

# Eagle Pharmaceuticals

February 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, the ability of Symbio to obtain regulatory approval for its bendamustine products; whether Symbio will be successful at commercializing the licensed products; whether Eagle and Symbio will perform their respective obligations under the license agreement; inaccurate sales forecasts and estimates; forecasted sales of \$90 million in 2018; forecasted sales of Bendeka in 2018; Symbio’s plans to secure regulatory approval of bendamustine HCl in a 500 mL ready to infuse and/or a 50 mL rapid infusion presentation; Symbio’s target to market the smaller volume product in Japan in 2020; the success of Eagle’s commercial relationship with Symbio and the companies’ ability to successfully work together; payments due to Eagle under the license with Symbio, including milestone and royalty payments; Argatroban, which is marketed by Chiesi USA and Sandoz pursuant to separate agreements and Ryanodex, which we market ourselves, as well as our ability to replicate our marketing successes for our other product candidates such as Ryanodex for EHS or other additional indications, our pemetrexed product candidate, our long infusion bendamustine candidate, or our fulvestrant product candidate, either through joint or direct marketing efforts; the potential lack of a need for human safety and efficacy data for the submission of an NDA for Ryanodex and the adequacy of the regulatory pathway to complete an NDA submission; the Company’s share repurchase authorization and timing and ability to continue to repurchase shares of the Company’s common stock under a share repurchase program; the business path forward for the Company between now and beyond 2026; the label expansions of Ryanodex for EHS patients and for the treatment of ecstasy and methamphetamine intoxication and for the treatment of neurological impact and nerve agent exposure; the strength of the Company’s cash position and the ability to optimize the deployment of capital and take advantage of market opportunities; the potential of the Company’s pipeline to drive value between now and beyond 2026; the contribution of the Ryanodex portfolio to the Company’s growth; the timing of Ryanodex for EHS obtaining FDA approval, if ever, and, entering the market; and the advancement of any of the Company’s 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; and our ability to use the acquisition of Arsia Therapeutics (now Eagle Biologics) to enter into the biologics market and to effectively carry out our strategy in this new market. 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 our animal studies will support the safety and efficacy of Ryanodex for the treatment of EHS, ecstasy and methamphetamine intoxication, and neurological impact of nerve agent exposure; whether the FDA will ultimately approve Ryanodex for these indications; whether the FDA will approve our application for pemetrexed, and, if filed, fulvestrant; 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 which may affect the Company’s share repurchase program; the success of our commercial relationship with Teva and our other marketing partners and the parties’ ability to work effectively together; whether Eagle and Teva and our other marketing partners will successfully perform their respective obligations under their agreements with us; 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; 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; 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; and other factors that are discussed in Eagle’s Annual Report on Form 10-K for the year ended December 31, 2016, its Quarterly Reports on Form 10-Q for each of the quarters ended March 31, 2017, June 30, 2017 and September 30, 2017 and its 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.



# Eagle 2018 At A Glance

Driving near-term, sustainable value

## Fulvestrant

Pivotal trial commenced Q4 2017

- Positive regulatory feedback
- Innovative formulation offers opportunity similar to Bendeka

## Ryanodex

Promoted by Eagle salesforce; pursuing add'l indications

- Agreed to a path forward on EHS with FDA (Feb 2018)
- Phase II clinical trial for MDMA/meth intoxication underway
- Potential next indication: treatment of neurological impact of exposure to nerve agents

## AMRI

Two compounds in development

- Combined branded sales of ~\$500 million

## Pemetrexed

Granted tentative approval for PEMFEXY™

- Began patent litigation in 2017

## Bendamustine

97% market share

- Orphan Drug Designation / in litigation for ODE
- Retained rights to launch big bag
- Licensed to SymBio in Japan in 2017
- Unique J-Code effective January 1, 2017
- 13 Orange Book Listed patents for Bendeka
- Sued four ANDA filers for patent infringement in 2017

