

Eagle Pharmaceuticals, Inc.

Teva Motion to Dismiss in '524 Lawsuit; Launch of RTU Benadamustine in 2015 Possible; Reiterate Outperform Rating

Before the markets opened Wednesday, September 17, Eagle Pharmaceuticals announced that Teva Pharmaceuticals (TEVA \$52.23) subsidiary Cephalon moved to dismiss its first lawsuit, filed in the U.S. District Court for the District of Delaware in October 2013, claiming that Eagle's bendamustine product infringed on its U.S. patent No. 8,445,524, entitled, "Solid forms of bendamustine hydrochloride." This lawsuit was being brought against Eagle even though the company's 505(b)2 product was a liquid formulation, which Eagle argued, and apparently Teva agreed, was not covered by '524.

While the '524 patent is no longer in dispute, Teva/Cephalon recently filed a second lawsuit that remains pending, alleging that Eagle's bendamustine product infringes on the late listed U.S. patent No. 8,791,270, entitled, "Bendamustine pharmaceutical compositions," which was issued on July 29, 2014, is included in the Orange Book, and will not expire until 2026. Ultimately, we believe that bendamustine, which was initially synthesized in 1963 in Germany, should face generic competition in the next 18 months, more than 50 years after its discovery. We understand that Teva will maintain the brand market for the therapy as long as possible given the value of the high-margin product to the generics company, and we continue to assume that Teva will pursue all means for keeping Eagle's 505(b)2 (as well as the generics) from entering the market. Additional tactics will likely include a request by the company for an injunction against Eagle, which may occur in the near term.

Since the '270 patent has only recently been added to the Orange Book, there will be no 30-month stay associated with it, and Eagle may be in position to launch ready-to-use (RTU) bendamustine in September 2015, when Treanda's orphan exclusivity covering non-Hodgkin's lymphoma (NHL) expires. While in our model we assume a launch in September 2015 given the company's enterprise value of \$122 million, we believe that investors still heavily discount this possibility, and the launch would clearly be a transformative event for the company. In exhibit 1, on the following page, we include our views on the potential timing of events related to the Eagle bendamustine franchise. During the second quarter, Teva reported \$190 million in sales (up 7% year-over year), which suggests that sales are annualizing at \$760 million, and we estimate the product could reach over \$800 million by 2016 (exhibit 2, on the following page).

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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September 17, 2014

Stock Rating: **Outperform**
Company Profile: **Aggressive Growth**
Price Target: \$24.00

Symbol: EGRX (NASDAQ)
Price: \$12.55 (52-Wk.: \$9-\$16)
Market Value (mil.): \$170
Fiscal Year End: September
Long-Term EPS Growth Rate: NA
Dividend/Yield: None

	2013A	2014E	2015E
Estimates			
EPS Q1	NA	A\$-0.20	NA
Q2	NA	A\$-0.36	NA
Q3	NA	A\$-0.21	NA
Q4	NA	\$-0.41	NA
FY	\$-0.51	\$-1.18	\$0.60
CY			
Sales (mil.)	NA	17,492	52,150
Valuation			
FY P/E	NM	NM	20.9x
CY P/E		NA	NA

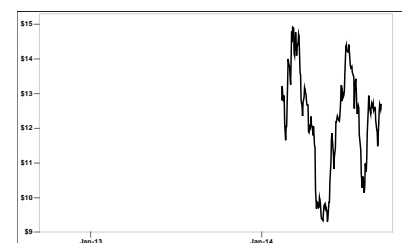
Trading Data (FactSet)

Shares Outstanding (mil.)	14
Float (mil.)	3
Average Daily Volume	67,015

Financial Data (FactSet)

Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	3.0
Return on Equity (TTM)	0.0

