

**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): **June 4, 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**

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))

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

<u>Title of each class</u>	<u>Trading symbol</u>	<u>Name of each exchange on which registered</u>
Common stock, \$0.001 par value per share	EGRX	NASDAQ Global Market

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 7.01 Regulation FD Disclosure.**

On June 4, 2019, Eagle Pharmaceuticals, Inc., or the Company, released an updated investor presentation of the Company’s business model, products, and product candidates. The investor presentation will be used from time to time in meetings with investors.

A copy of the above-referenced presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information furnished pursuant to Item 7.01 of this current report, including Exhibit 99.1, shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended. As such, this information shall not be incorporated by reference into any of the Company’s reports or other filings made with the Securities and Exchange Commission. The furnishing of the information in this Current Report on Form 8-K is not intended to, and does not, constitute a determination or admission by the Company that the information in this Current Report on Form 8-K is material or complete, or that investors should consider this information before making an investment decision with respect to any security of the Company.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Presentation of the Company dated June 2019</a>

**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: June 4, 2019

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

# Eagle Pharmaceuticals

June 2019

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**EAGLE**<sup>®</sup>  
PHARMACEUTICALS

# Forward Looking Statements

This presentation 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 such as “will,” “underway,” “allow,” “expect(ed),” “pursuing,” “may,” “would,” “addressing,” “creating,” “intends,” “anticipate(s),” “plan,” “partner,” “could,” “enables,” “potential(ly),” 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 continued commercial performance of our marketed products, including but not limited to Bendeka, which is marketed by our partner Teva, Ryanodex, which we market ourselves, as well as our ability to replicate our marketing successes for our other product candidates such as Ryanodex for Exertional Heat Stroke (EHS) or other additional indications, our pemetrexed candidate, or our fulvestrant candidate, either through joint or direct marketing efforts; Eagle’s ability to advance Ryanodex in the treatment of Acute Radiation Syndrome (ARS); Eagle’s plans to continue to evaluate the data and conduct further research with respect to Ryanodex in the treatment of ARS; successful compliance with FDA and other governmental regulations applicable to our products and businesses; the label expansions of Ryanodex for EHS patients and for the treatment of neurological impact and nerve agent exposure; our ability to protect the longevity of the bendamustine franchise; the strength of our cash position and the ability to optimize the deployment of capital and take advantage of market opportunities; the continued year over year growth of our revenue, EBITDA, adjusted non-GAAP earnings per share and profit margins; the continued growth of the global biologics market and our ability to use Arsia Therapeutics (now Eagle Biologics) to enter into the biologics market and to effectively carry out our strategy in this new market; the contribution of the Ryanodex portfolio to our growth; the timing of Ryanodex for EHS obtaining FDA approval, if ever, and entering the market; the advancement of any of our other product candidates including, but not limited to, fulvestrant and pemetrexed, through the development process including FDA approval and the ability of any such products to have commercial success and to access significant new markets; the Company’s plans to finance and consummate the stock repurchase program, including the accelerated share repurchase (ASR); and the anticipated outcome of the stock repurchase program, including the ASR. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond our 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 FDA will ultimately approve Ryanodex for the treatment of EHS and neurological impact of nerve agent exposure; whether we can continue to make progress with the development of fulvestrant, whether our bendamustine product offering will achieve the anticipated market share; fluctuations in the trading volume and market price of shares of our common stock; 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 product candidates or that may have an impact on any of our products or product candidates, successful compliance with FDA and other governmental regulations applicable to product approvals, manufacturing facilities, products and/or businesses; the strength and enforceability of our intellectual property rights or the rights of third parties; competition from other pharmaceutical and biotechnology companies; the timing of product launches; the successful marketing of our products; the risks inherent in the early stages of drug development and in conducting pre-clinical studies and clinical trials; the possibility that the study results with respect to Ryanodex may be inaccurate or incomplete; management’s determination of alternative needs and uses of our cash resources; the impact of general economic, industry, or political conditions in the United States or internationally; the performance of financial markets, the fluctuation of interest rates; and other factors that are discussed in our Annual Report on Form 10-K for the year ended December 31, 2018, our Quarterly Reports on Form 10-Q, and our other filings with the U.S. 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 we do 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

