Eagle Pharmaceuticals Reports Second Quarter 2021 Results

August 9, 2021

Q2 2021 net income was $0.28 per basic and $0.27 per diluted share and adjusted non-GAAP net income was $0.95 per basic and $0.93 per diluted share

Announced licensing agreement for U.S. commercial rights to Landiolol, a beta-1 adrenergic blocker and a leading hospital emergency use product in Europe and Japan

Responded to CRL for vasopressin and anticipates commercial launch by year-end; vasopressin patent trial decision expected around mid-September

FDA maintained Priority Review for the Company's Abbreviated New Drug Application ("ANDA") for vasopressin and assigned a GDUFA date of December 15, 2021

Expects approximately $20-$25 million from combined royalty and milestone revenue next year for TREAKISYM (bendamustine), if TREAKISYM RI formulation is approved

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, 2021.

Business and Recent Highlights:

- Entered into a licensing agreement for the U.S. commercial rights to Landiolol, a leading hospital emergency use product in Europe and Japan. Landiolol is currently approved in Europe for the treatment of non-compensatory sinus tachycardia and tachycardic supraventricular arrhythmias. Eagle will support the submission of a new drug application ("NDA") to the U.S. Food and Drug Administration ("FDA") seeking approval for Landiolol for the short-term reduction of ventricular rate in patients with supraventricular tachycardia ("SVT"), including atrial fibrillation and atrial flutter.
- Advanced vasopressin program and continue to expect a commercial launch prior to year-end:
  - Responded to the Complete Response Letter ("CRL") for its Abbreviated New Drug Application ("ANDA") for vasopressin received from FDA in February 2021;
  - FDA maintained Priority Review for the Company's ANDA for vasopressin and assigned a GDUFA date of December 15, 2021;
  - Patent trial against Endo Par Innovation Company, LLC took place on July 7, 2021; Court ruling expected around mid-September.
- Approval of TREAKISYM (bendamustine) ready-to-dilute ("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 for bendamustine;
- Filing of TREAKISYM rapid infusion ("RI") (50ml) liquid formulation with the PMDA in Japan. Eagle expects RTD, and RI, if approved, formulations to generate approximately $20-$25 million of combined royalty and milestone revenue**;**
- Appointed former FDA Official and Public Health Expert Dr. Luciana Borio to its Board of Directors; and
- Continue to pursue additional in-licensing and acquisition opportunities to broaden Eagle's pipeline and revenue streams.

Financial Highlights

Second Quarter 2021

Total revenue for Q2 2021 was $48.1 million, compared to $41.9 million in Q2 2020, primarily reflecting higher product sales of BELRAPZO® and RYANODEX®, partially offset by lower product sales of BENDEKA®.

- Q2 2021 net income was $3.6 million, or $0.28 per basic and $0.27 per diluted share, compared to net loss of $0.3 million, or ($0.02) per basic and diluted share in Q2 2020.
- Q2 2021 adjusted non-GAAP net income was $12.4 million, or $0.95 per basic and $0.93 per diluted share, compared to adjusted non-GAAP net income of $8.0 million, or $0.59 per basic and $0.57 per diluted share, in Q2 2020.
- Cash and cash equivalents were $108.7 million, net accounts receivable was $52.7 million, and debt was $30 million as of June 30, 2021.

"We had a strong and productive quarter on multiple fronts and have laid the foundation for important growth drivers going forward. We made good progress with vasopressin during the quarter and continue to believe that we will be able to launch that important product before year-end. We are just months away from our February 2022 PEMFEXY ™ launch, which allows us an initial period of exclusivity in a billion-dollar market. With the potential for an additional royalty and milestone revenue stream of $20-$25 million from the expanding TREAKISYM franchise in Japan, next year could be a record earnings year for Eagle," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

“The licensing agreement for Landiolol represents Eagle’s first new chemical entity and is a true catalyst in reshaping our company as we evolve from a specialty pharmaceutical company into a mainstream pharmaceutical company, with a vibrant pipeline of products. Landiolol solidifies our hospital and critical care product portfolio, and we plan to leverage our current sales force with little additional infrastructure costs to promote the product. We are also pursuing other such opportunities to build value for the company and look forward to providing updates,” concluded Tarriff.

