# Eagle Pharmaceuticals

November 2018



## 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 column 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, 2017, our Quarterly Reports on Form 10-Q for each of the quarters ended March 31, 2018, June 30, 2018, and September 30, 2018, 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

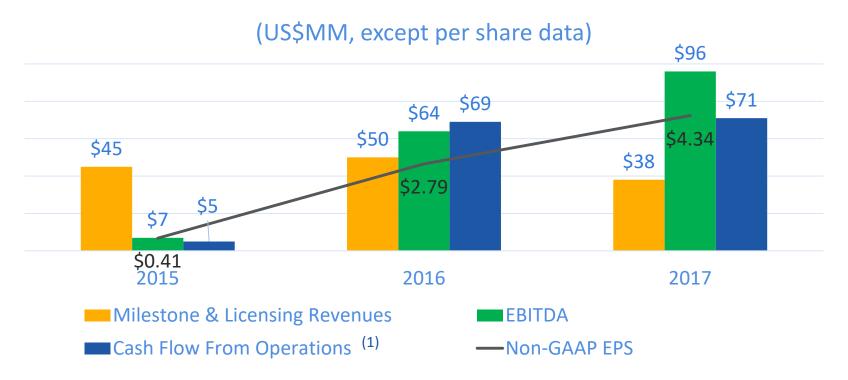
In addition to financial information prepared in accordance with U.S. GAAP, this presentation also contains adjusted non-GAAP net income, adjusted non-GAAP earnings per share and adjusted non-GAAP EBITDA attributable to the Company. The Company believes these measures provide investors and management 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, 2017, 2016 and 2015, and adjusted non-GAAP EBITDA amounts, for the twelve months ended December 31, 2017, 2016 and 2015 and September 30, 2018, 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.



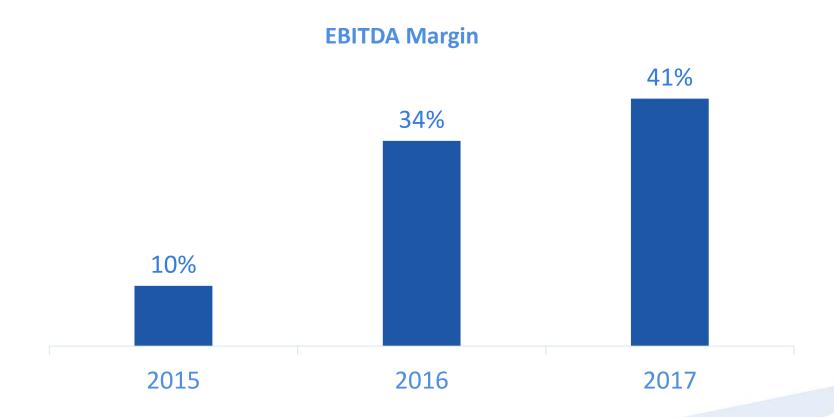
## Significant Growth since IPO



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



## Strong EBITDA Margin





#### 2018 to date:

#### **1st half of 2018**

- First-to-file Vasopressin ANDA
- Launched 500 ml bendamustine ("big bag")
- Orphan Drug Exclusivity granted for Bendeka

#### **2nd half of 2018**

- EHS enrollment of 2<sup>nd</sup> study completed; preliminary analysis of the data replicated treatment effect of 2015 Hajj
- Nerve agent: signed CRADA with US Military
- Acute Radiation Syndrome
- EA-111 (IM product in RYANODEX® franchise)
- Biostudy planning ongoing for second ANDA
- Fulvestrant



#### RYANODEX®: Multiple Label Expansion Opportunities

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

#### Marketed

#### **Potential Label Expansion**

#### Malignant Hyperthermia

- Breakthrough formulation of dantrolene sodium
- Approved in July 2014; launched in August 2014

# No. 4287-540-32 Single Use Drift Discord Discord Classed Partial Discord Classed Partial Programme Company of the Company of t

