William Blair

Eagle Pharmaceuticals, Inc.

July 07, 2014

RTU Bendamustine Receives Orphan Designation for CLL and NHL; Maintaining Outperform

- During market hours today, July 7, Eagle Pharmaceuticals received FDA orphan designation for its ready-to-use (RTU) 50 ml bendamustine product. The product was designated for the indication of chronic lymphocytic leukemia (CLL) and indolent B-cell non-Hodgkin's lymphomas (NHL). The NHL orphan designation covers seven subtypes, including follicular lymphoma, small lymphocytic lymphoma, lymphoplasmacytic lymphoma, splenic marginal zone lymphoma, extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue (MALT), and nodal marginal zone lymphoma. The orphan designation in almost all cases leads to seven years of exclusivity pending an approval of the therapy by the FDA. We view today's news as significantly improving the durability of Eagle's 50 ml bendamustine product, pending an approval, and likely increases the strategic value of the product.

- The next steps for the RTU bendamustine 50 ml formulation include an update on the ongoing patent case with Teva Pharmaceuticals (TEVA $54.20), the brand marketer of Treanda following its acquisition of Cephalon for $6.8 billion in 2011. We expect the court schedule to be clarified over the next month. Regarding the history between the two companies, Eagle filed an application with the FDA for RTU bendamustine through the 505(b)(2) regulatory pathway, referencing Teva's lyophilized bendamustine product on September 6, 2013. Teva subsequently filed a patent-infringement lawsuit on October 21, 2013. After the company received tentative approval of the company's initial RTU bendamustine formulation last week, the ongoing patent case between Teva and Eagle will need to be clarified prior to a full approval of Eagle's RTU formulation and subsequent marketing of the product.

- Treanda, the brand name for bendamustine, has orphan exclusivity for NHL through October 2015 and March 2015 for CLL. In addition, with previously granted six months of pediatric exclusivity, those dates are April 2016 for NHL and September 2015 for CLL. However, we believe the consensus assumes a launch in line with the first-to-file generic during the first half of 2016. Following discussions with management, we believe that given today's news, Eagle would be able to challenge and possibly break Teva's orphan exclusivity if the company's 10-minute 50 ml infusion product is approved in 2015. Data from the bioequivalence and safety trial for the 10-minute product will be reported during the third quarter. Given the open-label nature of the trial, we anticipate the safety profile to be relatively clean. Pending bioequivalence, we believe Eagle might be able to file for an approval of the 10-minute infusion sometime before the end of the year, which suggests a possible approval during the third quarter of 2015. A launch any time prior to the 30-month stay for generics would enable Eagle to enter a $700 million-plus market with a best-in-class formulation prior to generics.

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.

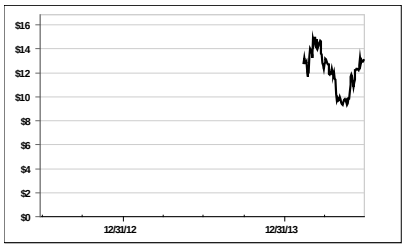
Stock Rating:	**Outperform**
Company Profile:	**Aggressive Growth**
Price Target:	$22.00
Symbol:	EGRX (NASDAQ)
Price:	$14.42 (52-Wk.: $9-$16)
Market Value (mil.):	$199
Fiscal Year End:	September
Long-Term EPS Growth Rate:	
Dividend/Yield:	None

	2013A	2014E	2015E
Estimates			
EPS Q1	NA	A$-0.20	NA
Q2	NA	A$-0.25	NA
Q3	NA	$-0.39	NA
Q4	NA	$-0.48	NA
FY	$-0.51	$-1.33	$0.45
CY			
Sales (mil.)	NA	14,250	47,750
Valuation			
FY P/E	NM	NM	32.0x
CY P/E		NA	NA

Trading Data (FactSet)	
Shares Outstanding (mil.)	9
Float (mil.)	3
Average Daily Volume	120,658

Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	3.2
Return on Equity (TTM)	0.0

Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

Tim Lugo
+1 415 248 2870
tlugo@williamblair.com

- The next meaningful update in the company's litigation with Teva over the ability to bring the company's 505(b)(2) to the market will likely be the scheduling of the case. At this time in the patent case process, a summary judgment is possible, which would effectively end the litigation and allow Eagle to enter the market. While this would be a clear win, we believe a more conservative scenario includes the scheduling of a trial, which we would also view as upside to consensus 2016 launch expectations. Overall, while we believe the Street is focused on the lifting of the current Teva litigation overhang, we believe management execution during this early period for Eagle as a public company remains impressive.

- As the company proceeds through the Teva litigation, we continue to believe 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. This profile could support a safety advantage over the 500 ml formulation given the issues with renal impairment in the hematology market. Further, the infusion rate of 10 minutes is well below the 30- and 60-minute infusion times of the current product formulation. While the 10-minute infusion product is a significant improvement over branded bendamustine, the company's RTU formulation also holds a differentiated profile with three months of improved stability over the approved but not-yet-marketed liquid formulation of Treanda.

- The next major event is the July 22 PDUFA date for Ryanodex, the formulation of dantrolene for the indication of malignant hyperthermia. The company received orphan drug designation for Ryanodex in August, and it expects to launch this product in the second half of calendar 2014. While the malignant hyperthermia market approximates only $40 million worldwide, we believe there is potential for Eagle to bring a premium-priced product into the market given the severity of malignant hyperthermia and the best-in-class formulation of Ryanodex. The company also plans to dose its first patient in a pilot study for the designation of exertional heat stroke in Saudi Arabia later this year, which could enable off-label sales of the product pending positive data.

- We maintain our Outperform rating on shares of Eagle Pharmaceuticals because management continues to execute through significant milestones and we view several near-term events as potential catalysts for shares of EGRX. Over the near term, we anticipate a positive outcome on or near the PDUFA date for Ryanodex, a readout from the company's 10-minute infusion pharmacokinetic clinical trial, and a likely update on the timing of ongoing litigation with Teva. Our $22 price target is based on a strong risk/reward profile given the potential for significant profitability as early as 2015 pending successful development of the bendamustine and dantrolene products.

Exhibit 1
Eagle Pharmaceuticals, Inc.
Timeline and Events

Date	Product	Event	Description/Comments
2014			
22-Jul	Ryanodex (1 vial dantrolene)	Regulatory	PDUFA date on July 22 for treatment of malignant hypothermia
Q3	RTU Bendamustine	Legal	Scheduling of ongoing litigation between Teva and Eagle Pharmaceuticals over right to launch RTU bendamustine
Q3	RTU Bendamustine	Clinical	Company will report pivotal results from 10-minute infusion trial, increased sample size 10 to 12 patients
2014	Ryanodex (1 vial dantrolene)	Clinical	Begin Phase III trial for Ryanodex in exertional heat stroke, Trial in Saudi Arabia to dose first patient
2014	Ryanodex (1 vial dantrolene)	Regulatory	Potential launch of Ryanodex in malignant hypothermia
2015			
2015	RTU Bendamustine	Regulatory	Potential launch of RTU bendamustine following outcome of Teva litigation
2015	Ryanodex (1 vial dantrolene)	Clinical	Potential top-line data from exertional heat stroke clinical trial
2015	RTU Bivalirudin	Regulatory	Filing of NDA for bivalirudin (brand name Angiomax)
2015	RTU Pemetrexed	Regulatory	Filing of NDA for pemetrexed (brand name Alimta)

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

Valuation

We maintain our Outperform rating and $22 price target on shares of Eagle Pharmaceuticals based on a net present value of the company's lead development programs. We assume an 85% penetration of Ryanodex into the current dantrolene domestic market and no potential for price increases in out-years. Our model does not include any sales for Ryanodex for the indication of exertional heat stroke. While we assume a launch of RTU bendamustine in late 2015, this timing will be influenced heavily by the outcome of litigation between Teva Pharmaceuticals and Eagle over the ability to market its product. Our full model with additional details is available from a William Blair salesperson.