Second Quarter 2021 Financial Results

Total revenue for the three months ended June 30, 2021 was $48.1 million, compared to $41.9 million for the three months ended June 30, 2020.

Q2 2021 BELRAPZO product sales were $7.6 million, compared to $4.1 million in Q2 2020.

Q2 2021 RYANODEXproduct sales were $7.9 million, compared to $4.7 million in Q2 2020.

Royalty revenue was $28.5 million in the second quarter of 2021, compared to $27.6 million in the second quarter of 2020. BENDEKA royalties were $27.8 million in the second quarter of 2021, compared to $27.5 million in the second quarter of 2020. A summary of total revenue is outlined below:

	Three Months Ended June 30,	
	2021	2020
	(unaudited)	(unaudited)
Revenue (in thousands):		
Product sales, net	$19,621	$14,376
Royalty revenue	28,503	27,562
Total revenue	$48,124	$41,938

Gross Margin was 78% during the second quarter of 2021, as compared to 69% in the second quarter of 2020. The increase in gross margin for the second quarter of 2021 was driven by revenue mix.

R&D expense was $9.9 million for the second quarter of 2021, compared to $7.1 million in the second quarter of 2020. The increase is largely attributable to development cost for vasopressin of $1.5 million, RYANODEX related projects of $0.8 million and PEMFEXY of $0.6 million, partially offset by $0.5 million decrease in development activity related to fulvestrant. Excluding stock-based compensation and other non-cash and non-recurring items, R&D expense during the second quarter of 2021 was $9.2 million.

SG&A expenses in the second quarter of 2021 totaled $16.6 million compared to $18.0 million in the second quarter of 2020. The decrease is primarily related to lower stock compensation expense and marketing spend. Excluding stock-based compensation and other non-cash and non-recurring items, second quarter 2021 SG&A expense was $12.4 million.

Net income for the second quarter of 2021 was $3.6 million, or $0.28 per basic and $0.27 per diluted share, compared to net loss of $0.3 million, or ($0.02) per basic and diluted share, in the second quarter of 2020, due to the factors discussed above.

Adjusted non-GAAP net income for the second quarter of 2021 was $12.4 million, or $0.95 per basic and $0.93 per diluted share, compared to adjusted non-GAAP net income of $8.0 million or $0.59 per basic and $0.57 per diluted share in the second 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 $34-$38 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.

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, 2021, the Company had $108.7 million in cash and cash equivalents plus $52.7 million in net accounts receivable. The Company had $30 million in outstanding debt. Therefore, as of June 30, 2021, the Company had net cash plus receivables of $131.4 million.

In the second quarter of 2021, the Company purchased $2.9 million of its common stock as part of its $160.0 million Share Repurchase Program. From August 2016 through June 30, 2021, the Company has repurchased $211.2 million of its common stock.

Conference Call

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

Date	Monday, August 9, 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 888-562-2815 (US) or 402-220-7352 (International) and entering conference call ID EGRXQ221. 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; potential future revenue or earnings of the Company; the Company's clinical development plan for the product candidates in its portfolio; 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, and the Company's ability to maintain regulatory approval of its products and product candidates; the potential timing of the Company's commercial launch of PEMFEXY, vasopressin or Landiolol, if ever; the Company's plans for and ability to support the commercial launch of Landiolol in the United States, if approved; the ability of the Company's product candidates, including Landiolol, vasopressin and PEMFEXY, to deliver value to stockholders; 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 timing of court decisions or other actions with respect to ongoing litigation; 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; delays in or failure to obtain regulatory approval of any license agreements with third parties; 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 the Company's 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 June 30, 2021, which the Company expects to file with the SEC on August 9, 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, fair value adjustments related to derivative instrument, convertible promissory note related credit losses, accretion of discount on convertible promissory note 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)

