

Equity Research

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Eagle Pharmaceuticals Inc. (EGRX-\$10.99)

Rating: BUY

Target Price: \$30.00

Higher Ryanodex Price Boosts Estimates; Maintain BUY, Raise PT to \$30 from \$22

<u>REV</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2013A	1.5A	2.5A	5.1A	0.0A
<i>Prev</i>	—	—	0.0A	—
2014E	5.5A	5.0A	5.8A	1.9E
<i>Prev</i>	—	—	3.3E	2.1E
2015E	—	—	—	—
<u>EPS</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2013A	(1.09)A	(1.84)A	(0.11)A	0.00A
<i>Prev</i>	—	—	0.00A	—
2014E	(1.44)A	(0.36)A	(0.21)A	(0.57)E
<i>Prev</i>	—	—	(0.39)E	(0.42)E
2015E	—	—	—	—
<u>FY</u>	<u>2013A</u>	<u>2014E</u>	<u>2015E</u>	
REV	13.7A	18.2E	14.2E	
<i>Prev</i>	—	15.9E	8.9E	
P/S	11.2x	8.5x	10.9x	
EPS	(0.51)A	(1.31)E	(1.61)E	
<i>Prev</i>	—	(1.35)E	(1.80)E	
P/E	(21.5)x	(8.4)x	(6.8)x	

- **3Q:FY14 beat due to an unexpected milestone:** Eagle reported revenues of \$5.8M and a loss per share of (\$0.21) versus FactSet consensus revenue estimates of \$3.4M and loss per share estimates of (\$0.37). Sales were unexpectedly boosted by a one-time \$3.5M milestone associated with FDA approval of generic diclofenac/misoprostol. Otherwise the company would have missed consensus estimates (with \$2.3M in revenue, and loss of (\$0.46)). Both product sales and royalty income were adversely impacted by entry of argatroban generics in July 2014. However, the company plans to launch its Ryanodex for malignant hyperthermia (MH) at the end of August, which should help offset some of the losses associated with argatroban. This drug has been priced significantly above our initial expectations, which led to a revision in our model forecast, and we therefore raise our PT to \$30 from \$22 and reiterate our BUY rating.
- **Ryanodex commercialization plans:** Ryanodex, Eagle's rapid delivery formulation of dantrolene, can be reconstituted in 1 minute relative to 15-20 minutes for existing dantrolene, which allows for improved patient safety when fast administration is critical. We estimate a slow/steady switch to Ryanodex by hospitals as current dantrolene stock expires. Eagle plans to price Ryanodex at \$2,300 with an early stocking discount of 10%, which represents ~2.6x the cost of the current dantrolene. Eagle will drop ship the product and book sales upon customer receipt. We had used the older pricing in our forecasts and now grew peak market value to \$65M from \$25M/year. This excludes any upside from the exertional heat stroke indication, which is currently in early stage development. Hospitals are required to keep 3-4 doses in stock. Management expects to spend \$4M on launch costs, and we have raised 4Q:FY14 SG&A to account for a portion of this spend. The Ryanodex launch is expected to validate Eagle's business model, and any unexpected impediments could be risky to the story, in our view.
- **Modeling peak sales of \$0.5M for diclofenac/misoprostol.** FDA approved Eagle's ANDA for diclofenac/ misoprostol tablets in March, and Eagle recognized \$3.5M in revenues this quarter related to a milestone payment from Hikma. This drug is a generic form of Arthrotec, an arthritis pain medication that will launch in October. Pfizer and Actavis already dominate the generic space for this product, having captured approximately 92% of the branded market. Eagle plans to compete on price, and we therefore model minimal revenues for this asset. Eagle is one of three approved generics for this drug (with Sandoz and Actavis).

