

# **Eagle Pharmaceuticals, Inc.**

# Ryanodex Receives Priority Review, PDUFA Date July 22, Ahead of **Our Prior Fourth-Quarter Launch Estimate**

- Eagle Pharmaceuticals announced that the FDA has granted the company's NDA for Ryanodex priority review and issued a PDUFA date of July 22. The Ryanodex 505(b)(2) NDA was submitted in January and we had anticipated the earliest approval for the product would be in the fourth quarter. This morning's news suggests an earlier-thananticipated third-quarter approval is possible for the product.
- Ryanodex is Eagle's ready-to-use formulation of dantrolene, which is under review for the treatment of malignant hyperthermia, a rare disease that can be fatal and is normally associated with the administration of certain general anesthetics. While malignant hyperthermia is a rare disease, current guidelines state that hospitals must carry at least two doses of the current formulation of dantrolene in their pharmacies. We believe the market for dantrolene approximates \$20 million domestically and an additional \$20 million internationally. Pending an approval of Ryanodex, Eagle will launch the product with a limited salesforce of 5-10 hospital reps calling on pharmacies at the corporate level. However, with that commercial buildout coming earlier than anticipated, we believe today's news may also catalyze business development opportunities, as management would likely seek to further leverage the limited sales infrastructure put in place surrounding Ryanodex.
- To administer the current formulation of dantrolene, an average of 12 vials must be reconstituted for the patient in more than 700 milliliters of IV fluid, a process that may take 15-20 minutes. This product preparation must occur during a critical period for the physician and patient, with malignant hyperthermia episodes characterized by a rapid increase in body temperature and rapid presentation of symptoms. Eagle's Ryanodex is a ready-to-use formulation of dantrolene that can be administered with 95% less volume in under a minute. Given the crisis environment in which dantrolene is normally administered, we believe there may be room for a pricing at premium to the current formulation; however, pricing for the Ryanodex product will likely not be disclosed until approval.
- Outside of malignant hyperthermia, we believe Eagle is progressing on the design of the company's clinical program utilizing the Ryanodex formulation for the treatment of exertional heat stroke. While we estimate peak sales in the U.S. of Ryanodex at \$20 million, its expansion into the treatment of exertional heat stroke could expand the peak sales potential of Ryanodex to over \$200 million, in our view.
- We remain Outperform rated on shares of Eagle and maintain our \$22 price target. We will update our Ryanodex expectations pending approval of the therapy and clarity on pricing. Given what we believe are modest assumptions for the peak penetration and timing of the bendamustine launch, as well as dantrolene and the bivalirudin product, we derive a net present value (NPV) for the company's pipeline of \$22 per share. However, given the potentially significant cash flow available to Eagle following a launch of bendamustine, we believe management may seek to deploy that cash through in-licensing and acquisitions. Risks for Eagle include the significant litigation the company will likely face as it attempts to bring its 505(b)(2) pipeline to the market.

Eagle Pharmaceuticals is a developer of best-in-class injectable therapeutics. The company is using the 505(b)(2) pathway to enter the market before first-to-file generics.

## Tim Lugo

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#### March 20, 2014

Stock Dating

btock rating.	Outperform
	<b>Aggressive Growth</b>
Price Target:	\$22.00
Symbol	FCRY (NASDAO)

Outperform

Price: \$14.89 (52-Wk.: \$11-\$16) Market Value (mil.): Fiscal Year End: September Long-Term EPS Growth Rate:

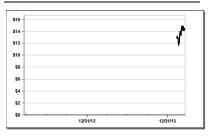
Dividend/Yield: None

	2013A	2014E	2015E
Estimates			
EPS FY	\$-0.51	\$-1.33	\$0.30
CY			
Valuation			
FY P/E	NM	NM	49.6x
CY P/E		NA	NA

Trading Data (FactSet)	
Shares Outstanding (mil.)	14
Float (mil.)	3
Average Daily Volume	449,219

Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	3.3
Enterprise Value (mil.)	146.9
EBITDA (TTM)	-8.5
Enterprise Value/EBITDA (TTM)	-17.2x
Return on Equity (TTM)	-35.8

### **Two-Year Price Performance Chart**



Sources: FactSet, William Blair & Company estimates

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#### Valuation

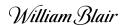
We believe shares of Eagle continue to hold a strong risk/reward profile, given the potential for significant profitability pending successful development of the company's four disclosed products. The company's pathway through a 505(b)(2) approval process, in our view, holds a reduced development risk compared with many small-cap development-stage specialty pharmaceutical companies.

