Zafgen

Equity Research

Earnings Update

May 13, 2015

Price: $34.23 (05/12/2015)

Price Target: $60.00

OUTPERFORM (1)

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Key Data

Symbol	NASDAQ: ZFGN
52-Week Range:	$55.36 - 16.01
Market Cap (MM):	$919.3
Net Debt (MM):	$(5.5)
Cash/Share:	NA
Dil. Shares Out (MM):	25.6
Enterprise Value (MM):	$799.8
ROIC:	NA
ROE (LTM):	NA
BV/Share:	NA
Dividend:	NA

FY (Dec)	2014A	2015E	2016E
Earnings Per Share			
Q1	$(0.98)	$(0.53)A	-
Prior Q1	-	*$(0.65)*	-
Q2	$(2.96)	$(0.71)	-
Prior Q2	-	*$(0.76)*	-
Q3	$(0.65)	$(0.78)	-
Prior Q3	-	*$(0.81)*	-
Q4	$(0.48)	$(0.85)	-
Prior Q4	-	*$(0.86)*	-
Year	$(3.00)	$(2.87)	$(2.85)
Prior Year	-	*$(3.08)*	*$(3.08)*
P/E	NM	NM	NM
Consensus EPS	$(3.19)	$(2.99)	$(3.14)

Consensus source: Thomson Reuters

Revenue (MM)			
Year	$0.0	$0.0	$0.0
EV/S	-	-	-

U.S. Phase III PWS Trial Completing Enrollment With Data Likely In Q1:16

The Cowen Insight

ZFGN reported Q1 financials. Beloranib's U.S. Ph. III PWS trial has reached target enrollment and data are expected in Q1:16. After discussions with FDA, the trial will now need to hit both co-primary endpoints of changes in total body weight and hyperphagia score. We continue to think the consistent weight loss data generated in Ph. II predicts Ph. III success and expect ZFGN to outperform.

bestPWS Enrollment Completing, Primary Endpoints Adjusted After FDA Discussions.

Zafgen announced that its U.S. Phase III trial of beloranib in Prader-Willi Syndrome (bestPWS) has reached targeted enrollment (n=102), though a few more patients may still be added as they are completing the screening process. With the acceleration of enrollment in recent months, ZFGN now expects results from bestPWS to be released in early Q1:16, vs. prior Q2:16 guidance. ZFGN noted that it has had recent discussions with FDA over the trial's endpoints and statistical analysis. bestPWS will now need to meet both primary endpoints, change in body weight and change in hyperphagia behavior-related scores, with a p-value of less than or equal to 0.05. As originally designed the trial could hit either primary endpoint with $p<0.025$. Moreover, after discussions with the FDA, one of the co-primary endpoints was changed from change in fat mass to change in body weight. Management noted that the trial is 95% powered to demonstrate beloranib's effect versus placebo based on an assumed 1.5% difference in weight and a 4.5 unit delta in hyperphagia score. Zafgen indicated that the modifications to the trial design was based on "constructive" discussions with the FDA. Zafgen noted that the trial is showing good retention with lower than expected drop out rates. Management indicated that the FDA may consider one trial sufficient for filing should bestPWS generate compelling clinical efficacy with safety, otherwise data from the EU Ph. III may be necessary.

E.U. PWS Phase III Trial Remains On-Track To Begin In Mid-2015.

Zafgen remains on-track to initiate an E.U. pivotal Phase III trial of beloranib in ~150 PWS patients in mid-2015. Zafgen expects the trial will incorporate a four-week dose escalation phase followed by the evaluation 2.4mg beloranib vs. placebo. Similar to bestPWS, Zafgen expects the trial will also have co-primary endpoints of change in body weight and hyperphagia behavior-related scores.

Other Clinical Programs Progressing.