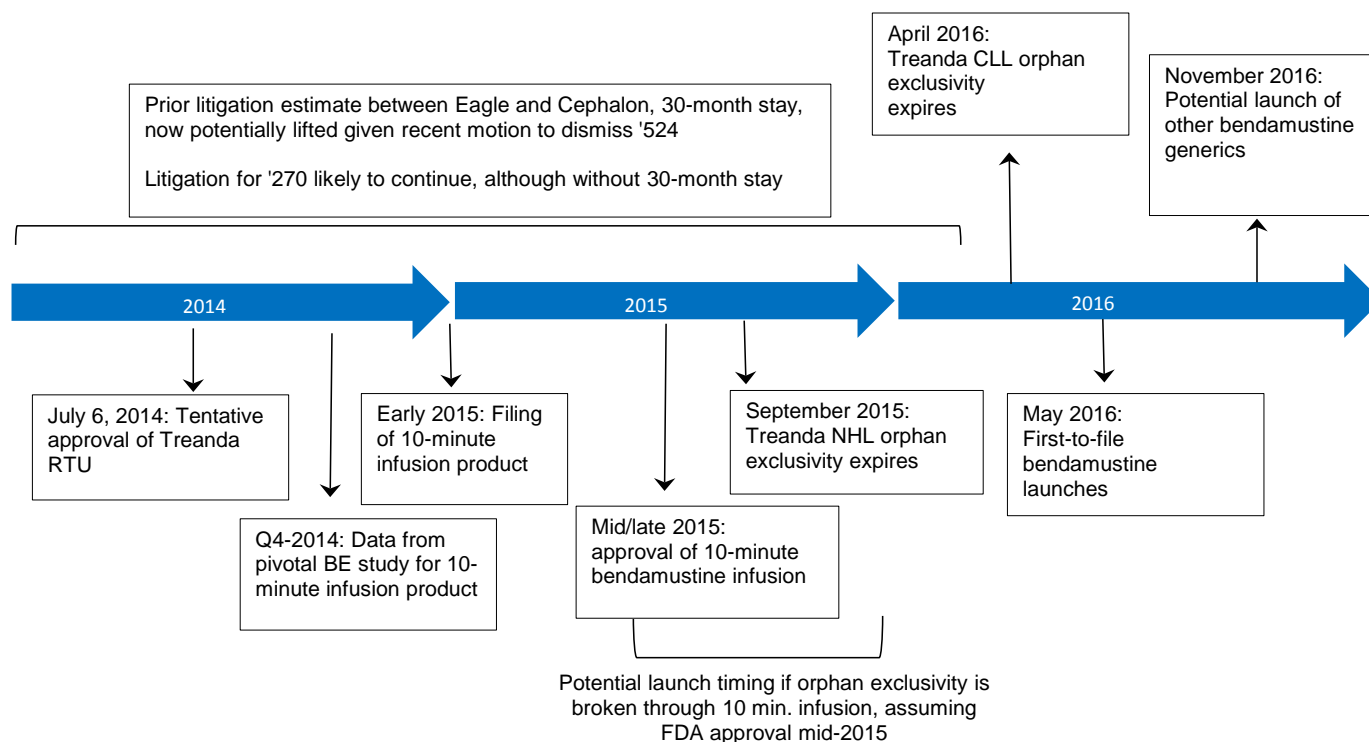
Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

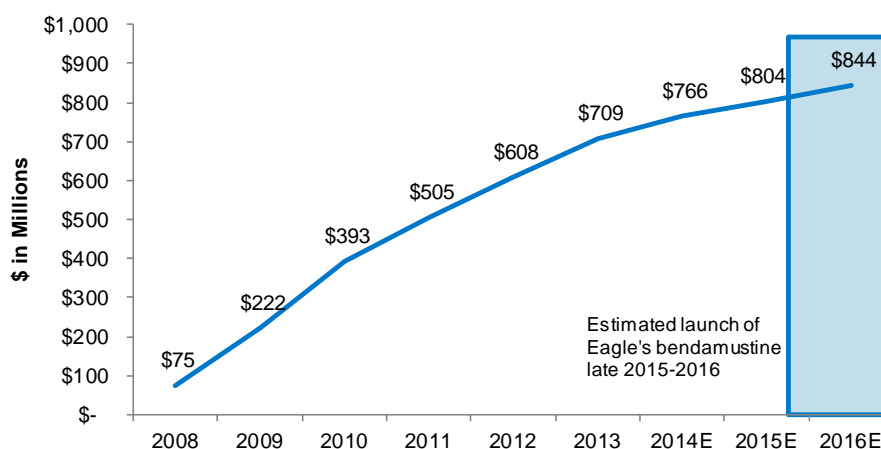
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Exhibit 1
Eagle Pharmaceuticals, Inc.
Timing of Events Related to Potential Bendamustine Launch



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

Exhibit 2
Yearly Sales and Estimates—Treanda Brand



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

Since Teva will continue to litigate '270, Eagle could be faced with the decision to bring RTU bendamustine to the market itself, and if litigation on '270 does not favor Eagle, damages to Teva could easily exceed hundreds of millions given the success of Treanda. With RTU bendamustine reaching the market, however, the cash flow to Eagle will be substantial while litigation proceeds. Eagle is now lined up to enter the market eight months before the ending of the expiration of the 30-month stay for generics, so Eagle's improved formulation is likely to gain significant market share in that time frame. In exhibit 3, on the following page, we have included the Orange Book-listed patents surrounding Teva's Treanda franchise. We note that Eagle has not been sued for either '190 or '863.

