

# **Eagle Pharmaceuticals, Inc.**

# BE Study Positive for Short Infusion Bendamustine Product; Launch in September 2015 or Earlier

- Before the markets opened Monday, November 10, Eagle Pharmaceuticals announced positive pivotal results from a bioequivalence study for the company's 10-minute infusion bendamustine product. The bioequivalent study showed that Eagle's 50 mL formulation, which is administered over 10 minutes, was bioequivalent to Teva's (TEVA \$58.31) branded Treanda product, which is infused over an hour with 500 mL of liquid.
- The study evaluated 81 patients with solid or hematologic malignancies for which no curative or standard therapy was appropriate, suggesting an end-stage patient population. Overall safety assessments are ongoing and complete in 80% of patients and will be complete by November 17; however, full data will not be available to the company until December. The incidence of infusion-related and general adverse events was comparable to Treanda. Eagle management will meet with the FDA in the near term to discuss the filing of the company's 505(b)2 product.
- In addition to the positive results from the rapid infusion product, Eagle was issued a second patent covering the product, which has also been granted orphan drug status by the FDA. With two patents and orphan status granted, we believe the company is in a strong position to launch the product if approved by the FDA during 2015 despite the dispute with Teva/Cephalon over the late-listed '270 patent. We continue to believe Eagle's 10-minute bendamustine infusion product has the potential to be best-in-class with a 50 ml bag reducing the volume infused into the patient by 90% over the currently used 500 ml bag. This reduction in volume is likely a significant safety differentiation for the product given the high rate of patients with compromised kidney function in the hematologic markets.
- Recall that Eagle has already gained a tentative approval for a ready-to-use formulation of RTU Bendamustine and may launch the product in September 2015, when Treanda's orphan exclusivity covering non-Hodgkin lymphoma (NHL) expires. We believe that Eagle management will discuss with the FDA at its upcoming meeting weather the company will file the 10-minute infusion product as a sNDA to the company's currently approved RTU-bendamustine or pursue other filing options. Since our model assumes a launch in September 2015, we believe a launch of the 10-minute infusion product at that time is not only very possible, but may hold upside if the company were to receive a priority review for the 10-minute infusion product given the granted orphan drug status.
- Given the company's enterprise value of roughly \$125 million, we believe that
  investors still heavily discount the possibility of either the RTU-bendamustine or the
  10-minute infusion being launched in 2015, which we view as increasingly likely and
  would be a transformative event for the company. In exhibit 1, on the following page,
  we include our views on the potential timing of events related to the Eagle
  bendamustine franchise.

Eagle Pharmaceuticals is a developer of best-in-class injectable therapeutics. The company is using the 505(b)(2) pathway to enter the market before first-to-file generics.

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#### November 10, 2014

Stock Rating:

| 0.10.111.111.00                   | p                            |
|-----------------------------------|------------------------------|
| Company Profile:<br>Price Target: | Aggressive Growth<br>\$24.00 |
| Symbol:                           | EGRX (NASDAQ)                |
| Price:                            | \$12.48 (52-Wk.: \$9-\$16)   |
| Market Value (mil                 | .): \$175                    |
| Fiscal Year End:                  | September                    |
| Long-Term EPS Gr                  | owth Rate: NA                |
| Dividend/Yield:                   | None                         |

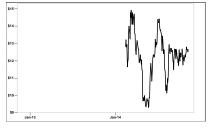
Outperform

|              | 2013A   | 2014E   | 2015E  |
|--------------|---------|---------|--------|
| Estimates    |         |         |        |
| EPS FY       | \$-0.51 | \$-1.18 | \$0.60 |
| CY           |         |         |        |
| Sales (mil.) | NA      | 17,492  | 52,150 |
| Valuation    |         |         |        |
| FY P/E       | NM      | NM      | 20.8x  |
| CY P/E       |         | NA      | NA     |
|              |         |         |        |

| Trading Data (FactSet)    |        |
|---------------------------|--------|
| Shares Outstanding (mil.) | 14     |
| Float (mil.)              | 3      |
| Average Daily Volume      | 44,085 |

| Financial Data (FactSet)           |     |
|------------------------------------|-----|
| Long-Term Debt/Total Capital (MRQ) | 0.0 |
| Book Value Per Share (MRQ)         |     |
| Return on Equity (TTM)             | 0.0 |

