

## Eagle Pharmaceuticals, Inc.

### Ryanodex Pricing Ahead of Expectations, Bendamustine 10-minute Infusion Data Next Significant Catalyst

- Before the markets opened Monday, August 11, Eagle Pharmaceuticals announced third-quarter earnings results. Third-quarter financials were a relative nonevent for the company although it made headway during the quarter on several product development with the FDA approval of Ryanodex, a dantrolene sodium injectable suspension for the treatment of malignant hypothermia, as well as a tentative approval and orphan designation of its ready-to-use (RTU) bendamustine product for the indication of chronic lymphocytic leukemia (CLL) and seven subtypes of non-Hodgkin's lymphomas (NHL). During the quarter, Eagle also received an approval of its ANDA for diclofenac/misoprostol, a legacy ANDA, for which we hold measured expectations given the difficulty in marketing a stand-alone ANDA.
- The Ryanodex 505(b)(2) NDA was approved on July 23 after being designated for priority review earlier in the year. On the call, management said that an FDA decision on seven-year orphan exclusivity was roughly one month away despite receiving an orphan drug designation before the review process. 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 average hospital stocks about three to four vials for a total cost range of roughly \$7,000 to \$9,000 or, using the two-year shelf-life of Ryanodex, \$3,000 to \$5,000 per year. With shipping beginning in August, management is focusing on the stocking phase with 9,000 outlets, including 6,000 hospitals and 3,000 ambulatory care centers. As we note in exhibit 1, we estimate the market to approximate \$32 million per year given the two-year shelf-life of Ryanodex. This estimate excludes outside-the-U.S. potential for the product, although we believe management is targeting a regulatory filing in Europe in early 2015. Regarding the durability of the product outside the potential orphan exclusivity decision likely announced during September, the company also expects to have four Orange Book patents listed by the end of September for Ryanodex, which should cover the product from 2022 to 2025.
- Despite the premium to current pricing, the company is confident in the adoption of Ryanodex as a result of its significant benefits over the current dantrolene formulation. To administer the current formulation of dantrolene, an average of 12 vials must be reconstituted for the patient in more than 700 milliliters of IV fluid, a process that may take 15-20 minutes. This product preparation must occur during a critical period for the physician and patient, with malignant hyperthermia episodes characterized by a rapid increase in body temperature and rapid presentation of symptoms, all of which occur during an operation since malignant hyperthermia is triggered through certain anesthesia. Eagle's Ryanodex is a ready-to-use formulation of dantrolene that can be administered with 95% less volume (250 mg of Ryanodex in 5 mL of sterile water) and can be administered in less than a minute, an important distinction given the acute needs of malignant hyperthermia in the clinic.

*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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August 11, 2014

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

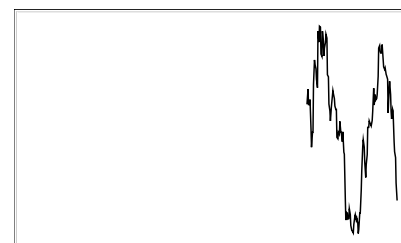
Symbol: EGRX (NASDAQ)  
Price: \$10.99 (52-Wk.: \$9-\$16)  
Market Value (mil.): \$145  
Fiscal Year End: September  
Long-Term EPS Growth Rate: NA  
Dividend/Yield: None

	2013A	2014E	2015E
<b>Estimates</b>			
EPS Q1	NA	A\$-0.22	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
<b>Valuation</b>			
FY P/E	NM	NM	18.3x
CY P/E		NA	NA

<b>Trading Data (FactSet)</b>	
Shares Outstanding (mil.)	9
Float (mil.)	3
Average Daily Volume	82,018

<b>Financial Data (FactSet)</b>	
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

Please consult pages 8-9 of this report for all disclosures. Analyst certification is on page 8. William Blair & Company, L.L.C. does and seeks to do business with companies covered in its research reports. As a result, investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as a single factor in making an investment decision.