Current Statistics

Market Cap (\$Mil)	\$154.1	Float Shares (Mil):	14.400
Avg. Daily Trading Volume (3 mo.):	80,898		
Shares Out (Mil):	14.020		

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

Exhibit 1: EGRX 3Q:FY14 Variance Analysis (\$ in millions, except per share data)

	3Q:FY14E	3Q:FY14A	% Variance	Y/Y Growth	Q/Q Growth	Comments
Revenues	3.3	5.8	76.7%	14.1%	15.7%	
Total Revenues	3.3	5.8	76.7%	14.1%	15.7%	\$3.4M Consensus
COGS	2.5	1.6	-38.1%	-46.8%	-53.7%	
Gross Profit	0.8	4.2	455.2%	97.0%	157.5%	
SG&A	2.3	2.7	16.2%	-460.3%	83.8%	
R&D	4.0	4.5	13.6%	178.5%	19.8%	
EBIT	-5.5	-3.0	NM	-336.7%	-17.2%	
Interest and Other Income	0.0	0.0	539.4%	-109.6%	-112.8%	
Pre-tax income	-5.5	-2.9	NM	-488.8%	-26.3%	
Income tax expense	0.0	0.0	NM	NM	-100.0%	
Net Income	-5.5	-2.9	NM	-488.8%	9.3%	
Dividend Payment	0.0	0.0	NM	-100.0%	-100.0%	
Net Loss Attributable to Common Shareholders	-5.5	-2.9	NM	816.7%	-8.8%	
Diluted shares	14.2	14.0	-1.3%	360.0%	58.2%	
Operating EPS	(\$0.39)	(\$0.21)	NM	99.3%	-42.4%	(\$0.37) Consensus

Source: Company reports, Cantor Fitzgerald estimates, and FactSet

Other key updates:

- **No updates on Teva litigation, and we continue to model 2016 Treanda RTD launch.** We continue to await the results of summary judgment in the Teva patent litigation case following Eagle's tentative approval of this product. Our market entry estimate of 2016 assumes a favorable patent infringement lawsuit settlement with Teva, though management remains hopeful about an even earlier market launch in 1Q:15-1Q:16. Teva reported \$190 million in global Treanda sales (+7% Y/Y) but we don't have a sense of the drug's performance in the U.S. since the launch of Imbruvica, and therefore maintain our U.S. estimates in the ~\$600M range. Teva has not yet launched its liquid formulation of Treanda, but if the market does switch over to the liquid version it may provide Eagle a competitive advantage over generic products that are lyophilized powder formulations. Imbruvica had its label expanded earlier this year (2/12/14) to include patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy, and again on 7/28/14 to include CLL patients with a 17p deletion (roughly 5% of the CLL population¹), which makes us slightly more conservative about the market size and growth for Treanda.
- **Ryanodex for exertional heat stroke program is on track:** In addition to the malignant hyperthermia indication, management is exploring Ryanodex in exertional heat stroke, which is a leading cause of death for student athletes and military personnel. Eagle currently plans to launch a pilot study in Saudi Arabia at the end of the year in conjunction with the Saudi Arabian government, but the source of financing for the study has not yet been determined. It is possible that Eagle may need to bear the cost of the trial in the future. We believe that the new \$2,300/vial pricing announced today would greatly benefit this opportunity. Management previously estimated sales of \$87 million in the fifth year post-launch using pricing of \$1,000/vial with 3% annual price increases. Therefore, with the new pricing, the theoretical market opportunity could be closer to \$200 million. We exclude this product from our estimates for now and continue to view it as a sweetener to potential acquirers of the company.
- **Eagle's Angiomax formulation development continues:** Management indicated that it anticipates filing an NDA for its bivalirudin formulation in 1H:15 with a best case scenario launch in 1Q:16 (with a summary judgment) in addition to filing for approval with the EMA by mid-2015. We still model a 2017 launch. We have no update on the Hospira litigation.

¹ Stilgenbauer, Stephan, and Thorsten Zenz. "Genetics in chronic lymphocytic leukemia." *Leukemia* 16 (2002): 993-1007.