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 108,717	$ 103,155
Accounts receivable, net	52,659	50,678
Inventories	8,294	8,075
Prepaid expenses and other current assets	5,834	4,157
Total current assets	175,504	166,065
Property and equipment, net	1,967	2,077
Intangible assets, net	11,505	12,917
Goodwill	39,743	39,743
Deferred tax asset, net	14,061	15,180
Other assets	21,462	17,208
Total assets	$ 264,242	$ 253,190
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 11,136	$ 6,268
Accrued expenses and other liabilities	25,528	23,817
Current portion of long-term debt	8,000	8,000
Total current liabilities	44,664	38,085
Other long-term liabilities	3,360	3,959
Long-term debt, less current portion	21,371	25,135
Total liabilities	69,395	67,179
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of June 30, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value; 50,000,000 shares authorized; 16,879,974 and 16,739,203 shares issued as of June 30, 2021 and December 31, 2020, respectively	17	17
Additional paid in capital	316,249	305,403
Accumulated other comprehensive loss	(904)	—
Retained earnings	87,680	84,489
Treasury stock, at cost, 3,782,861 and 3,682,176 shares as of June 30, 2021 and December 31, 2020, respectively	(208,195)	(203,898)
Total stockholders' equity	194,847	186,011
Total liabilities and stockholders' equity	$ 264,242	$ 253,190

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,	
	2021	2020	2021	2020
Revenue:				
Product sales, net	$ 19,621	$ 14,376	$ 36,741	$ 32,070
Royalty revenue	28,503	27,562	52,632	55,888
Total revenue	48,124	41,938	89,373	87,958
Operating expenses:				
Cost of product sales	7,907	10,313	16,349	15,078
Cost of royalty revenue	2,850	2,822	5,263	5,860
Research and development	9,911	7,135	24,199	16,562
Selling, general and administrative	16,636	17,959	36,515	42,714
Total operating expenses	37,304	38,229	82,326	80,214
Income from operations	10,820	3,709	7,047	7,744
Interest income	163	150	198	496
Interest expense	(422)	(786)	(844)	(1,675)

Other (expense) income	(5,013)	2,300	487	(4,200)
Total other (expense) income, net	(5,272)	1,664	(159)	(5,379)
Income before income tax provision	5,548	5,373	6,888	2,365
Income tax provision	(1,936)	(5,629)	(3,697)	(5,492)
Net Income (Loss)	$ 3,612	$ (256)	$ 3,191	$ (3,127)
Earnings (Loss) per share attributable to common stockholders:				
Basic	$ 0.28	$ (0.02)	$ 0.24	$ (0.23)
Diluted	$ 0.27	$ (0.02)	$ 0.24	$ (0.23)
Weighted average number of common shares outstanding:				
Basic	13,108,998	13,664,951	13,116,370	13,666,279
Diluted	13,262,164	13,664,951	13,293,920	13,666,279