Risks

We believe the ongoing litigation with Teva Pharmaceuticals and other companies whose products are being targeted by Eagle are a major risk. 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.

William Blair

Rating: Outperform
Company Profile: Aggressive Growth

Tim Lugo
415.248.2870
tlugo@williamblair.com

Eagle Pharmaceuticals
Earnings Model
5/14/14
($ in thousands except EPS data)

	FY 2012(A)	FY 2013(A)	Dec. 13 Q1(A)	Mar. 14 Q2(A)	June 14 Q3(E)	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	1100.0	1350	3,550	42,750	184,000	256,750
EP-3101 (bendamustine RTD)	-	-	-	-	-	0	-	36,000	168,000	150,000
Ryanodex (dantrolene)	-	-	-	-	-	250	250	3,500	14,000	17,000
EP-6101 (bivalirudin)	-	-	-	-	-	-	-	-	-	87,750
EP-5101 (pemtrexed)	-	-	-	-	-	-	-	-	-	-
EP-1101 (argatroban)	-	-	-	1,100	1,100	1,100	3,300	3,250	2,000	2,000
EP-2101 (topotecan)	-	-	-	-	-	-	-	-	-	-
Royalty Revenue	1,384	8,364	2800	3600	2000	2000	10,400	5,000	4,000	3,000
Other Revenue				300	300	400	1,000			
Total Revenue	2,539.4	13,679	2,800	5,000	3,100	3,350	14,250	47,750	188,000	259,750
yr/yr growth		NM	NA	NA	NA	NA	4.2%	235.1%	293.7%	38.2%
q/q growth			NA	78.6%	-77.3%	8.1%				
incremental rev q/q										
Cost of Goods Sold	3166.6	7,381	1400	3359	2077	2077	8913	7,083	20,742	43,011
Gross Profit	-627.2	6,298	1400	1641	1023	1273	5337	40668	167258	216,739
Royalty Expense								1988	29,050	71,050
SG&A	6,399	4,958	1,620	1,454	2,700	2,700	9000	17,250	29,500	32,450
Growth							82%	92%	71%	10%
		-								
R&D	12,804.7	9,796	3,075	3,793.0	3,800.0	5,000.0	15,375	16,000	20,000	21,000
		0%					57%	4%	25%	5%
		-	-	-	-	-	-	-	-	-
Total Operating Expenses	22,370.14	22,134.03	4,695	8,606	6,500	7,700	27,501	35,238	78,550	124,500
growth			NA	NA	NA	NA	24%	28%	123%	58%
									58%	
Operating Income	(19,830.7)	(8,455.1)	(3,295.0)	(3,606.0)	(5,477.0)	(6,427.0)	(22,164.0)	3,442.5	88,707.6	92,238.8
EBIT Margin							NA	7%	47%	36%
growth y/y (%)			NA	NA	NA	NA	162%	-116%	2477%	4%
Depreciation and Amortization	477.7	1,322.3	250	250	250	250	1,000	1,000	1,000	1,000
EBITDA		(7,133)	(3,045)	(3,356)	(5,227)	(6,177)	(17,805)	6,430	89,708	93,239
							NA	13%	48%	36%
	-									
Other income	(333.2)	1,507.9	750	-376.0	750.0	750.0	3,000	2,000	6,000	8,000
Income Before Taxes	(20,163.9)	(6,947.2)	(2,545.0)	(3,982.0)	(4,727.0)	(5,677.0)	(16,931)	7,430	94,708	100,239
Income Tax Provision	781.26	898.70	225.00	1,294.00	225.00	225.00	900	1,000	1,000	35,083.56
Effective Tax Rate			NA	NA	NA	NA	-5%	NA	NA	35%
Net Income (GAAP)	$ (19,382.6)	$ (6,048.5)	(2,770.0)	(2,688.0)	(4,951.9)	(5,902.0)	$ (17,830.9)	$ 6,430.1	$ 93,707.7	$ 65,155.3
Converitble preferred stock	$ (3,933.4)	$ (3,836.8)	-	(534.0)	-	-	-	-	-	-
Net loss attributable to common stockholders	$ (23,316.1)	$ (9,885.3)	$ (2,770.0)	$ (3,222.0)	$ (4,951.9)	$ (5,902.0)	$ (16,845.9)	$ 6,430.1	$ 93,707.7	$ 65,155.3
Basic and diluted net loss per common share	$ (2.20)	$ (0.51)	(0.20)	(0.36)	(0.35)	(0.42)	$ (1.33)	$ 0.45	$ 6.37	$ 4.31
Basic and diluted weighted avg. shares of common out	10,595	19,514	13,918	8,862	13,962	14,062	12,701	14,312	14,712	15,112
Key Ratios (GAAP unless noted)										
Gross Margin	NM	NM	NM	33%	33%	33%	33%	83.4%	88.7%	83.2%
R&D (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	33.5%	10.6%	8.1%
SG&A (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	36.1%	15.7%	12.5%
Operating Margin	NM	NM	NM	NM	NM	NM	NM	NM	47.2%	35.5%
Net Income Margin	NM	NM	NM	NM	NM	NM	NM	13.5%	49.8%	25.1%
Revenue Growth										
Growth Yr/Yr	NM	439%	NM	NM	NM	NM	4%	235%	294%	38%
Growth Q/Q	NM		NM	NM	NM	NM				
SG&A Growth										
Growth Yr/Yr	NM	-23%	NM	NM	NM	NM	82%	92%	71%	10%
Growth Q/Q	NM		NM	NM	NM	NM				
R&D Growth										
Growth Yr/Yr	NM	-24%	NM	NM	NM	NM	57%	4%	25%	5%
Growth Q/Q	NM		NM	NM	NM	NM				

