

Eagle Pharmaceuticals, Inc.

Tentative Approval for RTU Bendamustine; Ryanodex PDUFA on July 22; Maintaining Outperform Rating

- During market hours, Eagle Pharmaceuticals received FDA approval for its ready-to-use bendamustine product. The tentative approval requires litigation with Teva (TEVA \$54.57) to be resolved prior to the product's launch. Despite the continued litigation overhang that needs to be lifted prior to product launch, we believe management's execution during this early period as a public company is perhaps a more-significant positive than the FDA decision. The approval also sets the stage for several additional catalysts likely to read out through the summer.
- The next steps for the bendamustine RTU formulation include a likely update on the ongoing patent case with Teva Pharmaceuticals, the brand marketer of Treanda, as we expect the court schedule to be clarified over the next month. At this time, a summary judgment is possible that would effectively end the litigation and allow Eagle to enter the market. In addition, scheduling a trial could also provide possible upside to consensus launch timing expectations. A launch any time prior to the 30-month stay for generics would enable Eagle to enter an over \$700 million market with a best-in-class formulation prior to generics. While our current estimates include a launch in September 2015, we believe consensus assumes a launch in line with the first-to-file generic during the first half of 2016.
- Regarding the company's 10-minute infusion bendamustine formulation, we believe the trial is progressing well and expect safety and bioequivalence data some time during the summer. We also believe the FDA may decide on granting orphan exclusivity for the 10-minute product during the next several months as well. Exhibit 1 details the timeline of events for the company through 2015.
- As the company proceeds through the Teva litigation 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 profile could support a safety advantage over the 500 ml formulation, given the issues with renal impairment in the hematology market. Further, the infusion rate of 10 minutes with Treanda is well below the 30- and 60-minute infusion times of the current product formulation. While the 10-minute infusion product is a significant improvement over brand bendamustine, the company's RTU formulation also holds an improved profile, with 3 months of improved stability over the currently approved, but not yet marketed liquid formulation of Treanda.

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.

Tim Lugo
+1 415 248 2870
tlugo@williamblair.com

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July 02, 2014

Stock Rating: **Outperform**
Company Profile: **Aggressive Growth**
Price Target: \$22.00

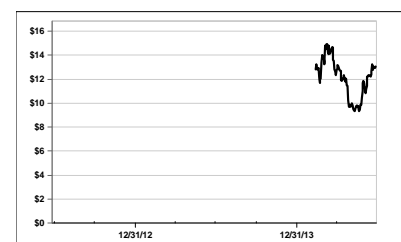
Symbol: EGRX (NASDAQ)
Price: \$13.91 (52-Wk.: \$9-\$16)
Market Value (mil.): \$202
Fiscal Year End: September
Long-Term EPS Growth Rate:
Dividend/Yield: None

	2013A	2014E	2015E
Estimates			
EPS FY	\$-0.51	\$-1.33	\$0.45
CY			
Sales (mil.)	NA	14,250	47,750
Valuation			
FY P/E	NM	NM	30.9x
CY P/E		NA	NA

Trading Data (FactSet)	
Shares Outstanding (mil.)	9
Float (mil.)	3
Average Daily Volume	120,803

Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	3.2
Return on Equity (TTM)	0.0

Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

- The next major event in the coming weeks is the July 22 PDUFA date for Ryanodex, the formulation of dantrolene, for the indication of malignant hypothermia (MH). The company received orphan drug designation for Ryanodex in August, and expects to launch this product in the second half of calendar 2014. While the MH market only approximates \$40 million worldwide, we believe there is potential for Eagle to bring a premium-priced product into the market given the severity of MH and the best-in-class formulation of Ryanodex. The company also plans to dose its first patient in a pilot study for the designation of EHS in Saudi Arabia later this year, which could enable off-label sales of the product pending positive data.
- We remain Outperform rated on shares of Eagle Pharmaceuticals, as management continues to execute through significant milestones over the next 90 days, with another PDUFA date, readout from the company's 10-minute infusion pharmacokinetic clinical trial, and a likely update on the timing of ongoing litigation with Teva. We also maintain our \$22 price target, and we continue to believe shares hold a strong risk/reward profile given the potential for significant profitability as early as 2015 pending successful development of the bendamustine and dantrolene products.