#### **Exertional Heat Stroke**

- Completed enrollment of 2<sup>nd</sup> safety and efficacy study
  - Meet with FDA to discuss next steps
- Potential to be the first drug to market for EHS
  - A hyperthermic/hypermetabolic condition related to MH
- Orphan Drug Designation
- Plan to meet with FDA to discuss next steps

Progress being made on an IM product in the RYANODEX franchise

#### **Nerve Agent**

- Treatment of neurological damage secondary to nerve agent exposure (NAE) as potential next indication
- Positive results of an initial study to evaluate the neuroprotective effects of RYANODEX in an established rodent model for NAE

#### **Acute Radiation Syndrome**

- Treat 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



#### 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 .07-.08
  - 92%-93% chance that the results we have are not random
  - Treatment effect is clinically meaningful
- Believe we further removed randomness, duplicated results of 2015 study with similar study results from 2<sup>nd</sup> 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 and plan to meet with FDA as soon as possible

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

Additional indications for Ryanodex under review with more information to be provided at the appropriate times



# RYANODEX for the Treatment of Nerve Agent Exposure

- Nerve agent (NA) exposure is often deadly; survivors frequently experience severe neurological consequences
- Q4 2018: Entered into agreement with the United States Army Medical Research Institute of Chemical Defense (USAMRICD)
  - Study to evaluate the neuroprotective effects of RYANODEX
- GLP Study Design:
  - Treatment will include the current standard of care, atropine and oxime
  - Randomized to receive RYANODEX or a control vehicle as added treatment
  - Potentially pivotal trial

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



## RYANODEX for NA Pilot Study Summary

- Over 50 rodents exposed to a high dose of the NA soman
  - Treated with the known antidote for acute poisoning (atropine and HI-6)
  - All surviving study rodents developed severe status epilepticus and were treated with standard AEDs according to protocol
- Study rodents were randomly assigned to receive RYANODEX or control vehicle as added treatment
- No safety issues were observed
- Rodents treated with RYANODEX + AEDs had better performance in neurobehavioral testing, compared to animals treated with AEDs only, and substantially less brain damage
  - Showed substantially lower level of brain cell necrosis
  - Rodents treated with standard therapy showed a mean necrosis score of 2.6 in fronto-parietal cortex, compared to a group of RYANODEX treated rodents showing a score of 0.6 in the same anatomical region
  - The scoring system for cell necrosis ranges between 0 (normal, no necrosis) to 5 (cellular necrosis greater than 80%)



## RYANODEX for Acute Radiation Syndrome (ARS)

- Positive results of a proof-of-concept (POC) study in a Total-Body Radiation Animal Model
  - Objective of the study was to evaluate the efficacy of intravenous administration of RYANODEX® to prevent or mitigate ARS in a total body irradiated C57BL/6 male mouse hematopoietic model
- 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
- 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"
- Additional research ongoing to evaluate hematopoietic syndrome in certain cancer patients undergoing radiation therapy



### EA-111 Development

- Developed new chemical entities ("NCE") related to dantrolene
- Continue advancing IM formulations with NCE
  - IM product to provide in vivo dantrolene levels similar to Ryanodex
- IM product allows easier and even more rapid administration than RYANODEX
  - Enables immediate, non-professional administration to patients in need
  - Eliminates IV infusion requirement
  - Eliminates need and wait time for professional IV administration
- Anticipate 5 year NCE regulatory exclusivity after FDA approval



## Seven Year Orphan Drug Exclusivity (ODE) Granted for BENDEKA by Court

- U.S. District Court for the District of Columbia issued a decision requiring FDA to grant seven years of ODE in the U.S. for BENDEKA
- FDA will not be able to approve any drug applications referencing BENDEKA until ODE expires in December 2022
- Generic TREANDA® entry now not expected until December 2022
- Further Protects Longevity of BENDEKA franchise