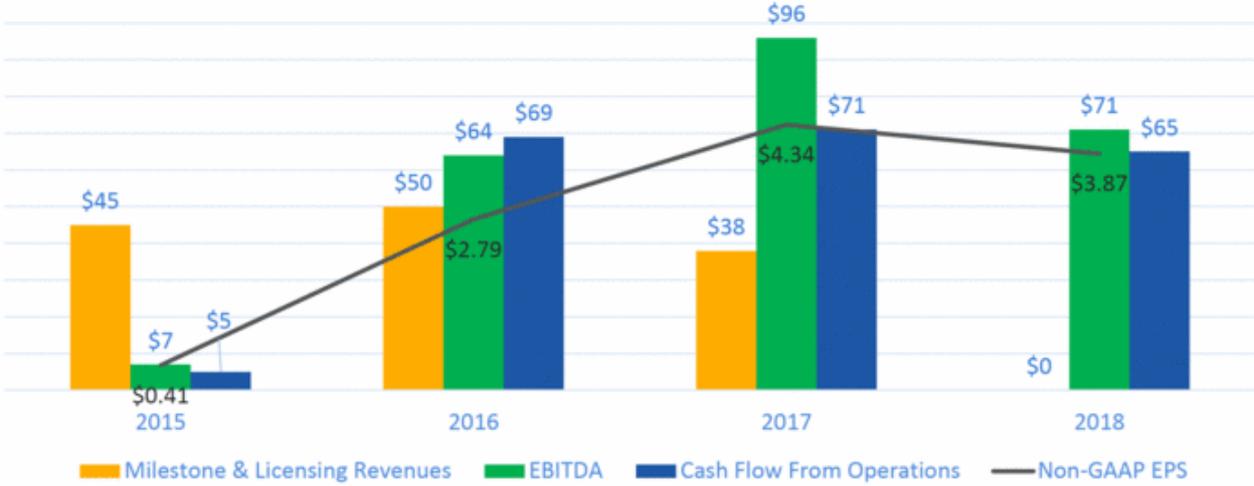
In addition to financial information prepared in accordance with U.S. GAAP, this presentation also contains adjusted non-GAAP net income, adjusted non-GAAP earnings per share and adjusted non-GAAP EBITDA attributable to the Company. The Company believes these measures provide investors and management 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, gain on sale of asset, debt issuance costs, severance, expense of acquired in-process research and development, asset impairment charge, legal settlement, non-cash interest expense 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 following 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 and adjusted non-GAAP earnings per share amounts for the twelve months ended December 31, 2018, 2017, 2016 and 2015, and adjusted non-GAAP EBITDA amounts, for the twelve months ended March 31, 2019 and December 31, 2018, 2017, 2016 and 2015, 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.