Exhibit 1
Eagle Pharmaceuticals, Inc.
Timeline and Events

Date	Product	Event	Description/Comments
2014			
22-Jul	Ryanodex (1 vial dantrolene)	Regulatory	PDUFA date on July 22 for treatment of malignant hypothermia
Q3	RTU Bendamustine	Legal	Scheduling of ongoing litigation between Teva and Eagle Pharmaceuticals over right to launch RTU bendamustine
Q3	RTU Bendamustine	Clinical	Company will report pivotal results from 10-minute infusion trial, increased sample size 10 to 12 patients
2014	Ryanodex (1 vial dantrolene)	Clinical	Begin Phase III trial for Ryanodex in exertional heat stroke, Trial in Saudi Arabia to dose first patient
2014	Ryanodex (1 vial dantrolene)	Regulatory	Potential launch of Ryanodex in malignant hypothermia
2015			
2015	RTU Bendamustine	Regulatory	Potential launch of RTU bendamustine following outcome of Teva litigation
2015	Ryanodex (1 vial dantrolene)	Clinical	Potential top-line data from exertional heat stroke clinical trial
2015	RTU Bivalirudin	Regulatory	Filing of NDA for bivalirudin (brand name Angiomax)
2015	RTU Pemetrexed	Regulatory	Filing of NDA for pemetrexed (brand name Alimta)

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

Valuation

We maintain our Outperform rating and a price target of \$22 on shares of Eagle Pharmaceuticals, based on a net present value of the company's lead development programs. We assume an 85% penetration of Ryanodex into the current dantrolene domestic market and no potential for price increases in out-years. Our model does not include any sales for Ryanodex for the indication of exertional heat stroke. 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 and Eagle over the ability to market its product. Our full model with additional details is available from a William Blair 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.



Eagle Pharmaceuticals

Earnings Model

5/14/14

(\$ in thousands except EPS data)

Rating: Outperform

Company Profile: Aggressive Growth

Tim Lugo

415.248.2870

tlugo@williamblair.com

	FY 2012(A)	FY 2013(A)	Dec. 13 Q1(A)	Mar. 14 Q2(A)	June 14 Q3(E)	Sept.14 Q4(E)	FY 2014(E)	FY 2015(E)	FY 2016(E)	FY 2017(E)
Product Revenue	1,155	5,315	0.0	1100.0	1100.0	1350	3,550	42,750	184,000	256,750
EP-3101 (bendamustine RTD)	-	-	-	-	-	0	-	36,000	168,000	150,000
Ryanodex (dantrolene)	-	-	-	-	-	250	250	3,500	14,000	17,000
EP-6101 (bivalirudin)	-	-	-	-	-	-	-	-	-	87,750
EP-5101 (pemetrexed)	-	-	-	-	-	-	-	-	-	-
EP-1101 (argatroban)	-	-	-	1,100	1,100	1,100	3,300	3,250	2,000	2,000
EP-2101 (topotecan)	-	-	-	-	-	-	-	-	-	-
Royalty Revenue	1,384	8,364	2800	3600	2000	2000	10,400	5,000	4,000	3,000
Other Revenue	-	-	-	300	300	400	1,000	-	-	-
Total Revenue	2,539.4	13,679	2,800	5,000	3,100	3,350	14,250	47,750	188,000	259,750
yr/yr growth		NM	NA	NA	NA	NA	4.2%	235.1%	293.7%	38.2%
q/q growth			NA	78.6%	-77.3%	8.1%				
incremental rev q/q										
Cost of Goods Sold	3166.6	7,381	1400	3359	2077	2077	8913	7,083	20,742	43,011
Gross Profit	-627.2	6,298	1400	1641	1023	1273	5337	40668	167258	216,739
Royalty Expense								1988	29,050	71,050
SG&A	6,399	4,958	1,620	1,454	2,700	2,700	9000	17,250	29,500	32,450
Growth							82%	92%	71%	10%
R&D	12,804.7	9,796	3,075	3,793.0	3,800.0	5,000.0	15,375	16,000	20,000	21,000
		0%					57%	4%	25%	5%
Total Operating Expenses	22,370.14	22,134.03	4,695	8,606	6,500	7,700	27,501	35,238	78,550	124,500
growth			NA	NA	NA	NA	24%	28%	123%	58%
Operating Income	(19,830.7)	(8,455.1)	(3,295.0)	(3,606.0)	(5,477.0)	(6,427.0)	(22,164.0)	3,442.5	88,707.6	92,238.8
EBIT Margin							NA	7%	47%	36%
growth y/y (%)			NA	NA	NA	NA	162%	-116%	2477%	4%
Depreciation and Amortization	477.7	1,322.3	250	250	250	250	1,000	1,000	1,000	1,000
EBITDA		(7,133)	(3,045)	(3,356)	(5,227)	(6,177)	(17,805)	6,430	89,708	93,239
							NA	13%	48%	36%
Other income	(333.2)	1,507.9	750	-376.0	750.0	750.0	3,000	2,000	6,000	8,000
Income Before Taxes	(20,163.9)	(6,947.2)	(2,545.0)	(3,982.0)	(4,727.0)	(5,677.0)	(16,931)	7,430	94,708	100,239
Income Tax Provision	781.26	898.70	225.00	1,294.00	225.00	225.00	900	1,000	1,000	35,083.56
Effective Tax Rate			NA	NA	NA	NA	-5%	NA	NA	35%
Net Income (GAAP)	\$ (19,382.6)	\$ (6,048.5)	(2,770.0)	(2,688.0)	(4,951.9)	(5,902.0)	\$ (17,830.9)	\$ 6,430.1	\$ 93,707.7	\$ 65,155.3
Convertible preferred stock	\$ (3,933.4)	\$ (3,836.8)	-	(534.0)	-	-	-	-	-	-
Net loss attributable to common stockholders	\$ (23,316.1)	\$ (9,885.3)	\$ (2,770.0)	\$ (3,222.0)	\$ (4,951.9)	\$ (5,902.0)	\$ (16,845.9)	\$ 6,430.1	\$ 93,707.7	\$ 65,155.3
Basic and diluted net loss per common share	\$ (2.20)	\$ (0.51)	(0.20)	(0.36)	(0.35)	(0.42)	\$ (1.33)	\$ 0.45	\$ 6.37	\$ 4.31
Basic and diluted weighted avg. shares of common out	10,595	19,514	13,918	8,862	13,962	14,062	12,701	14,312	14,712	15,112