#### **Two-Year Price Performance Chart**



Sources: FactSet, William Blair & Company estimates

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- During the third quarter, Teva reported \$180 million (up 2% year-over year) in sales, suggesting that sales are annualizing at \$720 million. We continue to view the value of this franchise to Teva as significant given the brand product's likely high margins versus the company's generic business. We continue to estimate that a product with seven years of orphan exclusivity is worth well more than \$1 billion to Teva. While we will not be aware if the 10-minute product is granted seven years of exclusivity until approved, in a majority of cases this exclusivity is granted.
- Aside from its bendamustine product, Eagle is launching Ryanodex for the treatment of malignant hypothermia, which we believe approximates a potential \$60 million market in the United States alone. The company is also progressing on the design of the company's clinical program using the Ryanodex formulation for the treatment of exertional heat stroke (EHS), which may begin in calendar 2015. We anticipate additional updates on all programs when the company announces fiscal fourth-quarter results in mid-December.
- We maintain our Outperform rating on shares of Eagle as company management has executed on all of its stated goals since becoming a public company in 2015. While the company's share price has not reflected such major milestones as Teva dismissing its '524 case, the tentative approval of RTU-bendamustine, and Monday's positive data from the company's 10-minute infusion product, we believe the company is in a strong position heading into 2015 and offers significant upside from current levels with little clinical risk. With what we believe are modest assumptions for the peak penetration and timing of the bendamustine and dantrolene launches, we derive a net present value (NPV) for the company's pipeline of \$24 per share. However, we note that a majority of our out-year revenue (more than 80%) is attributed the bendamustine franchise, and we believe approval of the 10-minute infusion product will be important to this franchise's durability.

Exhibit 1

Eagle Pharmaceuticals, Inc. Timing of Events Related to Potential Bendamustine Launch April 2016: Treanda CLL orphan November 2016: exclusivity Potential launch of expires other bendamustine generics Litigation betwen Teva and Eagle over patent '270 likely to continue although without 30-month stay 2016 2015 2014 September 2015: May 2016: Dec. '14: Meet with FDA Treanda NHL orphan First-to-file over filing of 10-minute exclusivity expires bendamustine infusion product launches Mid/Late 2015: Approval of 10-minute bendamustine infusion Potential launch timing if orphan exclusivity is broken through 10 min. infusion, assuming FDA approval mid-2015

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Sources: William Blair & Company, L.L.C. estimates and company reports

#### **Valuation**

We believe shares of Eagle continue to hold a strong risk/reward profile, given the potential for significant profitability pending successful development of the company's four disclosed products. In our view, the company's pathway through a 505(b)(2) approval process holds a reduced development risk compared with many small-cap development-stage specialty pharmaceutical companies.

Our price target for shares of Eagle Pharmaceuticals is \$24, based on an NPV of the company's lead development programs, EP-3101 (ready-to-use bendamustine) for CLL and NHL, Ryanodex for malignant hypothermia, and EP-6101 (RTU-bivalirudin). In this calculation, we assume a launch of Ryanodex in fourth quarter 2014 and a launch of EP-3101 in late 2015; however, the timing of the later product will be heavily influenced by the outcome of litigation between Teva Pharmaceuticals and Eagle over the ability to market its product. We note that a majority of our out-year revenue (more than 80%) is attributed the bendamustine franchise, and we believe the 10-minute infusion product will be important to this franchise's durability. Our full model with additional details is available from a William Blair salesperson.

#### Risks

While most risks in development-stage therapeutic companies involve clinical risk, we believe the litigation with Teva and likely other companies whose products Eagle is targeting with its pipeline is the major risk for Eagle. In addition to the litigation risk, investment in shares of Eagle also involves regulatory, commercialization, and financial risk, common in development-stage specialty pharmaceutical companies. The company expects to announce safety data from its 10-minute bendamustine infusion during 2014; this safety trial may hold some risk given the faster infusion time of the product, which could lead to higher rates of nausea.

The company's pipeline is also focused on products near the end of their life cycles, and generic companies are traditionally strong competitors for market share, sometimes taking prices to unsustainable levels. We believe pricing and the resulting market share gains or losses will be a risk for Eagle as the company brings its therapies to the market.

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Within the past 12 months William Blair has provided or is providing investment banking services to or has an investment services relationship with Eagle Pharmaceuticals, Inc.

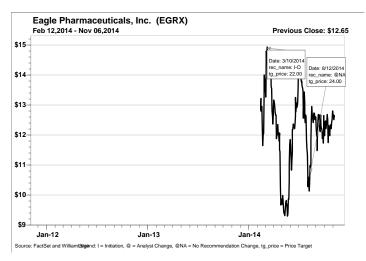
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DOW JONES: 17,573.93 S&P 500: 2,031.92 NASDAQ: 4,632.53



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| Coverage Universe     | Percent | Inv. Banking Relationships* | Percent |
|-----------------------|---------|-----------------------------|---------|
| Outperform (Buy)      | 65      | Outperform (Buy)            | 16      |
| Market Perform (Hold) | 31      | Market Perform (Hold)       | 3       |
| Underperform (Sell)   | 1       | Underperform (Sell)         | 0       |

<sup>\*</sup>Percentage of companies in each rating category that are investment banking clients, defined as companies for which William Blair has received compensation for investment banking services within the past 12 months.

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