Zafgen expects to establish a regulatory path for beloranib in Hypothalamic injury-associated obesity (HIAO) in 2015 and to initiate a Phase III program in 2016. The Phase IIb trial (ZAF-203) of beloranib in patients with severe obesity and type 2 diabetes is approximately two-thirds enrolled and Zafgen continues to expect data by YE or early 2016. Zafgen anticipates completion of preclinical work for ZGN-839, an orally-active 2nd-gen MetAP2 inhibitor, and to file an IND in NASH by mid-year.

At A Glance

Our Investment Thesis

Zafgen's lead asset beloranib is in development for the treatment of hyperphagia (insatiable appetite) and obesity in Prader-Willi syndrome (PWS), hypothalamic injury associated obesity (HIAO), and severe obesity in the general population. In 6 clinical trials with >200 subjects including obese volunteers and patients with PWS or HIAO, beloranib has reduced fat mass and controlled hyperphagia while maintaining an acceptable tolerability and safety profile. Our consultants find the >50% decrease in hyperphagia produced in PWS patients particularly striking, as beloranib is the first agent to demonstrate such activity. Beloranib's striking ability to induce weight loss was reaffirmed in a positive Ph. II HIAO trial and we think it de-risks the drug's U.S. Ph. III trial in PWS (bestPWS). Initial data from bestPWS is expected in Q1:16. We think ZFGN is undervalued based on beloranib's potential in PWS and HIAO alone, with no contribution from other indications or pipeline programs.

Forthcoming Catalysts

- File IND for ZGN-839 in NASH, mid-15
- Initiate EU Phase III trial of beloranib in Prader-Willi, mid-15
- Six-month data from Phase II trial of beloranib in severe obese patients with type 2 diabetes, Q4:15/Q1:16
- Initial data from U.S. Ph. III trial of beloranib in Prader-Willi, early Q1:16

Base Case Assumptions

- Beloranib is successfully developed for Prader-Willi and HIAO, achieving $1.0B in sales by 2026.
- Beloranib is not developed for any other indications.
- The rest of Zafgen's pipeline does not contribute significant value.

Upside Scenario

- Beloranib is successfully developed for Prader-Willi and HIAO, achieving > $1.0B in sales by 2026.
- Beloranib is also successfully developed for other indications.
- ZGN-839 is successfully developed for NASH and/or type 2 diabetes
- Another pipeline candidate contributes significant value.

Downside Scenario

- Beloranib is not successfully developed for Prader-Willi and/or HIAO.
- Beloranib does not achieve $1.0B in sales by 2026.
- The rest of Zafgen's pipeline does not contribute much value.

Price Performance

Source: Bloomberg

Company Description

Zafgen is dedicated to improving the health and well-being of patients affected by obesity. Zafgen's beloranib is a novel small molecule inhibitor of methionine aminopeptidase 2 (MetAP2). Beloranib has produced solid weight loss data with favorable safety in Phase II trials in patients with either Prader-Willi syndrome (PWS), hypothalamic injury associated obesity (HIAO), or severe obesity. Initial data from ongoing U.S. Phase III trial in PWS is expected in Q1:15 while an E.U. PWS Phase III trial is ready to begin in mid-2015. Data from a severe obesity Phase II trial is expected by Q1:16. PWS and HIAO are orphan disorders that each afflict ~20K patients in the U.S. and EU. We estimate that beloranib could address a $1.5B+ opportunity in these two conditions. Zafgen is also developing an orally active MetAP2 inhibitor, ZGN-839 which has shown efficacy in preclinical models of Nonalcoholic Steatohepatitis (NASH) and type 2 diabetes. Zafgen plans to submit an IND for '839 in mid-15.

Analyst Top Picks

	Ticker	Price (05/12/2015)	Price Target	Rating
BioMarin Pharmaceutical	BMRN	$121.09	$125.00	Outperform
Gilead Sciences	GILD	$105.56	$125.00	Outperform
Portola Pharmaceuticals	PTLA	$37.85	$45.00	Outperform

Q1 Financials; Funding Sufficient For The Next 18 Months.

