

# Eagle Pharmaceuticals

October 2019

Innovation in Pharmaceuticals: Transforming Patient Care  
by Targeting Best-in-Class Solutions

# 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 FDA approval for Ryanodex for EHS, nerve agent exposure and other indications, if ever, and entering the market; the advancement of any of our other product candidates including, but not limited to, fulvestrant, pemetrexed and vasopressin, 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 success of our near-term product candidate pipeline, 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, nerve agent exposure and other indications; our relationship with our partners, including the United States Army Medical Research Institute of Chemical Defense, the market opportunity for Pemfexy, whether we can continue to make progress with the development of fulvestrant and vasopressin, 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, 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 June 30, 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.

# The Eagle Story: Building from Our Successes

**Two significant initial successes:** bendamustine and RYANODEX®

From 2015-1H2019: generated \$250 mm+ in cash flow from operations\*  
creating substantial profitability

Efficient business model and successful cash re-investment:

- ✓ Share repurchase: bought back \$169 mm, or 17%, vs. \$110 mm issued; only 13.7 million basic shares outstanding
- ✓ Invested 20%+ of revenue in non-GAAP Research & Development

**Healthy balance sheet:** no net debt and ability to deploy capital for in-licensing/acquisitions

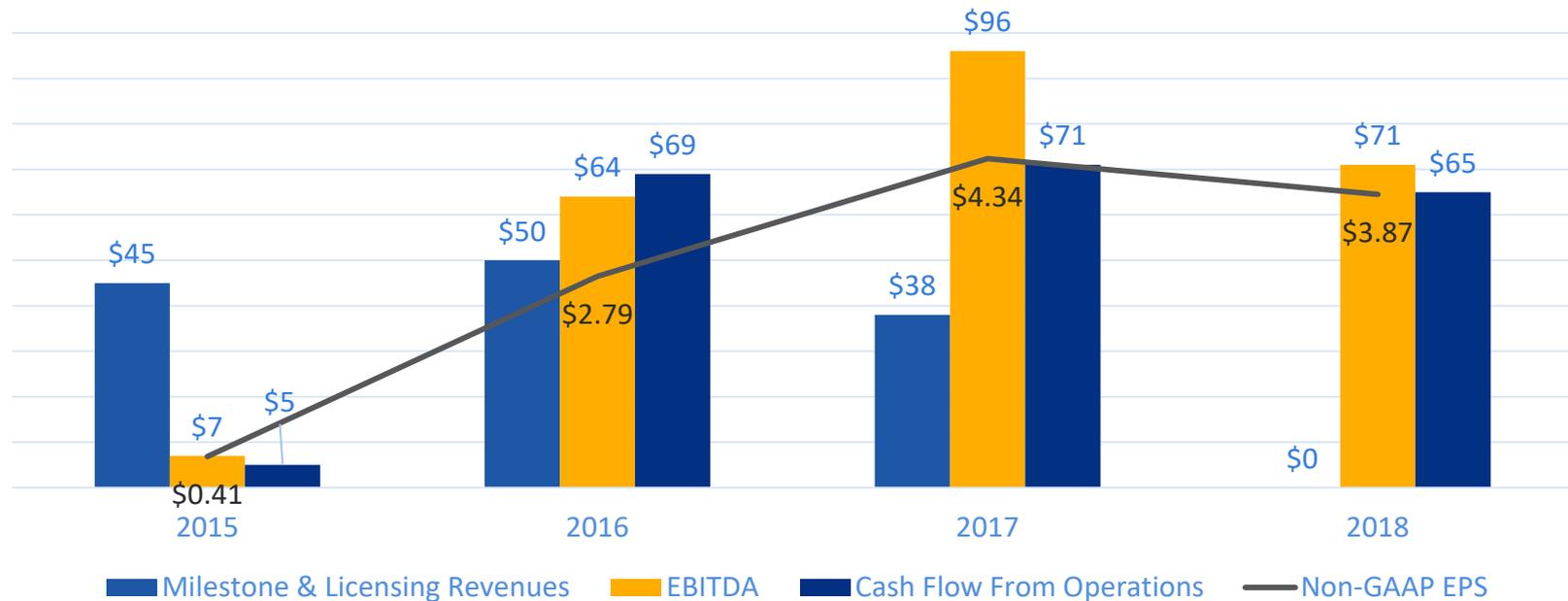
**Significant near-term pipeline:** focus on best-in-class oncology and critical care (including medical countermeasures against terrorism)

