COWEN
AND COMPANY

Biotechnology

Zafgen

Equity Research

Earnings Update

March 20, 2015

Price: $51.34 (03/19/2015)

Price Target: $60.00 (Prior $45.00)

OUTPERFORM (1)

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Key Data

Symbol	NASDAQ: ZFGN
52-Week Range:	$52.11 - 16.01
Market Cap (MM):	$1,368.2
Net Debt (MM):	$(6.2)
Cash/Share:	$48.25
Dil. Shares Out (MM):	22.8
Enterprise Value (MM):	$1,248.7
ROIC:	NA
ROE (LTM):	NA
BV/Share:	$4.90
Dividend:	NA

FY (Dec)	2014A	2015E	2016E
Earnings Per Share			
Q1	$(0.98)	$(0.65)	-
Prior Q1	-	*$(0.56)*	-
Q2	$(2.96)	$(0.76)	-
Prior Q2	-	*$(0.58)*	-
Q3	$(0.65)	$(0.81)	-
Prior Q3	-	*$(0.62)*	-
Q4	$(0.48)	$(0.86)	-
Prior Q4	*$(0.54)*	*$(0.63)*	-
Year	$(3.00)	$(3.08)	$(3.08)
Prior Year	*$(2.89)*	*$(2.40)*	*$(2.75)*
P/E	NM	NM	NM
Consensus EPS	$(3.19)	$(2.41)	$(2.34)

Consensus source: Thomson Reuters

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

Reports Q4; Data From Beloranib's PWS Ph. III Expected Q2:16

The Cowen Insight

ZFGN reported Q4. Data from beloranib's U.S. Ph. III PWS trial is now expected in Q2:16, while the E.U. Ph. III trial remains on-track to begin mid-year. We think beloranib's Ph. IIa in HIAO produced impressive data which de-risks the Ph. III trials in PWS. We are raising our PT from $45 to $60 to reflect our confidence in the likely success of beloranib in both indications.

Q4 Financials; Funding Into H2:16.

Zafgen reported a Q4 net loss of $10.9MM vs. our $12.3MME and ended 2014 with $115.5MM in cash. Inclusive of a net $129.5MM secondary offering in January, Zafgen anticipates its pro-forma cash balance of $245MM will fund operations into H2:16. Management anticipates significant increases in R&D and G&A spending during 2015 as the company executes on two Phase III trials and one Phase II trial of beloranib, adds key personnel, and furthers its commercial preparation.

Initial Data From U.S. PWS Phase III Trial Expected In Q2:16.

In September, Zafgen initiated the "bestPWS" 102 patient pivotal Phase III trial of beloranib in Prader-Willi Syndrome. The trial is evaluating 1.8mg or 2.4mg beloranib versus placebo with dual primary endpoints of improvement in total weight and improvement in hyperphagia-related behaviors. Zafgen disclosed that the DSMB recommended the open-label extension portion of the study include only the 2.4mg beloranib dose based on its acceptable safety and tolerability profile. Zafgen noted that the trial has achieved 2/3 of target enrollment with all 15 trial sites active and enrolling patients, though this is somewhat slower than what the management had originally anticipated. Zafgen now expects results from the trial in Q2:16 versus prior guidance of YE:15. Hurdles that the company had to overcome include finalizing trial site contracts, getting sites up and running, completing IRB approvals, and screening PWS patients with moderate to high hyperphagia. To accelerate enrollment, Zafgen is working with PWS foundations and advocacy groups to increase awareness. Zafgen will also reduce the lower threshold of BMI for enrollment to 27 kg/m2 from 30 kg/m2, as well as allow eager Canadian patients into the trial. Management indicated that these updates are consistent with the U.S. and E.U regulatory recommendations and the company expects these patients to respond to beloranib or placebo in a similar manner as the 2/3 of the patients already enrolled in the trial. Zafgen does not expect these changes to meaningfully impact the results of the trial.

