

Equity Research

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Eagle Pharmaceuticals Inc. (EGRX-\$12.98)

Rating: BUY

Target Price: \$30.00

Treanda Visibility and Lots of Action Expected in 2015; Maintain BUY and \$30 PT

<u>REV</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2014A	5.5A	5.0A	5.8A	2.8A
Prev	—	—	—	1.9E
2015E	2.5E	3.3E	3.7E	4.2E
2016E	—	—	—	—
<u>EPS</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2014A	(1.44)A	(0.36)A	(0.21)A	(0.65)A
Prev	—	—	—	(0.57)E
2015E	(0.60)E	(0.59)E	(0.65)E	(0.69)E
2016E	—	—	—	—
<u>FY</u>	<u>2014A</u>	<u>2015E</u>	<u>2016E</u>	
REV	19.1A	13.7E	102.0E	
Prev	18.2E	14.2E	—	
P/S	9.5x	13.3x	1.8x	
EPS	(1.97)A	(2.53)E	1.68E	
Prev	(1.31)E	(1.61)E	—	
P/E	(6.6)x	(5.1)x	7.7x	

- **4Q:FY14 beat on top line but op-ex came in higher than expected:** Eagle reported revenues of \$2.8M and a loss per share of (\$0.65) versus FactSet consensus estimates of \$2.7M and per share loss of (\$0.49). In 2015 we expect Eagle to advance its Treanda and Angiomax pipeline, which we think should increase investor confidence, while ramping newly launched Ryanodex. We have selected EGRX as our top pick for 2015 and reiterate our BUY rating and \$30 PT.
- **Simplifying Eagle's Treanda story:** We currently expect Eagle to receive final FDA approval, and launch its version of Treanda liquid in early 2016 after expiration of Teva's Orphan Drug Exclusivity on 5/1/16. Management is meeting with FDA this month to propose amending its tentatively approved liquid bendamustine NDA to include language on rapid dosing, but should be able to launch the bigger 500 mL bag in 2016 irrespective of this discussion. More important, management believes that Teva could prevent a broader Treanda generic launch until resolution of Teva's expected appeal in late 2017 at the earliest (District Court trial with 16 generic filers is in Dec 2015). If Teva settles this case to push out generic Treanda launch beyond 2017, we would expect to see even more upside to Eagle, which could then sell its slightly discounted formulation of a \$700M drug in a two-player hospital market over several years. We currently model generic entrants in 2018, but there could be meaningful upside to our estimates in case of a settlement. Eagle's Markman Hearing on its remaining '270 patent litigation with Teva is expected in March 2015.
- **Ryanodex launch update:** Eagle reported Ryanodex sales of \$0.8M as compared to our estimate of \$0.4M, which represents just one month of sales. The company sold 386 vials into 65 customers, who include some of the top hospitals in the U.S., and indicated that the NIH and Kaiser are converting to Ryanodex. Management estimates that there are 6,000 hospitals and another 3,000 ambulatory outlets that stock dantrolene for a total of 9,000 potential locations and an opportunity to sell 45,000 vials, which management values at approximately \$80M. We model \$11M in sales in 2015, but note that this estimate could be conservative.
- **Other 2015 potential catalysts:** (1) FDA is expected to grant Ryanodex Orphan Drug Exclusivity. (2) Eagle is on track to file its RTU Angiomax NDA in 1H:15 and anticipates possible launch in late 2016 (if Hospira settles with MDCO, Eagle's product could gain additional time on the market). (3) Management plans to initiate a pivotal study of Ryanodex in exertional heat stroke in Saudi Arabia at the Hajj in September 2015.

Current Statistics

Market Cap (\$Mil)	\$182.0	Free Float (%):	14.400
Avg. Daily Trading Volume (3 mo.):	31,145		
Shares Out (Mil):	14.020		

The Disclosure Section may be found on pages 7 - 8.