- RYANODEX® for Nerve Agent (NA) Exposure, Acute Radiation Syndrome (ARS) and Exertional Heat Stroke (EHS)
- Fulvestrant, PEMFEXY™
- Anticipate important short-term news flow over the next six months

\*Excludes receivables build

# Built a Highly Profitable Company Since Our IPO; Durable Cash Flow Generation; No Net Debt

(US\$MM, except per share data)



# The Eagle Story: Building from Our Successes

Our innovative products **make a significant difference in patient care:**

- Improve the treatment of underlying conditions
- New indications for existing drugs
- Address urgent problems for patient populations

Our marketed products and **significant near-term pipeline:**

- **BENDEKA:**
  - Meaningful innovation in cancer care for Non-Hodgkin's Lymphoma (NHL) and Chronic Lymphocytic Leukemia (CLL); dosing in 10 minutes
- **RYANODEX:**
  - Malignant hyperthermia (MH) and EHS
  - NA Exposure and ARS: protecting our military around the globe and potentially U.S. civilians as well
  - Undisclosed indications
- **EA-111:** developing the next ryanodine receptor inhibitor for acute care administration
- **Fulvestrant:** potential for better outcomes in the treatment of breast cancer
- **PEMFEXY:** innovate ready-to-dilute (RTD) formulation eliminating reconstitution steps

Our **priority: reinvest our R&D dollars** to build for future success

# Oncology Portfolio: Targeting Best-in-Class Solutions

# Oncology Assets: Building from Our Successes

## Bendamustine: *highly successful franchise*

- Established royalty revenue beyond 2025
- TREANDA generics: not expected before Dec 2022
- Long-term cash flow stream
- 15 OB listed patents through 2033 and unique J-code
- BENDEKA royalty increase: from 25% to 30% on 10/1/19 and then increases by 1 percentage point on each anniversary thereafter until it reaches 32%



## PEMFEXY:

- Pemetrexed: multi-billion dollar market opportunity (LTM Sales: \$1.23B U.S., \$0.93B Ex-U.S., \$2.15B WW)<sup>1</sup>
- Indicated for the treatment of certain cancers
- FDA granted tentative approval of Eagle's pemetrexed RTD PEMFEXY on Oct. 27, 2017
- Trial scheduled to begin on October 28, 2019

<sup>1</sup> Alimta® (pemetrexed) (Eli Lilly & Co.). Source: Eli Lilly & Company Quarterly Results; Statements of Consolidated Income – As Reported Q2 2019; <https://investor.lilly.com/financial-information/quarterly-results>

# Oncology Assets: Building from Our Successes

## Fulvestrant: Breast Cancer Overview

Breast cancer is diagnosed every **29 seconds** around the world, and in the U.S. it's every **2 minutes.** 

About **292,130 women** and about **2,350 men** will be diagnosed with breast cancer in the U.S. **this year.**

About **1 in 8 women** in the U.S. will get breast cancer in her lifetime. 

- Multi-billion-dollar worldwide market opportunity targeting patients across estrogen receptor positive (ER+) breast cancer
- 2018 sales of branded product<sup>1</sup>:
  - LTM U.S. \$529 mm
  - WW: \$1+ B

It is estimated that **86.4%** of people will survive **5** or more years after being diagnosed with breast cancer.

There is estimated to be more than **2.8 million** breast cancer survivors in the U.S. 

 **Breast cancer** is the leading cause of cancer death in women, after lung cancer. The chance of a woman dying from early stage breast cancer is estimated to be **1 in 36** (about 3%).

