

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **May 7, 2019**

Eagle Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-36306

(Commission File Number)

20-8179278

(IRS Employer Identification No.)

50 Tice Boulevard, Suite 315

Woodcliff Lake, NJ

(Address of principal executive offices)

07677

(Zip Code)

Registrant's telephone number, including area code: **(201) 326-5300**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class

Common stock, \$0.001 par value per share

Trading symbol

EGRX

Name of each exchange on which registered

NASDAQ Global Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On May 7, 2019, Eagle Pharmaceuticals, Inc., or the Company, issued a press release announcing its financial results for the fiscal first quarter ended March 31, 2019. A copy of the Company’s press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including the information contained in the press release furnished as Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section, and shall not be deemed incorporated by reference into any of the Company’s filings under the Securities Act of 1933, as amended or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of the Company dated May 7, 2019

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Eagle Pharmaceuticals, Inc.

Dated: May 7, 2019

By: /s/ Scott Tarriff
Scott Tarriff
Chief Executive Officer



For Immediate Release

Eagle Pharmaceuticals, Inc. Reports First Quarter 2019 Results

- Q1 2019 net income of \$0.64 per basic and \$0.62 per diluted share and adjusted non-GAAP net income of \$1.05 per basic and \$1.01 per diluted share —
- Revised licensing agreement for BENDEKA® extends term of contract and increases royalty rate to 32% in 2021 —
- CMS issues unique J-code for BELRAPZO™ (500mL infusion bendamustine solution) —
- Announced statistically significant neuroprotective effects of RYANODEX® in a well-established nerve agent model —

WOODCLIFF LAKE, NJ—May 7, 2019—Eagle Pharmaceuticals, Inc. (“Eagle” or the “Company”) (Nasdaq: EGRX) today announced its financial results for the three months ended March 31, 2019. Highlights of, and subsequent to, the first quarter of 2019 include:

Business and Recent Highlights:

- Completed a successful study to evaluate the neuroprotective effects of RYANODEX® (dantrolene sodium) for the treatment of nerve agent exposure:
 - Conducted in collaboration with the United States Army Medical Research Institute of Chemical Defense (USAMRICD), the nation’s leading science and technology laboratory in the area of medical chemical countermeasures research and development;
 - The Company plans to meet with the U.S. Food and Drug Administration (FDA) as soon as possible;
- Announced a revised licensing agreement for BENDEKA that extends the term of the agreement until the product is no longer sold and increases Eagle’s royalty rate from 25% to 30% in October 2019 and by 1% annually until it reaches 32%;
- The FDA issued a decision in favor of Eagle regarding the scope of BENDEKA’s Orphan Drug Exclusivity (ODE), further protecting the longevity of the BENDEKA franchise; and
- The Centers for Medicare and Medicaid Services (CMS) established a unique, product specific, billing code (J-code: J9036) effective July 1, 2019, for BELRAPZO, the brand name under which Eagle’s currently marketed 500mL infusion bendamustine solution will be sold beginning June 3, 2019.

Financial Highlights:

- Total revenue for the first quarter of 2019 was \$49.8 million, compared to \$46.6 million in the first quarter of 2018;
 - Q1 2019 bendamustine hydrochloride 500ml solution (“Big Bag” or “BELRAPZO”) product sales were \$3.2 million;
 - Q1 2019 RYANODEX product sales were \$4.0 million, compared to \$4.4 million in Q1 2018;
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Eagle Pharmaceuticals Reports First Quarter 2019 Results

- Q1 2019 net income was \$9.0 million, or \$0.64 per basic and \$0.62 per diluted share, compared to net income of \$2.6 million, or \$0.18 per basic and \$0.17 per diluted share in Q1 2018;
- Q1 2019 adjusted non-GAAP net income was \$14.6 million, or \$1.05 per basic and \$1.01 per diluted share, compared to adjusted non-GAAP net income of \$8.2 million, or \$0.55 per basic and \$0.53 per diluted share in Q1 2018; and
- Cash and cash equivalents were \$102.1 million, net accounts receivable was \$63.9 million, and debt was \$42.5 million as of March 31, 2019.

“This is an exciting time at Eagle as we continue to position the Company for growth. We have solidified our bendamustine franchise by securing marketing exclusivity for BENDEKA and effectively preventing generic competition through the end of 2022, revising our licensing agreement for BENDEKA to extend the term of the agreement well beyond 2025 and increase our royalty rate, and launching BELRAPZO, our 500mL infusion bendamustine product, which will have its own unique J-code effective July 1st of this year. Combined, these efforts now give us the most certitude for our bendamustine portfolio since launch and should provide a very strong base of earnings upon which we can continue to build to further grow the Company,” stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

“With bendamustine as a solid base for many years to come, we are excited about our pipeline. Today’s news about RYANODEX for nerve agent exposure is an important step in diversifying our product line and building growth,” concluded Tarriff.