Zafgen reported a Q1 net loss of $13.5MM vs. our $17.5MME. Inclusive of a net $129.6MM secondary offering in January, the company ended Q1 with $234MM in cash. Zafgen reiterated that it expects to end 2015 with >$145MM in cash and expects its cash balance to be sufficient to fund operations for the next 18 months.

Investment Thesis

Zafgen is a biopharmaceutical company dedicated to significantly improving the health and well-being of patients affected by obesity. Zafgen's lead asset, beloranib, is a novel small molecule inhibitor of methionine aminopeptidase 2 (MetAP2) that is in development for the treatment of hyperphagia (insatiable appetite) and obesity in Prader-Willi Syndrome (PWS), hypothalamic injury associated obesity (HIAO), and severe obesity in the general population. Zafgen has completed six clinical trials in over 200 subjects including obese volunteers, PWS patients, and patients with HIAO. In these trials beloranib has reduced fat mass and controlled hyperphagia while maintaining an acceptable tolerability and safety profile. Our consultants find the >50% decrease in hyperphagia produced in PWS patients particularly striking, as beloranib is the first agent shown to produce a reduction in food seeking behaviors in these patients, a key area of unmet need. Beloranib entered a U.S. Phase III trial in PWS in September 2014, with initial data possible in Q1:2016. The company anticipates to start a Phase III study in Europe in mid-2015. In December 2014, Zafgen initiated a Phase IIb trial in severely obese patients with type 2 diabetes. Six-month data from the trial is expected in late 2015 or early 2015. In January 2015, Zafgen announced positive results from a Phase II trial in HIAO that reaffirmed beloranib's ability to induce weight loss even in individuals with hypothalamic dysfunction. The positive readout further de-risks the Phase III trial in PWS as hypothalamic dysfunction is thought to also cause the obesity and hyperphagia associated with PWS. Zafgen plans to pursue HIAO as an extension of beloranib's PWS indication and are in talks with regulators for a registration pathway. PWS and HIAO are orphan disorders that each afflict approximately 20K patients in the U.S. and EU. We estimate that beloranib could address a $1.5B+ opportunity in these two conditions. Behind beloranib, Zafgen is developing an orally active second-generation MetAP2 inhibitor, ZGN-839. ZGN-839 has shown early efficacy in preclinical models of Nonalcoholic Steatohepatitis (NASH) and type 2 diabetes. Zafgen plans to submit an IND for ZGN-839 in mid-2015. Our DCF analysis suggests that Zafgen is undervalued based on beloranib's potential in Prader-Willi and HIAO alone, with no contribution from other indications or pipeline programs. We maintain our Outperform rating and a $60 price target.

Zafgen Upcoming Milestones

Milestone	Timing
Initiate E.U. Phase III trial of 2.4mg beloranib vs. placebo in PWS	Mid-2015
Complete enrollment for Phase IIb trial of beloranib in severe obesity with type 2 diabetes	Mid-2015
File IND for ZGN-839 in NASH	Mid-2015
Interim 6-month Phase IIb data from beloranib in severe obesity with type 2 diabetes (complete Phase IIb; development decision point)	YE:15 or Q1:16
Phase III data from beloranib in PWS in U.S. (ZAF-311-bestPWS)	Early Q1:2016
Initiate beloranib's Phase III program in HIAO	2016
Data from Phase I PK/safety/tolerability trials	2016
Nomination of second-generation MetAP2i candidate	2016
Initiate Phase I trial with second-generation MetAP2i candidate	2016

Source: Cowen and Company

Zafgen Quarterly P&L ($MM)