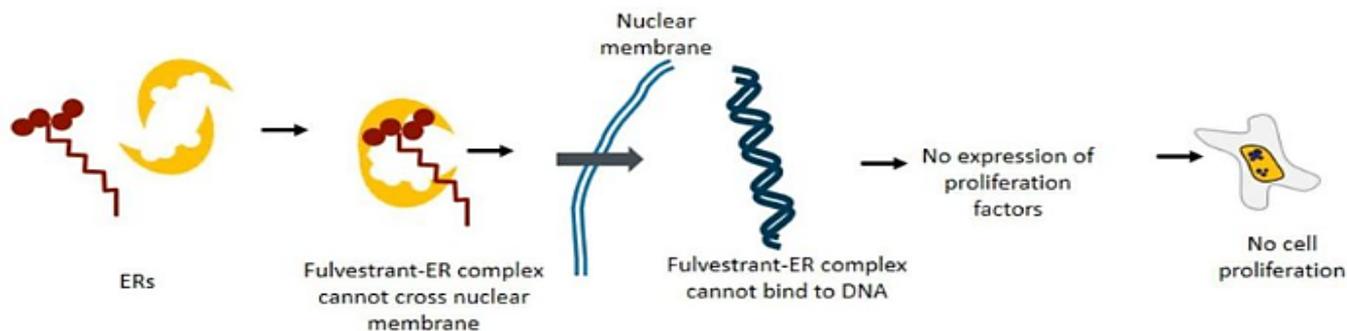
### INCIDENCE OF BREAST CANCER PER 100,000 CASES BY RACE

<b>127.9</b>	<b>124.4</b>	<b>96.3</b>	<b>92.1</b>	<b>82.0</b>
White (Caucasian)	African American	Asian/Pacific Islander	Hispanic	American Indian/ Alaska Native

<sup>1</sup>2018 Sales of AstraZeneca's Faslodex

# Fulvestrant Opportunity: Potential to Change Treatment of ER+ Breast Cancer

- Approximately 75% of breast cancers are ER+
- Fulvestrant is a selective estrogen receptor (ER) degrader (SERD)
  - Acts as an antagonist at the ER
  - Does not exhibit any known agonist activity
- Fulvestrant acts in ER+ breast cancer by binding competitively to the ER
  - Inhibits estrogen-stimulated cell division
  - Reduces the number of ERs through degradation and downregulation



# Fulvestrant Opportunity: Potential to Change Treatment of ER+ Breast Cancer

- Eagle's original fulvestrant formulation studied in 2018 clinical trial in 600 healthy post-menopausal (PM) women over 140 days
  - 300 subjects received the branded product FASLODEX®
  - 300 subjects received Eagle's formulation
- Eagle's research on the delivery of fulvestrant resulting from the Company's 2018 clinical trial has led to the discovery of significant areas of improvement of existing therapies
- Through Eagle's proprietary research, the Company has developed improved delivery technology that may enhance blocking of the proliferative activity of estrogen and downregulating the estrogen receptor

# Fulvestrant Development Progress

- Following Eagle's 2018 clinical study, the Company has met with FDA twice to propose the study design for Eagle's new delivery platform
- FDA accepted Eagle's proposal
- A pilot study in healthy PM women is starting shortly
- Based on the results of the pilot study in healthy PM women, a pivotal study will commence in PM ER+ cancer patients
  - Pivotal study will intend to evaluate multiple pharmacokinetic parameters and residual ER availability
  - Hope to complete the Pivotal Study within 12 months after initiation of enrollment
- Results of the pilot study will strongly inform the final design of the pivotal trial

Critical Care  
(including medical  
countermeasures for  
terrorism)  
Targeting Best-in-Class  
Solutions

# RYANODEX: Building from Our Successes

## RYANODEX today:

*Approved for malignant hyperthermia (MH): a life-saving drug*

- Innovative formulation of dantrolene sodium allowing for fast and efficient treatment
- Approved July 2014; launched August 2014
- Eight U.S. patents issued to date, expiring between 2022 and 2025

