

Eagle Pharmaceuticals Inc. (EGRX)

Overweight

More Progress On The Bendamustine Front; Reiterate Overweight

CONCLUSION

This morning, Eagle announced it has successfully completed a bioequivalence study for its lower-volume, ready-to-dilute (RTD) liquid form of bendamustine (known as EP-3102) that requires a shorter infusion time compared to Teva's predecessor product (i.e., Treanda). Recall this is the second of two bendamustine products EGRX is developing. An NDA on EP-3102 is expected in 2015. With the potential for two products on the market by next year (EGRX's enhanced form of dantrolene, known as Ryanodex, was recently launched for malignant hyperthermia (MH)), visibility on significant top-line growth is strong in our view. Given these dynamics, and especially the potential of even bigger value drivers (such as the expansion of Ryanodex in exertional heat stroke (EHS)), EGRX in our view is valued attractively in the context of a market cap of under \$200M. We reiterate our Overweight rating and \$23 price target.

- Stage now set for an NDA filing in 2015.** Recall that the first of Eagle's bendamustine products (known as EP-3101; this product received a tentative approval (TA) in early July) is a liquid formulation of bendamustine that is ready-to-dilute (RTD), though like Teva's predecessor product is infused over 30-60 minutes. In contrast, EP-3102 has a 10 minute infusion time. In an open-label study of 81 patients, EGRX noted that 50 mL of EP-3102 infused over 10 minutes was shown to be bioequivalent to 500 mL of Treanda infused over 60 minutes, with a safety profile similar to that of the predecessor product. EGRX expects to have a pre-NDA meeting with the FDA in December, paving the way for an NDA filing in 2015. Assuming an NDA filing in the early part of the year and assuming the filing is granted a 6-month priority review (as was the case for EP-3101), we could see a launch of EP-3102 before the end of 2015. This of course is contingent on EGRX prevailing in its patent litigation versus Teva (more on this below). We note that EP-3102 was granted Orphan Drug designation by the FDA for chronic lymphocytic leukemia (CLL) and indolent B-cell non-Hodgkin's lymphoma (NHL). This is important in our view given that it was thought that the FDA could be precluded from issuing final approval of EGRX's filings for its bendamustine products for CLL and NHL until the orphan exclusivities granted to Treanda expire (Treanda has orphan exclusivity for NHL through April 2016 and for CLL through September 2015). That said, with EGRX having its own orphan designation for EP-3102 in place, Teva's orphan status is no longer a potential roadblock.
- Litigation remains the key wild card.** We could see a decision on EGRX's motion for summary judgment in the current litigation by the end of 2014 or in early 2015. Recall that the only Treanda patent that Teva is defending 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 could be construed as relatively simple given that its product is a liquid form (i.e., polymorphs denote a solid structure; refer to our initiation report on 3/9/14 for more details on our thinking here). That said, we do note that Teva recently filed a second suit in the Federal District Court of Delaware alleging infringement of Teva's newly-issued patent #8,791,270 by EGRX's bendamustine product (i.e., EP-3101).

COMPANY DESCRIPTION

Eagle is focused on optimized generic injectibles.

PRICE: US\$12.48

TARGET: US\$23.00

17x 2018E non-GAAP EPS of \$2.16, disc. 20%

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Related Companies:

Related Companies:	Share Price:
EGRX	12.48
TEVA	57.70

RISKS TO ACHIEVEMENT OF PRICE TARGET

Pipeline setbacks and risks related to patent litigation.

Price Performance - 1 Year



Source: Bloomberg

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R: Resuming Coverage
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
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