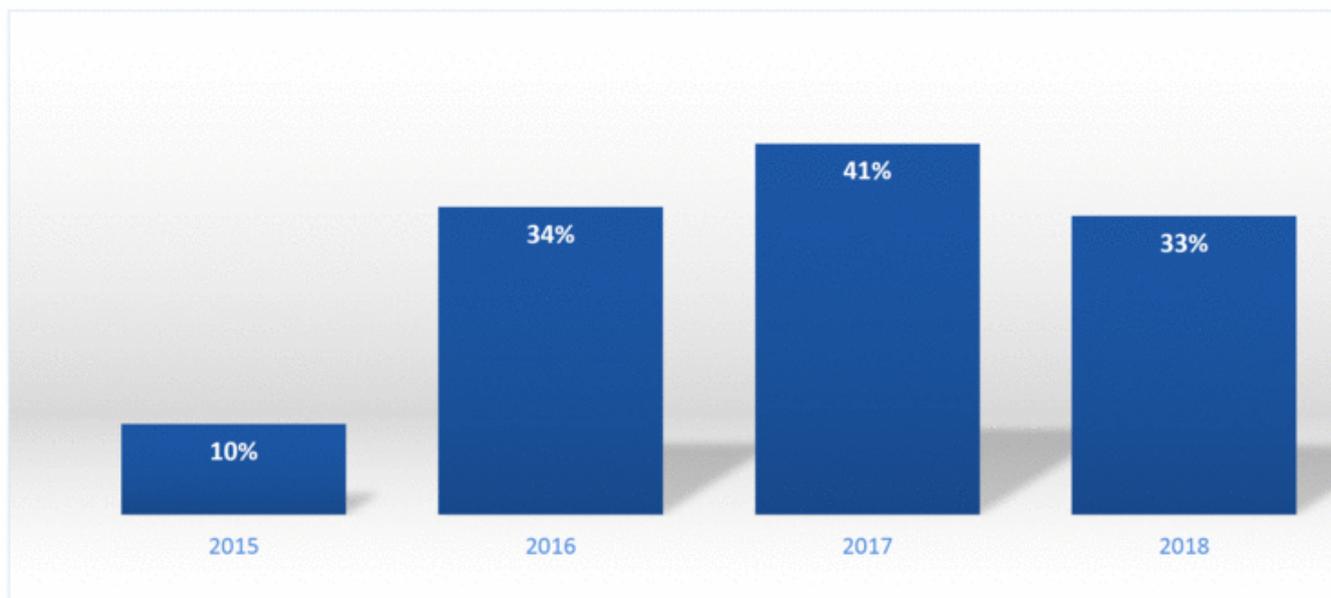
# Significant Growth Since IPO

(US\$MM, except per share data)



#16 on Fortune’s 100 List of Fastest-Growing Companies with #1 ranking for both 3-year EPS and revenue growth

