

# **Eagle Pharmaceuticals, Inc.**

# Teva Agreement Removes Major Overhang and Moves Company to Profitability; Increasing Price Target to \$43 From \$25

- Before the markets opened Tuesday, February 17, Eagle and Teva Pharmaceuticals (TEVA \$56.26) announced that the companies entered an exclusive licensing agreement for EP-3102, Eagle's bendamustine rapid infusion product for the treatment of chronic lymphocytic leukemia and B-cell non-Hodgkin's lymphoma that would have taken significant market share away from Teva's over \$700 million annualized product, Treanda. Under the agreement, Eagle has responsibility for obtaining all regulatory approvals, including any potential post-approval studies and initially supplying the drug to Teva. In exchange, Teva will pay Eagle an up-front cash payment of \$30 million with eligibility to receive up to \$90 million in regulatory approval/sales milestones and double-digit royalties on net sales, which we estimate will begin at 20%. Overall, we believe that this is a significant positive for Eagle as litigation risk is now taken off the table and moves the company immediately into profitability, which we believe will be sustained as soon as EP-3102 is launched. We believe that Teva will transfer about 75% of the Treanda market onto EP-3102. which nets to peak revenue to Eagle of roughly \$713 million in 2017 before generic erosion to Treanda, which we believe will hit in 2018, following an appeals process. However, this time frame is a best conservative estimate given the potential for litigation victories or settlements by Teva and the generic challengers. We are also not assuming a launch of EP-3102 until the end of 2015; however, this may be moved up to August/September 2015 if Eagle is awarded a priority review, which will be known in the near term.
- The agreement announced Tuesday ends a saga between the two companies and removes the biggest overhang on Eagle's stock since its IPO last March. In October 2013, Teva/Cephalon filed a lawsuit in the U.S. District Court for the District of Delaware, claiming that Eagle's ready-to-use (RTU) bendamustine product infringed on its U.S. patent No. 8,445,524 titled, "Solid forms of bendamustine hydrochloride." On September 17, 2013, Teva/Cephalon moved to dismiss this lawsuit and filed a second lawsuit alleging that Eagle's bendamustine product infringed on the late listed U.S. patent No. 8,791,270 titled, "Bendamustine pharmaceutical compositions." Eagle has already gained a tentative approval (tentative because of the litigation, which should now be removed) for an RTU formulation of bendamustine and completed a positive study that showed that Eagle's 10-minute, 50 mL bendamustine infusion product was bioequivalent to Teva's Treanda, which is infused over an hour with 500 mL of liquid.
- On the call Tuesday, Eagle stated that it has submitted the sNDA for the 10-minute, 50 mL bendamustine infusion product for priority review, which if granted would move the PDUFA date timeline up six months. Eagle's 10-minute infusion has already received orphan status, and we continue to believe the 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.

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.

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#### February 17, 2015

Stock Rating:	Outperform
Company Profile:	<b>Aggressive Growth</b>
Price Target:	\$43.00

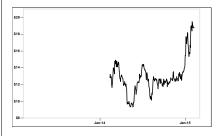
Symbol: EGRX (NASDAQ)
Price: \$25.89 (52-Wk.: \$9-\$22)
Market Value (mil.): \$294
Fiscal Year End: September
Long-Term EPS Growth Rate: NA
Dividend/Yield: None

	2013A	2014A	2015E
<b>Estimates</b>			
EPS Q1	NA	A\$-0.20	NA
Q2	NA	A\$-0.36	NA
Q3	NA	A\$-0.21	NA
Q4	NA	A\$-0.65	NA
FY	\$-0.51	\$-1.55	\$0.32
Valuation			
FY P/E	NM	NM	NM

Trading Data (FactSet)	
Shares Outstanding (mil.)	14
Float (mil.)	8
Average Daily Volume	67,786

Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	2.4
Return on Equity (TTM)	-97.6

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



Sources: FactSet, William Blair & Company estimates

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This reduction in volume is likely a significant safety differentiation for the product given the high rate of patients with compromised kidney function in the hematologic markets. In exhibit 1, we show comparisons between Eagle's bendamustine products and Treanda. Eagle's bendamustine products have received U.S. patent No. 8,609,707, U.S. patent No. 0,094,496, and U.S. patent No. 0,253,025; management believes that several of these patents will be listed in the Orange Book following approval of EP-3102.