## Eagle Biologics

Entry into fastest growing pharma sector

- 'Biobetter' product potential



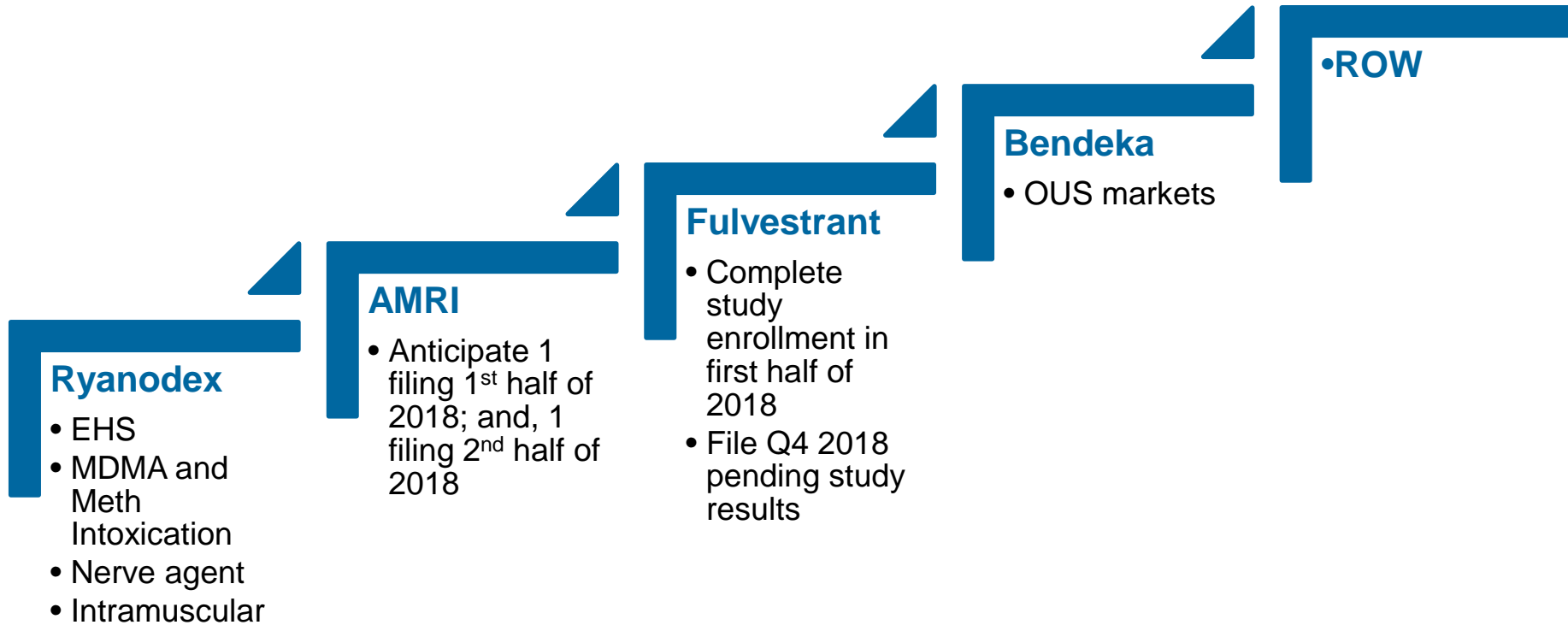
# 2018 Tax Reform Impact

- Eagle, as a U.S.-based tax payer, is expecting to benefit directly from the reduction in the U.S. Corporate tax rate from 35% to 21% beginning in 2018
- As Eagle expands its portfolio globally, we may benefit further from even lower corporate rates in certain foreign jurisdictions
- The shift to territorial system obviates the need for U.S. companies to invert



# 2018: Poised for Growth

Multiple potential regulatory filings in 2018



# RYANODEX®: Multiple Label Expansion Opportunities

Creating additional value by addressing life-threatening, unmet needs

Eight patents issued to date expiring from 2022 to 2025

## Marketed

### Malignant Hyperthermia

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



## Potential Label Expansion

### Exertional Heat Stroke

- Agreed to path forward with FDA (Feb 2018)
- Potential to be the first drug to market for EHS
- Orphan Drug Designation

### MDMA & Methamphetamine Intoxication

- Preclinical studies by NIDA/NIH completed
- Phase II clinical trial for MDMA & meth intoxication ongoing
- Broadened endpoint to include severe organ dysfunction and damage
- 125K U.S. ED visits in 2011 due to MDMA & meth intoxication
- New patent issued

### Nerve Agent

- Treatment of neurological impact of nerve agent exposure as potential next indication
- Positive results of an initial study to evaluate the neuroprotective effects of RYANODEX in an established rodent model
- Plan to meet with FDA to discuss next steps