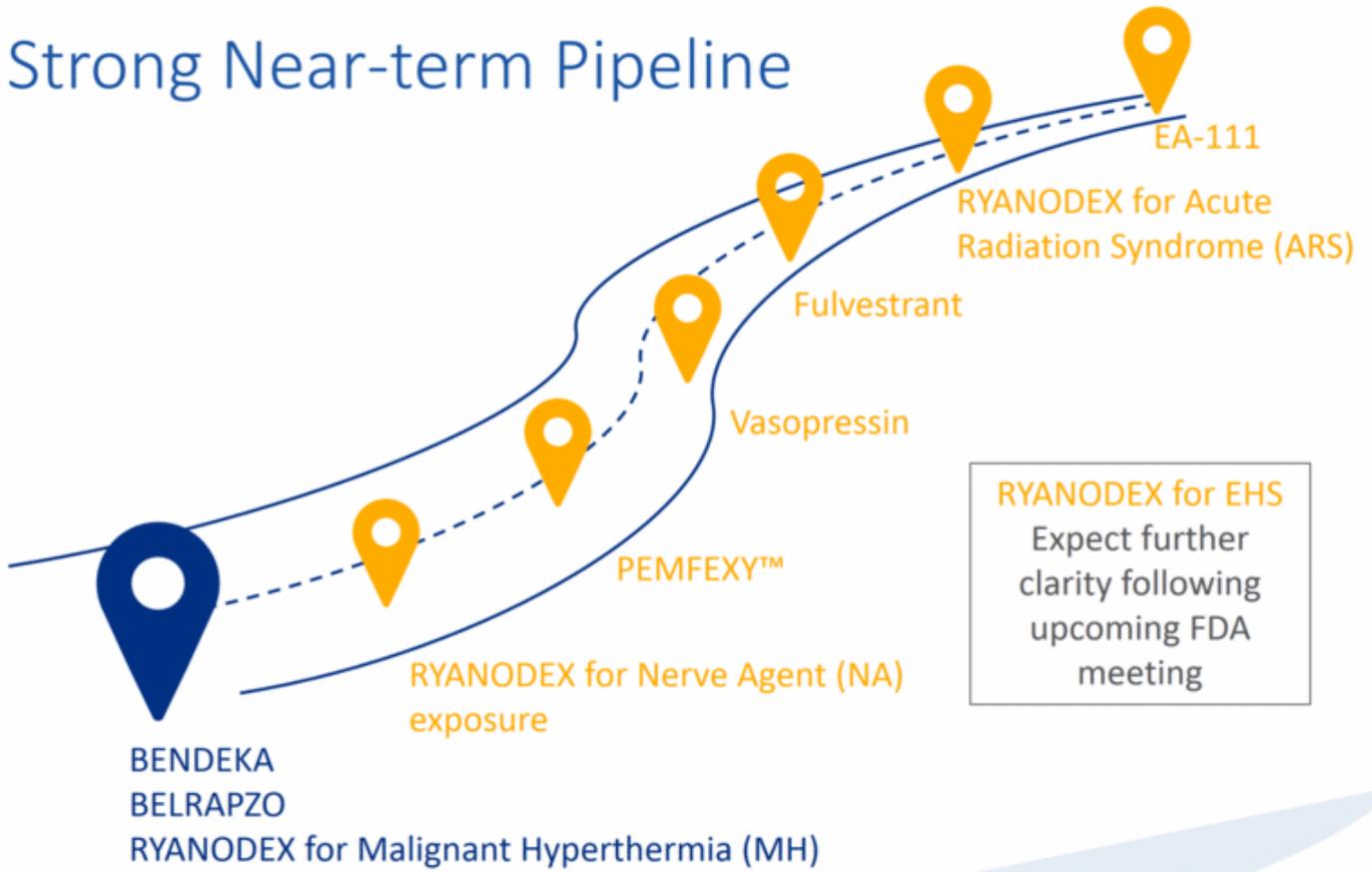
## Strong EBITDA Margin



# Recent Developments

- FDA rules in Eagle's favor on ODE scope for BENDEKA®
- Licensing agreement expanded for BENDEKA
  - Royalty increases from 25% to 30% on 10/1/19, and then increases by 1 percentage point on each anniversary thereafter until it reaches 32%
  - Term of agreement extended from 2025 until product no longer sold
- Unique J-code issued for BELRAPZO™ effective July 1, 2019
- Completed RYANODEX® nerve agent study with U.S. Military
  - Positive topline results; achieved statistical significance and met primary endpoint
  - Eagle believes study supports neuroprotective effects of RYANODEX

# Strong Near-term Pipeline



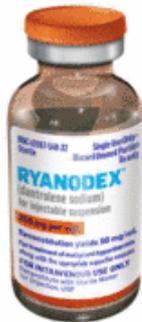
# RYANODEX: Multiple Label Expansion Opportunities

Creating additional value by addressing life-threatening, unmet needs  
Eight U.S. patents issued to date, expiring between 2022 to 2025

## Marketed

### Malignant Hyperthermia

- Breakthrough formulation of dantrolene sodium
- Approved July 2014
- Launched August 2014



## Potential Label Expansion

### Nerve Agent Exposure

- Treatment of brain damage secondary to nerve agent (NA) exposure as potential next indication
- Positive results demonstrated in initial study in 2017
- Robust statistically significant data from a study conducted in partnership with U.S. Army in 2019
  - Demonstrated the neuroprotective effects of RYANODEX in a well-established NA soman model

### Acute Radiation Syndrome

- Treatment of individuals exposed to high doses of radiation (nuclear power plant leakage/nuclear weapons)
- Additional research ongoing to evaluate hematopoietic syndrome in certain cancer patients undergoing radiation therapy

### Exertional Heat Stroke

- Completed enrollment of 2<sup>nd</sup> safety and efficacy clinical study
- Potential to be the first drug to market for EHS
  - EHS is a hyperthermic/hypermetabolic condition related to MH
- Orphan Drug Designation
- FDA meeting to discuss next steps June 2019

### IM Formulation (NCE)

- IM version would allow for point-of-care administration

# What are Nerve Agents?

Nerve agents (NA) are the most toxic of the known chemical warfare agents, synthesized in the 1930s; they are chemically similar to organophosphate pesticides and exert their biological effects by inhibiting certain enzymes

These agents are clear, colorless, and tasteless substances that are miscible in water and most organic solvents

Routes of human exposure include inhalation, skin/eye contact and ingestion

Acute exposure causes a cholinergic syndrome, including excess respiratory and oral secretions, diarrhea and vomiting, diaphoresis, convulsions, altered mental status, miosis, bradycardia, and generalized weakness that can progress to paralysis, respiratory arrest and death

Rapid treatment with atropine and pralidoxime decreases risk of mortality but does not ameliorate the risk of brain damage

NA survivors may experience permanent neurologic damage and often death

# RYANODEX: Treatment of Nerve Agent Exposure

**If approved, RYANODEX would be a first of its kind neuroprotective treatment for the amelioration of brain damage due to NA exposure**