- Regarding the company's bendamustine product, the next meaningful update in the company's litigation with Teva (TEVA \$51.29) 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 as a public company continues to be impressive.
- Outside of 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. As we view this product as holding a more significant differentiation over the RTU bendamustine product, which received tentative approval during the second quarter, 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. 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 brand bendamustine, 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.
- Regarding the company's financials, the company reported total revenue of \$5.8 million primarily due to a \$3.5 million milestone associated with diclofenac/misoprostol ANDA approval, which was greater than our estimate of \$4.4 million. The company also reported higher R&D costs of \$4.5 million due to the development of its RTU bivalirudin, RTU bendamustine, and diclofenac/misoprostol products. This was higher than our estimate of \$3.8 million. SG&A expense was in line with our estimate of \$2.7 million, and the loss per share was \$0.21, better than both our estimate of a loss of \$0.33 per share and the consensus of a loss of \$0.37 per share. At the end of the quarter, the company has roughly \$49.8 million in cash and cash equivalents and a working capital surplus of \$41.5 million. We have included a table of reported earnings, our estimates, and consensus in exhibit 2.
- Regarding next steps for the company, it is planning to launch the diclofenac/misoprostol product, a generic of Pfizer's (PFE \$28.34) Arthrotec, in October 2014. According to IMS, over the last 12 months, Arthrotec had total prescriptions of about 54,000 with sales of roughly \$13 million, but we are unsure of the total capture rate of these numbers. As of November 2012, there were two generic competitors with significant market share, which we have shown in exhibit 3. We have updated our model to include revenue generated from this product, which we find to be marginal compared with the potential revenue generated from Ryanodex and RTU-bendamustine, if approved. In addition to the diclofenac/misoprostol product, an ANDA filing of the company's RTU bivalirudin is expected in the first half of 2015, while other pipeline products to be named may include a 505(b)(2) cubicin, for which the company holds IP covering formulations with improved stability.
- Outside of malignant hyperthermia, Eagle is progressing on the design of the company's clinical program using the Ryanodex formulation for the treatment of exertional heat stroke (EHS). Given the increased pricing, we have updated our expectations for Ryanodex and now view the product as holding peak sales in the United States of \$27 million, while the expansion of Ryanodex 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 year end, 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 Eagle given two recent positive FDA decisions and its obtaining of orphan drug designation for its bendamustine 10-minute infusion formulation. 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, up from our prior estimate of \$22. However, a majority of our out-year revenue (more than 80%) is attributed the bendamustine franchise, and we believe the 10-minute infusion product will be important to this franchise's durability. Risks for Eagle include the significant litigation the company will likely face as it attempts to bring its 505(b)(2) pipeline to the market, particularly from Teva.

**Exhibit 1**  
**Eagle Pharmaceuticals**

Price per vial	2300
Vials per order	3.5
Outlets	9000
Discounting	10%
Market	65,205,000
Market 2-year shelf life (Yearly)	32,602,500