Exhibit 3
Eagle Pharmaceuticals, Inc.
Treanda Orange Book Listed Intellectual Property

Patent Number	Title	Expiration	Drug Product Claim	Date Published	Comments
8436190	Bendamustine pharmaceutical compositions	10/26/30	Y	5/7/13	No lawsuit to date
8436190*PED		4/26/31			Pediatric designation adds 6 months to patent life
8445524	Solid forms of bendamustine hydrochloride	3/26/29	Y	5/21/13	Teva moved to dismiss with prejudice the lawsuit alleging Eagle infringed on '524
8445524*PED		9/26/29			Pediatric designation adds 6 months to patent life
8609863	Bendamustine pharmaceutical compositions	1/12/26	Y	12/17/13	No lawsuit to date
8609863*PED		7/12/26			Pediatric designation adds 6 months to patent life
8791270	Bendamustine pharmaceutical compositions	1/12/26	Y	7/29/14	Teva recently filed lawsuit alleging Eagle infringed on '270, still pending

U-1402: For use in the treatment of patients with chronic lymphocytic leukemia (CLL) and/or indolent B-cell non-Hodgkin lymphoma (NHL)

U-1542: For use in the treatment of patients with chronic lymphocytic leukemia and/or non-Hodgkin's lymphoma

Sources: U.S. FDA website and Google Patent Search

Aside from the litigation, we continue to believe that 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. Data from the company's 10-minute infusion trial will likely be available during the fourth quarter. Since this product is more differentiated versus the current RTU bendamustine, and could be filed and on the market by mid-2015 if given priority review, we would view a positive study result as a significant catalyst. Recall that the bioequivalence/safety study is open label, and we believe that one half of the study, namely the safety of the product, continues to suggest an approvable product. In addition, the 10-minute infusion formulation may hold a safety advantage over the 500 ml formulation given the issues with renal impairment in the hematology market. The company's RTU formulation also holds a differentiated profile with three months of improved stability over the currently approved but not yet marketed liquid formulation of Treanda.

On July 22, Eagle received a tentative approval and orphan designation of its ready-to-use (RTU) bendamustine product for the indication of chronic lymphocytic leukemias and non-Hodgkin's lymphomas. The orphan designation in almost all cases leads to seven years of exclusivity pending an approval of the therapy by the FDA. Because of the orphan drug exclusivity held by Cephalon, a tentative approval cannot be converted to a final approval until September 2015 at the earliest unless Eagle is able to show that its bendamustine product is clinically superior to the current marketed formulation, which we believe will be easier with the 10-minute infusion product versus the RTU bendamustine. Ultimately, we view the seven years of exclusivity, if granted, to represent a significant value for the company. If Teva were to gain access to the 10-minute infusion product, assuming it is a 50% net margin product for the company, the value of seven years of exclusivity would be more than \$1.7 billion, which we include below in exhibit 4. However, this value to Teva might be conservative since we believe that the company is marketing Treanda with only a 100-person salesforce, and without a royalty burden, our margin assumptions are likely very conservative. In addition, the value of that cash flow to Teva's earnings and debt repayment is likely significant.

Exhibit 4
Value of Seven-Year Exclusivity to Treanda Franchise
(\$ in millions)

Year	1	2	3	4	5	6	7
Total Treanda Market	760	760	760	760	760	760	760
Margin	50%	50%	50%	50%	50%	50%	50%
Cash Flow	380	380	380	380	380	380	380
Discount rate	11%	11%	11%	11%	11%	11%	11%
Discounted NPV	342	308	278	250	226	203	183
Sum	1,791						

Source: William Blair & Company, L.L.C. estimates

Aside from its bendamustine product, Eagle is preparing for a launch of Ryanodex for the treatment of malignant hypothermia. The pricing of Ryanodex was announced at \$2,300 per vial with a 10% early stocking discount. This price point amounts to three times the cost of the legacy product, which suggests a potential \$60 million market in the United States alone, without additional pricing power. The company is also progressing on the design of its clinical program using the Ryanodex formulation for the treatment of exertional heat stroke (EHS). We view Ryanodex as holding peak sales in the United States of \$27 million, given increased pricing announced previously, while the expansion into the treatment of EHS would expand the peak sales potential of Ryanodex to more than \$200 million in our estimates. Management will begin an exploratory study in EHS by the end of the year, and while data produced from the study will likely only be informative for next steps, off-label use of the product may begin as early as calendar 2015 in select settings such as the military.

