
**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): **February 20, 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))

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 February 20, 2019, the U.S. Food and Drug Administration, or the FDA, issued a decision in favor of Eagle Pharmaceuticals, Inc., or the Company, regarding the scope of exclusivity for BENDEKA™. Pursuant to the decision, no bendamustine product (including generic versions of TREANDA®) may launch in the United States until December 7, 2022 unless it is clinically superior to BENDEKA. Prior to the decision, generic versions of TREANDA were poised to enter the market in November 2019.

On February 21, 2019, 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	Presentation of the Company dated February 2019

SIGNATURES

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

Eagle Pharmaceuticals, Inc.

Dated: February 21, 2019

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

Eagle Pharmaceuticals

February 2019

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

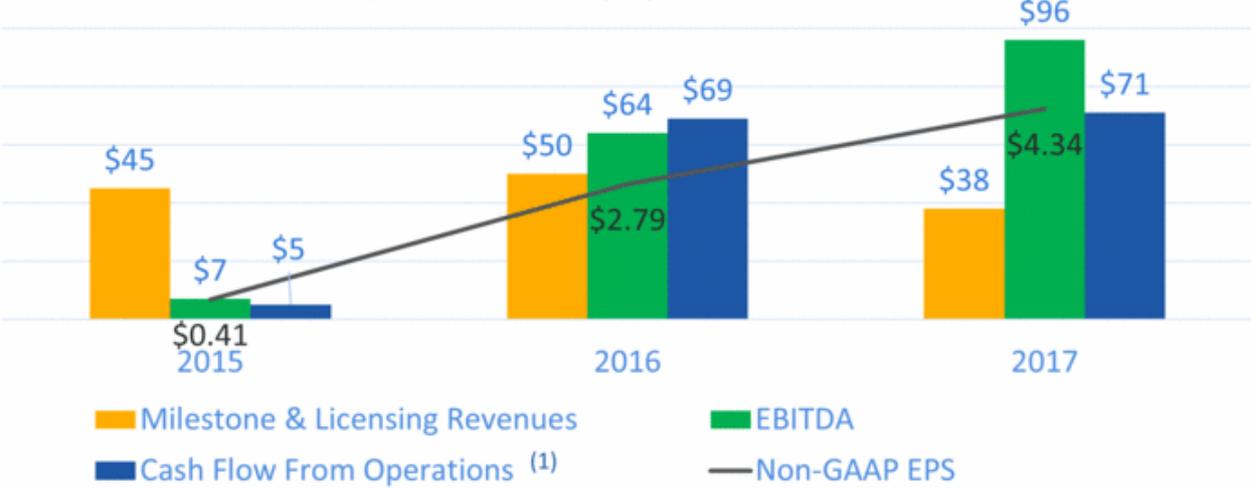
In addition to financial information prepared in accordance with U.S. GAAP, this presentation also contains adjusted non-GAAP net income, adjusted non-GAAP earnings per share and adjusted non-GAAP EBITDA attributable to the Company. The Company believes these measures provide investors and management 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

(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



2018 in Review:

- First-to-file Vasopressin ANDA
- Launched 500 ml bendamustine (“big bag”)
- Orphan Drug Exclusivity granted for BENDEKA
- EHS enrollment of 2nd 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

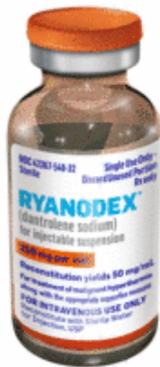
RYANODEX: Multiple Label Expansion Opportunities

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

Marketed

Malignant Hyperthermia

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



Progress being made on an IM product in the RYANODEX franchise

Potential Label Expansion

Exertional Heat Stroke

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

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 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

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 2nd 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

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

- In June 2018, 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
- On February 20, 2019, FDA issued a decision in favor of Eagle regarding the 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 they are clinically superior to BENDEKA
 - Prior to the decision, generic versions of TREANDA were poised to enter the market in November 2019
- Generic TREANDA entry now not expected until December 2022
- Further Protects Longevity of BENDEKA franchise

Bendamustine Long Life Cycle

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 2nd manufacturing site
- TRENDA 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

U.S. Patent No.	Patent Expiration
8,609,707	1/28/2031
8,791,270 (owned by Teva Pharmaceutical Industries Ltd.)	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

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 October 31, 2018
 - 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)¹