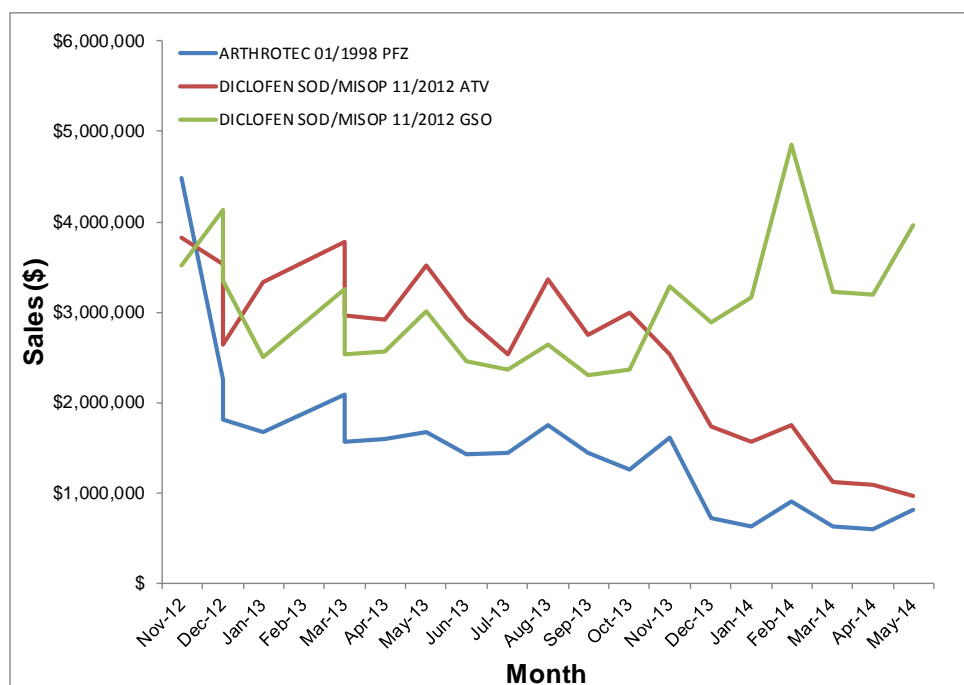
Source: company reports

**Exhibit 2**  
**Eagle Pharmaceuticals**  
**Third Quarter 2014 Results**

	EGRX Q3 14A	WB Q3 14E	Consensus Q3 14E	Q/Q Growth	Y/Y Growth
(\$ in millions except EPS)					
Product Sales	\$ 0.4	\$ 1.1	NA	-68%	-86%
Royalty Income	\$ 1.9	\$ 2.0	NA	-46%	-25%
Other Income	\$ 3.5	\$ 0.3	NA	NM	NA
<b>Total Revenue</b>	<b>\$ 5.8</b>	<b>\$ 4.4</b>	<b>NA</b>	<b>16%</b>	<b>14%</b>
Cost of Goods/Revenue	\$ 1.6	\$ 2.1	NA	-54%	-47%
R&D	\$ 4.5	\$ 3.8	NA	20%	178%
SG&A	\$ 2.7	\$ 2.7	NA	78%	114%
Operating Income	\$ (3.0)	\$ (5.2)	NA	17%	NM
(Loss) income before taxes	\$ (2.9)	\$ (4.4)	NA	27%	NM
Net Income	\$ (2.9)	\$ (4.7)	NA	-9%	NM
<b>EPS</b>	<b>\$ (0.21)</b>	<b>\$ (0.33)</b>	<b>\$ (0.37)</b>	<b>42%</b>	<b>-91%</b>

Source: Company reports, William Blair & Company L.L.C. estimates  
Consensus estimates reported by FactSet  
GAAP estimates

**Exhibit 3**  
**Eagle Pharmaceuticals**  
**Diclofenac/Misoprostol Branded and Generic Product Sales by Month**



Source: IMS Health, William Blair & Company, L.L.C.

**Exhibit 4**  
**Eagle Pharmaceuticals**  
**Revised and New Estimates**

	EGRX Old 2014E		EGRX New 2014E		EGRX Old 2015E		EGRX New 2015E		EGRX Old 2016E		EGRX New 2016E	
(\$ in millions except EPS)												
Product Sales	\$	3.6	\$	3.0	\$	42.8	\$	47.2	\$	184.0	\$	195.2
Royalty Income	\$	10.4	\$	10.3	\$	5.0	\$	5.0	\$	4.0	\$	4.0
Other Income	\$	1.0	\$	4.2	\$	-	\$	-	\$	-	\$	-
Total Revenue	\$	15.0	\$	17.5	\$	47.8	\$	52.2	\$	188.0	\$	199.2
COGS	\$	8.9	\$	8.4	\$	7.0	\$	7.1	\$	20.7	\$	21.2
R&D	\$	15.4	\$	16.7	\$	16.0	\$	18.0	\$	20.0	\$	20.0
SG&A	\$	9.0	\$	8.9	\$	17.3	\$	17.3	\$	29.5	\$	26.0
Operating Income	\$	(18.1)	\$	(16.5)	\$	3.4	\$	5.6	\$	88.7	\$	100.7
(Loss) Income Before Taxes	\$	(16.2)	\$	(15.3)	\$	7.4	\$	9.7	\$	94.7	\$	106.7
Net Income	\$	(17.1)	\$	(16.2)	\$	6.4	\$	8.7	\$	93.7	\$	105.7
EPS	\$	(1.27)	\$	(1.18)	\$	0.45	\$	0.60	\$	6.37	\$	7.16

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

## Valuation

We believe 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. The company's pathway through a 505(b)(2) approval process, in our view, holds a reduced development risk compared with many small-cap development-stage specialty pharmaceutical companies.

We are raising the price target to \$24 from \$22, 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 the fourth quarter of 2014 and a launch of EP-3101 in late 2015; however, the timing of the later product will be heavily influenced by the outcome of litigation between Teva Pharmaceuticals and Eagle over the ability to market its product. We note a majority of our out-year revenue (more than 80%) is attributed the bendamustine franchise and we believe the 10-minute infusion product will be important to this franchise's durability. Our full model with additional details from is available from a William Blair & Company, L.L.C. salesperson.

### **Risks**

While most risks in development-stage therapeutic companies involve clinical risk, we believe the continuing litigation with Teva Pharmaceuticals and likely other companies whose products Eagle is targeting with its pipeline is the major risk for Eagle Pharmaceuticals. 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 model is included on the following page.