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

An E.U. pivotal Phase III trial of beloranib in ~150 PWS patients remains on-track to begin in mid-2015. With the favorable DSMB review of the U.S. Phase III trial, Zafgen has eliminated the 1.8mg beloranib arm and will now evaluate 2.4mg beloranib vs. placebo in the trial with the same dual primary endpoint as in bestPWS. With only one dose being tested, the powering of the trial will be increased.

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 possible in Q2:16. 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, Q2:16

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 Q2:16 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 (03/19/2015)	Price Target	Rating
BioMarin Pharmaceutical	BMRN	$127.49	$125.00	Outperform
Dynavax Technologies	DVAX	$23.19	$60.00	Outperform
Gilead Sciences	GILD	$101.44	$125.00	Outperform

Phase IIa Trial Of Beloranib In HIAO Successful And De-Risks Phase III PWS Trials

Earlier in the month, at ENDO, Zafgen presented impressive data from beloranib's Phase IIa trial in hypothalamic injury associated obesity (HIAO). MRI-confirmed HIAO patients treated with 1.8mg beloranib achieved a mean weight reduction after 4 weeks of 3.4kg vs. a 0.3kg reduction in the placebo group (p=0.01). Patients who participated in the optional four week open-label extension experienced further mean weight reduction of 6.2kg over the eight week treatment period. Beloranib treatment also led to improvements in cardiovascular disease risk factors including lipids, and inflammation as measured by C-reactive protein. Beloranib was well tolerated and safe with no serious or severe AEs reported in the trial. Zafgen plans to pursue HIAO as an extension of beloranib's PWS indication and expects to meet with U.S. and E.U. regulators to establish a regulatory pathway for registrational programs to be initiated in 2016. We continue to view the striking data from the trial as impressive and more importantly we think the data provides a read-through and de-risks the Phase III PWS trials. We are raising our price target from $45 per share to $60 per share to reflect our increased confidence in the likely success of beloranib in both PWS and HIAO.

Other Pipeline Updates

In mid-2015, Zafgen will file an IND for ZGN-839, an orally-active second-generation MetAP2 inhibitor, in NASH. In late Q4:15 or early 2016, following the announcement of interim six-month data from a Phase IIb study of beloranib in severe obesity with type 2 diabetes, Zafgen expects to provide development decisions for beloranib or a follow-up compound in severe obesity.

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 Prader-Willi Syndrome in September 2014, with initial data possible in Q2:2016. The company anticipates to start a Phase III 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 Q4:2015. 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
Complete enrollment for U.S. Phase III trial of beloranib in PWS	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)	Q2:2016
Nomination of second-generation MetAP2i candidate	2016
Initiate beloranib's Phase III program in HIAO	2016

Source: Cowen and Company

Zafgen Quarterly P&L ($MM)

	Q1:14A	Q2:14A	Q3:14A	Q4:14A	2014A	Q1:15E	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	12.5	14.0	15.0	16.0	57.5
SG&A	1.2	1.3	2.3	3.3	8.1	4.7	6.0	6.5	7.0	24.2
Other	-	-	-	-	-					-
Operating Expenses	4.5	6.0	14.4	10.7	35.5	17.2	20.0	21.5	23.0	81.7
Operating Income / (Loss)	(4.5)	(6.0)	(14.4)	(10.7)	(35.5)	(17.2)	(20.0)	(21.5)	(23.0)	(81.7)
Interest Income	-	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.4
Interest Expenses	(0.0)	(0.4)	(0.2)	(0.2)	(0.9)	(0.4)	(0.4)	(0.4)	(0.4)	(1.6)
Foreign Currency Transaction Gains (Losses), n	0.1	0.0	(0.1)	(0.1)	(0.1)	-	-	-	-	-
Pretax net income	(4.5)	(6.4)	(14.7)	(10.9)	(36.5)	(17.5)	(20.3)	(21.8)	(23.3)	(82.9)
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)	(17.5)	(20.3)	(21.8)	(23.3)	(82.9)
GAAP EPS	**$ (0.98)**	**$ (2.96)**	**$ (0.65)**	**$ (0.48)**	**$ (3.00)**	**$ (0.65)**	**$ (0.76)**	**$ (0.81)**	**$ (0.86)**	**$ (3.08)**
Diluted Shares Outstanding (MM)	4.6	2.2	22.7	22.8	12.2	26.7	26.9	27.0	27.1	26.9