- As a result of the details provided by the company, we have updated our model to reflect the \$30 million milestone payment, potential regulatory/sales milestones, and double-digit royalty payments, which we have started at 20% in 2015 and increased to 25% in 2019. With these licensing agreement assumptions and midsingle-digit growth for bendamustine products from 2015 to 2017, we derive peak sales for the franchise of \$950 million in 2017 followed by generic price erosion. For our generic erosion assumptions, we have assumed a 20% decrease in revenue in 2018 followed by step-wise decreases from 2019 to 2023, the year EP-3102 loses orphan exclusivity. Lastly, we have included calendar-year EPS estimates in our model to reflect the imminent change of Eagle's 2015 fiscal year, which has been approved by the company's board of directors and will end on December 31, 2015. Our old and new estimates for 2015-2017 are shown in exhibit 2.
- Aside from Tuesday's news, the company has Ryanodex, which is in its second quarter of launch for the treatment of
  malignant hypothermia. In addition, Eagle expects to conduct a pivotal trial in exertional heat stroke (EHS) for Ryanodex
  in the second half of 2015. We model Ryanodex as holding peak sales in the United States of about \$20 million; however,
  the expansion into the treatment of EHS or a meaningful European launch would expand the peak sales potential of
  Ryanodex. In exhibit 3, we show Eagle's product portfolio, indication, company-defined market opportunity, and status.
- We maintain our Outperform rating on shares of Eagle as management has executed on all of its stated goals since the company came public in 2014. We believe that Eagle is in a strong position and offers significant upside from current levels with little clinical risk as it transforms into a profitable specialty pharmaceuticals company with significant cash flow pending the approval of EP-3102. With what we believe are modest assumptions for the peak penetration and royalties from the bendamustine agreement and Ryanodex launch, we derive a net present value for the company's pipeline of \$43 per share, as shown in exhibit 4, on the following page.

Exhibit 1

Eagle Pharmaceuticals

Comparisons between Treanda and Eagle's bendamustine products

	Treand	a®	Eag	gle									
Key Product Characteristics	Treanda⊛ Lyophilized	Treanda⊚ Liquid	EP-3101	EP-3102 rapid infusion	EP-3101/EP-3102 Potential Benefits								
Product description	Lyophilized powder for reconstitution (5 mg/mL)	Ready-to- dilute (90 mg/mL)	Ready-to-dilute liquid (25 mg/mL)		Ready-to-dilute liquid (25 mg/mL)		Ready-to-dilute liquid (25 mg/mL)		Ready-to-dilute liquid (25 mg/mL)		Ready-to-dilute liquid (25 mg/mL)		Relative to lyophilized Treanda, reduced risk of dosing errors, less exposure to cytotoxic powders and time savings; Joint Commission-preferred
Shelf-life	24 months	12 months	24 months In		24 months		Increased stability over Treanda® liquid						
Multi-use vial	No, product must be diluted 30 minutes after reconstitution	No	Yes, must be used within 28 days if stored at 2-8° C and protected from light		Reduced potential for waste over both Treanda® products								
Admixture stability (all must be refrigerated 24 hrs.)	Room Temp: 3 hrs.	Room Temp: 3 hrs.	Room Temp: 3 hrs.	Room Temp: 6 hrs. 5% dextrose water (D5W) 4 hrs.	Improved admixture stability over both Treanda® products. Additional admixture vehicle avoiding sodium for renally impaired patients								
Infusion time	30-60 minutes	30-60 minutes	30-60 minutes	10 minutes	Less time in infusion chair for EP-3102 patient; greater office efficiencies due to less nursing time with each patient								
Admixture fluid volume	500 mL	500 mL	500 mL	50 mL	Less potential for EP-3102 patient fluid load and edema								

