing activities:		
Purchase of equity investment security	—	(17,500)
Purchase of property and equipment	(384)	(472)
Purchase of convertible promissory note	(5,000)	—
Net cash used in investing activities	(5,384)	(17,972)
Cash flows from financing activities:		
Proceeds from common stock option exercises	1,963	330
Employee withholding taxes related to stock-based awards	(1,551)	(1,276)
Proceeds from existing revolving credit facility	—	110,000
Payment of debt	(2,000)	(1,000)
Repurchases of common stock	(1,432)	(999)
Net cash (used in) provided by financing activities	(3,020)	107,055
Net increase in cash and cash equivalents	2,074	92,241
Cash and cash equivalents at beginning of period	103,155	109,775
Cash and cash equivalents at end of period	$ 105,229	$ 202,016
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Income taxes, net	$ 267	$ 24
Interest	321	576
Right-of-use asset obtained in exchange for lease obligation - lease amendment	—	842

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

	Three Months Ended March 31,	
	2021	**2020**
Net loss - GAAP	$ (421)	$ (2,871)
Adjustments:		

Cost of product revenues:		
Amortization expense	301	261
Research and development:		
Stock-based compensation expense	895	1,550
Depreciation expense	53	177
Severance	274	—
Selling, general and administrative:		
Stock-based compensation expense	5,613	5,922
Expense related to collaboration with Tyme	—	2,500
Amortization expense	405	405
Depreciation expense	137	74
Severance	306	245
Other:		
Non-cash interest expense	118	118
Fair value adjustments on equity investment	(5,600)	6,500
Tax effect of the non-GAAP adjustments	1,086	(3,179)
Adjusted non-GAAP net income	$ 3,167	$ 11,702
Adjusted non-GAAP earnings per share:		
Basic	$ 0.24	$ 0.86
Diluted	$ 0.24	$ 0.84
Weighted number of common shares outstanding:		
Basic	13,069,373	13,667,606
Diluted	13,276,283	14,000,932

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

	Three Months Ended March 31,		Twelve Months Ended March 31,	Twelve Months Ended December 31,
	2021	**2020**	**2021**	**2020**
Net (loss) income - GAAP	$ (421)	$ (2,871)	$ 14,439	$ 11,989
Add back:				
Interest expense, net of interest income	387	543	1,859	2,015
Income tax provision (benefit)	1,761	(137)	12,586	10,688
Depreciation and amortization expense	896	917	3,517	3,538
Add back:				
Stock-based compensation expense	6,508	7,472	23,792	24,756
Fair value adjustments on equity investment	(5,600)	6,500	(6,800)	5,300
Fair value adjustments on settled accelerated share repurchase agreement	—	—	2,962	2,962
Expense related to collaboration with Tyme	—	2,500	—	2,500
Severance	580	245	1,259	924
Adjusted Non-GAAP EBITDA	$ 4,111	$ 15,169	$ 53,614	$ 64,672

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