Exhibit 1: EGRX 4Q:FY14 Variance Analysis (\$ in millions, except per share data)

	4Q:FY14E	4Q:FY14A	% Variance	Y/Y Growth	Q/Q Growth	Comments
Revenues	1.9	2.8	49.8%	-39.4%	-51.5%	
Total Revenues	1.9	2.8	49.8%	-39.4%	-51.5%	\$2.7M Consensus
COGS	1.3	2.2	68.8%	-25.8%	39.7%	
Gross Profit	0.6	0.6	8.2%	-62.7%	-85.0%	
SG&A	4.5	3.9	-14.9%	370.1%	44.2%	
R&D	4.2	5.9	40.2%	72.2%	29.5%	
EBIT	-8.1	-9.1	11.9%	259.8%	205.3%	
Interest and Other Income	0.0	0.0	-88.8%	-99.9%	-95.9%	
Pre-tax income	-8.1	-9.1	12.1%	-1984.9%	210.3%	
Income tax expense	0.0	0.0	NM	NM	NM	
Net Income	-8.1	-9.1	12.1%	-1984.9%	210.3%	
Dividend Payment	0.0	0.0	NM	NM	NM	
Net Loss Attributable to Common Shareholders	-8.1	-9.1	12.1%	1302.8%	210.3%	
Diluted shares	14.2	14.0	-1.3%	360.0%	0.0%	
Operating EPS	(\$0.57)	(\$0.65)	13.5%	204.9%	210.2%	(\$0.49) Consensus

Source: Company reports, Cantor Fitzgerald estimates, and FactSet

Other key updates:

- Teva is converting the hospital market to using its liquid Treanda formulation which should benefit Eagle, in our view:** Teva announced that it launched its liquid form of Treanda in November 2014, which is positive for Eagle as hospitals will likely develop a preference for the liquid formulation and become less likely to switch back to the lyophilized powder when generics enter the market. Management reiterates that its rapid infusion bendamustine formulation offers several benefits over Teva's liquid form including increased stability, longer shelf life, faster infusion time, and reduced waste from its multi-dose vial. These benefits combined with discounted pricing should help Eagle capture significant Treanda market share in 2016. We model that Eagle will capture 20% share in 2016 (for just over 70% of the year) and 40% of the market share in 2017.
- Ryanodex for exertional heat stroke (EHS) could launch in 2017-2018 but is excluded from our numbers for now:** Management provided more color on the pivotal exertional heat stroke trial it plans to run in September 2015. Eagle will conduct the trial at the Hajj in Saudi Arabia (and pay for the study itself). This religious pilgrimage has drawn as many as 2 million participants during a month when temperatures can average 95 degrees. Management indicated that a few hundred people suffered from heat stroke at the Hajj last year, which shows the concentration of candidates for the trial and the demand for a potential treatment. There are heat stroke tents throughout the Hajj and Ryanodex will be administered at two of the tents, where Quintiles staff will pre-screen patients for exertional heat stroke (which most closely mimics malignant hyperthermia, and exclude regular heat stroke patients) and treat them either with standard of care (fluids and ice) or standard of care plus Ryanodex. Management hopes to accrue 30 patients to the control and 30 to the treatment arms of the study. Management plans to meet with FDA in early 2015 to discuss study design and endpoints. Data from the Hajj study are expected in late 2015. The company would test a smaller dantrolene dose for EHS. Dantrolene has been on the market for about 40 years so safety is not a major concern and a registrational study after this trial may suffice for approval. If FDA requests additional patients, Eagle may conduct more EHS trials during Spring 2016. If all goes well, we think that Ryanodex could gain FDA approval for EHS in 2017-2018.

- **Ryanodex to be filed in Europe:** Management also plans to submit Ryanodex for approval for malignant hyperthermia outside of the United States. It expects to submit in Europe in 2015 after recently being granted Orphan designation.

Milestones:

We summarize key Eagle milestones in Exhibit 2 below.