**Eagle Pharmaceuticals  
Earnings Model**

8/11/14  
(\$ 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	-	-	-
<b>Total Revenue</b>	<b>2,539.4</b>	<b>13,679</b>	<b>2,800</b>	<b>5,000</b>	<b>5,792</b>	<b>3,900</b>	<b>17,492</b>	<b>52,150</b>	<b>199,213</b>	<b>273,040</b>
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										
<b>Cost of Goods Sold</b>	<b>3166.6</b>	<b>7,381</b>	<b>1400</b>	<b>3360</b>	<b>1556</b>	<b>2077</b>	<b>8392</b>	<b>7,120</b>	<b>21,162</b>	<b>43,521</b>
Gross Profit	-627.2	6,298	1400	1640	4236	1823	9100	45030	178051	229,519
<b>Royalty Expense</b>								2100	31,360	73,855
<b>SG&amp;A</b>	<b>6,399</b>	<b>4,958</b>	<b>1,608</b>	<b>1,454</b>	<b>2,673</b>	<b>3,200</b>	<b>8936</b>	<b>17,250</b>	<b>26,000</b>	<b>28,600</b>
Growth							80%	93%	51%	10%
<b>R&amp;D</b>	<b>12,804.7</b>	<b>9,796</b>	<b>3,335</b>	<b>3,793.8</b>	<b>4,545.2</b>	<b>5,000.0</b>	<b>16,674</b>	<b>18,000</b>	<b>20,000</b>	<b>22,000</b>
		0%					70%	8%	11%	10%
<b>Total Operating Expenses</b>	<b>22,370.14</b>	<b>22,134.03</b>	<b>4,943</b>	<b>5,248</b>	<b>7,219</b>	<b>8,200</b>	<b>25,610</b>	<b>37,350</b>	<b>77,360</b>	<b>124,455</b>
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%
<b>Net Income (GAAP)</b>	<b>\$ (19,382.6)</b>	<b>\$ (6,048.5)</b>	<b>(3,018.2)</b>	<b>(2,689.3)</b>	<b>(2,934.1)</b>	<b>(5,852.0)</b>	<b>\$ (16,237.5)</b>	<b>\$ 8,680.2</b>	<b>\$ 105,691.1</b>	<b>\$ 73,491.8</b>
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%
<b>Revenue Growth</b>										
Growth Yr/Yr	NM	439%	NM	NM	NM	NM	28%	198%	282%	37%
Growth Q/Q	NM		NM	NM	NM	NM				
<b>SG&amp;A Growth</b>										
Growth Yr/Yr	NM	-23%	NM	NM	NM	NM	80%	93%	51%	10%
Growth Q/Q	NM		NM	NM	NM	NM				
<b>R&amp;D Growth</b>										
Growth Yr/Yr	NM	-24%	NM	NM	NM	NM	70%	8%	11%	10%
Growth Q/Q	NM		NM	NM	NM	NM				



### IMPORTANT DISCLOSURES

William Blair was a manager or co-manager of a public offering of equity securities for Eagle Pharmaceuticals, Inc. within the prior 12 months.

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.

This report is available in electronic form to registered users via R\*Docs™ at [www.rdocs.com](http://www.rdocs.com) or [www.williamblair.com](http://www.williamblair.com).

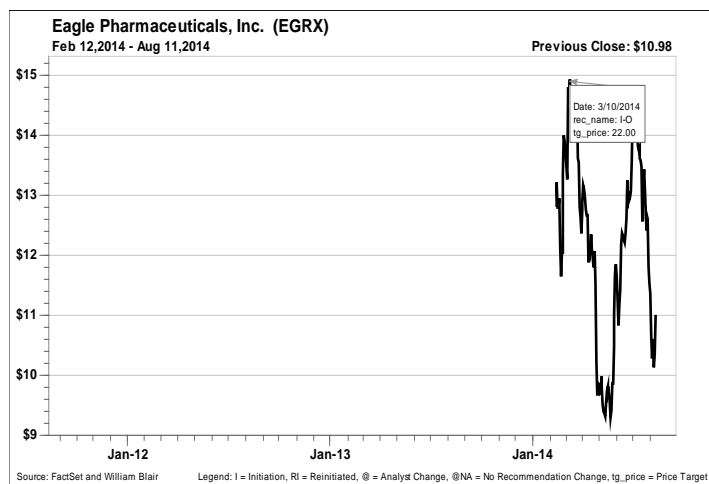
Please contact us at +1 800 621 0687 or consult [williamblair.com/Research-and-Insights/Equity-Research/Coverage.aspx](http://williamblair.com/Research-and-Insights/Equity-Research/Coverage.aspx) for all disclosures.

Tim Lugo attests that 1) all of the views expressed in this research report accurately reflect his/her personal views about any and all of the securities and companies covered by this report, and 2) no part of his/her compensation was, is, or will be related, directly or indirectly, to the specific recommendations or views expressed by him/her in this report. We seek to update our research as appropriate, but various regulations may prohibit us from doing so. Other than certain periodical industry reports, the majority of reports are published at irregular intervals as deemed appropriate by the analyst.

DOW JONES: 16,553.93

S&P 500: 1,931.59

NASDAQ: 4,370.90



### Current Rating Distribution (as of 07/31/14)

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

\*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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