Progress being made to an IM version of RYANODEX

# MDMA (Ecstasy) and Methamphetamine Intoxication

- Use of illegal stimulants constitutes a growing public health problem in the US and EU<sup>1</sup>
- Over 125,000 ED visits related to MDMA (ecstasy) and methamphetamine use in the US alone (2011)<sup>1</sup>
- ED visits involving MDMA among patients 21 years and younger grew over 128% between 2005-2011<sup>1</sup>
- In 2011, 42% of ED visits among people 18-29 years old involved illicit stimulant drugs<sup>1</sup>
- Associated with body and brain hyperthermia, high incidence of severe cardiovascular and neurologic complications, and lifetime neurologic sequelae<sup>2</sup>
- Can be fatal or lead to permanent damage if not treated promptly<sup>2</sup>

## References:

1. Center for Behavioral Health Statistics and Quality, SAMHSA, Drug Abuse Warning Network, National Estimates of Drug-Related Emergency Department Visits, 2011.
2. E Musselman M, Saely S. Diagnosis and treatment of drug-induced hyperthermia. *Am J Health-Syst Pharm.* 2013 Vol 70.



# RYANODEX® for MDMA (Ecstasy) & Methamphetamine Intoxication

## Positive pre-IND Meeting with FDA

- FDA suggested and we are broadening the indication to evaluate 'organ damage and/or severe dysfunction' in patients with MDMA and Methamphetamine intoxication
- No additional preclinical work required to support the efficacy of RYANODEX for this indication
- A single robust, controlled and well powered clinical trial may be sufficient for filing the NDA
- Phase II clinical trial for MDMA & Methamphetamine intoxication underway
  - enrollment slower than expected
  - next wave of recruiting expected to begin at the end of March 2018
- Patent directed to this indication issued in October 2017





# RYANODEX® for Exertional Heat Stroke

- Received a CRL from the FDA on July 26, 2017
- Based on our recent meeting with the FDA, we have agreed on a path forward for an additional clinical trial for RYANODEX for EHS
- Will conduct additional clinical trial in August 2018 during the Hajj pilgrimage
  - Similar to study conducted during the Hajj in 2015
- Believe strongly in RYANODEX given that there is no pharmacological option available for patients in need for this life-threatening condition
  - Label expansion for an already approved drug
  - No safety or CMC issues
  - Priority Review and Fast Track designation



# Fulvestrant Opportunity

## INDICATIONS for FASLODEX®

Label expanded in the U.S. to first line breast cancer in August 2017

### Monotherapy

FASLODEX is indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy, or HR-positive advanced breast cancer in postmenopausal women with disease progression following endocrine therapy

- Currently marketed by AstraZeneca
- Administered monthly in a doctor's office as 2 separate intramuscular injections, one in each buttock
- FDA has recently required revising the FASLODEX label

Faslodex® is a registered trademark of AstraZeneca.

### Combination Therapy

FASLODEX in combination with palbociclib is indicated for the treatment of HR-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in women with disease progression after endocrine therapy.



# The Problem

- 2 deep intramuscular injections of high viscosity product per dose of treatment (5 mL each)
- Administered over 1-2 minutes into each buttock
- Painful procedure
- FASLODEX injection reactions have been associated with peripheral nerve adverse reactions, including risk of damaging the sciatic nerve



## WARNINGS AND PRECAUTIONS

### 5.3 Injection Site Reaction

Injection site related events including sciatica, neuralgia, neuropathic pain, and peripheral neuropathy have been reported with FASLODEX injection. Caution should be taken while administering FASLODEX at the dorsogluteal injection site due to the proximity of the underlying sciatic nerve.

# Eagle's Solution



- Innovative formulation administered in far less time (seconds) vs. 1-2 minutes per injection
- Eagle formulation may allow warning on insert to be eliminated
- Eagle formulation does not contain castor oil
- Eagle's lower viscosity formulation allows for administration with smaller 23-gauge needle, 25% thinner than the current needle used to administer FASLODEX

# Fulvestrant Clinical Protocol

## Positive Regulatory Feedback from FDA

- Pre-IND meeting responses are aligned with Eagle's development plan
- A single PK and safety study in healthy female volunteers may be sufficient for filing
  - Commenced dosing Q4 2017 with last patient being dosed around end of April 2018
  - Aiming to file an NDA by the early fourth quarter of 2018
  - Could qualify for a new J-code
- FDA has agreed to consider not including *Injection Site Reaction (Warning & Precautions)* language in Eagle's label, provided that our clinical data demonstrates a significant safety improvement