## Multiple exciting new indications\* underway:

- Treatments for NA Exposure, ARS, EHS
- Two undisclosed indications that we expect to announce soon

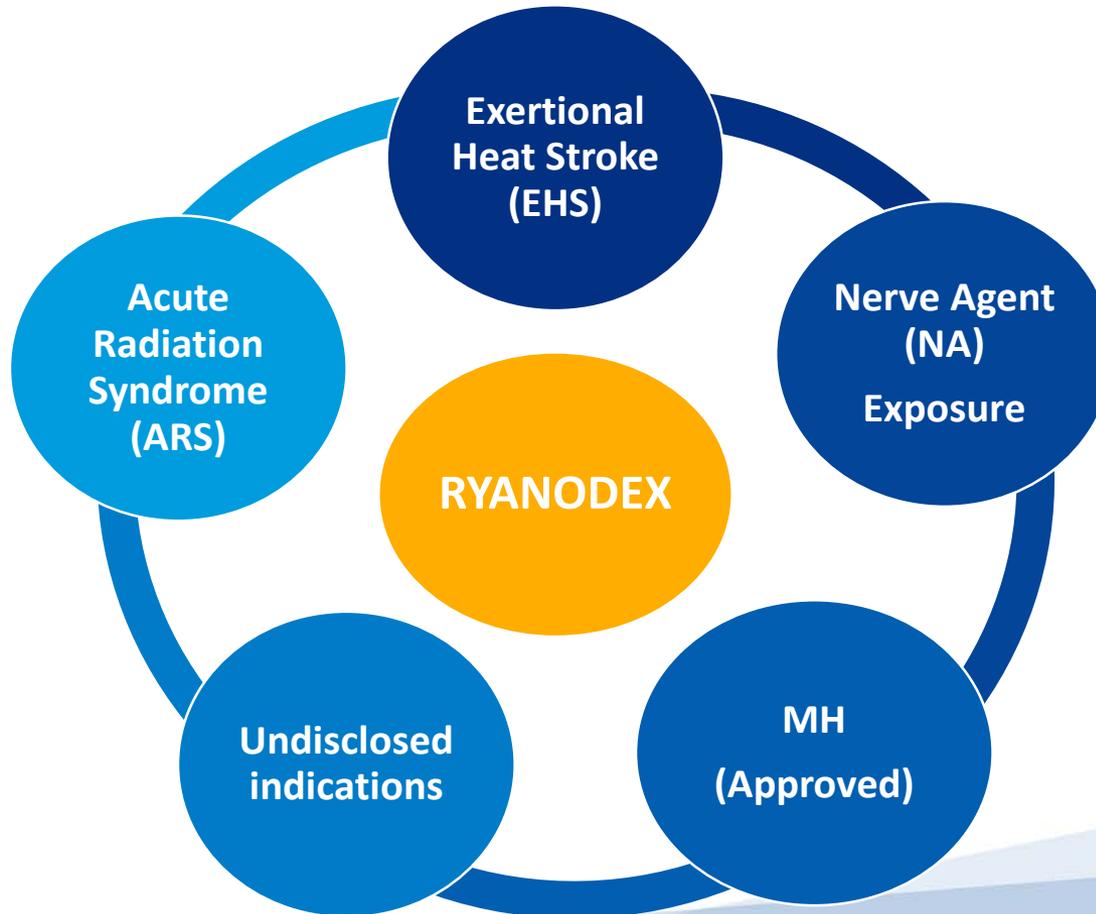
## EA-111: new chemical entity and administration method



\*not yet approved by U.S. FDA

# RYANODEX: Building a Successful Franchise

New Indications Under Development



# Understanding Medical Countermeasures<sup>1</sup> (MCMs)

- **Medical Countermeasures:** FDA-regulated products (biologics, drugs, devices) that may be used in the event of a potential public health emergency stemming from a terrorist attack with a biological, chemical, or radiological/nuclear material, or a naturally occurring emerging disease.
- MCMs can be used to:
  - Diagnose, prevent, protect from, or treat conditions associated with chemical, biological, radiological, or nuclear (CBRN) threats, or emerging infectious diseases.

