

Equity Research

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## Eagle Pharmaceuticals Inc. (EGRX-\$11.44)

**Rating: BUY**

**Target Price: \$22.00**

### EGRX 2Q:14 Update; Maintain BUY and Raise PT to \$22 from \$21

<u>REV</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2013A	1.5A	2.5A	0.0A	0.0A
Prev	—	0.0A	—	—
2014E	5.5A	5.0A	3.3E	2.1E
Prev	—	4.8E	1.7E	1.3E
2015E	—	—	—	—
<u>EPS</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2013A	(1.09)A	(1.84)A	0.00A	0.00A
Prev	—	0.00A	—	—
2014E	(1.44)A	(0.36)A	(0.39)E	(0.42)E
Prev	—	(0.16)E	(0.30)E	(0.47)E
2015E	—	—	—	—
<u>FY</u>	<u>2013A</u>	<u>2014E</u>	<u>2015E</u>	
REV	13.7A	15.9E	8.9E	
Prev	—	13.3E	7.4E	
P/S	11.7x	10.1x	18.0x	
EPS	(0.51)A	(1.35)E	(1.80)E	
Prev	—	(1.55)E	(1.69)E	
P/E	(22.4)x	(8.5)x	(6.4)x	

- **Revenue beat in 2Q:14:** Eagle Pharmaceuticals reported revenues of \$5.0M and a loss per share of (\$0.36) versus FactSet consensus revenue estimates of \$3.1M and loss per share estimates of (\$0.25) and our revenue estimates of \$4.8M and loss per share estimates of (\$0.16). Management expects entry of argatroban generics in July 2014 to slow sales. This loss should be offset to some extent by the earlier-than-expected launch of Ryanodex for malignant hyperthermia (MH) in 3Q:14. We reiterate our BUY rating and raise our PT to \$22 from \$21, which is based on lower discount factors in our DCF analysis.
- **We expect Ryanodex to achieve peak sales of \$25M:** Ryanodex has a PDUFA date of July 22nd and if approved, it could be launched in malignant hyperthermia as early as 3Q:14. Ryanodex will represent the first product that Eagle will commercialize without a partner, and we think it will serve as a useful example of the company's commercial strategy. Separately, Eagle plans to start a pilot study of Ryanodex for exertional heat stroke in Saudi Arabia by year-end. The company is still in discussions about study financing sources. Management expects to partner the drug OUS and receive a sales royalty, which is currently excluded from our estimates.
- **Generic litigation updates:** (1) Management indicated that the Treanda RTD litigation with Teva was progressing as expected with news expected shortly. Timing of summary judgment is uncertain, though we would expect Teva to appeal the case and attempt to delay the launch. We continue to believe that a more likely scenario is a generic settlement that would allow launch of Eagle's rapid dose (50 mL bag) formulation in 2016. (2) The Medicines Company launched an appeal in May after the recent ruling that Hospira's generic Angiomax did not infringe its patents. Generic Angiomax could launch as late as 2019 if the patents are upheld, providing Eagle with the opportunity to market without generics for up to a year, but there is now more uncertainty around this outcome. We are leaving our estimates unchanged at this time. (3) A recent ruling in the United States upheld Lilly's '209 Alimta patent, which protects Alimta until 2022. We have not modeled any revenues associated with this asset to date and expect Eagle to launch its Alimta RTD in 2022, priced at a slight premium to generics.

#### Current Statistics

Market Cap (\$Mil)	\$160.4	Float Shares (Mil):	14.400
Avg. Daily Trading Volume (3 mo.):	108,725		
Shares Out (Mil):	14.020		