Federal Agencies, including the Departments of Homeland Security and Health and Human Services, have issued multiple documents highlighting the risks of exposure to these extremely toxic chemical warfare agents

Q4 2018: Entered into agreement with the United States Army Medical Research Institute of Chemical Defense (USAMRICD) to evaluate the neuroprotective effects of RYANODEX in a well-established NA model

Q2 2019: Results of the study conducted by USAMRICD demonstrated statistically significant lower level of brain damage secondary to NA exposure in RYANODEX-treated animals, compared to controls (p value  $\leq 0.04$ )

# Nerve Agent Topline Study with U.S. Military Results

- Statistically significant neuroprotective effects of RYANODEX in critical cortical areas of the brain
- In six areas of the brain examined, RYANODEX-treated animals experienced a lower level of brain damage

# RYANODEX for Acute Radiation Syndrome (ARS)

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Study objective: Evaluate efficacy of IV administration of RYANODEX to prevent or mitigate ARS in a total body irradiated C57BL/6 male mouse hematopoietic model



Positive results of a proof-of-concept (POC) study in a Total-Body Radiation Animal Model

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Animals in each treatment group received a well-characterized, high-dose of radiation to their whole body and also received randomly-assigned RYANODEX in different treatment modalities



RYANODEX treatment group had overall less mortality post-treatment than non-treated animals with ARS

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Further explore an investigational indication for RYANODEX for the treatment of hematopoietic syndrome in individuals exposed to high doses of radiation, such as nuclear power plant leakage or nuclear weapons



Indication is likely to be developed under FDA's "Animal Rule"

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Additional research ongoing to evaluate hematopoietic syndrome in certain cancer patients undergoing radiation therapy

# RYANODEX for Exertional Heat Stroke

- P-value of 0.05 means that study results reported are 95% due to treatment effect rather than randomness
- Treatment effect observed after two distinct trials, regardless of sample size:
  - p-value of 0.07 - 0.08
  - 92%-93% chance that the positive efficacy results are attributed to the effect of RYANODEX and are not due to randomness
  - Observed treatment effect is clinically meaningful
- Believe we further removed randomness by duplicating results of 2015 study with similar study results from 2018 Hajj study
  - Mathematical separation between active and control group
- No drugs on the market to treat EHS
  - Orphan Drug Designation
  - Fast Track and Priority Review
- Confident RYANODEX works as anticipated; FDA meeting planned June 2019

**6:1 odds ratio**  
6-fold higher likelihood that patient will have full CNS recovery using RYANODEX compared to standard of care cooling alone

# EA-111 Development

- Developed new chemical entities (“NCE”) related to dantrolene
- Advancing IM-formulation NCE
- IM version would allow for easier and more rapid administration
  - Enables point-of-care administration to patients in need
  - Eliminates IV-infusion
- Anticipate 5-year NCE regulatory exclusivity post-FDA approval

# Orphan Drug Exclusivity (ODE) Granted for BENDEKA

- June 2018 - U.S. District Court for the District of Columbia issued decision requiring FDA to grant seven years of ODE in the U.S. for BENDEKA
- February 20, 2019 - FDA issued decision favoring Eagle regarding scope of BENDEKA's exclusivity
  - Pursuant to that decision, no bendamustine product (including generic versions of TREANDA®) may launch in the United States until December 7, 2022, unless clinically superior to BENDEKA
  - Prior to the decision, generic versions of TREANDA were poised to enter the market in November 2019
- Generic TREANDA entry not expected until December 2022
- Further protects longevity of BENDEKA franchise

# Bendamustine Longevity Beyond 2025

Most certitude since launch

FDA ODE scope: TREANDA generics not expected before December 2022

## BENDEKA

- Unique J-code for BENDEKA
- Bendeka royalty increases from 25% to 30% on 10/1/19, and then increases by 1 percentage point on each anniversary thereafter until it reaches 32%
- Extended U.S. licensing agreement until BENDEKA no longer sold (previous expiry 2025)
- Japan: double-digit royalty plus potential milestone payments

## Big Bag/BELRAPZO

- Launched in 2018 for CLL and NHL
  - Complementary to BENDEKA
  - Internal salesforce
- Unique J-code for BELRAPZO, effective July 1, 2019
- Target market share of up to 12%
  - Enables us to provide value to a cost-conscious segment of the market
- Japan: double-digit royalty plus potential milestone payments

