

Eagle Pharmaceuticals Inc. (EGRX)

Overweight

One Hurdle for Bendamustine Out of the Way; Now Its All About the Litigation

CONCLUSION

Eagle gained a tentative approval (TA) of its NDA for its ready-to-dilute (RTD) liquid form of bendamustine (aka Treanda, a \$700M+ brand sold by Teva) for the treatment of indolent B-cell non-Hodgkins lymphoma (NHL). The wild card now of course is the outcome of the patent litigation versus Teva, though we continue to believe EGRX has a reasonably strong chance of success given the thin intellectual property surrounding the innovator product. The legal uncertainties notwithstanding, the approval is an important milestone and clear evidence of management's ability to execute. The combination of the bendamustine opportunity, an enhanced form of dantrolene (FDA action in malignant hyperthermia is expected by 7/22/14) and additional 505(b)(2)-based injectible filings to come point to strong visibility to cash generation in the 2016/2017 timeframe, pointing to an attractive risk/reward in the context of a market cap of around \$200M. We reiterate our Overweight rating and \$22 PT.

- **EGRX executes on a timely bendamustine approval.** Recall that this is the first of two enhanced forms of bendamustine that EGRX is developing. EGRX is planning a second filing in 2015 on another enhanced form of the product, though in this case the product would require a shorter infusion time versus the innovator product. Both of EGRX's products are in liquid form and do not require reconstitution. We note that Teva's currently marketed Treanda formulation is a lyophilized powder that needs to be reconstituted (though the company has approval for a newer liquid formulation that we expect will launch in the not-too-distant future). We are aware of at least 9 traditional abbreviated NDA (aNDA) filers on the Treanda lyophilized powder (so if Teva succeeds at switching over the market to the liquid form, one could argue that this is a net positive for EGRX provided that EGRX either succeeds in its litigation or works out a favorable settlement with Teva).
- **Litigation now the main wild card.** The only Treanda patent that Teva is defending in this particular case is patent #8,445,524, which expires in March 2029. On a simplistic level, the patent has claims surrounding a solid form of bendamustine (this is a patent with claims surrounding a single polymorph). According to patent consultants we spoke with, EGRX's case is relatively simple given that its product is a liquid form (and provided it can reliably show that its product did not exist as a solid structure, at least on U.S. soil) (refer to our initiation report dated 3/9/14 for more on our thinking here).
- **Our thinking on the sales potential for bendamustine.** Treanda has orphan exclusivity for NHL through April 2016. That said, EGRX will try to make a case to the FDA that its formulation that has a shorter infusion time constitutes an improvement for patients, allowing the company to do an end-around Teva's orphan status. Its most likely a longshot but there's no harm in making the case to the FDA. Should Teva succeed in switching the market to its liquid form, there is the potential that EGRX and Teva could be the only players on the market for a period of time while the aNDA filers set their sights on copying the new formulation. Another plausible scenario is Teva switching over the market but some aNDA filers on the lyophilized powder still launch anyway (provided they succeed in court). Even then we could see annual sales for EGRX's product of potentially \$40M-\$55M (advantages of EGRX's product should give it a leg up in terms of its ability to retain significant volume share).

COMPANY DESCRIPTION

Eagle is focused on optimized generic injectibles.

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Eagle Pharmaceuticals Inc.

PRICE: US\$14.25

TARGET: US\$22.00

17x 2018E non-GAAP EPS of \$2.20, disc.
20%

David Amsellem

Sr. Research Analyst, Piper Jaffray & Co.
212 284-9455, david.a.amsellem@pjc.com

Traver A. Davis

Research Analyst, Piper Jaffray & Co.
212 284-5031, traver.a.davis@pjc.com

Related Companies:

EGRX

TEVA

Share Price:

14.25

54.42

RISKS TO ACHIEVEMENT OF PRICE TARGET

Pipeline setbacks and risks related to patent litigation.

* Share Price as of the close July 2, 2014

Price Performance - 1 Year

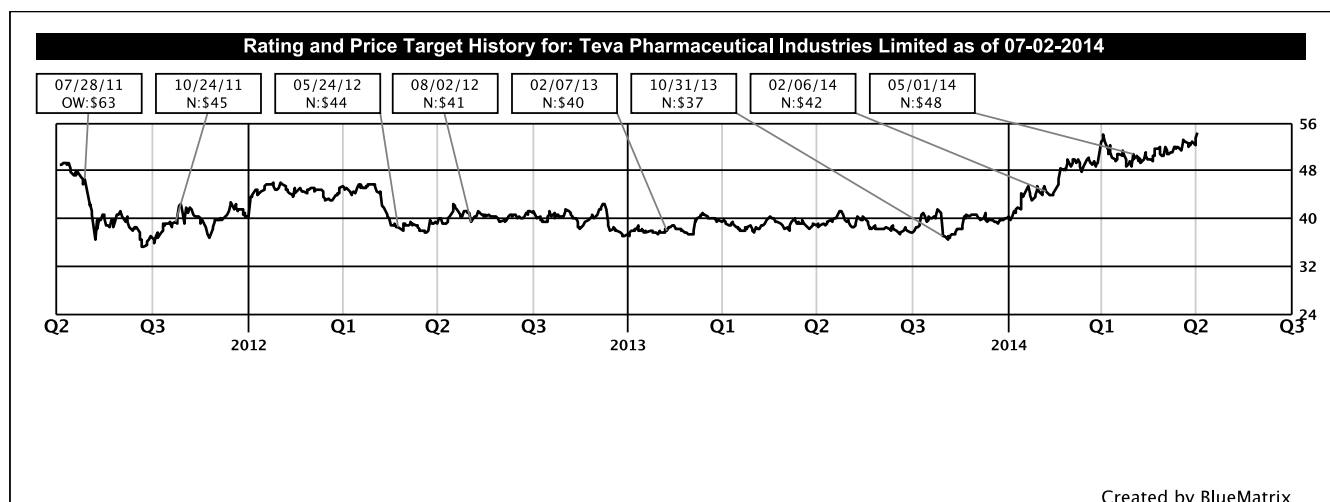


Source: Bloomberg

Rating, Price Target, and Risks

Teva Pharmaceutical (TEVA) is currently rated Neutral with a \$48 price target based on 10x 2015E EPS of \$4.84. Risks include the Copaxone competition and generic pricing risks.

IMPORTANT RESEARCH DISCLOSURES



Notes: The boxes on the Rating and Price Target History chart above indicate the date of the Research Note, the rating, and the price target. Each box represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first Note written during the past three years.

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T: Transferring Coverage
D: Discontinuing Coverage
S: Suspending Coverage
OW: Overweight
N: Neutral
UW: Underweight
NA: Not Available
UR: Under Review

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			Count	Percent
BUY [OW]	356	62.02	87	24.44
HOLD [N]	204	35.54	22	10.78
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Analyst Certification — David Amsellem, Sr. Research Analyst

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