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	57.5	70.0	75.0	60.0	65.0	70.0
SG&A	8.1	24.2	30.0	40.0	50.0	60.0	75.0
Other	-	-	-	-	-	-	-
Operating Expenses	35.5	81.7	100.0	117.0	116.8	138.0	164.5
Operating Income / (Loss)	(35.5)	(81.7)	(100.0)	(92.0)	(21.8)	62.0	160.5
Interest Income	0.0	0.4	0.3	0.8	0.8	0.4	0.9
Interest Expenses	(0.9)	(1.6)	(0.8)	(0.4)	-	-	-
Foreign Currency Transaction Gains (Losses), net	(0.1)	-	-	-	-	-	-
Pretax net income	(36.5)	(82.9)	(100.5)	(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)	(82.9)	(100.5)	(91.6)	(21.0)	62.4	161.4
GAAP EPS	**$ (3.00)**	**$ (3.08)**	**$ (3.08)**	**$ (2.74)**	**$ (0.62)**	**$ 1.81**	**$ 4.60**
Diluted Shares Outstanding (MM)	12.2	26.9	32.7	33.4	33.8	34.4	35.1

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
DVAX	Dynavax Technologies
GILD	Gilead Sciences
ZFGN	Zafgen

Analyst Certification

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Zafgen and Dynavax Technologies have been client(s) of Cowen and Company, LLC in the past 12 months.

Cowen and Company, LLC and/or its affiliates expect to receive, or intend to seek, compensation for investment banking services in the next 3 months from Zafgen and Dynavax Technologies.

Zafgen and Dynavax Technologies is or was in the past 12 months a client of Cowen and Company, LLC; during the past 12 months, Cowen and Company, LLC provided IB services.

Cowen and Company, LLC and/or its affiliates received in the past 12 months compensation for investment banking services from Zafgen and Dynavax Technologies.

Cowen and Company, LLC and/or its affiliates managed or co-managed a public offering of Zafgen and Dynavax Technologies within the past twelve months.

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Cowen and Company Rating System effective May 25, 2013

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

Cowen Securities, formerly known as Dahlman Rose & Company, Rating System until May 25, 2013

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

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

Hold – The fundamentals/valuations of the subject company are neither improving nor deteriorating and the investment return is expected to be in line with the general market return