First Quarter 2019 Financial Results

Total revenue for the three months ended March 31, 2019 was \$49.8 million, as compared to \$46.6 million for the three months ended March 31, 2018. We recorded \$9.0 million in revenue during the first quarter of 2019 upon execution of an agreement to terminate Teva’s obligation to pay future milestones and royalties on BENDEKA sales outside of the U.S.

Royalty revenue was \$26.3 million in the first quarter of 2019, compared to \$35.8 million in the first quarter of 2018. BENDEKA royalties were \$26.0 million in the first quarter of 2019, compared to \$34.0 million in the first quarter of 2018. A summary of total revenue is outlined below:

	Three Months Ended March 31,	
	2019 (unaudited)	2018 (unaudited)
Revenue (in thousands):		
Product sales	14,472	10,838
Royalty revenue	26,313	35,788
License and other income	9,000	—
Total revenue	49,785	46,626

Gross Margin was 74% during the first quarter of 2019, as compared to 75% in the first quarter of 2018.

R&D expenses were \$6.4 million for the quarter, compared to \$17.3 million in the same quarter in the prior year. The first quarter year over year decrease reflects a substantial reduction in fulvestrant expense, partially offset by the cost to bring vasopressin to market. Excluding stock-based compensation and other non-cash and non-recurring items, R&D expense during the first quarter was \$5.2 million.

SG&A expenses in the first quarter of 2019 increased to \$18.1 million compared to \$15.2 million in the first quarter of 2018. External legal expenses associated with litigation on PEMFEXY, vasopressin and bendamustine and higher stock compensation expense account for the year over year increase. Excluding stock-based compensation and other non-cash and non-recurring items, first quarter 2019 SG&A expense was \$12.9 million.

Net income for the first quarter of 2019 was \$9.0 million, or \$0.64 per basic and \$0.62 per diluted share, compared to net income of \$2.6 million, or \$0.18 per basic and \$0.17 per diluted share in the three months ended March 31, 2018, due to the factors discussed above.

Adjusted non-GAAP net income for the first quarter of 2019 was \$14.6 million, or \$1.05 per basic and \$1.01 per diluted share, compared to Adjusted non-GAAP net income of \$8.2 million or \$0.55 per basic and \$0.53 per diluted share in the prior year quarter. For a full reconciliation of adjusted non-GAAP net income to the most comparable GAAP financial measures, please see the tables at the end of this press release.

2019 Expense Guidance

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

The guidance provided in this section represents forward-looking information, and actual results may vary. Please see the risks and assumptions referred to in the Forward-Looking Statements section of this press release.

Liquidity

As of March 31, 2019, the Company had \$102.1 million in cash and cash equivalents and \$63.9 million in net accounts receivable, \$46.6 million of which was due from Teva Pharmaceutical Industries Ltd. The Company had \$42.5 million in outstanding debt. Therefore, at March 31, 2019, the Company had net cash and receivables of \$123.6 million.

Conference Call

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

Date	Tuesday, May 7, 2019
Time	8:30 A.M. EDT

Toll free (U.S.)	877-876-9176
International	785-424-1670
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 800-839-5493 (US) or 402-220-2552 (International) and entering conference call ID EGRXQ119. The webcast will be archived for 30 days at the aforementioned URL.

About Eagle Pharmaceuticals, Inc.

Eagle is a specialty pharmaceutical company focused on developing and commercializing injectable products that address the shortcomings, as identified by physicians, pharmacists and other stakeholders, of existing commercially successful injectable products. Eagle’s main strategy is to utilize the FDA’s 505(b) (2) regulatory pathway. Additional information is available on the Company’s website at www.eagleus.com.