## Bendamustine Long Life Cycle

#### **Orphan Drug Exclusivity Granted**

#### 2016 - 2025

- Improved product profile and unique J-code for BENDEKA
- 15 OB listed patents through 2033
- Up to 97% market share for BENDEKA
- BENDEKA Royalty of 25% of US net sales (increased from 20% in Q4 2016)
- FDA approval for 2<sup>nd</sup> manufacturing site
- TREANDA generics not expected before December 2022
- Expansion to OUS markets (20% royalty)
- Launched "big bag" with potential market share of up to 12%

Significant BENDEKA royalties and milestones earned

- 1/1/15-9/30/18: **\$126 mm** in aggregate **milestones earned**
- 1/1/16-9/30/18: \$337 mm in royalties earned



## Fifteen Orange Book Patents Running from 2026-2033

#### Protecting the longevity of the bendamustine franchise

Patent Expiration
1/28/2031
7/12/2026
3/15/2033
3/15/2033
3/15/2033
1/28/2031
1/28/2031
1/28/2031
3/15/2033
3/15/2033
3/15/2033
3/15/2033
3/15/2033
1/28/2031
3/15/2033

Eagle/Teva asserting all patents challenged by ANDA filers



## Launch of "big bag"

Ready-to-dilute (RTD) bendamustine hydrochloride (HCl) solution

- 500 ml admixture for the treatment of patients with CLL and NHL
- Launched our ready-to-dilute product with our internal sales force
- Expands our bendamustine product offering and is complementary to BENDEKA
- Enables us to provide value to a cost-conscious segment of the market
- Anticipate over time achieving up to a 12% market share



## **Fulvestrant Opportunity**

- Data released 10/31/18
  - Trial did not meet PK endpoints
  - Safety profile consistent with expectations
  - We continue to review the details of the study to determine if there might be a path forward



## Pemetrexed Opportunity

- At this time, Lilly's Alimta patent litigations prevent current ANDA filers from launching until May 24, 2022
- FDA granted tentative approval of Eagle's Pemetrexed RTD PEMFEXY™ Oct. 27, 2017
- Lilly sued Eagle on August 14, 2017 in Indiana. That case was dismissed. Lilly then sued Eagle in Delaware on Sept. 11, 2017. Trial scheduled to begin on Sept. 9, 2019; 30 month stay expires in February 2020. Eagle moved to dismiss the Delaware case, which the Court denied Oct. 26, 2018. Eagle's litigation remains pending.
- There are four 505(b)(2) filers (DRL, Hospira, Actavis/Teva, Apotex) with a similar approach to Eagle's (ours appears to be a differentiated product). All were sued in Indiana.
  - DRL and Hospira both filed Motions for Summary Judgment of Noninfringement, and DRL went to trial
    - Both DRL's and Hospira's summary judgment motions were denied
    - The DRL trial court held that DRL infringed Lilly's patent
    - The Hospira court granted Lilly's cross-motion for summary judgment of infringement
  - Actavis' litigation is stayed pending the DRL appeal.
  - Apotex's litigation is pending. Trial is scheduled for January 2020.
  - Eagle continues evaluating all litigations and outcomes
- Multi-billion market opportunity (LTM Sales: \$1.09B U.S., \$1.01B Ex-U.S., \$2.10B WW)<sup>1</sup>

<sup>1</sup> Alimta® (pemetrexed) (Eli Lilly & Co.). Source: Eli Lily & Company Quarterly Results; Statements of Consolidated Income – As Reported Q3 2018; <a href="https://investor.lilly.com/financial-information/quarterly-results">https://investor.lilly.com/financial-information/quarterly-results</a>



## 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 \$390 billion in value over the next five years<sup>1</sup>
- Growing at nearly 2X the rate of pharma<sup>1</sup>
- By the end of 2020, biologics could account for 28% of the global pharmaceuticals market<sup>1</sup>
- The global biosimilar market may reach \$20 \$26 billion by 2020<sup>2</sup>