### Significant BENDEKA royalties and milestones earned

- 1/1/15-3/31/19: **\$135 mm** in aggregate milestones earned
- 1/1/16-3/31/19: **\$395 mm** in royalties earned

- 15 OB listed patents through 2033
- FDA approved 2<sup>nd</sup> manufacturing site 2018

# Fifteen Orange Book Patents Running from 2026-2033

Protecting the longevity of the bendamustine franchise

U.S. Patent No.	Patent Expiration
8,609,707	1/28/2031
8,791,270*	1/12/2026
9,000,021	3/15/2033
9,034,908	3/15/2033
9,144,568	3/15/2033
9,265,831	1/28/2031
9,572,796	1/28/2031
9,572,797	1/28/2031
9,572,887	3/15/2033
9,579,384	3/15/2033
9,579,397	3/15/2033
9,579,398	3/15/2033
9,579,399	3/15/2033
10,010,533	1/28/2031
10,052,385	3/15/2033

\*owned by Teva Pharmaceutical Industries Ltd.

# Fulvestrant Opportunity

- Data released October 30, 2018
  - Trial did not meet PK endpoints
  - Safety profile consistent with expectations
- We believe we can reformulate our product in a way that may result in a better drug than the current brand
- Met with the FDA regarding reformulation
- Next meeting with FDA June 2019

# Pemetrexed Opportunity

- Multi-billion market opportunity (LTM Sales: \$1.17B U.S., \$0.97B Ex-U.S., \$2.14B WW)<sup>1</sup>
- Currently, Lilly's Alimta® patent prevents current ANDA filers from launching until May 24, 2022
- Four 505(b)(2) filers (DRL, Hospira, Actavis/Teva, Apotex) were all sued in Indiana
  - DRL and Hospira lost at district court, both based on a certain claim construction different from the one issued in Eagle's case; appellate decision expected Fall 2019
  - Actavis/Teva litigation stayed pending DRL/Hospira appeal
  - Apotex's litigation pending; trial scheduled January 2020
- FDA granted tentative approval of Eagle's pemetrexed RTD PEMFEXY™ Oct. 27, 2017
  - Lilly suit against Eagle remains pending in Delaware; Court ruled in Eagle's favor on claim construction and as a result, Lilly dropped literal infringement claim
  - Trial scheduled Sept. 9, 2019; 30-month stay expires February 2020
- Eagle continues to evaluate all litigations and outcomes

<sup>1</sup> Alimta® (pemetrexed) (Eli Lilly & Co.). Source: Eli Lilly & Company Quarterly Results; Statements of Consolidated Income – As Reported Q1 2019; <https://investor.lilly.com/financial-information/quarterly-results>

# Eagle Biologics Market Opportunity

- Acquired Arsia Therapeutics in 2016
  - Enhances Eagle’s formulation capabilities and expands product development opportunities
  - Extends Eagle’s strategy: plan to partner with key Biosimilar or Bioinnovator companies to alter their existing pipeline into “Biobetters”
  - \$45 million investment
- The global biologics market could exceed **\$400 billion** in value by 2025<sup>1</sup>
- Growing at nearly **2X** the rate of pharma<sup>2</sup>
- By the end of 2020, biologics could account for **28%** of the global pharmaceuticals market<sup>2</sup>
- The global biosimilar market may reach **\$20 - \$26 billion** by 2020<sup>3</sup>

**References:** 1. Evaluate Pharma, June 2019. 2. PRA Health Sciences Whitepaper. *The Value of Biobetters*. December 2015. 3. IMS Medicines Use and Spending in the U.S. – *A Review of 2015 and Outlook to 2020*. April 2015.