We maintain our Outperform rating on shares of Eagle given two recent positive FDA decisions, obtaining of orphan drug designation for its bendamustine 10-minute infusion formulation and Wednesday's announcement of Teva/Cephalon's motion to dismiss with prejudice its first patent lawsuit. With what we believe are modest assumptions for the peak penetration and timing of the bendamustine and dantrolene launches, we derive a net present value (NPV) for the company's pipeline of \$24 per share. However, we note that a majority of our out-year revenue (over 80%) is attributed the bendamustine franchise, and we believe the 10-minute infusion product will be important to this franchise's durability.

Valuation

We believe that shares of Eagle continue to hold a strong risk/reward profile, given the potential for significant profitability pending successful development of the company's four disclosed products. 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 Pharmaceuticals is \$24, 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). In this calculation, we assume a launch of Ryanodex in fourth quarter 2014 and a launch of EP-3101 in late 2015; however, the timing of the latter product will be heavily influenced by the outcome of litigation between Teva and Eagle over the ability to market its product.

Risks

While most risks in development-stage therapeutic companies involve clinical risk, we believe the litigation with Teva and likely other companies whose products Eagle is targeting with its pipeline is the major risk for Eagle. 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. The company expects to announce safety data from its 10-minute bendamustine infusion during 2014; this safety trial may hold some risk given the faster infusion time of the product, which could lead to higher rates of nausea.

The company'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.

Our earnings model is included on the following page.

William Blair & Company, L.L.C.

William Blair

**Eagle Pharmaceuticals
Earnings Model**

9/17/14
(\$ in thousands except EPS data)

Rating: Outperform
Company Profile: Aggressive Growth
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	FY 2012(A)	FY 2013(A)	Dec. 13 Q1(A)	Mar. 14 Q2(A)	June 14 Q3(A)	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	350.4	1500	2,950	47,150	195,213	270,040
EP-3101 (bendamustine RTD)	-	-	-	-	-	-	-	36,000	168,000	150,000
Ryanodex (dantrolene)	-	-	-	-	-	400	400	5,600	22,400	27,200
Diclofenac/Misoprostol	-	-	-	-	-	-	-	2,300	2,813	3,090
EP-6101 (bivalirudin)	-	-	-	-	-	-	-	-	-	87,750
EP-5101 (pemtrexed)	-	-	-	-	-	-	-	-	-	-
EP-1101 (argatroban)	-	-	-	1,100	350	1,100	2,550	3,250	2,000	2,000
EP-2101 (topotecan)	-	-	-	-	-	-	-	-	-	-
Royalty Revenue	1,384	8,364	2800	3600	1942	2000	10,342	5,000	4,000	3,000
Other Revenue	-	-	-	300	3500	400	4,200	-	-	-
Total Revenue	2,539.4	13,679	2,800	5,000	5,792	3,900	17,492	52,150	199,213	273,040
yr/yr growth		NM	NA	NA	NA	NA	27.9%	198.1%	282.0%	37.1%
q/q growth			NA	78.6%	-57.7%	-32.7%				
incremental rev q/q										
Cost of Goods Sold	3166.6	7,381	1400	3360	1556	2077	8392	7,120	21,162	43,521
Gross Profit	-627.2	6,298	1400	1640	4236	1823	9100	45030	178051	229,519
Royalty Expense	-	-	-	-	-	-	-	2100	31,360	73,855
SG&A	6,399	4,958	1,608	1,454	2,673	3,200	8936	17,250	26,000	28,600
Growth							80%	93%	51%	10%
R&D	12,804.7	9,796	3,335	3,793.8	4,545.2	5,000.0	16,674	18,000	20,000	22,000
		0%					70%	8%	11%	10%
Total Operating Expenses	22,370.14	22,134.03	4,943	5,248	7,219	8,200	25,610	37,350	77,360	124,455
growth			NA	NA	NA	NA	16%	46%	107%	61%
Operating Income	(19,830.7)	(8,455.1)	(3,543.2)	(3,607.3)	(2,982.4)	(6,377.0)	(16,509.9)	5,580.1	100,691.0	105,064.2
EBIT Margin							NA	11%	51%	38%
growth y/y (%)			NA	NA	NA	NA	95%	-134%	1704%	4%
Depreciation and Amortization	477.7	1,322.3	250	250	250	250	1,000	1,000	1,000	1,000
EBITDA	-	(7,133)	(3,293)	(3,357)	(2,732)	(6,127)	(15,510)	8,680	101,691	106,064
							NA	17%	51%	39%
Other income	(333.2)	1,507.9	750	-376.0	48.3	750.0	3,000	2,000	6,000	8,000
Income Before Taxes	(20,163.9)	(6,947.2)	(2,793.2)	(3,983.3)	(2,934.1)	(5,627.0)	(15,338)	9,680	106,691	113,064
Income Tax Provision	781.26	898.70	225.00	1,294.00	-	225.00	900	1,000	1,000	39,572.47
Effective Tax Rate			NA	NA	NA	NA	-6%	NA	NA	35%
Net Income (GAAP)	\$ (19,382.6)	\$ (6,048.5)	(3,018.2)	(2,689.3)	(2,934.1)	(5,852.0)	\$ (16,237.5)	\$ 8,680.2	\$ 105,691.1	\$ 73,491.8
Convertible preferred stock	\$ (3,933.4)	\$ (3,836.8)	-	(534.0)	-	-	-	-	-	-
Net loss attributable to common stockholders	\$ (23,316.1)	\$ (9,885.3)	\$ (3,018.2)	(3,223.3)	\$ (2,934.1)	(5,852.0)	\$ (15,027.6)	\$ 8,680.2	\$ 105,691.1	\$ 73,491.8
Basic and diluted net loss per common share	\$ (2.20)	\$ (0.51)	(0.22)	(0.36)	(0.21)	(0.41)	\$ (1.18)	\$ 0.60	\$ 7.16	\$ 4.84
Basic and diluted weighted avg. shares of common out	10,595	19,514	13,918	8,862	14,020	14,120	12,730	14,370	14,770	15,170