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



## 2018 & Beyond: Poised for Growth

Multiple potential regulatory filings in 2018

•ROW Bendeka/ bendamustine family **Eagle ANDA Assets** Launched "big" bag" • Filed vasopressin Q1 May 2018 2018; first to file status Ryanodex OUS markets Advancing 2<sup>nd</sup> product ODE granted • EHS Nerve agent Intramuscular



## Financial Highlights

#### As of 09/30/18

- LTM 9/30/18 EBITDA: \$65.7 mm
- Cash: \$91.2 mm
  - A/R: \$78.5 mm
- Share Repurchase Plan
  - \$154 mm repurchased since August 2016, including \$50 mm ASR executed 10/30/18
  - \$150 mm new authorization (including \$50mm ASR) approved by the Board October 2018
- 14.2 mm basic shares outstanding at 11/01/18 (potential further reduction pursuant to final settlement of ASR)
- \$150 mm credit facility August 2017
  - \$100 mm term loan (\$45 mm outstanding at 09/30/18)
  - \$50 mm revolver



## Thank You

November 2018



## **APPENDIX**



# Reconciliation of GAAP to Adjusted Non-GAAP Net Income

	Twelve Months Ended December 31,							
(unaudited, in thousands, except share and per share amounts)	2015		2015 2016		2017			
Net income - GAAP	\$	2,571	\$	81,453	\$	51,943		
Before tax adjustments:								
Cost of product sales:								
Amortization of acquired intangible assets (1)		-		746		1,194		
Research and development:								
Share-based compensation expense		-		2,914		3,942		
Depreciation			-		74			
Expense of acquired in-process research & development		-		-		1,000		
Selling, general and administrative:								
Share-based compensation expense	4,051		4,051 6,853			11,48		
Amortization of acquired intangible assets (2)	-		203		-			1,620
Depreciation		112		640		85		
Debt issuance costs		-		-		28		
Severance		-		-		26		
Other:								
Non-cash interest expense		-		8		238		
Changes in fair value of contingent consideration (3)		-		957		(7,378		
Gain on sale of asset (4)		-	- (1,75			-		
Asset impairment charge		-		-		7,23		
Legal settlement		-		-		1,650		
Tax adjustments (5)		-		(46,103)		(5,368		
Adjusted non-GAAP net income		6,734		45,921		69,049		
Adjusted non-GAAP earnings per share								
Basic	\$	0.44	\$	2.96	\$	4.5		
Diluted	\$	0.41	\$	2.79	\$	4.34		
Weighted number of common shares outstanding:	Ψ	0.11	Ψ	2.,,	Ψ	1.5		
Basic	15	250,154	14	5,533,681	1	5,102,890		
Diluted		253,781		6,434,104		5,908,211		
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#### **Explanation of Adjustments:**

- Amortization of intangible assets for Ryanodex and Docetaxel
- Amortization of intangible assets for Eagle Biologics
- Changes in the fair value of contingent consideration (Docetaxel and Eagle Biologics)
- 4) Gain on divestiture of diclofenacmisoprostol
- 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

	1	December 31,		Twelve Months Ended September 30,
unaudited, in thousands) 2015 2016	ands) 2015 2016 2017		2018	
Net income - GAAP	\$ 2,571	\$ 81,453	\$ 51,943	\$ 28,398
Add back:				
Interest expense (income), net	(14)	(76)	1,045	2,585
Provision for income taxes	3	(28,026)	21,002	345
Depreciation and amortization	112	1,589	3,746	3,790
Add back:				
Stock-based compensation	4,051	9,768	15,429	18,323
Changes in fair value of contingent consideration	-	957	(7,378)	(2,537)
Debt issuance costs	-	-	286	-
Asset impairment charges	-	-	7,235	2,704
Gain on sale of asset	-	(1,750)	-	-
Expense of acquired in-process research & development	-	-	1,000	2,200
Severance	-	-	268	734
Restructuring	-	-	-	7,479
Legal settlement	_	-	1,650	1,650
Adjusted non-GAAP EBITDA	\$ 6,723	\$ 63,915	\$ 96,226	\$ 65,671

