

Equity Research

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## Eagle Pharmaceuticals Inc. (EGRX-\$34.00)

**Rating: BUY**

**Target Price: \$37.00**

### Ryanodex Gains Orphan Drug Exclusivity; Reiterate BUY and \$37 PT

<u>REV</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2014A	5.5A	5.0A	5.8A	2.8A
2015E	31.6E	1.9E	2.9E	20.0E
2016E	—	—	—	—
<u>EPS</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2014A	(1.44)A	(0.36)A	(0.21)A	(0.65)A
2015E	1.42E	(0.63)E	(0.73)E	0.18E
2016E	—	—	—	—
<u>FY</u>	<u>2014A</u>	<u>2015E</u>	<u>2016E</u>	
REV	19.1A	56.4E	164.1E	
P/S	25.0x	8.5x	2.9x	
EPS	(1.97)A	0.22E	4.37E	
P/E	(17.3)x	—	7.8x	

- **Ryanodex gained seven years of Orphan Drug market exclusivity:** On Feb 23 Eagle announced that FDA granted Ryanodex seven years of Orphan Drug Exclusivity for the treatment of malignant hyperthermia (MH) following FDA approval in July 2014. Ryanodex is Eagle's rapid delivery formulation of dantrolene, an existing treatment for MH which hospitals are required to stock. Eagle recently launched Ryanodex in August 2014 and has patent protection until 2025. This additional Orphan Drug Exclusivity should protect the brand until July 2021. A different dosage of this drug may get a second Orphan Drug Exclusivity in exertional heat stroke (EHS) in the future. We reiterate our BUY rating and \$37 PT, which is based on DCF analysis.
- **Ryanodex represents a nice niche opportunity for Eagle, in our view:** As Ryanodex offers significant convenience benefits to hospitals such as fewer vials to reconstitute, shorter administration time, and a lower fluid load, we assume Eagle can capture the majority of the market over time. We assume a slow, steady switch to Ryanodex by hospitals as current dantrolene stock expires. Ryanodex is currently priced at \$2,300 (Eagle is currently giving an early stocking discount of 10%). Management previously estimated there are 6,000 hospitals and 3,000 ambulatory centers that stock dantrolene for an opportunity to sell 45,000 vials, which management estimates as an \$80M opportunity. We are modeling 2015 sales of \$8.6M, growing to \$59M in 2020.
- **Additional Ryanodex indication is not in our numbers and provides potential upside to our estimates:** Eagle is also developing Ryanodex for EHS and plans to launch a pivotal trial of Ryanodex in EHS in Saudi Arabia at the Hajj in September 2015. Estimates of EHS range from 23,000-38,000 cases annually, and there are no drugs currently approved for the indication. Ryanodex has already received Orphan designation for EHS, which is encouraging, in our view.
- **Key pending catalysts:** We expect the next major catalyst for the name to be resolution of the HSP/MDCO Angiomax litigation appeal (expected 2Q:15). We also model FDA approval of Eagle's rapid infusion Treanda (recently licensed to Teva) in 4Q:15. It is possible that this product may gain priority review (which would mean earlier 3Q:15 FDA approval that may be accompanied by an undisclosed regulatory milestone from Teva). Finally, we expect management to start discussing its development program for Lilly's cancer drug Alimta, which we believe could be the next big brand extension deal for Eagle (similar to the Treanda licensing deal with Teva).

#### Current Statistics

Market Cap (\$Mil)	\$477.1	Free Float (%):	14.400
Avg. Daily Trading Volume (3 mo.):	170,848		
Shares Out (Mil):	14.032		

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**Valuation**

We value Eagle Pharmaceuticals using a discounted cash flow (DCF) analysis. We assume a weighted average cost of capital (WACC) of 12% due to lower litigation risk following the Teva settlement. We assign a 1% terminal growth rate to the company since Eagle has patent estate around several other undisclosed product reformulations and generic applications. We would raise our growth rate on the business once some of these additional opportunities became more visible. We arrive at a \$37 price target using this methodology.

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**Risks**

1. Launch delays associated with generic litigation are the chief risk for Eagle, in our view, since early launch timing is critical to the company's success. This risk has now shifted to the launch of Eagle's RTD Angiomax, in our view.
2. Each of the company's reformulated injectable products needs to secure FDA regulatory approval, so there is some degree of clinical risk to the business (although this risk is significantly lower than that for new chemical entities).
3. Manufacturing issues or supply chain disruptions are another source of risk, and the company already dealt with a supply disruption for argatroban in 2012. We checked on recent FDA inspections of Eagle's manufacturing partners and note that we did not see anything worrisome.
4. Hospital decision makers may become less accessible to drug manufacturers, which could adversely impact Eagle's ability to educate hospitals about its products and build demand.

## Company Description

*Eagle Pharmaceuticals is a specialty pharmaceutical company focused on developing and commercializing reformulated versions of injectable products in the hospital market utilizing the 505(b)(2) pathway.*

## Companies Mentioned:

Eli Lilly and Company (LLY - NYSE): NC

Hospira Inc. (HSP - NYSE): NC

Teva Pharmaceutical Industries Limited (TEVA - NYSE): NC

The Medicines Co. (MDCO - NASDAQ): NC

## Disclosures Appendix

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#### Distribution of Ratings/Investment Banking Services (IB) as of 02/24/15

Rating	Cantor		IB Serv./Past 12 Mos.	
	Count	Percent	Count	Percent
BUY [B]	94	62.67	25	26.60
HOLD [H]	47	31.33	9	19.15
SELL [S]	9	6.00	1	11.11