Forward-Looking Statements

This press release contains forward-looking information within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other securities laws. Forward-looking statements are statements that are not historical facts. Words and phrases such as “anticipated,” “forward,” “will,” “would,” “may,” “remain,” “potential,” “prepare,” “expected,” “believe,” “plan,” “near future,” “belief,” “guidance,” and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding future events including, but not limited to: the Company’s expense guidance for fiscal year 2019, the Company’s confidence in the remaining products in its pipeline; the Company’s ability to deliver value in 2019 and over the long term; the Company’s timing and ability to repurchase additional shares of the Company’s common stock, if any, under its share repurchase program; and the Company’s plans and ability to advance the products in its pipeline. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond Eagle’s control, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. Such risks include, but are not limited to: whether the Company will incur unforeseen expenses or liabilities or other market factors; whether the FDA will ultimately approve the products in its pipeline for any indications; whether the Company can successfully market and commercialize its product candidates, including RYANODEX, BENDEKA and BELRAPZO, in the treatment of any indications; fluctuations in the trading volume and market price of shares of the Company’s common stock, general business and market conditions and management’s determination of alternative needs and uses of the Company’s cash resources, all of which may affect the Company’s long-term performance and the share repurchase program; the success of our commercial relationship with Teva and the parties’ ability to work effectively together; whether Eagle and its commercial partners will successfully perform their respective obligations under their respective agreements; difficulties or delays in manufacturing; the availability and pricing of third party sourced products and materials; the outcome of litigation involving any of our products or that may have an impact on any of our products; successful compliance with the FDA and other governmental regulations applicable to product approvals, manufacturing facilities, products and/or businesses; general economic conditions; the strength and enforceability of our intellectual property rights or the rights of third parties; competition from other pharmaceutical and biotechnology companies and the potential for competition from generic entrants into the

market; the timing of product launches; the successful marketing of our products; the risks inherent in the early stages of drug development and in conducting clinical trials; that Eagle's redirection of resources to other products in its pipeline may not be successful; and other factors that are discussed in Eagle's filings with the SEC. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and the Company does not undertake any obligation to revise and disseminate forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of or non-occurrence of any events.

Non-GAAP Financial Performance Measures

In addition to financial information prepared in accordance with U.S. GAAP, this press release also contains adjusted non-GAAP net income and adjusted non-GAAP earnings per share attributable to Eagle. The Company believes these measures provide investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information.

Adjusted non-GAAP net income excludes share-based compensation expense, depreciation, amortization of acquired intangible assets, changes in fair value of contingent consideration, severance, non-cash interest expense, expense of acquired in-process research and development, and tax 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 explanations 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, for the three-months ended March 31, 2019.

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.

Investor Relations for Eagle Pharmaceuticals, Inc.:

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— Financial tables follow —

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

	<u>March 31, 2019</u> (unaudited)	<u>December 31, 2018</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 102,139	\$ 78,791
Accounts receivable, net	63,930	66,486
Inventories	10,265	8,304
Prepaid expenses and other current assets	5,895	10,263
Total current assets	<u>182,229</u>	<u>163,844</u>
Property and equipment, net	2,333	2,397
Intangible assets, net	17,473	18,103
Goodwill	39,743	39,743
Deferred tax asset, net	14,109	13,822
Other assets	3,565	694
Total assets	<u>\$ 259,452</u>	<u>\$ 238,603</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 16,786	\$ 9,917
Accrued expenses	22,436	23,519
Current portion of long-term debt	5,000	6,250
Total current liabilities	<u>44,222</u>	<u>39,686</u>
Other long-term liabilities	2,870	—
Long-term debt, less current portion	36,999	38,155
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of March 31, 2019 and December 31, 2018	—	—
Common stock, \$0.001 par value; 50,000,000 shares authorized; 16,519,728 and 16,504,283 shares issued as of March 31, 2019 and December 31, 2018, respectively	17	17
Additional paid in capital	262,084	256,458
Retained earnings	67,160	58,187
Treasury stock, at cost, 2,590,258 and 2,590,258 shares as of March 31, 2019 and December 31, 2018, respectively	(153,900)	(153,900)
Total stockholders' equity	<u>175,361</u>	<u>160,762</u>
Total liabilities and stockholders' equity	<u>\$ 259,452</u>	<u>\$ 238,603</u>

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

	Three Months Ended March 31,	
	2019	2018
Revenue:		
Product sales	\$ 14,472	\$ 10,838
Royalty revenue	26,313	35,788
License and other income	9,000	—
Total revenue	<u>49,785</u>	<u>46,626</u>
Operating expenses:		
Cost of product sales	9,554	7,223
Cost of royalty revenue	3,546	4,585
Research and development	6,375	17,320
Selling, general and administrative	18,141	15,193
Total operating expenses	<u>37,616</u>	<u>44,321</u>
Income from operations	12,169	2,305
Interest income	494	27
Interest expense	(686)	(675)
Total other expense, net	<u>(192)</u>	<u>(648)</u>
Income before income tax (provision) benefit	11,977	1,657
Income tax (provision) benefit	<u>(3,004)</u>	<u>959</u>
Net income	<u>\$ 8,973</u>	<u>\$ 2,616</u>
Earnings per share attributable to common stockholders:		
Basic	\$ 0.64	\$ 0.18
Diluted	\$ 0.62	\$ 0.17
Weighted average number of common shares outstanding:		
Basic	13,925,227	14,819,530
Diluted	14,418,211	15,478,335