# Financial Highlights

## As of 3/31/19

- LTM EBITDA \$80.7 mm
- LTM Cash Flow from Operations, excluding A/R shifts \$84.1 mm
- Cash \$102.1 mm
- A/R \$63.9 mm
- Share Repurchase Plan as of 5/17/19
  - \$169 mm repurchased since August 2016, including \$50 mm ASR executed 10/30/18
  - 2.9 mm shares repurchased since August 2016
    - 1.9 mm shares repurchased through OMR
    - 1.0 mm shares repurchased through ASR
  - \$150 mm new authorization (including \$50 mm ASR) approved by the Board October 2018
    - \$85 mm remaining
- 13.7 mm basic shares outstanding at 5/17/19
- \$150 mm credit facility August 2017
  - \$100 mm term loan (\$42.5 mm outstanding at 3/31/19)
  - \$50 mm revolver

Thank you  
June 2019

# APPENDIX

# Reconciliation of GAAP to Adjusted Non-GAAP Net Income

	Twelve Months Ended December 31,			
	2018	2017	2016	2015
Net income - GAAP	\$ 31,903	\$ 51,943	\$ 81,453	\$ 2,571
<b>Adjustments:</b>				
Cost of product revenues:				
Amortization of acquired intangible assets (1)	895	1,194	746	-
Research and development:				
Share-based compensation expense	4,014	3,942	2,914	1,271
Depreciation	470	74	-	-
Expense of acquired in-process research & development	1,700	1,000	-	-
Severance	466	-	-	-
Selling, general and administrative:				
Share-based compensation expense	15,068	11,487	6,853	2,780
Amortization of acquired intangible assets (2)	1,620	1,620	203	-
Depreciation	685	858	640	112
Debt issuance costs	-	286	-	-
Severance	-	268	-	-
Other:				
Gain on sale of asset (3)	-	-	(1,750)	-
Non-cash interest expense	376	238	8	-
Change in fair value of contingent consideration (4)	(763)	(7,378)	957	-
Asset impairment charge	2,704	7,235	-	-
Restructuring charge	7,911	-	-	-
Legal settlement	-	1,650	-	-
Tax effect of the non-GAAP adjustments (5)	(7,894)	(5,368)	(46,103)	-
<b>Adjusted non-GAAP net income</b>	<b>\$ 59,155</b>	<b>\$ 69,049</b>	<b>\$ 45,921</b>	<b>\$ 6,734</b>
Adjusted non-GAAP earnings per share				
Basic	\$ 4.01	\$ 4.57	\$ 2.96	\$ 0.44
Diluted	\$ 3.87	\$ 4.34	\$ 2.79	\$ 0.41
Weighted number of common shares outstanding:				
Basic	14,768,625	15,102,890	15,533,681	15,250,154
Diluted	15,278,651	15,908,211	16,434,104	16,253,781

## Explanation of Adjustments:

- 1) Amortization of intangible assets for Ryanodex and Docetaxel
- 2) Amortization of intangible assets for Eagle Biologics
- 3) Gain on divestiture of diclofenac-misoprostol
- 4) Changes in the fair value of contingent consideration (Docetaxel and Eagle Biologics)
- 5) Reflects the estimated tax effect of the pretax adjustments, \$3.4 million of tax expense from U.S. tax reform which is reflected in 2017 and the reversal of a tax valuation allowance in 2016

# Reconciliation of GAAP to Adjusted Non-GAAP EBITDA

	Twelve Months Ended	Twelve Months Ended December 31,			
	March 31, 2019	2018	2017	2016	2015
Net income - GAAP	\$ 38,260	\$ 31,903	\$ 51,943	\$ 81,453	\$ 2,571
<b>Add back:</b>					
Interest expense (income), net	2,123	2,579	1,045	(76)	(14)
Income tax provision	6,098	2,135	21,002	(28,026)	3
Depreciation and amortization	3,530	3,670	3,746	1,589	112
Stock-based compensation	19,559	19,082	15,429	9,768	4,051
Change in fair value of contingent consideration	(790)	(763)	(7,378)	957	-
Debt issuance costs	-	-	286	-	-
Asset impairment charge	2,704	2,704	7,235	-	-
Gain on sale of asset	-	-	-	(1,750)	-
Expense of acquired in-process research & development	1,100	1,700	1,000	-	-
Severance	211	466	268	-	-
Restructuring charge	7,911	7,911	-	-	-
Legal settlement	-	-	1,650	-	-
<b>Adjusted Non-GAAP EBITDA</b>	<b>\$ 80,706</b>	<b>\$ 71,387</b>	<b>\$ 96,226</b>	<b>\$ 63,915</b>	<b>\$ 6,723</b>