<sup>1</sup> U.S. Food and Drug Administration Medical Countermeasures Initiative (MCMi) dated 12/19/18

# Overview of Strategic National Stockpile

- Designed to supplement and resupply state and local inventories of medicines and supplies during emergencies severe enough to exhaust local supplies.<sup>1</sup>
- HHS and the CDC look at multiple factors, including the medical vulnerability of the U.S. population (and of at-risk populations such as children and other vulnerable populations), current biological/chemical threats, the availability of medicines and medical supplies, and the ease of disseminating specific medicines.<sup>2</sup>

<sup>1</sup> CDC. "Strategic National Stockpile (SNS)" webpage. Available at [www.cdc.gov/phpr/stockpile/stockpile.htm](http://www.cdc.gov/phpr/stockpile/stockpile.htm).

<sup>2</sup> ASTHO. *The Strategic National Stockpile: From Concept to Achievement*. August 2010. Available at <http://www.astho.org/Programs/Preparedness/Strategic-National-Stockpile/The-Strategic-National-Stockpile--From-Concept-to-Achievement/>.

# RYANODEX: Development of NA Exposure Countermeasures Addresses Global Concern About Potential for an NA Attack

## Public Health Initiatives

*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*

## Agreement w/ US Army

*Q4 2018: Eagle entered into an 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*

## Statistically Significant Results

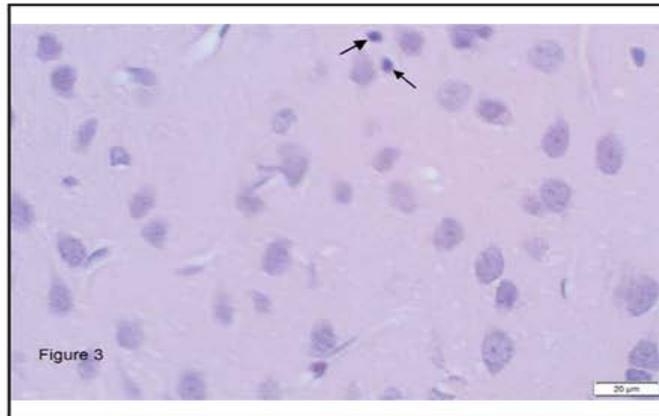
*Q2 2019: Results of the study conducted by USAMRICD demonstrated a statistically significant lower level of brain damage secondary to NA exposure in RYANODEX-treated animals, compared to controls (p value:  $\leq 0.04$ )*

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

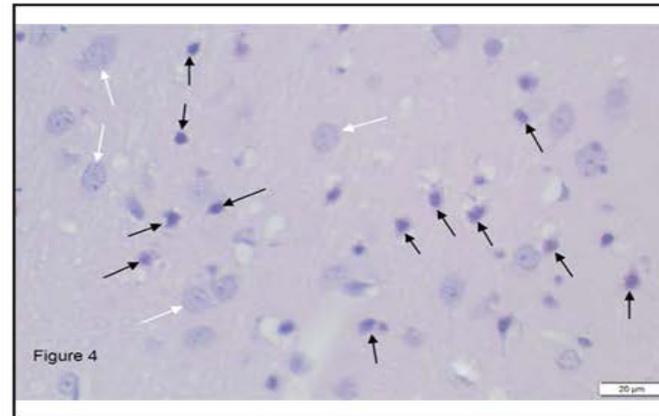
# Promising Results for a Critical Product: NA Countermeasures Topline Study with U.S. Military

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

## Histopathology of Frontal Cortex, comparing RYANODEX-treated animals (left) and control animals (right)



Ryanodex (30 mg/kg), 60 minutes post-seizure onset. Day 1, 20x objective magnification, H&E. Frontal cortex with grade 1 neuronal necrosis. Necrotic neurons denoted with black arrows.