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

	Three Months Ended March 31,	
	2019	2018
Cash flows from operating activities:		
Net income	\$ 8,973	\$ 2,616
Adjustments to reconcile net income to net cash provided by operating activities:		
Deferred income taxes	(287)	(123)
Depreciation expense	503	341
Amortization expense	630	670
Stock-based compensation expense	5,782	5,305
Change in fair value of contingent consideration	—	27
Amortization of debt issuance costs	94	94
Changes in operating assets and liabilities which provided (used) cash:		
Accounts receivable	2,556	395
Inventories	(1,961)	(1,023)
Prepaid expenses and other current assets	4,368	1,518
Accounts payable	6,869	(2,628)
Accrued expenses and other liabilities	(1,083)	(2,289)
Other assets and other long-term liabilities, net	(263)	18
Net cash provided by operating activities	<u>26,181</u>	<u>4,921</u>
Cash flows from investing activities:		
Purchase of property and equipment	(177)	(19)
Net cash used in investing activities	<u>(177)</u>	<u>(19)</u>
Cash flows from financing activities:		
Proceeds from common stock option exercises	42	1,166
Payments related to employee net option exercises	—	(3,051)
Employee withholding taxes related to stock-based awards	(198)	—
Payment of contingent consideration	—	(15,001)
Payment of debt	(2,500)	—
Repurchases of common stock	—	(7,003)
Net cash used in financing activities	<u>(2,656)</u>	<u>(23,889)</u>
Net increase (decrease) in cash and cash equivalents	23,348	(18,987)
Cash and cash equivalents at beginning of period	78,791	114,657
Cash and cash equivalents at end of period	<u>\$ 102,139</u>	<u>\$ 95,670</u>
Supplemental disclosures of cash flow information:		
Cash (received) paid during the period for:		
Income taxes	\$ (6,490)	\$ 96
Interest	625	368

EAGLE PHARMACEUTICALS, INC.
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)

	<u>Three Months Ended March 31,</u>	
	<u>2019</u>	<u>2018</u>
Net income - GAAP	\$ 8,973	\$ 2,616
Adjustments:		
Cost of product revenues:		
Amortization expense	225	265
Research and development:		
Stock-based compensation expense	1,143	1,260
Depreciation expense	69	169
Expense of acquired in-process research & development	—	600
Severance	—	255
Selling, general and administrative:		
Stock-based compensation expense	4,639	4,045
Amortization expense	405	405
Depreciation expense	172	172
Other:		
Non-cash interest expense	94	94
Change in fair value of contingent consideration	—	27
Tax effect of the non-GAAP adjustments	(1,091)	(1,727)
Adjusted non-GAAP net income	\$ 14,629	\$ 8,181
Adjusted non-GAAP earnings per share:		
Basic	\$ 1.05	\$ 0.55
Diluted	\$ 1.01	\$ 0.53
Weighted number of common shares outstanding:		
Basic	13,925,227	14,819,530
Diluted	14,418,211	15,478,335

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

	<u>Three Months Ended March 31,</u>		<u>Twelve</u>	<u>Twelve Months</u>
	<u>2019</u>	<u>2018</u>	<u>Months Ended</u>	<u>Ended</u>
			<u>March 31,</u>	<u>December 31,</u>
			<u>2019</u>	<u>2018</u>
Net income - GAAP	\$ 8,973	\$ 2,616	\$ 38,260	\$ 31,903
Add back:				
Interest expense, net of interest income	192	648	2,123	2,579
Income tax provision (benefit)	3,004	(959)	6,098	2,135
Depreciation and amortization expense	871	1,011	3,530	3,670
Add back:				
Stock-based compensation expense	5,782	5,305	19,559	19,082
Change in fair value of contingent consideration	—	27	(790)	(763)
Asset impairment charge	—	—	2,704	2,704
Expense of acquired in-process research & development	—	600	1,100	1,700
Severance	—	255	211	466
Restructuring charge	—	—	7,911	7,911
Adjusted non-GAAP EBITDA	<u>\$ 18,822</u>	<u>\$ 9,503</u>	<u>\$ 80,706</u>	<u>\$ 71,387</u>