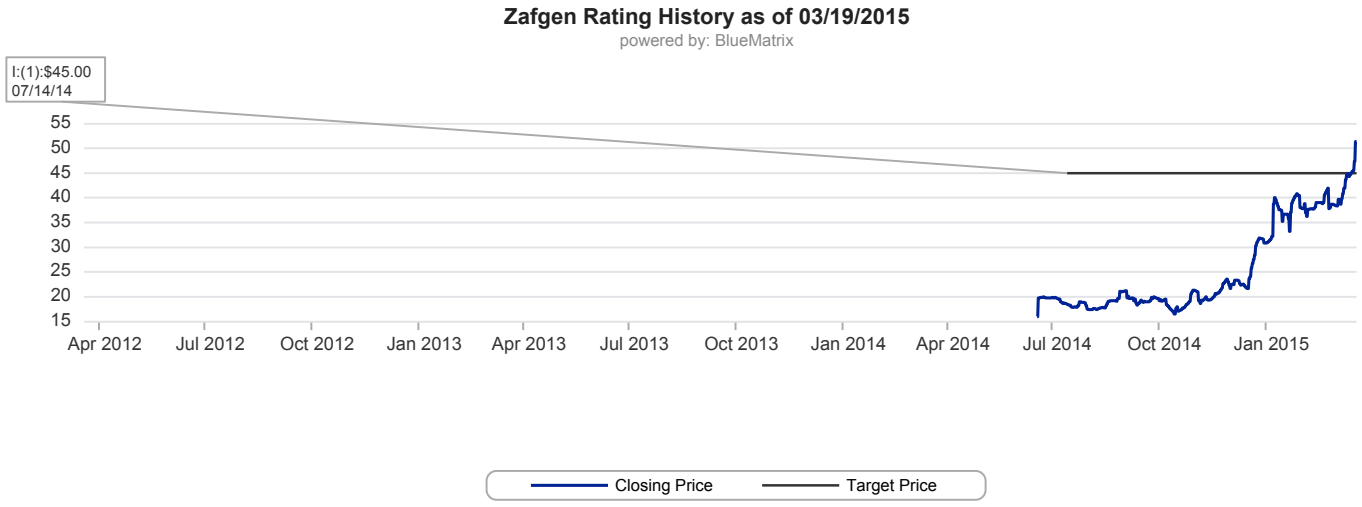
Cowen And Company Rating Definitions

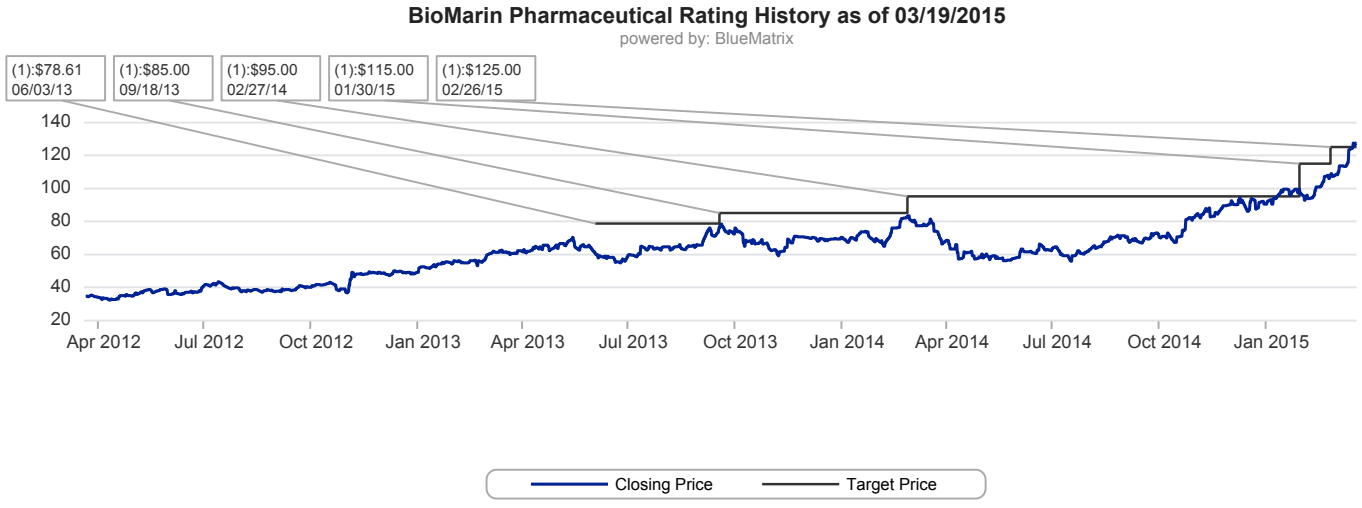
Distribution of Ratings/Investment Banking Services (IB) as of 12/31/14