Milestones:

We summarize key Eagle milestones in Exhibit 2 below.

Exhibit 2: Key Eagle Catalysts

Date	Milestone/Event
2014	
Aug-14	Expected U.S. launch for Ryanodex for MH
end-2014	Initiate pilot study for Ryanodex exertional heat stroke in Saudi Arabia
2015	
1H:2015	NDA filing for Eagle's Angiomax formulation
mid-2015	File marketing authorization applications with EMA for Ryanodex
Sep-15	Orphan Drug Exclusivity expiring on Treanda
Dec-15	End of 30 month stay on Treanda lyophilized powder generics
2016	
Mar-16	End of 30 month stay on Eagle's Treanda RTD
2016	Treanda RTD Short Infusion PDUFA and product launch
2017	
2017	Eagle's Angiomax formulation launch
2017	Ryanodex for Exertional Heat Stroke product launch

Source: Company reports and Cantor Fitzgerald estimates

Cash: Eagle reported \$49.8 million in cash and cash equivalents and 14.0 million outstanding shares as of June 30, 2014.

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 (previously \$22) price target using this methodology. We have raised our price target due to the higher-than-expected pricing of Ryanodex that was recently announced by the company. With regard to downside risk, we believe that later-than-expected launch of the Treanda RTD, or earlier-than-expected generic entry of Angiomax generics could result in (\$16/share) and (\$7/share) downside to our base case scenario, respectively.

Risks

1. Launch delays associated with generic 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:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenues:													
Product Sales	1.2	5.3	2.2	1.2	0.4	0.7	4.4	13.0	94.4	274.3	242.3	171.6	174.4
Royalty Income	1.4	8.4	3.3	3.6	1.9	1.2	10.0	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
Total revenues	2.5	13.7	5.5	5.0	5.8	1.9	18.2	14.2	95.5	275.3	243.3	172.5	175.3
Operating expenses:													
COGS	3.2	7.4	4.6	3.4	1.6	1.3	10.8	4.4	18.8	72.4	103.0	54.4	55.7
R&D	12.8	9.8	2.6	3.8	4.5	4.2	15.1	18.2	20.0	21.4	22.4	23.6	24.7
SG&A	6.4	5.0	1.3	1.5	2.7	4.5	10.0	15.0	26.0	31.2	32.8	34.4	36.1
Operating income (deficit)	(19.8)	(8.5)	(3.1)	(3.6)	(3.0)	(8.1)	(17.8)	(23.3)	30.6	150.4	85.1	60.1	58.7
Interest income	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
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
Pretax Income	(20.2)	(6.9)	(3.3)	(4.0)	(2.9)	(8.1)	(18.3)	(23.3)	30.7	150.5	85.2	60.3	58.9
Tax rate	0.0%	0.0%	0.0%	NM	0.0%	0.0%	NM	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	6.1	52.7	29.8	21.1	20.6
Net Loss	(19.4)	(6.0)	(3.3)	(2.7)	(2.9)	(8.1)	(17.0)	(23.3)	24.5	97.8	55.4	39.2	38.3
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
stockholders	(23.3)	(9.9)	(4.4)	(3.2)	(2.9)	(8.1)	(18.7)	(23.3)	24.5	97.8	55.4	39.2	38.3
Weighted average common shares	10.6	19.5	3.0	8.9	14.0	14.2	14.2	14.5	15.0	15.5	16.0	16.5	17.0
Diluted EPS	(\$2.20)	(\$0.51)	(\$1.44)	(\$0.36)	(\$0.21)	(\$0.57)	(\$1.31)	(\$1.61)	\$1.64	\$6.31	\$3.46	\$2.37	\$2.25
Consensus Revenues							2.9	16	12	139	221		
Consensus EPS							(\$0.43)	(\$1.35)	(\$1.80)	\$3.37	\$4.16		
Margin Analysis	2012	2013	1Q:14A	2Q:14A	3Q:14A	4Q:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Gross Margin	-24.7%	46.0%	15.8%	32.9%	73.1%	31.4%	40.4%	69.3%	80.3%	73.7%	57.7%	68.5%	68.2%
COGS	124.7%	54.0%	84.2%	67.1%	26.9%	68.6%	59.6%	30.7%	19.7%	26.3%	42.3%	31.5%	31.8%
SG&A	252.0%	36.2%	24.5%	29.1%	46.2%	241.2%	55.1%	105.7%	27.2%	11.3%	13.5%	19.9%	20.6%
R&D	504.2%	71.6%	47.1%	75.8%	78.5%	223.8%	83.3%	127.9%	20.9%	7.8%	9.2%	13.7%	14.1%
Operating Margin	-780.9%	-61.8%	-55.8%	-72.0%	-51.5%	-433.6%	-97.9%	-164.3%	32.1%	54.6%	35.0%	34.9%	33.5%
Net Income Margin	-918.2%	-72.3%	-79.9%	-64.3%	-50.7%	-432.7%	-102.7%	-164.0%	25.7%	35.5%	22.8%	22.7%	21.8%
Growth (Y/Y)	2012	2013	1Q:14A	2Q:14A	3Q:14A	4Q:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Net Sales		439%	270%	102%	14%		33%	-22%	572%	188%	-12%	-29%	2%
SG&A		-23%	-30%	-51%	-460%		102%	50%	73%	20%	5%	5%	5%
R&D		-24%	17%	50%	178%		54%	20%	10%	7%	5%	5%	5%
EBIT	-	-	-	-	-	-	-	-	-231%	391%	-43%	-29%	-2%
Interest income		-91%	98%	1468%	1621%		1285%	-12%	-27%	147%	77%	21%	6%
Interest expense	-	-	-	-	-	-	-	-	-	-	-	-	-
Tax	-	-	-	-	-	-	-	-	NM	758%	-43%	-29%	-2%
Net Income	-	-	-	-	-	-	-	-	-205%	299%	-43%	-29%	-2%
Diluted EPS	-	-	-	-	-	-	-	-	-202%	286%	-45%	-31%	-5%