# FASLODEX Market Opportunity

2017 total sales of the branded form of fulvestrant, FASLODEX, were up 13% to **\$941 million worldwide**

- 12% growth in US sales to \$492 mm
- 12% growth in EU sales to \$256 mm
- 15% growth in Established ROW sales to \$78 mm
- 20% growth in Emerging Markets sales to \$115 mm

# 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. Trial scheduled to begin on Sept. 9, 2019.
- 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)
  - DRL and Hospira both filed Motions for Summary Judgment of Noninfringement in late July 2017
    - DRL's summary judgment motion was denied
    - Hospira's summary judgment briefing scheduled to be completed in Q4 2018
  - DRL went to trial in February 2018. We anticipate a decision by Q4 2018. Hospira trial scheduled to begin Dec. 3, 2018
  - Apotex was sued in August 2017. Trial is presumptively scheduled for July 2019
  - Eagle continues evaluating all litigations and outcomes
- Multi-billion market opportunity (LTM Sales: \$1.03B U.S., \$1.03B Ex-U.S., \$2.06B WW)<sup>1</sup>

<sup>1</sup> Alimta® (pemetrexed) (Eli Lilly & Co.). Source: Eli Lilly & Company Quarterly Results; Statements of Consolidated Income – As Reported, Q4 2017; <https://investor.lilly.com/results.cfm>

# Bendeka: Long Life Cycle

## 2016 - 2019

- Unique J-code
- 8 newly listed patents through 2033
- 97% market share
- Royalty of 25% of US net sales (increased from 20% in Q4 2016)
- \$25 mm milestone earned from Teva in 2017
- US and expansion to OUS markets (20% royalty)
- \$12.5 mm upfront payment for licensing agreement with SymBio in Japan

## 2020 – 2026

- 6 years of royalty of 25% net sales
- Assuming large market share held post generic Treanda® entry
- Improved product profile and J-code

**Significant royalties and milestones earned**

- 1/1/15-9/30/17: **\$126 mm** in aggregate **milestones earned**
- 1/1/16-9/30/17: **\$200 mm** in **royalties earned**





# Thirteen Orange Book Patents Running from 2026-2033

Protecting the longevity of the bendamustine franchise

<b>U.S. Patent No.</b>	<b>Patent Expiration</b>
8,609,707	1/28/2031
8,791,270*PED (owned by Teva Pharmaceutical Industries Ltd.)	7/12/2026
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

Eagle/Teva asserting all patents challenged by ANDA filers



# SymBio Licensing Agreement for Bendamustine HCl

## Begins process to maximize value of Eagle's product portfolio worldwide

- Licensed Japanese Rights for Bendamustine Hydrochloride Products to SymBio Pharmaceuticals Limited in Q4 2017
  - Develop, market and sell Eagle's bendamustine HCl ready-to-dilute (RTD) and rapid infusion injection (RI) products
  - \$12.5 mm upfront payment plus future potential milestones and royalty payments
- SymBio will be responsible for securing regulatory approval of the RTD and RI injection in Japan; targeting product approval in 2020
- SymBio markets TREAKISYM<sup>®</sup> in Japan, a lyophilized powder formulation of bendamustine HCl for chronic lymphocytic leukemia (CLL); relapsed or refractory low-grade Hodgkin's lymphoma (NHL); mantle cell lymphoma (MCL); and as a first line treatment of low-grade NHL and MCL
  - 12-month sales ended June 30, 2017 for TREAKISYM in Japan were \$52 million
  - SymBio has estimated that sales of TREAKISYM will grow to \$90 million in 2018
  - SymBio is conducting a Ph 3 clinical trial for relapsed/refractory diffuse large B-cell lymphoma