**Exhibit 1: EGRX 2Q:14 Variance Analysis**

	2Q:14E	2Q:14A	% Variance	Comments
Revenues	4.8	5.0	4.7%	
<b>Total Revenues</b>	<b>4.8</b>	<b>5.0</b>	<b>4.7%</b>	<b>\$3.1M Consensus</b>
COGS	2.7	3.4	23.9%	
<b>Gross Profit</b>	<b>2.07</b>	<b>1.6</b>	<b>-20.4%</b>	
SG&A	1.50	1.5	-3.0%	
R&D	2.80	3.8	35.5%	
<b>EBIT</b>	<b>(2.2)</b>	<b>-3.6</b>	<b>NM</b>	
Interest and Other Income	0.00	-0.4	-29864.2%	
Pre-tax income	-2.2	-4.0	NM	
Income tax expense	0.0	-1.3	NM	
<b>Net Income</b>	<b>-2.2</b>	<b>-2.7</b>	<b>NM</b>	
Dividend Payment	0.00	-0.5	NM	
<b>Net Loss Attributable to Common Shareholders</b>	<b>-2.2</b>	<b>-3.2</b>	<b>NM</b>	
Diluted shares	13.90	8.9	-36.2%	
<b>Operating EPS</b>	<b>(\$0.16)</b>	<b>(\$0.36)</b>	<b>NM</b>	<b>(\$0.25 Consensus)</b>

Source: Company reports, Cantor Fitzgerald estimates, and FactSet

**Other key updates from the call:**

- **Events around Eagle's Treanda RTD program could result in meaningful stock appreciation, in our view:** Eagle's bendamustine RTD has a PDUFA date scheduled for July 6<sup>th</sup>, and we estimate market entry in early 2016 (management estimates an \$800 million market for Treanda in 2015). Market entry in 2016 assumes a favorable patent infringement lawsuit settlement with Teva, though management anticipates news on the summary judgment shortly (and remains hopeful about an even earlier market launch in 1Q:15-1Q:16). Management noted that its forms of bendamustine have a 24-month shelf life, which compares favorably to Teva's 12-month shelf life on the liquid product.
- **Ryanodex for exertional heat stroke makes progress:** Management is exploring Ryanodex in an additional indication, exertional heat stroke, which is a leading cause of death for student athletes and military personnel. Ryanodex was recently issued a new patent for the heat stroke indication and has already been granted Orphan drug designation. In addition to working with the U.S. military to develop this product, Eagle announced that it has been in discussions with the Saudi Arabian FDA and plans to initiate a pilot study in Saudi Arabia later this year. There has been no financing commitment from either the U.S. military or Saudi Arabia at this time. It is possible that Eagle may need to bear the cost of the trial in the future.
- **Eagle's Angiomax formulation development continues:** Eagle filed an additional patent for its formulation and has successfully completed three registration batches that are required for its NDA submission. Management indicated that it anticipates filing an NDA for this product in 2Q:15 with a best case scenario launch in 1Q:16 (with a summary judgment). We still model a 2017 launch.

**Milestones:**

We summarize key Eagle milestones in Exhibit 2 below.

**Exhibit 2: Key Eagle Catalysts**

Date	Milestone/Event
<b>2014</b>	
Jul-6-14	PDUFA date for Treanda RTD
22-Jul-14	PDUFA date for Ryanodex for malignant hyperthermia (MH)
Jul-14	Argatroban generic products entry
3Q:14	Expected U.S. launch for Ryanodex for MH
2H:14	Initiate pilot study for Ryanodex exertional heat stroke in Saudi Arabia
<b>2015</b>	
mid-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
<b>2016</b>	
Mar-16	End of 30 month stay on Eagle's Treanda RTD
2016	Treanda RTD Short Infusion PDUFA and product launch
<b>2017</b>	
2017	Eagle's Angiomax formulation launch
2017	Ryanodex for Exertional Heat Stroke product launch

Source: Company reports and Cantor Fitzgerald estimates

**Cash:** Eagle reported \$54.9 million in cash and cash equivalents and 14.02 million outstanding shares as of March 31, 2014.

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## 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 \$22 price target using this methodology (up from \$21 previously). 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.