Source: Eagle 10-K

Exhibit 2
Eagle Pharmaceuticals
Revised and New Estimates

		GRX	EGRX	EGRX	EGRX		EGRX		GRX
		Old	New	Old	New		Old		New
	20	015E	 2015E	2016E	2016E	2	2017E	2	017E
(\$ in millions except EPS)									
Product Sales	\$	46.5	\$ 10.5	\$ 195.2	\$ 27.2	\$	270.0	\$	120.0
Royalty Income	\$	5.0	\$ 5.0	\$ 4.0	\$ 50.9	\$	3.0	\$	132.0
Other Income	\$	-	\$ 30.0	\$ -	\$ 10.0	\$	-	\$	5.0
Total Revenue	\$	52.2	\$ 45.5	\$ 199.2	\$ 88.1	\$	273.0	\$	257.0
COGS	\$	7.1	\$ 4.6	\$ 21.2	\$ 1.1	\$	43.5	\$	36.0
R&D	\$	18.0	\$ 18.0	\$ 20.0	\$ 20.0	\$	22.0	\$	22.0
SG&A	\$	17.3	\$ 17.3	\$ 26.0	\$ 26.0	\$	124.5	\$	28.6
Operating Income	\$	5.6	\$ 3.3	\$ 100.7	\$ 34.8	\$	105.1	\$	119.1
(Loss) Income Before Taxes	\$	9.7	\$ 5.6	\$ 106.7	\$ 40.8	\$	113.1	\$	127.1
Net Income	\$	8.7	\$ 4.6	\$ 105.7	\$ 39.8	\$	73.5	\$	82.6
FY EPS	\$	0.44	\$ 0.32	\$ 7.20	\$ 2.71	\$	4.88	\$	5.48
CY EPS		N/A	\$ 1.18	N/A	\$ 3.39		N/A	\$	7.97

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

Exhibit 3
Eagle Pharmaceuticals
Product Portfolio

Product	U.S. Brand Reference Drug	Description	Indication	Market Opportunity (\$ in millions)	Status
Ryanodex⊚ (dantrolene sodium)	Dantrium <sub>®</sub> / Revonto <sub>®</sub>	Muscle relaxant	Malignant hyperthermia	\$75	Approved (U.S.)/Launched August 2014. Orphan drug designation received for MH (U.S.)
EP-1101 (argatroban)	Argatroban	Anti-coagulant; thrombin inhibitor	Heparin-induced thrombocytopenia	\$99	Approved (US); marketed by The Medicines Company and Sandoz
EP-3101 (bendamustine RTD)	Treanda⊚	Chemotherapeutic agent	Chronic lymphocytic leukemia (CLL); Indolent non-Hodgkin's lymphoma (NHL)	over \$700	Tentative approval for NHL July 2014
EP-3102 (rapidly infused bendamustine RTD)	ireanda <sub>®</sub> :		CLL; Indolent NHL	over \$700	Label expansion of EP-3101. Orphan drug designation for CLL and NHL (U.S.); Clinical trial completed with positive results announced November 2014.
EP-4104 (dantrolene sodium)	No drug currently approved	Muscle relaxant	Exertional heat stroke	\$150	Orphan drug designation received for heat stroke (U.S.); IND submission 2015
EP-6101 (bivalirudin)	Angiomax	Anti-Coagulant; thrombin inhibitor	Percutaneous transluminal angioplasty	\$609	Registration batches to support U.S. NDA filing manufactured in 2Q2014
EP-5101 (pemetrexed)	Alimta	Chemotherapeutic agent	Lung cancer and mesothelioma	\$1,210	Formulation work complete. NDA targeted for 2016

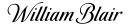
**Valuation:** We believe shares of Eagle continue to hold a strong risk/reward profile, given the potential for significant profitability. In our view, the company's pathway through a 505(b)(2) approval process holds a reduced development risk compared with many small-cap development-stage specialty pharmaceutical companies. Our price target for shares of Eagle is \$43, based on a net present value of the company's lead development programs, EP-3101 (ready-to-use bendamustine) for CLL and NHL, Ryanodex for malignant hypothermia, and EP-6101 (RTU-bivalirudin). Our full model with additional details is available from a William Blair salesperson; a summary is shown on the following page.