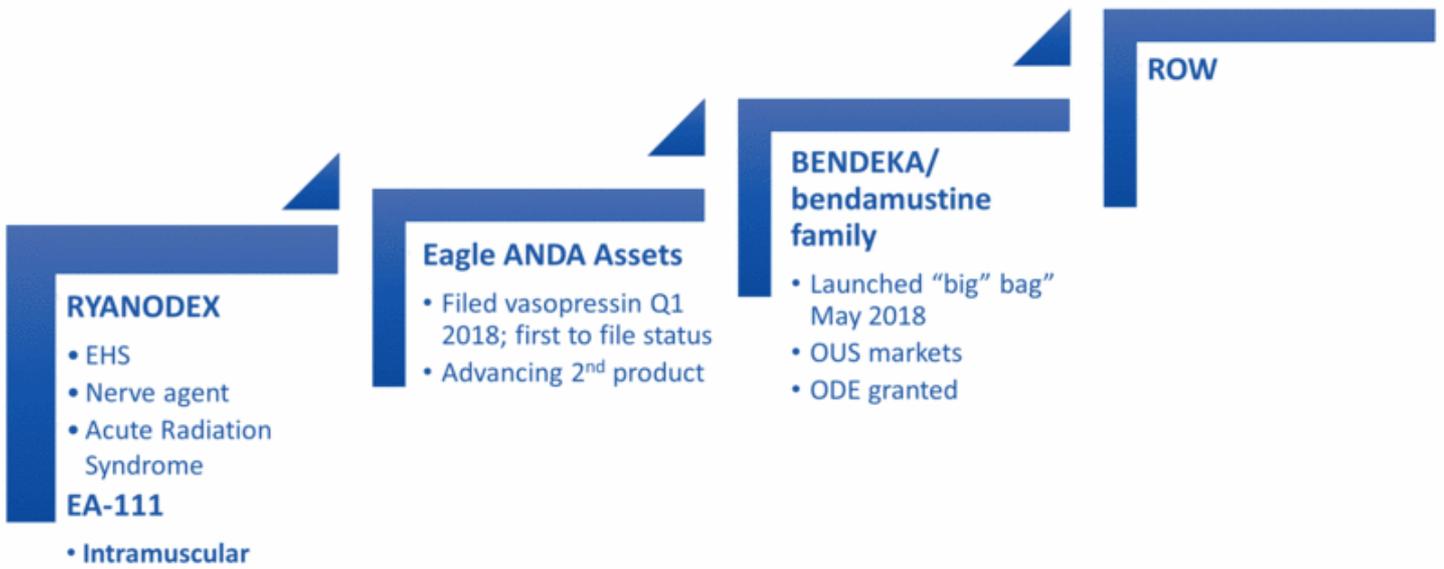
¹ Alimta® (pemetrexed) (Eli Lilly & Co.). Source: Eli Lilly & Company Quarterly Results; Statements of Consolidated Income – As Reported Q3 2018; <https://investor.lilly.com/financial-information/quarterly-results>

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 **\$390 billion** in value over the next five years¹
- Growing at nearly **2X** the rate of pharma¹
- By the end of 2020, biologics could account for **28%** of the global pharmaceuticals market¹
- The global biosimilar market may reach **\$20 - \$26 billion** by 2020²

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.

2019 & Beyond: Poised for Growth



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
 - 2.6 mm shares repurchased since August 2016
 - 1.6 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
- 13.9 mm basic shares outstanding at 12/31/18
- \$150 mm credit facility August 2017
 - \$100 mm term loan (\$45 mm outstanding at 09/30/18)
 - \$50 mm revolver

Thank You

January 2019

APPENDIX

Reconciliation of GAAP to Adjusted Non-GAAP Net Income

(unaudited, in thousands, except share and per share amounts)

	Twelve Months Ended December 31,		
	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	6,853	11,487
Amortization of acquired intangible assets (2)	-	203	1,620
Depreciation	112	640	858
Debt issuance costs	-	-	286
Severance	-	-	268
Other:			
Non-cash interest expense	-	8	238
Changes in fair value of contingent consideration (3)	-	957	(7,378)
Gain on sale of asset (4)	-	(1,750)	-
Asset impairment charge	-	-	7,235
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	\$ 4.57
Diluted	\$ 0.41	\$ 2.79	\$ 4.34
Weighted number of common shares outstanding:			
Basic	15,250,154	15,533,681	15,102,890
Diluted	16,253,781	16,434,104	15,908,211

Explanation of Adjustments:

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

(unaudited, in thousands)	December 31,			Twelve Months Ended
	2015	2016	2017	September 30, 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