IMPORTANT DISCLOSURES

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William Blair is a market maker in the security of Eagle Pharmaceuticals, Inc. and may have a long or short position.

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

Within the past 12 months William Blair has provided or is providing investment banking services to or has an investment services relationship with Eagle Pharmaceuticals, Inc.

Additional information is available upon request.

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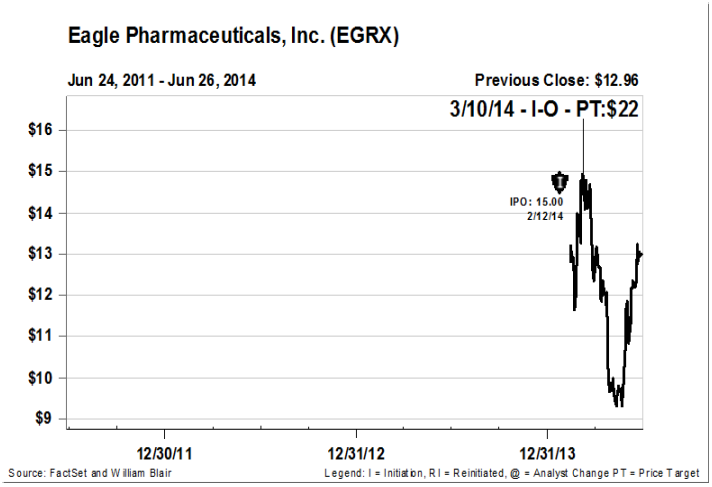
DOW JONES: 17,068.26
S&P 500: 1,985.44
NASDAQ: 4,485.93



Current Rating Distribution (as of 06/30/14)

Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	67	Outperform (Buy)	16
Market Perform (Hold)	30	Market Perform (Hold)	2
Underperform (Sell)	1	Underperform (Sell)	0

*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.

The compensation of the research analyst is based on a variety of factors, including performance of his or her stock recommendations; contributions to all of the firm's departments, including asset management, corporate finance, institutional sales, and retail brokerage; firm profitability; and competitive factors.

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