Exhibit 4

Discount Rate	11%
NPV	593
Cash	30
NPV+Cash	623
NPV+Cash/Share	\$ 42.95

Source: William Blair & Company estimates

**Risks:** An investment in Eagle involves regulatory, commercialization, and financial risk, common in development-stage specialty pharmaceutical companies. Eagle's pipeline is also focused on products near the end of their life cycles, and generic companies are traditionally strong competitors for market share, sometimes taking prices to unsustainable levels. We believe pricing and the resulting market share gains or losses will be a risk for Eagle as the company brings its therapies to the market.



William Blair
Eagle Pharmaceuticals
Earnings Model
2/17/15
(\$ in thousands except EPS data)

Rating: Outperform Company Profile: Aggressive Growth Tim Lugo 415.248.2870 tlugo@williamblair.com

				Dec. 14	Mar. 15	June 15	Sept.15			
	FY 2012(A)	FY 2013(A)	FY 2014(A)	Q1(E)	Q2(E)	Q3(E)	Q4(E)	FY 2015(E)	FY 2016(E)	FY 2017(E)
Product Program	4.455	5.045	4.000	4 700 0	0.000.4	0.000.4	0.400	40.540	07.040	400.040
Product Revenue EP-3101 (bendamustine RTD)	1,155	5,315	4,626	1,739.9	2,363.4	3,003.4	3,403	10,510	27,213	120,040
Ryanodex (dantrolene) Diclofenac/Misoprostol		1 1	200	400.0 339.9	960.0 653.4	1,600.0 653.4	2,000.0 653.4	4,960 2,300	22,400 2,813	27,200 3,090
EP-6101 (bivalirudin)	-	-	-	-	-	-	-	-	-	87,750
EP-5101 (pemtrexed) EP-1101 (argatroban)			- 2,127	1,000	750.0	- 750.0	- 750.0	- 3,250	2,000	2,000
EP-2101 (topotecan)	-	-	- 2,127	-	-	-	-	-	-	-
EP-3102 Royalties Other royalties Revenue	1,384	8,364	10,708	2000	1000	1000	1000	5,000	47,850 3,000	129,000 3,000
Other Revenue	1,004	0,004	3,765	2000	30000	1000	1000	30,000	10,000	5,000
Total Revenue	2,539.4	13,679	19,099	3,740	33,363	4,003	4,403	45,510	88,063	257,040
yr/yr growth		NM	39.6%	-32.4% 33.0%	572.0%	-30.9%	56.6%	138.3%	93.5%	191.9%
q/q growth incremental rev q/q				33.0%	792.1%	-79.0%	10.0%			
Cost of Goods Sold	3166.6	7,381	11714	1,500	1,500	1,500	100	4,600	1,120	36,021
Gross Profit	-627.2	6,298	7385	2240	31863	2503	4303 300	40910 300	86943 6,160	221,019 51,355
Royalty Expense SG&A	6,399	4,958	9326	3,105	3,795	5,175	5,175	17,250	26,000	28,600
Growth	6,399	4,956	88%	3,105	3,795	5,175	5,175	85%	51%	10%
R&D	12,804.7	9,796	16,816	4,500	4,500	5,400	5,400	18,000	20,000	22,000
Nab	12,00	0%	72%	74%	19%	19%	-8%	7%	11%	10%
Total Operating Expenses	22,370.14	22,134.03	26,142	7,605	8,295	10,575	10,875	37,350	52,160	101,955
growth			18%	93%	58%	46%	12%	43%	40% 41%	95%
Operating Income EBIT Margin	(19,830.7)	(8,455.1)	(18,757.4) NA	(5,365)	23,568	(8,072)	(6,572)	3,260.1 7%	34,783.4 39%	119,064.2 46%