# 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.



# Financial Highlights

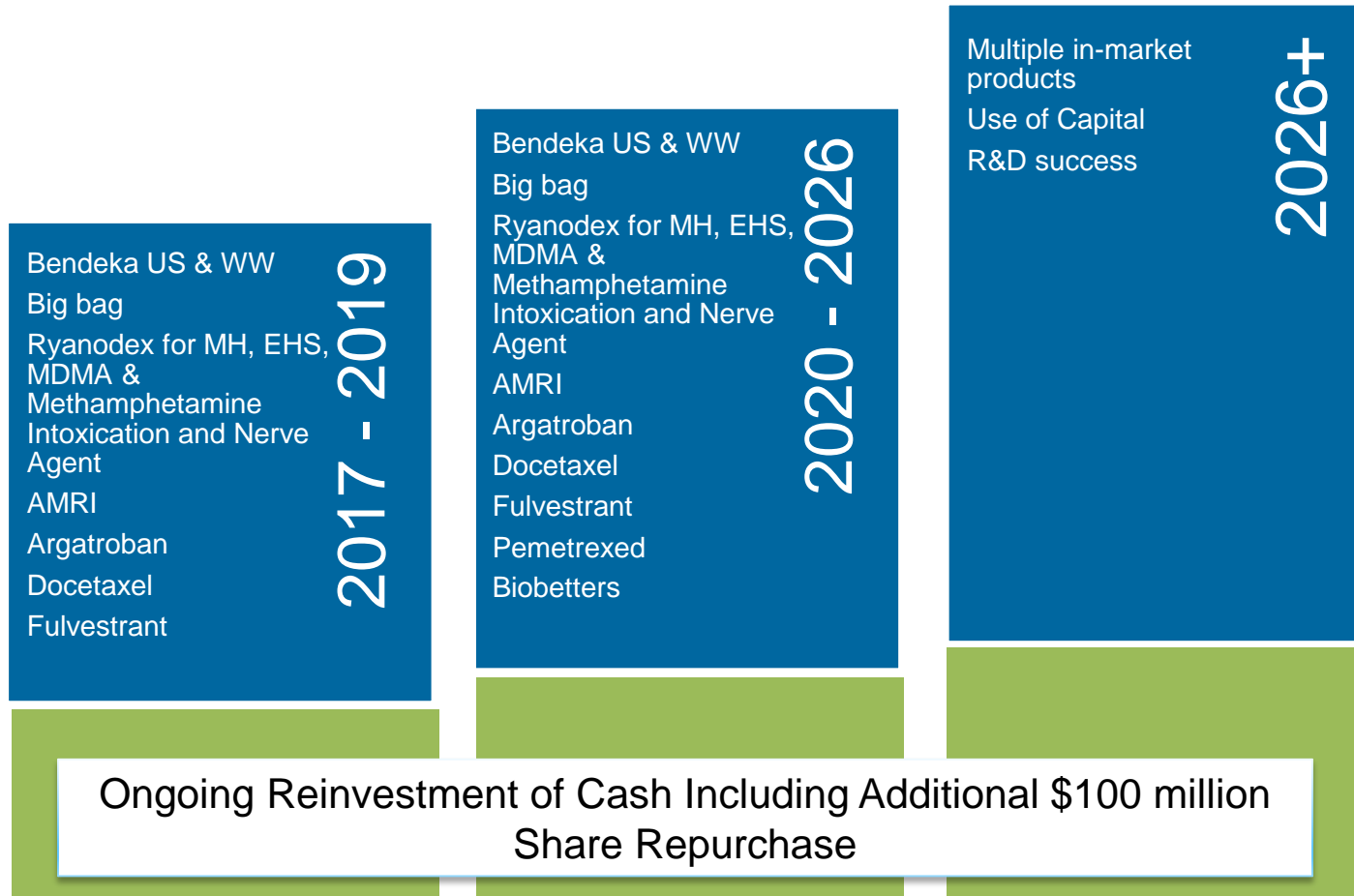
## As of 9/30/17

- LTM EBITDA: \$111 mm
  - LTM cash flow from operating activities, excluding A/R build: \$97 mm
- Cash: \$97.5 mm  
A/R: \$71.6 mm
- Share Repurchase Plan
  - \$80.8 mm repurchased (1.2 mm shares at \$65.09) since August 2016
  - \$100 mm additional authorization approved by the Board August 2017
- 14.9 mm basic shares outstanding
- \$150 mm credit facility August 2017
  - \$100 mm term loan (of which \$50 mm was drawn 8/8/17)
  - \$50 mm revolver



# Poised for Continued Growth Beyond 2020

Potential for multiple in-market products over the long-term



# Thank You

February 2018