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

	Six Months Ended June 30,	
	2021	**2020**
Cash flows from operating activities:		
Net income (loss)	$ 3,191	$ (3,127)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Deferred income taxes	1,119	(916)
Depreciation expense	378	460
Noncash operating lease expense related to right-of-use assets	508	471
Amortization expense of intangible assets	1,412	1,333
Fair value adjustments on equity investment	(400)	4,200
Stock-based compensation expense	10,789	13,713
Convertible promissory note related credit losses	100	—
Amortization of debt issuance costs	236	183
Fair value adjustments related to derivative instrument	(188)	—
Accretion of discount on convertible promissory note	(56)	—
Changes in operating assets and liabilities which provided (used) cash:		
Accounts receivable	(1,981)	1,223
Inventories	(219)	(1,325)
Prepaid expenses and other current assets	(1,802)	9,553
Accounts payable	4,868	8,246
Accrued expenses and other liabilities	1,710	(8,583)
Other assets and other long-term liabilities, net	(594)	(1,321)
Net cash provided by operating activities	19,071	24,110
Cash flows from investing activities:		
Purchase of equity investment security	—	(17,500)
Purchase of property and equipment	(269)	(376)
Purchase of convertible promissory note	(5,000)	—
Net cash used in investing activities	(5,269)	(17,876)
Cash flows from financing activities:		
Proceeds from common stock option exercises	1,608	513
Employee withholding taxes related to stock-based awards	(1,551)	(1,310)
Proceeds from existing revolving credit facility	—	110,000
Repayment of existing revolving credit facility	—	(110,000)
Payment of debt	(4,000)	(2,000)
Repurchases of common stock	(4,297)	(4,999)
Net cash used in financing activities	(8,240)	(7,796)
Net increase (decrease) in cash and cash equivalents	5,562	(1,562)
Cash and cash equivalents at beginning of period	103,155	109,775
Cash and cash equivalents at end of period	$ 108,717	$ 108,213
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Income taxes, net	$ 4,300	$ 502
Interest	625	1,458
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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net income (loss) - GAAP	$ 3,612	$ (256)	$ 3,191	$ (3,127)
Adjustments:				
Cost of product revenues:				
Amortization expense	301	262	602	523
Research and development:				
Stock-based compensation expense	641	1,034	1,536	2,584
Depreciation expense	54	60	107	134
Severance	-	-	274	-
Selling, general and administrative:				
Stock-based compensation expense	3,640	5,207	9,253	11,129
Expense related to collaboration with Tyme	-	-	-	2,500
Amortization expense	405	405	810	810
Depreciation expense	134	149	271	326
Severance	28	-	334	245
Other:				
Non-cash interest expense	118	118	236	236
Fair value adjustments on equity investment	5,200	(2,300)	(400)	4,200
Convertible promissory note related credit losses	-	-	100	-
Fair value adjustments related to derivative instrument	(188)	-	(188)	-
Accretion of discount on convertible promissory note	(56)	-	(56)	-
Tax effect of the non-GAAP adjustments	(1,489)	3,344	(403)	(3,457)
Adjusted non-GAAP net income	$ 12,400	$ 8,023	$ 15,667	$ 16,103
Adjusted non-GAAP earnings per share:				
Basic	$ 0.95	$ 0.59	$ 1.19	$ 1.18
Diluted	$ 0.93	$ 0.57	$ 1.18	$ 1.15
Weighted average number of common shares outstanding:				
Basic	13,108,998	13,664,951	13,116,370	13,666,279
Diluted	13,262,164	13,971,725	13,293,920	13,983,093

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,
	2021	2020	2021	2020	2021	2020
Net income (loss) - GAAP	$ 3,612	$ (256)	$ 3,191	$ (3,127)	$ 18,307	$ 11,989
Add back:						
Interest expense, net of interest income	259	636	646	1,179	1,482	2,015
Income tax provision	1,936	5,629	3,697	5,492	8,893	10,688
Depreciation and amortization expense	894	876	1,790	1,793	3,535	3,538
Add back:						
Stock-based compensation expense	4,281	6,241	10,789	13,713	21,832	24,756
Fair value adjustments on equity investment	5,200	(2,300)	(400)	4,200	700	5,300
Fair value adjustments on settled accelerated share repurchase agreement	-	-	-	-	2,962	2,962

Convertible promissory note related credit losses	-	-	100	-	100	-
Fair value adjustments related to derivative instrument	(188)	-	(188)	-	(188)	-
Expense related to collaboration with Tyme	-	-	-	2,500	-	2,500
Severance	28	-	608	245	1,287	924
Adjusted Non-GAAP EBITDA	$16,022	$10,826	$20,233	$25,995	$ 58,910	$ 64,672

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