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## 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:14E	4Q:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenues:													
Product Sales	1.2	5.3	2.2	1.2	1.2	0.9	5.5	7.7	83.5	251.4	214.7	138.9	141.1
Royalty Income	1.4	8.4	3.3	3.6	2.1	1.2	10.1	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	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0	0.0
Total revenues	2.5	13.7	5.5	5.0	3.3	2.1	15.9	8.9	84.6	252.5	215.7	139.8	142.0
Operating expenses:													
COGS	3.2	7.4	4.6	3.4	2.5	1.6	12.1	3.1	16.5	66.3	97.1	47.5	48.7
R&D	12.8	9.8	2.6	3.8	4.0	4.0	14.4	17.3	19.0	20.3	21.3	22.4	23.5
SG&A	6.4	5.0	1.3	1.5	2.3	2.5	7.6	15.0	26.0	31.2	32.8	34.4	36.1
Operating income (deficit)	(19.8)	(8.5)	(3.1)	(3.6)	(5.5)	(6.0)	(18.2)	(26.5)	23.2	134.7	64.5	35.5	33.7
Interest income	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4	0.3	0.8	1.4	1.7	1.8
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	(0.6)	0.0	0.0	0.0	0.0	0.0	0.0
Pretax Income	(20.2)	(6.9)	(3.3)	(4.0)	(5.5)	(6.0)	(18.8)	(26.0)	23.6	135.5	65.9	37.2	35.4
Tax rate	0.0%	0.0%	0.0%	NM	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	4.7	47.4	23.1	13.0	12.4
Net Loss	(19.4)	(6.0)	(3.3)	(2.7)	(5.5)	(6.0)	(17.5)	(26.0)	18.8	88.1	42.8	24.2	23.0
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
stockholders	(23.3)	(9.9)	(4.4)	(3.2)	(5.5)	(6.0)	(19.1)	(26.0)	18.8	88.1	42.8	24.2	23.0
Weighted average common shares	10.6	19.5	3.0	8.9	14.2	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)	(\$0.39)	(\$0.42)	(\$1.35)	(\$1.80)	\$1.26	\$5.68	\$2.68	\$1.46	\$1.35

Source: Company reports, Cantor Fitzgerald Estimates and FactSet Consensus

Exhibit 4: Eagle Sales Estimates (dollars in millions)

	2012	2013	1Q:14A	2Q:14A	3Q:14E	4Q:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
<b>Royalty Revenue</b>													
<b>ARGATROBAN</b>													
Sales	\$3.5	\$29.0	\$12.5	\$11.0	\$8.0	\$4.5	\$36.0	\$5.0	\$4.5	\$4.3	\$4.1	\$3.9	\$3.7
Growth							24.1%	-86.1%	-10.0%	-5.0%	-5.0%	-5.0%	-5.0%
Royalty	39.5%	28.8%	26.1%	32.4%	26.0%	25.6%	27.9%	24.9%	24.5%	24.2%	23.8%	23.4%	23.1%
ARGATROBAN ROYALTY REVENUE	\$1.4	\$8.4	\$3.3	\$3.6	\$2.1	\$1.2	\$10.1	\$1.2	\$1.1	\$1.0	\$1.0	\$0.9	\$0.8
Growth		504.3%	166.2%				20.3%	-87.6%	-11.3%	-6.4%	-6.4%	-6.4%	-6.5%
<b>Product Sales</b>													
<b>ARGATROBAN</b>													
Sales	\$1.2	\$5.3	\$2.2	\$1.2	\$1.0	\$0.7	\$5.1	\$0.8	\$0.7	\$0.7	\$0.6	\$0.6	\$0.5
Growth		360.0%	770.9%				-3.1%	-84.3%	-11.3%	-6.4%	-6.4%	-6.4%	-6.5%
<b>RYANODEX</b>													
Sales					0.2	\$0.2	\$0.4	\$6.9	\$11.7	\$19.1	\$21.9	\$24.8	\$25.3
Growth									70.0%	63.2%	14.8%	13.3%	2.0%
<b>TREANDA RTD</b>													
Sales									\$71.2	\$188.2	\$67.8	\$67.8	\$67.7
Growth										164.4%	-64.0%	0.0%	-0.1%
<b>ANGIOMAX RTU</b>													
Sales										\$43.6	\$124.4	\$45.8	\$47.6
Growth											185.7%	-63.2%	4.0%
<b>TOTAL REVENUE</b>	<b>\$2.5</b>	<b>\$13.7</b>	<b>\$5.5</b>	<b>\$4.7</b>	<b>\$3.3</b>	<b>\$2.1</b>	<b>\$15.6</b>	<b>\$8.9</b>	<b>\$84.6</b>	<b>\$252.5</b>	<b>\$215.7</b>	<b>\$139.8</b>	<b>\$142.0</b>
Growth		438.7%	270.3%				14.1%	42.8%	849.1%	198.3%	-14.6%	-35.2%	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:

Eagle Pharmaceuticals Inc. (EGRX - NASDAQ): BUY

Eli Lilly and Company (LLY - NYSE): NC

Hospira Inc. (HSP - NYSE): NC

Teva Pharmaceutical Industries Limited (TEVA - NYSE): NC

The Medicines Co. (MDCO - NASDAQ): NC

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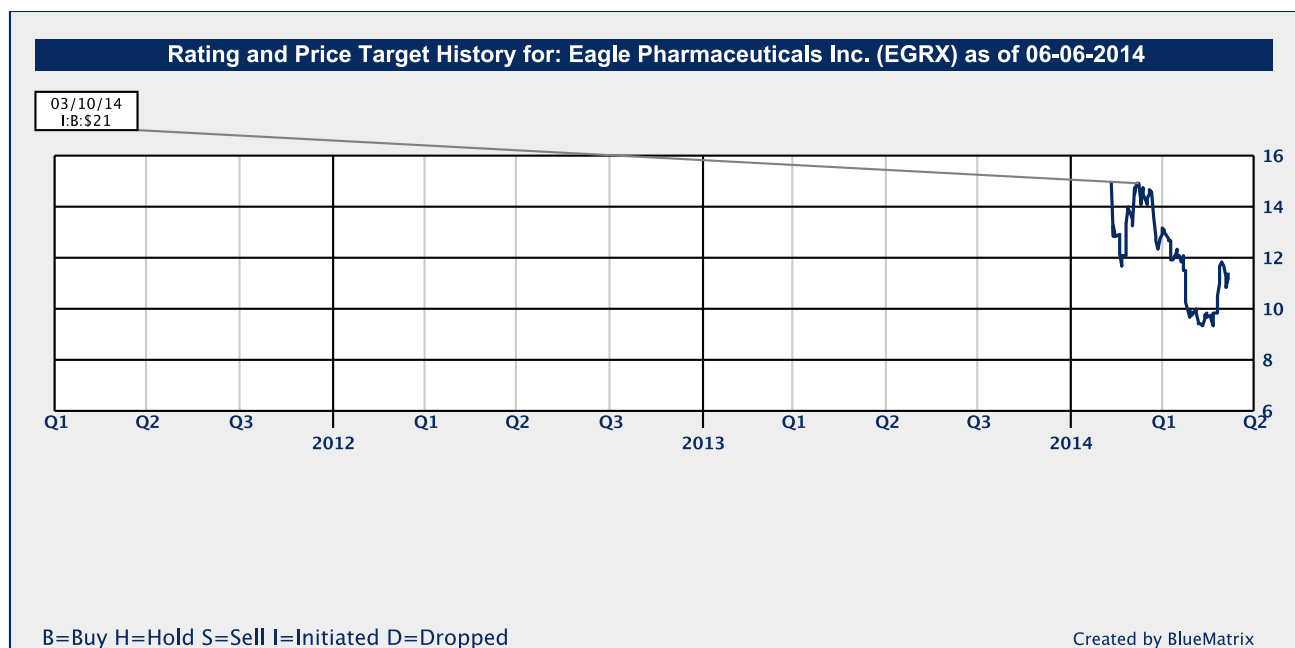
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