

# **Eagle Pharmaceuticals, Inc.**

### Ryanodex Receives Patent for Treatment of Exertional Heat Stroke; PDUFA Date of July 22 Still Focus

- Eagle Pharmaceuticals announced today that its dantrolene sodium injectable suspension (brand name Ryanodex) has received a patent for the treatment of exertional heat stroke, which will provide coverage through 2023. Patent '460 brings the company's IP surrounding Ryanodex to four issued patents. As the patent coverage surrounding the company's best-in-class formulation solidifies, Eagle will initiate a pilot study for the treatment of exertional heatstroke over the next several months. Given the acute nature of exertional heat stroke cases, we anticipate data from the pilot program to be available by year end, pending the initiation of clinical work this summer.
- It is estimated that there are 30,000 cases of exertional heat stroke every year, and it is one of the leading causes of sudden death among student athletes and noncombat death in the U.S. military. The significant impact on mortality in malignant hypothermia and the similarities between malignant hypothermia and heat stroke suggest that dantrolene could be effective in this indication as well. The pilot study for exertional heat stroke (EHS) will follow several smaller studies conducted in classic heat stroke, which produced mixed results against the current standard of care, evaporative cooling. However, we note that EHS represents a more severe form of heat stroke and data to date in classic heat stroke may not be readily applicable to EHS.
- In the near term, Ryanodex remains on course for a PDUFA date of July 22 for the treatment of malignant hypothermia. We believe the market for the current formulation approximates \$20 million domestically and an additional \$20 million internationally. To be conservative, our model does not include any sales for Ryanodex for the indication of exertional heat stroke. We assume an 85% penetration into the current dantrolene domestic market and no potential for price increases in out-years.
- Outside the Ryanodex franchise, the outcome of recent two patent cases has some read-through to Eagle's development pipeline. Yesterday, Eli Lilly (LLY \$58.55) gained a favorable ruling regarding the Alimta franchise while the Medicines Company (MDCO \$24.17) was dealt a setback with a ruling favoring Hospira's (HSP \$43.80) attempt to bring a bivalirudin generic to market during 2015. Eagle had viewed both franchises as possible candidates for 505(b)(2) therapies. We will continue to monitor the litigation surrounding both products and note that possible settlements, business development (potentially with Eagle), and appeals may still swing the potential value and attractiveness of these markets.
- We maintain our Outperform rating on shares of Eagle Pharmaceuticals and maintain our \$22 price target. Although we do not include indications for exertional heat stroke for Ryanodex in our model, we believe that shares of Eagle continue to hold a strong risk/reward profile given the potential for significant profitability pending successful development of the bendamustine and dantrolene franchises.

Eagle Pharmaceuticals is a developer of best-in-class injectable therapeutics. The company is using

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the 505(b)(2) pathway to enter the market before first-to-file generics.

## April 01, 2014 Stock Rating:

Company Profile Price Target:	:: Ag	gressive Growth \$22.00
Symbol:		EGRX (NASDAQ)
Price:	\$12.74	4 (52-Wk.: \$11-\$16)
Market Value (m	ıil.):	\$177
Fiscal Year End:		September

Outperform

Long-Term EPS Growth Rate:

Dividend/Yield: None

2014E

2015E

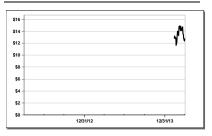
2013A

Estimates			
EPS FY	\$-0.51	\$-1.33	\$0.30
CY			
Valuation			
FY P/E	NM	NM	42.5x
CY P/E		NA	NA

Trading Data (FactSet)			
Shares Outstanding (mil.)	3		
Float (mil.)	3		
Average Daily Volume	389,338		

Financial Data (FactSet)			
Long-Term Debt/Total Capital (MRQ)	0.0		
Book Value Per Share (MRQ)	14.9		
Enterprise Value (mil.)	-15.8		
EBITDA (TTM)	-8.5		
Enterprise Value/EBITDA (TTM)	1.9x		
Return on Equity (TTM)	-25.8		

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



Sources: FactSet, William Blair & Company estimates

Please consult pages 3-4 of this report for all disclosures. Analyst certification is on page 3. William Blair & Company, L.L.C. does and seeks to do business with companies covered in its research reports. As a result, investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as a single factor in making an investment decision.

William Blair & Company, L.L.C.

#### **Valuation**

We maintain a price target of \$22 based on a net present value of the company's lead development programs. While we assume a launch of EP-3101 (bendamustine) in late 2015, this timing will be influenced heavily by the outcome of litigation between Teva Pharmaceuticals (TEVA \$52.63) and Eagle over the ability to market its product. Our full model with additional details is available from a William Blair & Company, L.L.C. salesperson.

#### Risks

Eagle filed an application previously with the FDA for EP-3101 through the 505(b)(2) regulatory pathway referencing Teva's Treanda product on September 6, 2013. Teva subsequently filed a patent infringement lawsuit on October 21, 2013. We believe the ongoing litigation with Teva Pharmaceuticals and other companies whose products are being targeted by Eagle are a major risk. 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.

William Blair & Company, L.L.C.

### **IMPORTANT DISCLOSURES**

William Blair was a manager or co-manager of a public offering of equity securities for Eagle Pharmaceuticals, Inc. within the prior 12 months.

William Blair is a market maker in the security of Eagle Pharmaceuticals, Inc. and may have a long or short position.

William Blair intends to seek investment banking compensation in the next three months from Eagle Pharmaceuticals, Inc.

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.

Additional information is available upon request.

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Tim Lugo attests that 1) all of the views expressed in this research report accurately reflect his/her personal views about any and all of the securities and companies covered by this report, and 2) no part of his/her compensation was, is, or will be related, directly or indirectly, to the specific recommendations or views expressed by him/her in this report. We seek to update our research as appropriate, but various regulations may prohibit us from doing so. Other than certain periodical industry reports, the majority of reports are published at irregular intervals as deemed appropriate by the analyst.

DOW JONES: 16,457.66 S&P 500: 1,872.34 NASDAQ: 4,198.99



#### Current Rating Distribution (as of 03/31/14)

Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	65	Outperform (Buy)	13
Market Perform (Hold)	32	Market Perform (Hold)	2
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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Outperform (O) – stock expected to outperform the broader market over the next 12 months; Market Perform (M) – stock expected to perform approximately in line with the broader market over the next 12 months; Underperform (U) – stock expected to underperform the broader market over the next 12 months; not rated (NR) – the stock is not currently rated. The valuation methodologies used to determine price targets (where used) include (but are not limited to) price-to-earnings multiple (P/E), relative P/E (compared with the relevant market), P/E-to-growth-rate (PEG) ratio, market capitalization/revenue multiple, enterprise value/EBITDA ratio, discounted cash flow, and others.

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