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:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Royalty Revenue													
ARGATROBAN													
Sales	\$3.5	\$29.0	\$12.5	\$11.0	\$5.9	\$4.7	\$34.0	\$5.0	\$4.5	\$4.3	\$4.1	\$3.9	\$3.7
Growth							17.2%	-85.3%	-10.0%	-5.0%	-5.0%	-5.0%	-5.0%
Royalty	39.5%	28.8%	26.1%	32.4%	32.4%	25.6%	29.2%	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	\$1.2	\$9.9	\$1.2	\$1.1	\$1.0	\$1.0	\$0.9	\$0.8
Growth		504.3%	166.2%	296.1%	-26.9%		18.6%	-87.5%	-11.3%	-6.4%	-6.4%	-6.4%	-6.5%
Product Sales													
ARGATROBAN													
Sales	\$1.2	\$5.3	\$2.2	\$1.2	\$0.4	\$0.3	\$4.1	\$0.8	\$0.7	\$0.7	\$0.6	\$0.6	\$0.5
Growth		360.0%	770.9%	-26.6%	-84.0%		-22.9%	-80.3%	-11.3%	-6.4%	-6.4%	-6.4%	-6.5%
DICLOFENAC/MISOPROSTOL													
Sales								\$0.50	\$0.5	\$0.5	\$0.4	\$0.4	\$0.4
Growth									-5.0%	-5.0%	-5.0%	-5.0%	-5.0%
RYANODEX													
Sales						0.4	\$0.4	\$11.6	\$22.0	\$41.5	\$49.0	\$57.0	\$58.2
Growth								89.0%	88.4%	18.2%	16.4%	2.0%	2.0%
TREANDA RTD													
Sales									\$71.2	\$188.2	\$67.8	\$67.8	\$67.7
Growth										164.4%	-64.0%	0.0%	-0.1%
ANGIOMAX RTU													
Sales										\$43.6	\$124.4	\$45.8	\$47.6
Growth											185.7%	-63.2%	4.0%
TOTAL REVENUE	\$2.5	\$13.7	\$5.5	\$4.7	\$2.3	\$1.9	\$14.4	\$14.2	\$95.5	\$275.3	\$243.3	\$172.5	\$175.3
Growth		438.7%	270.3%	89.6%	-54.9%		5.3%	-1.5%	572.4%	188.4%	-11.7%	-29.1%	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:

Actavis, Inc. (ACT - NYSE): NC
Eagle Pharmaceuticals Inc. (EGRX - NASDAQ): BUY
Hikma Pharmaceuticals (HIK.L - LSE): NC
Hospira Inc. (HSP - NYSE): NC
Pfizer Inc. (PFE - NYSE): NC
Teva Pharmaceutical Industries Limited (TEVA - NYSE): NC
Sandoz (a division of Novartis)

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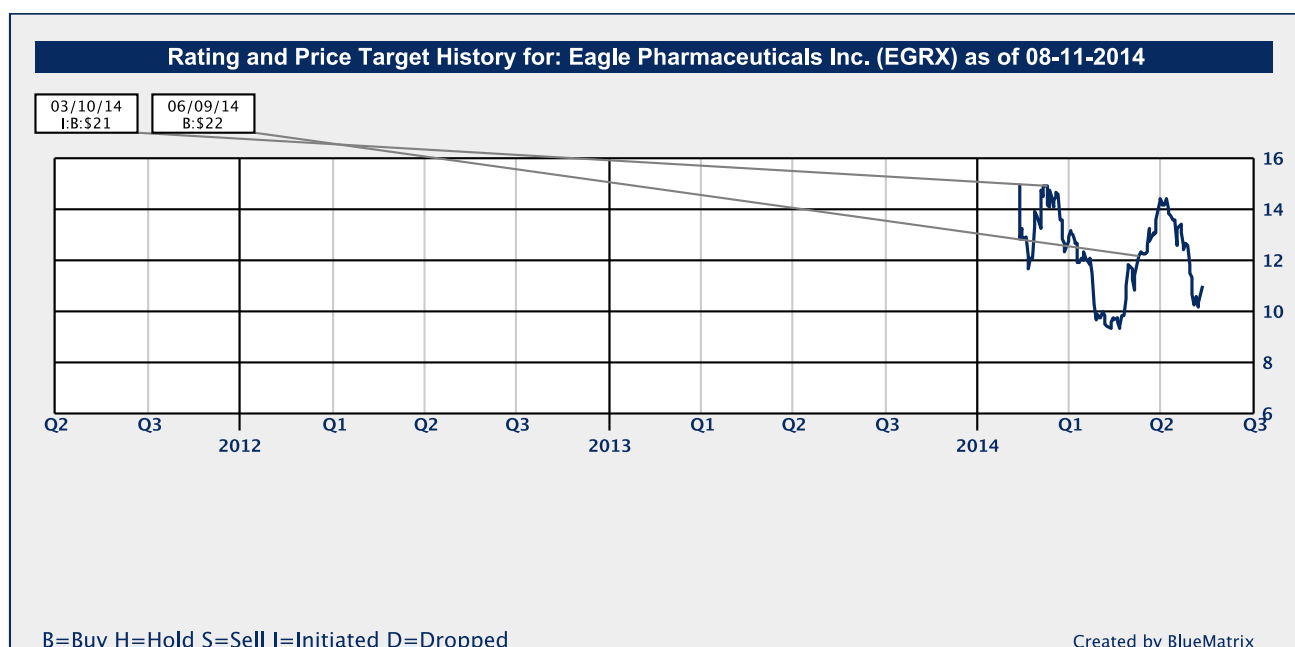
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