Exhibit 2: Key Eagle Potential Catalysts

Date	Milestone/Event
2014	
end-2014	Rapid infusion Treanda formulation pre-NDA meeting
2015	
1H:15	File NDA amendment for Eagle's rapid infusion Treanda formulation
1H:15	NDA filing for Eagle's RTU Angiomax formulation
mid-2015	File marketing authorization applications with EMA for Ryanodex
Sep-15	Initiate pivotal study for Ryanodex for exertional heat stroke in Saudi Arabia
Dec-15	End of 30 month stay on Treanda powder generics/ generics District Court trial
2016	
May-16	Orphan Drug Exclusivity expiring on Treanda
2016	Expected product launch for Eagle's Treanda RTD formulation
2016	Possible product launch for Eagle's RTU Angiomax formulation
2017	
2017	Possible launch for Ryanodex for exertional heat stroke

Source: Company reports and Cantor Fitzgerald estimates

Cash: Eagle reported \$42.7 million in cash, cash equivalents and short-term investments and 14 million outstanding shares at the end of the quarter.

Valuation

We value Eagle Pharmaceuticals using a discounted cash flow analysis (DCF). We assume a weighted average cost of capital (WACC) of 13% given the risks associated with generic litigation. We assign a 1% terminal growth rate to the company since Eagle has patent estate around several other undisclosed product reformulations and generic applications. We arrive at a \$30 price target using this methodology..

Risks

1. Launch delays associated with litigation are the chief risk for Eagle, in our view, since early launch timing is critical to the company's success. This risk is especially prominent for the launch of Eagle's RTD Treanda and Angiomax products.
2. Each of the company's reformulated injectable products needs to secure FDA regulatory approval, so there is some degree of clinical risk to the business (although this risk is significantly lower than that for new chemical entities).
3. Manufacturing issues or supply chain disruptions are another source of risk, and the company already dealt with a supply disruption for argatroban in 2012. We checked on recent FDA inspections of Eagle's manufacturing partners and note that we did not see anything worrisome.
4. Hospital decision makers may become less accessible to drug manufacturers, which could adversely impact Eagle's ability to educate hospitals about its products and build demand.

Exhibit 3: Eagle Income Statement (dollars in millions)