We hold a price target of \$22, based on a net present value of the company's lead development programs, Ryanodex, EP-3101 (bendamustine), and EP-6101 (RTU-bivalirudin). In this calculation, we assume a launch of EP-3101 in late 2015; however, this timing will be heavily influenced by the outcome of litigation between Teva Pharmaceuticals (TEVA \$50.24) and Eagle over the ability to market its product. Our full model with additional details from is available from a William Blair salesperson.

#### **Risks**

While most risks in development-stage therapeutic companies involve clinical risk, we believe the ongoing litigation with Teva Pharmaceuticals and likely other companies whose products Eagle is targeting with its pipeline is the major risk for Eagle Pharmaceuticals. In addition to the litigation risk, investment in shares of Eagle also involves regulatory, commercialization, and financial risk, common in development-stage specialty pharmaceutical companies. The company expects to announce safety data from its 10-minute bendamustine infusion during 2014; this safety trial may hold some risk, given the faster infusion time of the product, which could lead to higher rates of nausea.

The company's pipeline is also focused on products near the end of their life cycles, and generic companies are traditionally strong competitors for market share, sometimes taking prices to unsustainable levels. We believe pricing and the resulting market share gains or losses will be a risk for Eagle as the company brings its therapies to the market.



Eagle Pharmaceuticals
Earnings Model
3/20/14
(\$ in millions except EPS data)

Rating: Outperform Company Profile: Aggressive Growth Tim Lugo 415\_248\_2870 tlugo@williamblair.com