Key Ratios (GAAP unless noted)

Gross Margin	NM	NM	NM	33%	33%	33%	33%	84.9%	89.2%	83.9%
R&D (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	34.5%	10.0%	8.1%
SG&A (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	33.1%	13.1%	10.5%
Operating Margin	NM	NM	NM	NM	NM	NM	NM	NM	50.5%	38.5%
Net Income Margin	NM	NM	NM	NM	NM	NM	NM	16.6%	53.1%	26.9%
Revenue Growth										
Growth Yr/Yr	NM	439%	NM	NM	NM	NM	28%	198%	282%	37%
Growth Q/Q	NM		NM	NM	NM	NM				
SG&A Growth										
Growth Yr/Yr	NM	-23%	NM	NM	NM	NM	80%	93%	51%	10%
Growth Q/Q	NM		NM	NM	NM	NM				
R&D Growth										
Growth Yr/Yr	NM	-24%	NM	NM	NM	NM	70%	8%	11%	10%
Growth Q/Q	NM		NM	NM	NM	NM				

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William Blair intends to seek investment banking compensation in the next three months from Eagle Pharmaceuticals, Inc.

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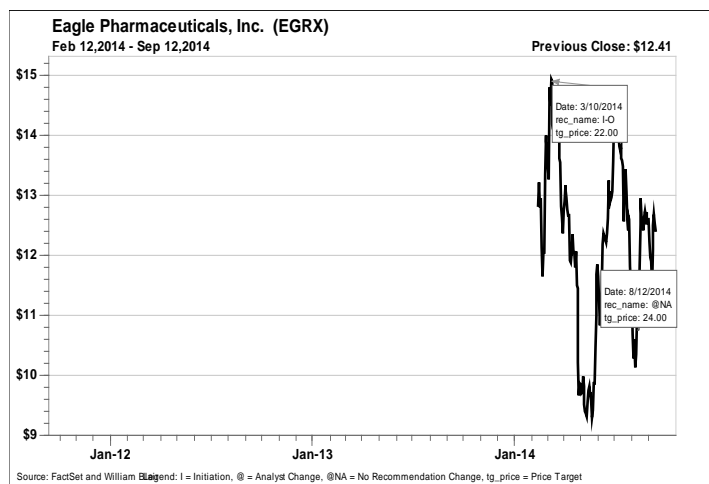
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DOW JONES: 17,131.97

S&P 500: 1,998.98

NASDAQ: 4,552.76



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Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	66	Outperform (Buy)	16
Market Perform (Hold)	31	Market Perform (Hold)	3
Underperform (Sell)	1	Underperform (Sell)	0

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