	2012	2013	1Q:14A	2Q:14A	3Q:14A	4Q:14A	2014A	1Q:15E	2Q:15E	3Q:15E	4Q:15E	2015E	2016E	2017E	2018E	2019E	2020E
Revenues:																	
Product Sales	1.2	5.3	2.2	1.2	0.4	0.9	4.6	2.1	2.9	3.5	4.0	12.5	100.9	279.4	246.7	172.0	174.9
Royalty Income	1.4	8.4	3.3	3.6	1.9	1.9	10.7	0.4	0.4	0.2	0.2	1.2	1.1	1.0	1.0	0.9	0.8
Collaborative licensing and development revenue	0.0	0.0	0.0	0.3	3.5	0.0	3.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total revenues	2.5	13.7	5.5	5.0	5.8	2.8	19.1	2.5	3.3	3.7	4.2	13.7	102.0	280.4	247.6	172.9	175.7
Operating expenses:																	
COGS	3.2	7.4	4.6	3.4	1.6	2.2	11.7	0.7	1.0	1.2	1.4	4.3	20.2	73.3	103.9	54.5	55.8
R&D	12.8	9.8	2.6	3.8	4.5	5.9	16.8	6.0	6.2	6.5	6.8	25.5	26.8	28.1	29.5	31.0	32.5
SG&A	6.4	5.0	1.3	1.5	2.7	3.9	9.3	4.2	4.5	5.3	6.0	20.0	24.0	28.8	29.4	30.0	30.6
Operating income (deficit)	(19.8)	(8.5)	(3.1)	(3.6)	(3.0)	(9.1)	(18.8)	(8.4)	(8.4)	(9.3)	(9.9)	(36.0)	31.0	150.2	84.9	57.5	56.8
Interest income	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.2	0.2
Interest expense	(0.1)	(0.3)	0.0	(0.0)	(0.0)	(0.0)	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other	(0.3)	1.8	(0.2)	(0.4)	0.0	0.0	(0.5)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pretax Income	(20.2)	(6.9)	(3.3)	(4.0)	(2.9)	(9.1)	(19.3)	(8.4)	(8.4)	(9.3)	(9.9)	(36.0)	31.0	150.3	85.0	57.6	57.0
Tax rate	0.0%	0.0%	0.0%	NM	0.0%	0.0	NM	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	35.0%	35.0%	35.0%	35.0%
Tax expense (benefit)	(0.8)	(0.9)	0.0	(1.3)	0.0	0.0	(1.3)	0.0	0.0	0.0	0.0	0.0	6.2	52.6	29.8	20.2	19.9
Net Loss	(19.4)	(6.0)	(3.3)	(2.7)	(2.9)	(9.1)	(18.0)	(8.4)	(8.4)	(9.3)	(9.9)	(36.0)	24.8	97.7	55.3	37.4	37.0
Dividend payment	(3.9)	(3.8)	(1.1)	(0.5)	0.0	0.0	(1.7)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
stockholders	(23.3)	(9.9)	(4.4)	(3.2)	(2.9)	(9.1)	(19.6)	(8.4)	(8.4)	(9.3)	(9.9)	(36.0)	24.8	97.7	55.3	37.4	37.0
Weighted average common shares	10.6	3.0	3.0	8.9	14.0	14.0	10.0	14.0	14.2	14.3	14.4	14.2	14.7	15.2	15.7	16.2	16.7
Diluted EPS	(\$2.20)	(\$3.25)	(\$1.44)	(\$0.36)	(\$0.21)	(\$0.65)	(\$1.97)	(\$0.60)	(\$0.59)	(\$0.65)	(\$0.69)	(\$2.53)	\$1.68	\$6.41	\$3.51	\$2.31	\$2.21
<div>Consensus Revenues14</div> <div>Consensus EPS(\$1.61)199\$7.16273\$4.84</div>																	
Margin Analysis																	
Gross Margin	-24.7%	46.0%	15.8%	32.9%	73.1%	22.7%	38.7%	66.0%	66.0%	66.0%	66.0%	66.0%	80.0%	73.8%	57.9%	68.3%	68.1%
COGS	124.7%	54.0%	84.2%	67.1%	26.9%	77.3%	61.3%	34.0%	34.0%	34.0%	34.0%	34.0%	20.0%	26.2%	42.1%	31.7%	31.9%
SG&A	252.0%	36.2%	24.5%	29.1%	46.2%	137.1%	48.8%	169.9%	136.9%	142.1%	141.3%	145.7%	23.5%	10.3%	11.9%	17.3%	17.4%
R&D	504.2%	71.6%	47.1%	75.8%	78.5%	209.5%	88.0%	242.7%	188.6%	174.2%	160.2%	185.7%	26.3%	10.0%	11.9%	17.9%	18.5%
Operating Margin	-780.9%	-61.8%	-55.8%	-72.0%	-51.5%	-323.9%	-98.2%	-341.4%	-255.1%	-248.3%	-234.1%	-262.4%	30.4%	53.6%	34.3%	33.2%	32.3%
Net Income Margin	-918.2%	-72.3%	-79.9%	-64.3%	-50.7%	-323.9%	-102.9%	-341.0%	-254.8%	-248.0%	-233.9%	-262.2%	24.3%	34.8%	22.3%	21.7%	21.1%
Growth (Y/Y)																	
Net Sales	439%	270%	102%	14%	-39%	40%	-55%	-34%	-36%	51%	-28%	643%	175%	-12%	-30%	2%	2%
SG&A	-23%	-30%	-51%	-460%	370%	88%	213%	209%	98%	56%	114%	20%	20%	2%	2%	2%	2%
R&D	-24%	17%	50%	178%	72%	72%	132%	63%	43%	15%	52%	5%	5%	5%	5%	5%	5%
EBIT	-	-	-	-	-	-	-	-	-	-	-	-186%	385%	-43%	-32%	-1%	-1%
Interest income	-91%	98%	1468%	1621%	400%	885%	676%	30%	-45%	96%	24%	-27%	147%	77%	21%	6%	6%
Interest expense	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tax	-	-	-	-	-	-	-	-	-	-	-	-	NM	748%	-43%	-32%	-1%
Net Income	-	-	-	-	-	-	-	-	-	-	-	-	-169%	294%	-43%	-32%	-1%
Diluted EPS	-	-	-	-	-	-	-	-	-	-	-	-	-167%	281%	-45%	-34%	-4%