growth y/y (%)			122%	77%	-747%	171%	-28%	-117%	967%	242%
Depreciation and Amortization	477.7	1,322.3	1,000	250	250	250	250	1,000	1,000	1,000
EBITDA		(7,133)	(17,757)	(5,115)	23,818	(7,822)	(6,322)	4,560	35,783	120,064
	_		NA					10%	41%	47%
Other income	(333.2)	1,507.9	(515)	500	500.0	500.0	500.0	2,000	6,000	8,000
Income Before Taxes	(20,163.9)	(6,947.2)	(19,272)	(4,865.1)	24,068.4	(7,571.6)	(6,071.6)	5,560	40,783	127,064
Income Tax Provision	781.26	898.70	1,295	250.00	250.00	250.00	250.00	1,000	1,000	44,472.47
Effective Tax Rate			NA	-5.1%	1.0%	-3.3%	-4.1%	NA	NA	35%
Net Income (GAAP)	\$ (19,382.6)	\$ (6,048.5)	\$ (17,979)	(5,115.1)	23,818.4	(7,821.5)	(6,321.6)	\$ 4,560.2	\$ 39,783.5	\$ 82,591.8
Converitble preferred stock	\$ (3,933.4)	\$ (3,836.8)	(1,666)	0 (5.445.4) (		-	- (0.004.0)	- 4.500.0	- 00.700.5	- 00.500
Net loss attributable to common stockholders  Basic and diluted net loss per common share	\$ (23,316.1) \$ (2.20)	\$ (9,885.3) \$ (0.51)	\$ (19,645) \$ (1.55)	\$ (5,115.1) \$ (0.36)	3,818.4 1.67	\$ (7,821.5) \$ (0.55)	(6,321.6) (0.44)	\$ 4,560.2 \$ 0.32	\$ 39,783.5 \$ 2.71	\$ 82,592 \$ 5.48
Basic and diluted weighted avg. shares of common out	10,595	19,514	12,705	14,121	14,221	14,321	14,421	14,271	14,671	15,071
Calendar diluted net loss per common								\$ 1.18	\$ 3.39	\$ 7.97
Key Ratios (GAAP unless noted)										
Gross Margin	NM	NM	27%	NM	NM	50.1%	50.0%	56.2%	95.9%	70.0%
R&D (% Total Rev.) SG&A (% Total Rev.)	NM NM	NM NM	NM NM	120.3% 83.0%	13.5% 11.4%	134.9% 129.3%	122.6% 117.5%	39.6% 37.9%	22.7% 29.5%	8.6% 11.1%
Operating Margin	NM	NM	NM	NM	NM	NM	-149.2%	NM	39.5%	46.3%
Net Income Margin	NM	NM	NM	NM	NM	NM	-143.6%	10.0%	45.2%	32.1%
Revenue Growth Growth Yr/Yr	NM	439%	40%	-25%	476%	42%	57%	138%	94%	192%
Growth Q/Q	NM	43970	4070	33%	792%	-88%	10%	130%	3470	13270
SG&A Growth										
Growth Yr/Yr Growth Q/Q	NM NM	-23%	88%	131% -19%	161% 22%	94% 36%	34% 0%	85%	51%	10%
R&D Growth	INIVI			-10/0	ZZ /0	30 /0	070			
Growth Yr/Yr	NM	-24%	72%	74%	19%	19%	-8%	7%	11%	10%
Growth Q/Q	NM			-24%	0%	20%	0%			

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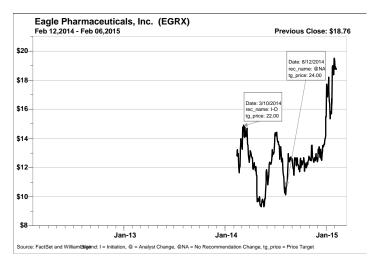
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DOW JONES: 18,019.35 S&P 500: 2,096.99 NASDAQ: 4,893.84



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Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	64	Outperform (Buy)	16
Market Perform (Hold)	32	Market Perform (Hold)	2
Underperform (Sell)	2	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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