

Equity Research

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## Eagle Pharmaceuticals Inc. (EGRX-\$13.50)

**Rating: BUY**

**Target Price: \$30.00**

### Clinical Success for Rapid Infusion Bendamustine; Maintain BUY and \$30 PT

<u>REV</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2013A	1.5A	2.5A	5.1A	0.0A
2014E	5.5A	5.0A	5.8A	1.9E
2015E	—	—	—	—
<u>EPS</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2013A	(1.09)A	(1.84)A	(0.11)A	0.00A
2014E	(1.44)A	(0.36)A	(0.21)A	(0.57)E
2015E	—	—	—	—
<u>FY</u>	<u>2013A</u>	<u>2014E</u>	<u>2015E</u>	
REV	13.7A	18.2E	14.2E	
P/S	13.8x	10.4x	13.3x	
EPS	(0.51)A	(1.31)E	(1.61)E	
P/E	(26.5)x	(10.3)x	(8.4)x	

- **Positive bioequivalence data advances key Eagle program:** Eagle announced positive results from its 81-patient Phase I trial of a 50 mL ten minute "rapid infusion" bendamustine, which demonstrated bioequivalence to a 60 minute infusion of Treanda. Adverse events were comparable to Treanda, which is notable in a product that is rapidly infused and was tested at maximum allowable doses in extremely sick patients. The pre-NDA meeting with FDA is scheduled in mid-December, which could allow Eagle to file as early as January. Treanda is a \$720M product, and Eagle could price its rapid infusion offering at a slight discount to capture significant market share in the hospital setting. The positive study results support management's solid execution to date, and increases the company's attractiveness to potential acquirers, in our view. We reiterate our BUY and \$30 PT.
- **If Eagle's rapid infusion bendamustine gains Orphan Drug Exclusivity, then an earlier launch is possible:** We currently model bendamustine rapid infusion launch in 2016 due to obstruction from Teva's Orphan Drug Exclusivity, which expires Sept 2015. Management indicated that an earlier launch is possible since its rapid infusion bendamustine received its own orphan drug designation that may transform into orphan drug exclusivity upon approval (following the recent legal precedent set by Gralise). We don't think that Eagle's product has improved safety/effectiveness relative to Treanda and may not represent a major contribution to patient care, and we therefore reiterate our more conservative launch timing assumption. We expect Eagle to submit the sNDA in early 2015 following its pre-NDA meeting in December. This sNDA should help Eagle to avoid the 30-month stay associated with a new NDA submission. Management indicated that the rapid infusion drug would only require a change to the "how administered" section of the product label and we therefore don't expect it to require a separate NDA. The remaining gating factor to launch is Teva's lawsuit that references its "later listed" patent, which Eagle management believes may not prevent it from launching its rapid infusion bendamustine.
- **Upcoming catalysts:** (1) Eagle will report earnings in mid-December and management plans to provide an update on the Ryanodex launch. (2) Results of the Angiomax Hospira litigation are expected to determine timing of generic entry. If generics are blocked until 2019, we expect that Eagle's formulation can launch in 2017 with significant runway prior to generics. In October, The Medicines Company announced a favorable judgment in the Mylan Angiomax litigation, in which it was determined that Mylan's ANDA infringed on the patents in question. This outcome was also favorable for Eagle, in our view.

#### Current Statistics

Market Cap (\$Mil)	\$189.3	Free Float (%):	14.400
Avg. Daily Trading Volume (3 mo.):	28,721		
Shares Out (Mil):	14.020		

The Disclosure Section may be found on pages 3 - 5.

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**Valuation**

We value Eagle Pharmaceuticals using a discounted cash flow analysis (DCF). We assume a weighted average cost of capital (WACC) of 13% given the risks associated with generic litigation. 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 arrive at a \$30 price target using this methodology. With regard to downside risk, we believe that later-than-expected launch of the Treanda RTD, or earlier-than-expected generic entry of Angiomax generics could result in (\$16/share) and (\$7/share) downside to our base case scenario, respectively.

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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 is especially prominent for the launch of Eagle's RTD Treanda and Angiomax products.
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. Eagle has several products in development that it expects to launch over 2015-2017.*

## Companies Mentioned:

Hospira Inc. (HSP - NYSE): NC

Teva Pharmaceutical Industries Limited (TEVA - NYSE): NC

The Medicines Co. (MDCO - NASDAQ): NC

## Disclosures Appendix

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**NC:** Not Covered. Cantor Fitzgerald does not provide an investment opinion or does not provide research coverage on this stock.

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**SELL** - denotes stocks that we expect to provide a total negative return of more than 15% over a 12 month period. A SELL rated stock is expected to underperform the total average return of the analyst's industry coverage universe on a risk adjusted basis.

**NC** - Not Covered. Cantor Fitzgerald does not provide research coverage on this company.

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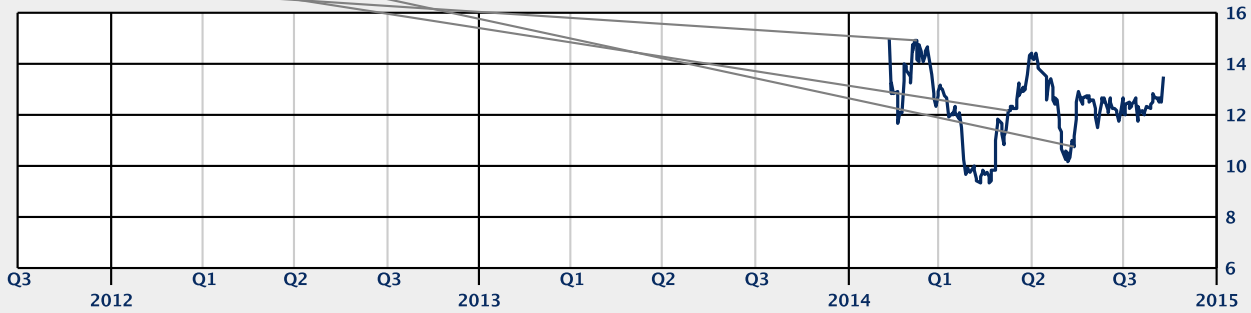
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**Rating and Price Target History for: Eagle Pharmaceuticals Inc. (EGRX) as of 11-10-2014**

03/10/14 I:B:\$21	06/09/14 B:\$22	08/12/14 B:\$30
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B=Buy H=Hold S=Sell I=Initiated D=Dropped

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**Rating and Price Target History for: Hospira Inc (HSP) as of 08-01-2012**



B=Buy H=Hold S=Sell I=Initiated D=Dropped

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**Rating and Price Target History for: Teva Pharma Indus ADS\* (TEVA) as of 08-01-2012**



B=Buy H=Hold S=Sell I=Initiated D=Dropped

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**Distribution of Ratings/Investment Banking Services (IB) as of 11/11/14**

**Cantor**

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [B]	89	60.54	21	23.60
HOLD [H]	49	33.33	10	20.41
SELL [S]	9	6.12	1	11.11