Key Ratios (GAAP unless noted)

Gross Margin	NM	NM	NM	33%	33%	33%	33%	83.4%	88.7%	83.2%
R&D (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	33.5%	10.6%	8.1%
SG&A (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	36.1%	15.7%	12.5%
Operating Margin	NM	NM	NM	NM	NM	NM	NM	NM	47.2%	35.5%
Net Income Margin	NM	NM	NM	NM	NM	NM	NM	13.5%	49.8%	25.1%
Revenue Growth										
Growth Yr/Yr	NM	439%	NM	NM	NM	NM	4%	235%	294%	38%
Growth Q/Q	NM		NM	NM	NM	NM				
SG&A Growth										
Growth Yr/Yr	NM	-23%	NM	NM	NM	NM	82%	92%	71%	10%
Growth Q/Q	NM		NM	NM	NM	NM				
R&D Growth										
Growth Yr/Yr	NM	-24%	NM	NM	NM	NM	57%	4%	25%	5%
Growth Q/Q	NM		NM	NM	NM	NM				

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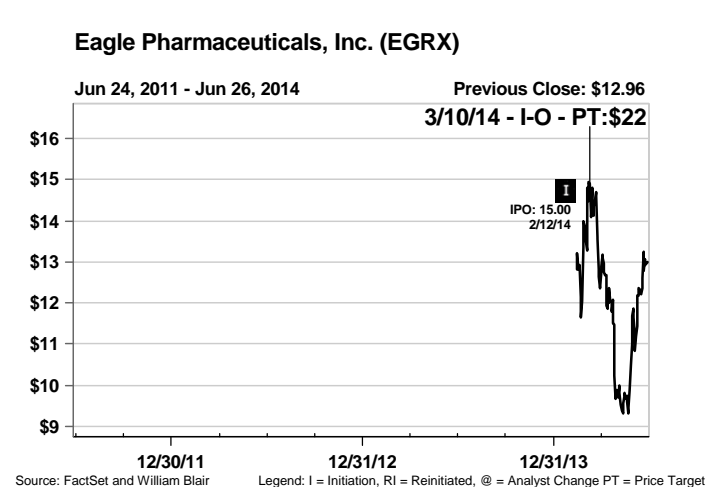
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DOW JONES: 16,956.07

S&P 500: 1,973.32

NASDAQ: 4,458.65



Current Rating Distribution (as of 06/30/14)

Coverage Universe	Percent	Inv. Banking Relationships*	Percent
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Market Perform (Hold)	30	Market Perform (Hold)	2
Underperform (Sell)	1	Underperform (Sell)	0

*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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