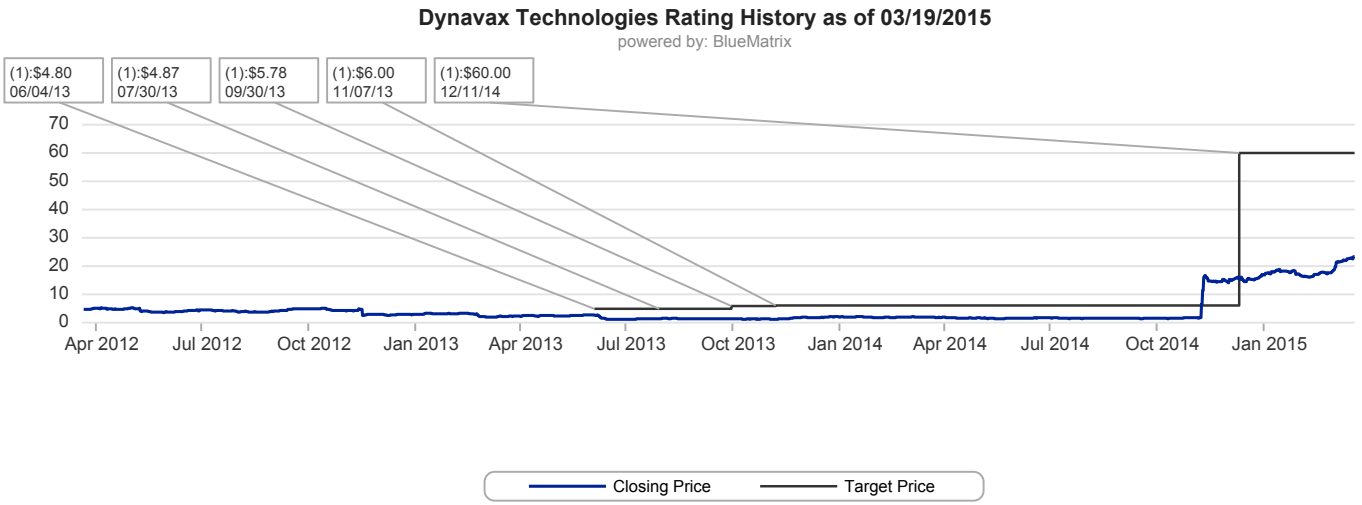
Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	461	60.50%	109	23.64%
Hold (b)	288	37.80%	14	4.86%
Sell (c)	13	1.71%	0	0.00%

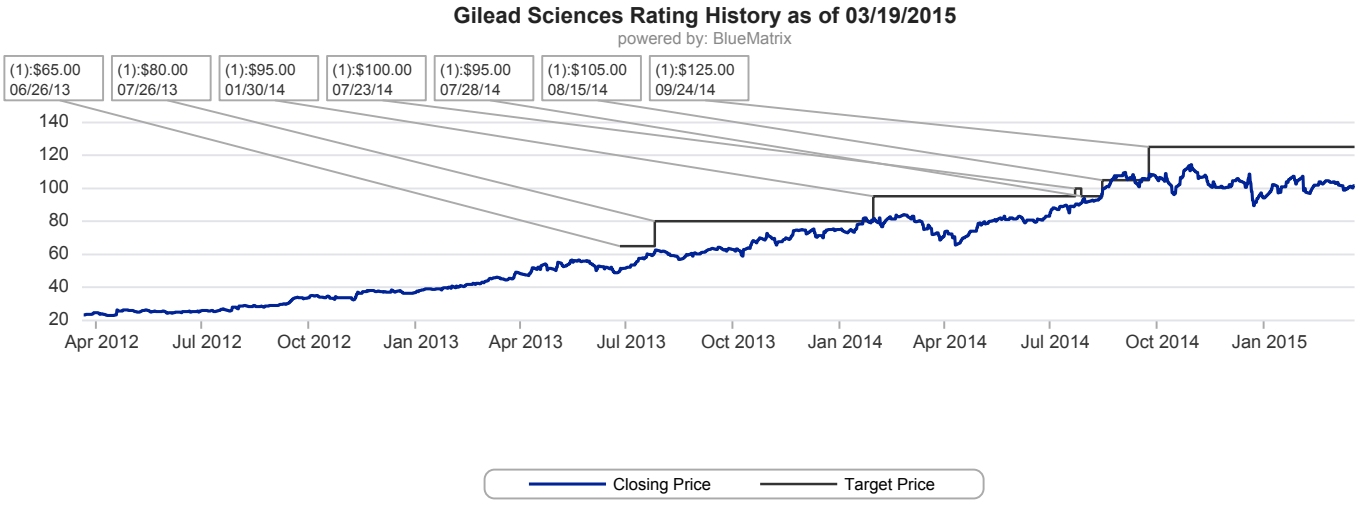
(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions.

Note: "Buy", "Hold" and "Sell" are not terms that Cowen and Company, LLC uses in its ratings system and should not be construed as investment options. Rather, these ratings terms are used illustratively to comply with FINRA and NYSE regulations.









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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