

Equity Research

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Eagle Pharmaceuticals Inc. (EGRX-\$13.07)

Rating: BUY

Target Price: \$22.00

Two For Two Approvals This Summer; Maintain BUY Rating and \$22 PT

<u>REV</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2013A	1.5A	2.5A	0.0A	0.0A
2014E	5.5A	5.0A	3.3E	2.1E
2015E	—	—	—	—
<u>EPS</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2013A	(1.09)A	(1.84)A	0.00A	0.00A
2014E	(1.44)A	(0.36)A	(0.39)E	(0.42)E
2015E	—	—	—	—
<u>FY</u>	<u>2013A</u>	<u>2014E</u>	<u>2015E</u>	
REV	13.7A	15.9E	8.9E	
P/S	13.4x	11.5x	20.6x	
EPS	(0.51)A	(1.35)E	(1.80)E	
P/E	(25.6)x	(9.7)x	(7.3)x	

- **FDA issued approval of Ryanodex and a tentative approval of Eagle's Treanda formulation on July 2nd:** FDA issued an approval of the Ryanodex NDA for the treatment of malignant hyperthermia. We estimate a Ryanodex launch in 3Q:14 and model peak sales of \$25.3 million in 2020. Earlier in the summer FDA also issued a tentative approval of Eagle's 505(b)(2) NDA for the ready-to-dilute formulation of Treanda (bendamustine) for the treatment of non-Hodgkin lymphoma (NHL). A final FDA approval can be issued after Eagle resolves its ongoing litigation with Teva and would pave the way for approval and launch of Eagle's second generation rapid infusion Treanda (via the easier sNDA regulatory pathway). We estimate a 2016 launch for the rapid infusion/small volume bag of Eagle's Treanda and model peak sales in 2017 of \$188.2 million. We appreciate management's strong execution to date and reiterate our BUY rating and \$22 PT, which are based on DCF valuation.
- **Ryanodex represents the next revenue stream for Eagle:** Ryanodex (a novel rapid administration formulation of dantrolene) will be the first product that Eagle is commercializing without a partner. Ryanodex is an Orphan Drug used for the treatment of malignant hyperthermia, a potentially fatal metabolic response triggered by anesthesia. Hospitals are required to stock dantrolene, and we believe that Eagle's new formulation offers convenience benefits such as fewer vials to reconstitute, a shorter administration time, and a lower fluid load for patients, which can translate into important safety benefits. We assume these characteristics will allow Ryanodex to capture the majority of the dantrolene market over time. Eagle is also pursuing a second Orphan indication for Ryanodex (exertional heat stroke) and plans to start a pilot study in Saudi Arabia before year-end.
- **We estimate 2016 launch of Treanda due to anticipated delays with Teva litigation:** The 30-month stay in the Teva patent litigation expires in March 2016. News is expected shortly regarding summary judgment, but we expect Teva to appeal if the decision favors Eagle and see a launch opportunity following expiration of the 30-month stay as more likely. Furthermore, Teva has Orphan Drug/pediatric exclusivity, which expires on 9/20/15 for the CLL indication (which creates another launch barrier). Our base case assumes approval of Eagle's rapid infusion Treanda in 3Q:15 via sNDA and launch of this second generation product rather than the first larger bag due to approval timing. The second generation improvements are meaningful, in our view, and we assume that Eagle will capture 40% of the market share by 2017 prior to generic entry, which we estimate in 2018.

Current Statistics

Market Cap (\$Mil)	\$183.2	Float Shares (Mil):	14.400
Avg. Daily Trading Volume (3 mo.):	82,676		
Shares Out (Mil):	14.020		

The Disclosure Section may be found on pages 3 - 4.

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 \$22 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.

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:

Teva Pharmaceutical Industries Limited (TEVA - NYSE): NC

Disclosures Appendix

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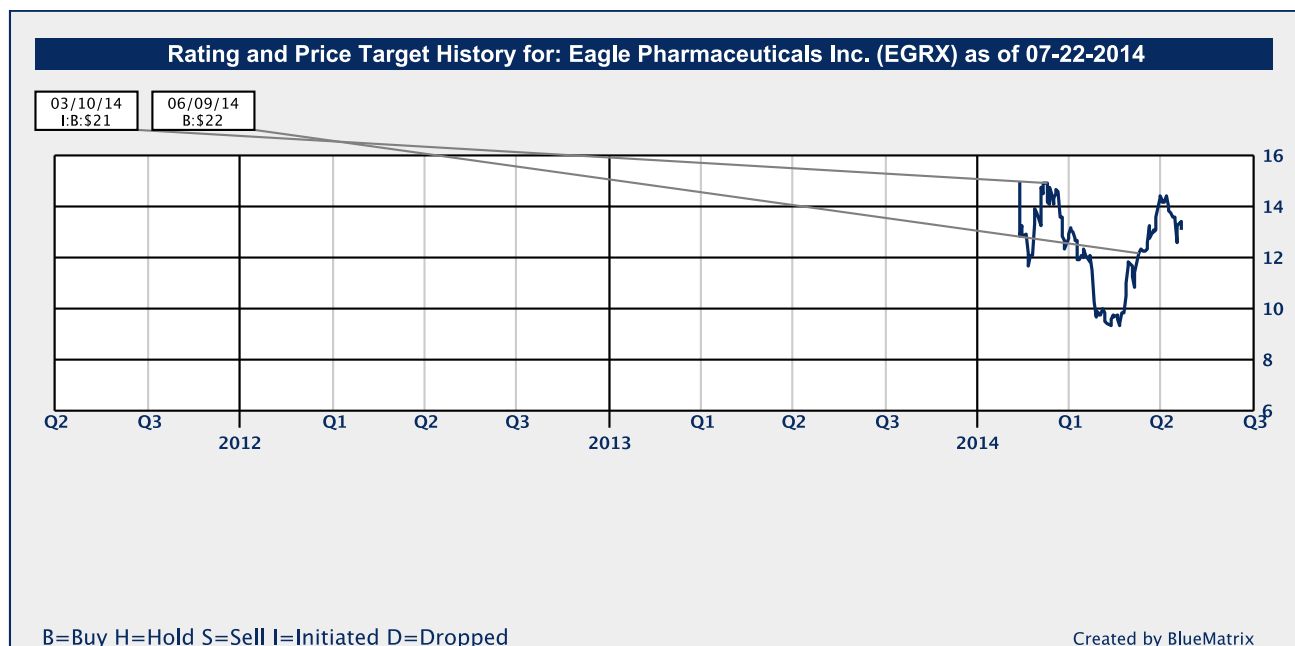
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Distribution of Ratings/Investment Banking Services (IB) as of 07/23/14

Rating	Cantor		IB Serv./Past 12 Mos.	
	Count	Percent	Count	Percent
BUY [B]	87	58.39	24	27.59
HOLD [H]	51	34.23	7	13.73
SELL [S]	11	7.38	1	9.09