Vehicle Control (15 mg/kg), 60 minutes post-seizure onset. Day 1, 20x objective magnification, H&E. Frontal cortex with grade 4 neuronal necrosis. Necrotic neurons denoted with black arrows. Unaffected neurons denoted with white arrows.

# RYANODEX: Animal Study for Acute Radiation Syndrome (ARS)

## 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 Animal Testing Results

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

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

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

## Further indication exploration

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

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

# RYANODEX: Exertional Heat Stroke (EHS)

## Study Objective

*Evaluate efficacy and safety of Ryanodex in addition to standard of care (body cooling) in patients with EHS*

## Unmet medical needs

*Currently there is no drug treatment for EHS. Efficient body cooling is not always available and is randomly administered. If approved, Ryanodex would be the first and only drug treatment for this rare and life-threatening condition.*

## Positive Results

*Completed two clinical trials – have collected a substantial amount of data to meet FDA expectations for regulatory review*

# EA-111 Development Is Under Way

- Developed new chemical entities (NCE) related to dantrolene
- Significant benefits of an intramuscular (IM) formulation
- EA-111 would allow for easier and more rapid administration in emergency situations (military and civilian)
  - Enables point-of-care administration to patients in need
  - Eliminates IV-infusion
- Anticipate 5-year NCE regulatory exclusivity post-FDA approval

# Vasopressin and Future In-Licensing Opportunities

## Vasopressin

- Indicated to increase blood pressure in adults with vasodilatory shock (eg post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamine
- Generic version of Endo International plc's original VASOSTRICT®
- Approximately \$454 million in brand sales in 2018
- Eagle is first-to-file an ANDA referencing VASOSTRICT; submission accepted for filing by FDA April 2019

## Supplement organic growth through in-licensing and acquisitions

- Use our balance sheet

# Financial Highlights

## As of 6/30/19

- LTM EBITDA \$80.2 mm
- LTM Cash Flow from Operations, excluding A/R shifts \$81.3 mm
- Cash \$108.1 mm
- A/R \$60.3 mm
- Share Repurchase Plan as of 6/30/19
  - \$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 7/31/19
- \$150 mm credit facility August 2017
  - \$100 mm term loan (\$41.3 mm outstanding at 6/30/19)
  - \$50 mm revolver

Thank you  
October 2019

Our Passion and Commitment to  
Patient Care: Building for Continued  
Success

# 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>
<b>Adjusted non-GAAP earnings per share</b>				
Basic	\$ 4.01	\$ 4.57	\$ 2.96	\$ 0.44
Diluted	\$ 3.87	\$ 4.34	\$ 2.79	\$ 0.41
<b>Weighted number of common shares outstanding:</b>				
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 (000's)

	Twelve Months Ended	Twelve Months Ended December 31,			
	June 30, 2019	2018	2017	2016	2015
Net income - GAAP	\$ 42,326	\$ 31,903	\$ 51,943	\$ 81,453	\$ 2,571
<b>Add back:</b>					
Interest expense (income), net	1,450	2,579	1,045	(76)	(14)
Income tax provision	11,756	2,135	21,002	(28,026)	3
Depreciation and amortization	3,414	3,670	3,746	1,589	112
Stock-based compensation	20,206	19,082	15,429	9,768	4,051
Change in fair value of contingent consideration	-	(763)	(7,378)	957	-
Debt issuance costs	-	-	286	-	-
Asset impairment charge	-	2,704	7,235	-	-
Gain on sale of asset	-	-	-	(1,750)	-
Expense of acquired in-process research & development	500	1,700	1,000	-	-
Severance	68	466	268	-	-
Restructuring charge	523	7,911	-	-	-
Legal settlement	-	-	1,650	-	-
<b>Adjusted Non-GAAP EBITDA</b>	<u>\$ 80,243</u>	<u>\$ 71,387</u>	<u>\$ 96,226</u>	<u>\$ 63,915</u>	<u>\$ 6,723</u>