Source: Company reports, Cantor Fitzgerald Estimates and FactSet Consensus

Exhibit 4: Eagle Sales Estimates (dollars in millions)

	2012	2013	1Q:14A	2Q:14A	3Q:14A	4Q:14A	2014A	1Q:15E	2Q:15E	3Q:15E	4Q:15E	2015E	2016E	2017E	2018E	2019E	2020E
Royalty Revenue																	
ARGATROBAN																	
Sales	\$3.5	\$29.0	\$12.5	\$11.0	\$5.9	\$4.7	\$34.0	\$1.84	\$1.62	\$0.86	\$0.68	\$5.0	\$4.5	\$4.3	\$4.1	\$3.9	\$3.7
Growth							17.2%	-85.3%	-85.3%	-85.3%	-85.3%	-85.3%	-10.0%	-5.0%	-5.0%	-5.0%	-5.0%
Royalty	39.5%	28.8%	26.1%	32.4%	32.4%	41.6%	31.4%	20.8%	25.8%	25.8%	33.1%	24.9%	24.5%	24.2%	23.8%	23.4%	23.1%
ARGATROBAN ROYALTY REVENUE	\$1.4	\$8.4	\$3.3	\$3.6	\$1.9	\$1.9	\$10.7	\$0.4	\$0.4	\$0.2	\$0.2	\$1.2	\$1.1	\$1.0	\$1.0	\$0.9	\$0.8
Growth		504.3%	166.2%	296.1%	-26.9%	-35.9%	27.5%	-88.3%	-88.3%	-88.3%	-88.3%	-88.3%	-11.3%	-6.4%	-6.4%	-6.4%	-6.5%
Product Sales																	
ARGATROBAN																	
Sales	\$1.2	\$5.3	\$2.2	\$1.2	\$0.4	\$0.1	\$3.9	\$0.5	\$0.2	\$0.1	\$0.0	\$0.8	\$0.7	\$0.7	\$0.6	\$0.6	\$0.5
Growth		360.0%	770.9%	-26.6%	-84.0%	-95.3%	-27.1%	-79.1%	-79.1%	-79.1%	-79.1%	-79.1%	-11.3%	-6.4%	-6.4%	-6.4%	-6.5%
DICLOFENAC/MISOPROSTOL																	
Sales								\$0.1	\$0.1	\$0.1	\$0.1	\$0.5	\$0.5	\$0.5	\$0.4	\$0.4	\$0.4
Growth													-5.0%	-5.0%	-5.0%	-5.0%	-5.0%
RYANODEX																	
Sales						\$0.8	\$0.8	\$1.5	\$2.5	\$3.3	\$3.9	\$11.2	\$28.5	\$46.5	\$53.4	\$57.5	\$58.6
Growth											384.8%	155.0%	63.2%	14.8%	7.7%	2.0%	2.0%
TREANDA RTD																	
Sales												\$71.2	\$188.2	\$67.8	\$67.8	\$67.8	\$67.7
Growth													164.4%	-64.0%	0.0%	0.0%	-0.1%
ANGIOMAX RTU																	
Sales													\$43.6	\$124.4	\$45.8	\$45.8	\$47.6
Growth														185.7%	-63.2%	4.0%	4.0%
TOTAL REVENUE	\$2.5	\$13.7	\$5.5	\$4.7	\$2.3	\$2.8	\$15.3	\$2.5	\$3.3	\$3.7	\$4.2	\$13.7	\$102.0	\$280.4	\$247.6	\$172.9	\$175.7
Growth		438.7%	270.3%	89.6%	-54.9%	-39.4%	12.2%	-55.0%	-30.6%	62.2%	51.0%	-10.5%	642.5%	175.0%	-11.7%	-30.2%	1.6%