	Q1:14A	Q2:14A	Q3:14A	Q4:14A	2014A	Q1:15A	Q2:15E	Q3:15E	Q4:15E	2015E
Boleranib	-	-	-	-	-	-	-	-	-	-
License/milestones revenue	-	-	-	-	-	-	-	-	-	-
Total Revenue	-	-	-	-	-	-	-	-	-	-
COGS	-	-	-	-	-	-	-	-	-	-
R&D	3.3	4.7	12.1	7.3	27.4	10.2	14.0	15.0	16.0	55.2
SG&A	1.2	1.3	2.3	3.3	8.1	3.0	4.0	5.0	6.0	18.0
Other	-	-	-	-	-					-
Operating Expenses	4.5	6.0	14.4	10.7	35.5	13.2	18.0	20.0	22.0	73.2
Operating Income / (Loss)	(4.5)	(6.0)	(14.4)	(10.7)	(35.5)	(13.2)	(18.0)	(20.0)	(22.0)	(73.2)
Interest Income	-	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.3
Interest Expenses	(0.0)	(0.4)	(0.2)	(0.2)	(0.9)	(0.2)	(0.4)	(0.4)	(0.4)	(1.4)
Foreign Currency Transaction Gains (Losses), n	0.1	0.0	(0.1)	(0.1)	(0.1)	(0.1)	-	-	-	-
Pretax net income	(4.5)	(6.4)	(14.7)	(10.9)	(36.5)	(13.5)	(18.3)	(20.3)	(22.3)	(74.3)
Accretion of redeemable convertible preferred st	(0.0)	(0.0)	-	-	(0.1)	-	-	-	-	-
Taxes	-	-	-	-	-	-	-	-	-	-
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
GAAP Net Income	(4.5)	(6.4)	(14.7)	(10.9)	(36.6)	(13.5)	(18.3)	(20.3)	(22.3)	(74.3)
GAAP EPS	**$ (0.98)**	**$ (2.96)**	**$ (0.65)**	**$ (0.48)**	**$ (3.00)**	**$ (0.53)**	**$ (0.71)**	**$ (0.78)**	**$ (0.85)**	**$ (2.87)**
Diluted Shares Outstanding (MM)	4.6	2.2	22.7	22.8	12.2	25.6	25.7	25.9	26.2	25.9

Source: Cowen and Company

Zafgen Annual P&L ($MM)

	2014A	2015E	2016E	2017E	2018E	2019E	2020E
Boleranib	-	-	-	25.0	95.0	200.0	325.0
License/milestones revenue	-	-	-	-	-	-	-
Total Revenue	-	-	-	25.0	95.0	200.0	325.0
COGS	-	-	-	2.0	6.8	13.0	19.5
R&D	27.4	55.2	65.0	75.0	60.0	65.0	70.0
SG&A	8.1	18.0	25.0	40.0	50.0	60.0	75.0
Other	-	-	-	-	-	-	-
Operating Expenses	35.5	73.2	90.0	117.0	116.8	138.0	164.5
Operating Income / (Loss)	(35.5)	(73.2)	(90.0)	(92.0)	(21.8)	62.0	160.5
Interest Income	0.0	0.3	0.3	0.8	0.8	0.4	0.9
Interest Expenses	(0.9)	(1.4)	(0.8)	(0.4)	-	-	-
Foreign Currency Transaction Gains (Losses), net	(0.1)	-	-	-	-	-	-
Pretax net income	(36.5)	(74.3)	(90.5)	(91.6)	(21.0)	62.4	161.4
Accretion of redeemable convertible preferred stoc	(0.1)	-	-	-	-	-	-
Taxes	-	-	-	-	-	-	-
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
GAAP Net Income	(36.6)	(74.3)	(90.5)	(91.6)	(21.0)	62.4	161.4
GAAP EPS	**$ (3.00)**	**$ (2.87)**	**$ (2.85)**	**$ (2.82)**	**$ (0.64)**	**$ 1.87**	**$ 4.73**
Diluted Shares Outstanding (MM)	12.2	25.9	31.7	32.5	32.8	33.4	34.1

Source: Cowen and Company

Valuation Methodology And Risks

Valuation Methodology

Biotechnology:
In calculating our 12-month target price, we employ one or more valuation methodologies, which include a discounted earnings analysis, discounted cash flow analysis, net present value analysis and/or a comparable company analysis. These analyses may or may not require the use of objective measures such as price-to-earnings or price-to-sales multiples as well as subjective measures such as discount rates.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon an assessment of their technology, the probability of pipeline success, and the potential market opportunity in the event of success. However, because these companies lack traditional financial metrics, we do not believe there are any good methodologies for assigning a specific target price to such stocks.