	FY 2012(A)	FY 2013(A)	Dec. 13 Q1(A)	Mar. 14 Q2(A)	June 14 Q3(E)	Sept.14 FQ4(A)	FY 2014(E)	FY 2015(E)	FY 2016(E)	FY 2017(E)
Product Reveue EP-3101 (bendamustine RTD)	1,155	5,315	0.0	0.0	0.0	0.0	-	39,250 36,000	182,000 168,000	254,750 150,000
Ryanodex (dantrolene)	-	-	-	-	-	-	-	3,250	14,000	17,000
EP-6101 (bivalirudin)	-	-	-	-	-		-	-	-	87,750
EP-5101 (pemtrexed) EP-1101 (argatroban)		-	-	-	-	-	-	-	-	- 1
EP-2101 (topotecan)	-	-	-	-	-	-	-	-	-	-
Royalty Revenue	1,384	8,364	2800	2800	800	800	7,200	3,200	6,000	8,000
Total Revenue	2,539.4	13,679	2,800.0	2,800.0	800.0	800.0	7,200.0	42,450.0	188,000.0	262,750.0
yr/yr growth q/q growth incremental rev q/q		NM	NA NA	NA 0.0%	NA -94.2%	NA 0.0%	-47.4%	489.6%	342.9%	39.8%
Cost of Goods Sold	3166.6	7,381	1400	1400	400	400	3600	3,795	20.742	43,011
Gross Profit	-627.2	6,298	1400	1400	400	400	3600	38655	167258	219,739
Royalty Expense	021.2	0,200	1100	1100	.00	100	0000	2025	29,050	71,050
SG&A	6.399	4.958	1.620	1.980	2.700	2.700	9000	17.250	29.500	32,450
Growth	0,000	4,500	1,020	1,300	2,700	2,700	82%	92%	71%	10%
R&D	12,804.7	9,796	3,075	3,500.0	3,800.0	5,000.0	15,375	16,000	20,000	21,000
	·	0%					57%	4%	25%	5%
	00.070.44	-	-		-		-	-		-
Total Operating Expenses growth	22,370.14	22,134.03	4,695 NA	5,480 NA	6,500 NA	7,700 NA	24,375 10%	35,275 45%	78,550 123%	124,500 58%
giowai			INA	INA	IVA	INA	1078	4576	58%	3676
Operating Income EBIT Margin	(19,830.7)	(8,455.1)	(3,295.0)	(4,080.0)	(6,100.0)	(7,300.0)	(20,775.0) NA	1,355.0 3%	88,707.6 47%	95,238.8 36%
growth y/y (%)			NA	NA	NA	NA	146%	-107%	6447%	7%
Depreciation and Amortization	477.7	1,322.3	250	250	250	250	1,000	1,000	1,000	1,000
EBITDA	4/7.7	(7,133)	(3,045)	(3,830)	(5,850)	(7,050)	(19,775)	4,380	89,708	96,239
ESITOR		(1,100)	(0,040)	(0,000)	(0,000)	(7,000)	(15,775) NA	10%	48%	37%
Other income	(333.2)	1,507.9	750	750.0	750.0	750.0	3,000	2,000	6,000	8,000
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Income Before Taxes	(20,163.9)	(6,947.2)	(2,545.0)	(3,330.0)	(5,350.0)	(6,550.0)	(17,775)	5,380	94,708	103,239
Income Tax Provision	781.26	898.70	225.00	225.00	225.00	225.00	900	1,000	1,000	36,133.56
Effective Tax Rate			NA	NA	NA	NA	-5%	NA	NA	35%
Net Income (GAAP)	\$ (19,382.6)	\$ (6,048.5)	(2,770.0)	(3,555.0)	(5,574.9)	(6,775.0)	\$ (18,674.9)	\$ 4,380.1	\$ 93,707.7	\$ 67,105.3
Converitble preferred stock	\$ (3,933.4)	\$ (3,836.8)	-	-	-	-	- 1	-	-	-
Net loss attributable to common stockholders	\$ (23,316.1)	\$ (9,885.3)	\$ (2,770.0)	\$ (3,555.0) \$	(5,574.9) \$	(6,775.0)	\$ (18,674.9)	\$ 4,380.1	\$ 93,707.7	\$ 67,105.3
Basic and diluted net loss per common share	\$ (2.20)	\$ (0.51)	(0.20)	(0.25)	(0.39)	(0.48)	\$ (1.33)	\$ 0.30	\$ 6.30	\$ 4.40
Basic and diluted weighted avg. shares of common out	10,595	19,514	13,918	14,018	14,118	14,218	14,068	14,468	14,868	15,268
Key Ratios (GAAP unless noted)										
Gross Margin	NM	NM	NM	NM	NM	NM	NM	90.3%	88.6%	83.1%
R&D (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	37.7%	10.6%	8.0%
SG&A (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	40.6%	15.7%	12.4%
Operating Margin Net Income Margin	NM NM	NM NM	NM NM	NM NM	NM NM	NM NM	NM NM	NM 10.3%	47.2% 49.8%	36.2% 25.5%
· ·	INIVI	INIVI	INIVI	INIVI	INIVI	INIVI	INIVI	10.3%	49.8%	20.5%
Revenue Growth Growth Yr/Yr	NM	439%	NM	NM	NM	NM	-47%	490%	343%	40%
Growth Q/Q	NM NM	439%	NM NM	NM NM	NM NM	NM NM	-41%	490%	343%	40%
SG&A Growth	TAIVI		14141	1 11111	( NIVI	1 4141				
Growth Yr/Yr	NM	-23%	NM	NM	NM	NM	82%	92%	71%	10%
Growth Q/Q	NM		NM	NM	NM	NM		- =	***	
R&D Growth										
Growth Yr/Yr	NM	-24%	NM	NM	NM	NM	57%	4%	25%	5%
Growth Q/Q	NM		NM	NM	NM	NM				

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William Blair intends to seek investment banking compensation in the next three months from Eagle Pharmaceuticals, Inc.

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DOW JONES: 16,222.17 S&P 500: 1,860.77 NASDAQ: 4,307.60



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Coverage Universe	Percent	Inv. Banking Relationships*	Percent	
Outperform (Buy)	64	Outperform (Buy)	13	
Market Perform (Hold)	33	Market Perform (Hold)	2	
Underperform (Sell)	1	Underperform (Sell)	0	

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