Source: Company reports and Cantor Fitzgerald Estimates

Company Description

Eagle Pharmaceuticals is a specialty pharmaceutical company focused on developing and commercializing reformulated versions of injectable products in the hospital market utilizing the 505(b)(2) pathway. Eagle has several products in development that it expects to launch over 2015-2017.

Companies Mentioned:

Hospira Inc. (HSP - NYSE): NC
Teva Pharmaceutical Industries Limited (TEVA - NYSE): NC
The Medicines Co. (MDCO - NASDAQ): NC
Kaiser Permanente (Private)

Disclosures Appendix

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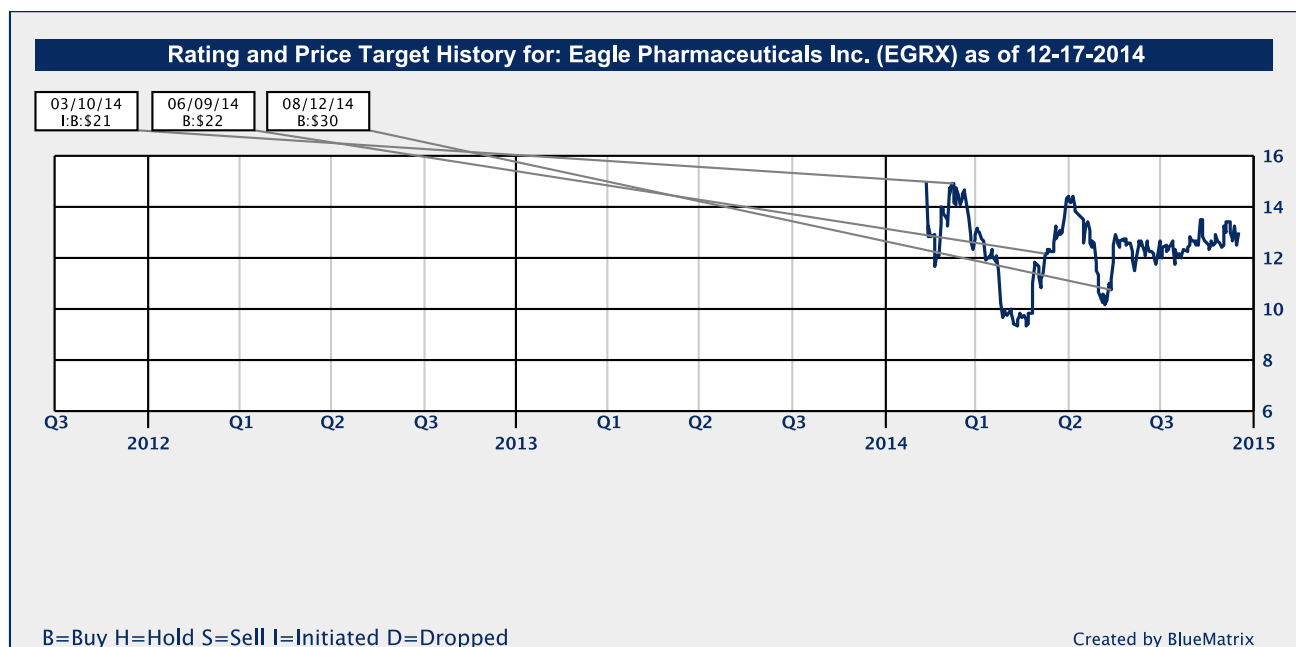
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Rating	Cantor		IB Serv./Past 12 Mos.	
	Count	Percent	Count	Percent
BUY [B]	89	60.14	22	24.72
HOLD [H]	50	33.78	10	20.00
SELL [S]	9	6.08	1	11.11