Investment Risks

Biotechnology:
There are multiple risks that are inherent with an investment in the biotechnology sector. Beyond systemic risk, there is also clinical, regulatory, and commercial risk. Additionally, biotechnology companies require significant amounts of capital in order to develop their clinical programs. The capital-raising environment is always changing and there is risk that necessary capital to complete development may not be readily available.

Risks To The Price Target

Zafgen is developing candidates for the treatment of orphan disorders, obesity, and metabolic conditions. The majority of Zafgen's market capitalization is dependent upon the success of lead candidate beloranib. Beloranib's value could be adversely impacted should its clinical trials fail, should the regulatory agencies deny approval, or should its commercial opportunity not materialize as we project. In fact, all of Zafgen's drug candidates face clinical and regulatory risk. With the future development path depending on the evolution of clinical data, future revenue forecasts are uncertain. The commercial outlook for Zafgen's candidates could additionally be altered by safety/efficacy findings, emerging competition, alterations in the medical treatment paradigm, or changes in the pricing environment. Some of Zafgen's projected market exclusivity depends on patents, which are subject to challenge by generic drugmakers.

Addendum

Stocks Mentioned In Important Disclosures

Ticker	Company Name
BMRN	BioMarin Pharmaceutical
GILD	Gilead Sciences
PTLA	Portola Pharmaceuticals
ZFGN	Zafgen

Analyst Certification

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Outperform (1): The stock is expected to achieve a total positive return of at least 15% over the next 12 months

Market Perform (2): The stock is expected to have a total return that falls between the parameters of an Outperform and Underperform over the next 12 months

Underperform (3): Stock is expected to achieve a total negative return of at least 10% over the next 12 months

Assumption: The expected total return calculation includes anticipated dividend yield

Cowen and Company Rating System until May 25, 2013

Outperform (1): Stock expected to outperform the S&P 500

Neutral (2): Stock expected to perform in line with the S&P 500

Underperform (3): Stock expected to underperform the S&P 500

Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period

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Sell – The fundamentals/valuations of the subject company are deteriorating and the investment return is expected to be 5 to 15 percentage points lower than the general market return

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Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	450	58.67%	103	22.89%
Hold (b)	302	39.37%	8	2.65%
Sell (c)	15	1.96%	0	0.00%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions.

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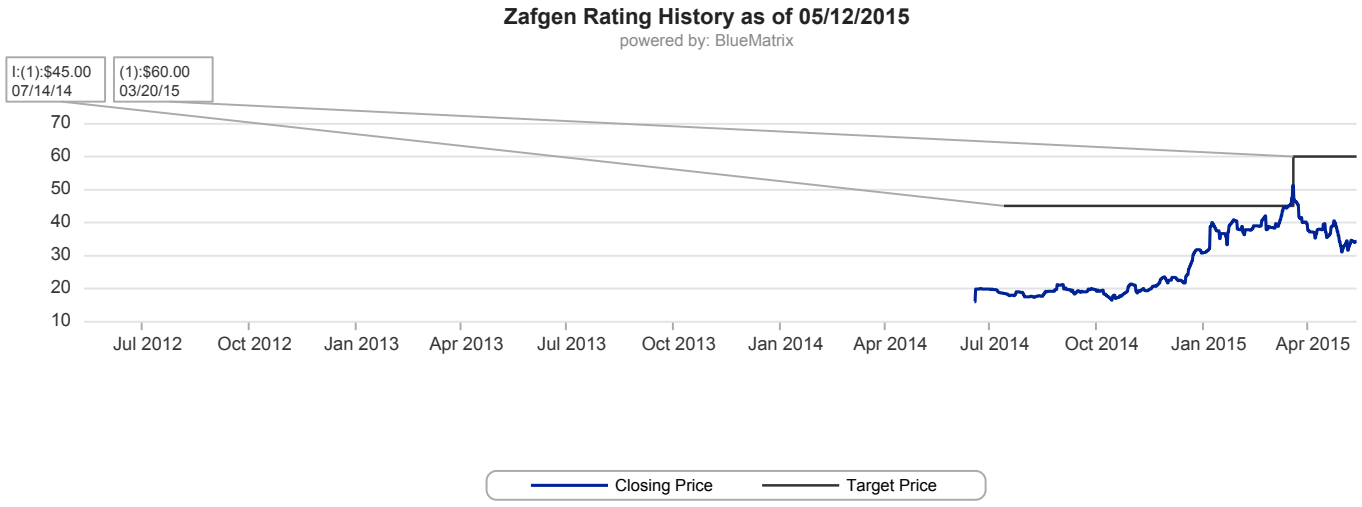

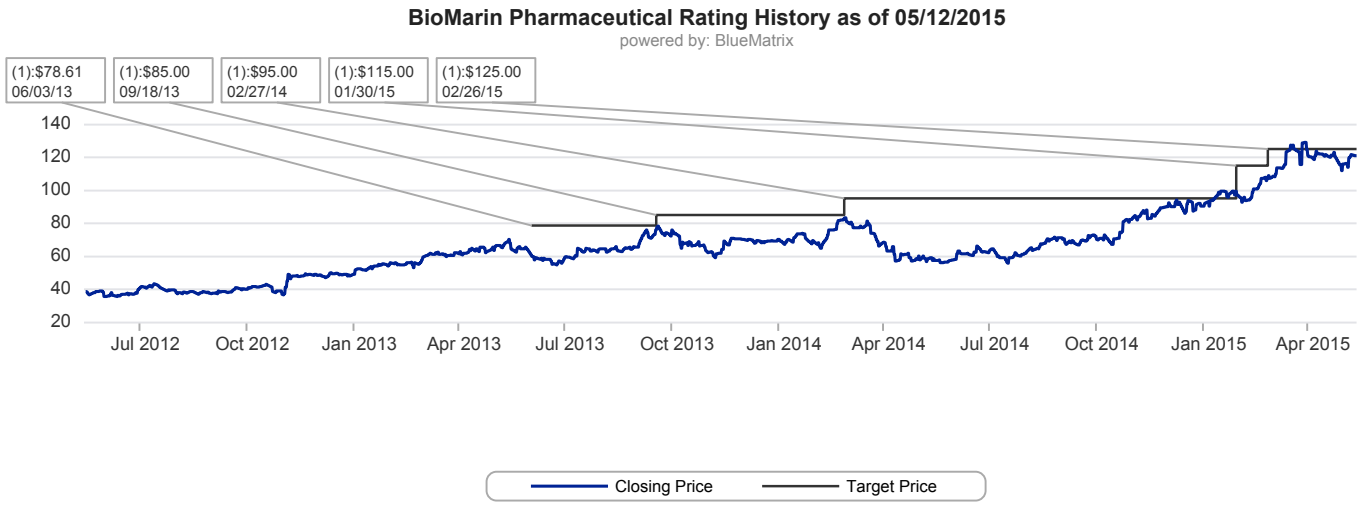

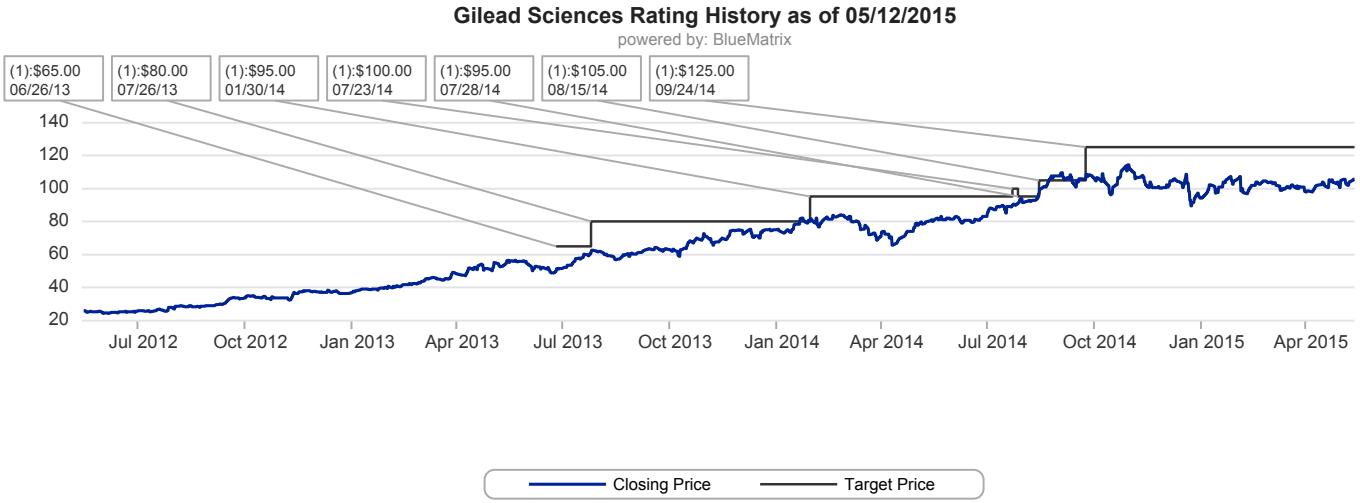

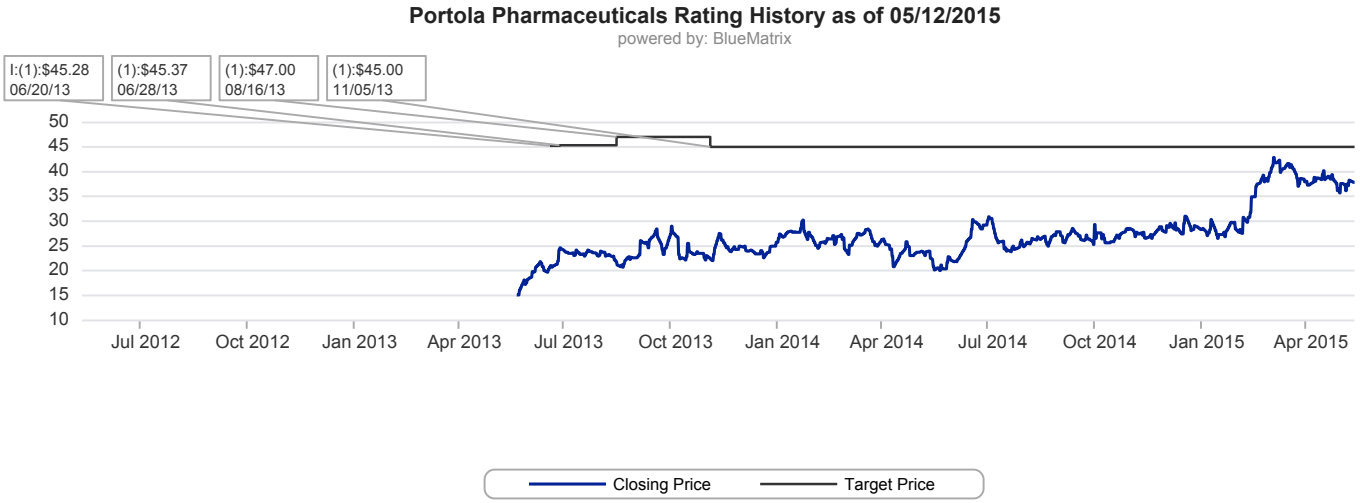

Legend for Price Chart:

I = Initiation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | UR = Price Target Under Review | T = Terminated Coverage | $xx = Price Target | NA = Not Available | S=Suspended

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