

Zafgen, Inc. (ZFGN)

Beloranib Continuing to Advance in Multiple Indications

MARKET DATA	
Price	\$53.55
52-Week Range:	\$16.01 - \$47.75
Shares Out. (M):	22.7
Market Cap (\$M):	\$1,215.6
Average Daily Vol. (000):	100.0
Cash (M):	\$245
Cash/Share:	\$9.20
Enterprise Value (M):	\$1,123
LT Debt (M):	\$0
Source: Thomson Reuters and JMP Securities LLC	

FY DEC		2014A	2015E	2016E		
Revenue (\$N	1) 1Q	\$0.3	\$0.0			
	2Q	\$0.0	\$0.0			
	3Q	\$0.0	\$0.0			
	4Q	\$0.0	\$0.0			
	FY	\$0.3	\$0.0	\$0.0		
EPS	1Q	(\$5.82)	(\$0.63)			
	2Q	(\$2.96)	(\$0.85)			
	3Q	(\$0.65)	(\$1.00)			
	4Q	(\$0.48)	(\$1.07)			
	FY	(\$9.91)	(\$3.56)	(\$3.48)		
Previo	us FY	(\$10.28)	(\$2.13)	(\$2.02)		
Source: Company reports and JMP Securities LLC						



MARKET OUTPERFORM | Price: \$53.55 | Target Price: UR

INVESTMENT HIGHLIGHTS

Progress with beloranib, although at a slightly slower pace than previously anticipated; reiterate our Market Outperform rating on Zafgen and place our price target under review. Zafgen reported 4Q14 earnings ahead of our and consensus estimates, primarily due to lower than expected R&D expenses. The company has a pro forma cash position of ~\$245MM (~\$115MM at year-end 2014 and an additional ~ \$130MM raised in the January follow-on offering) and guided to year-end 2015 cash of at least \$145MM. The company is making progress with enrollment in the Phase 3 trial evaluating beloranib in patients with Prader-Willi Syndrome (PWS). However, as it has taken longer than expected to bring sites on line to initiate patient enrollment, results are now expected in 2Q16 (vs. year-end 2015 previously).

PWS delay is an incremental disappointment, but our confidence in a positive outcome is unchanged. Management stated that over two-thirds of the planned 102 patients have now been enrolled in the Phase 3 PWS trial and it believes results will likely be available by early 2Q16. Note that the trial is being conducted at 15 sites in the U.S. and all sites are now activated and enrolling patients. To address the slower than expected enrollment, Zafgen is working with patient advocacy groups to raise awareness of beloranib and the Phase 3 trial, as well as now allowing patients from Canada to enroll. Additionally, the enrollment criteria have been amended to allow enrollment of patients with a BMI of at least 27, compared to the prior BMI cut off of 30. Management does not expect the mean baseline BMI in the trial to change meaningfully as a result of this amendment and we are confident that it will not impact the probability of a successful outcome. Management also stated that the drop-out rate seen in the trial so far has been lower than expected, potentially increasing the power of the trial. The second Phase 3 trial, in Europe, is on track to begin in mid-2015 and will only evaluate the higher 2.4mg dose.

P2 obesity/diabetes on track to complete enrollment by mid-2015. Enrollment in the Phase 2b trial for beloranib in severely obese adults with diabetes is progressing in line with expectations and full accrual is expected by mid-year. Six-month interim results from this trial are expected in late 2015 or early 2016, roughly in line with our prior expectation for data by year-end 2015.

HIAO results highlight broad potential for beloranib. Following the release of positive top-line results in January, full data from this 14-patient Phase 2 proof-of-concept trial were presented earlier this month at ENDO. Results from this trial will be used to inform the design of a pivotal program in this patient population.

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4Q14 FINANCIAL SUMMARY

Zafgen reported 4Q14 EPS loss of (\$0.48), ahead of our estimate of (\$0.86) and consensus of (\$0.65). As expected, the company did not report any revenue for the quarter. Total operating expenses were \$10.7MM, lower than our estimated of \$19.5MM, with the primary difference between our estimates and actual results being lower than expected R&D spending. R&D expenses were \$7.3MM, compared to our estimate of \$16.9MM, and SG&A expenses were \$3.3MM, vs. our \$2.6MM estimate.

Management guided to 2015 cash use of up to \$100MM and believes current cash resources are sufficient to fund operations for at least the next 18 months. R&D expenses are expected to significantly increase in 2015 vs. 2014 with multiple trials ongoing and increased headcount. SG&A expenses are also expected to increase vs. 2015 as headcount increases and commercial readiness activities for beloranib are initiated. A summary of 4Q14 financial results and changes to our model is provided in Figure 1.

FIGURE 1. 4Q14 Financial Summary

ZFGN	4Q14			20	14	2015 est	
	JMP est	Cons	Actual	JMP est	Actual	JMP old	JMP new
Revenue	0.0	0.0	0.0	0.3	0.3	0.0	0.0
R&D	16.9		7.3	37.0	27.4	40.6	77.3
SG&A	2.6		3.3	7.4	8.1	8.9	17.8
Total operating expense	19.5		10.7	44.4	35.5	49.6	95.1
Net income (loss)	(19.5)		(10.9)	(44.9)	(36.3)	(49.5)	(95.1)
Shares outstanding (diluted)	22.8		22.8	12.1	12.1	23.3	26.6
EPS (diluted)	(\$0.86)	(\$0.65)	(\$0.48)	(\$10.3)	(\$9.9)	(2.4)	(\$2.4)

Source: Company reports and JMP Securities LLC

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Company Description

Zafgen is a biopharmaceutical company focused on addressing the unmet need of severely obese patients and related orphan indications. The company's lead development candidate is beloranib, a first-in-class MetAP2 inhibitor. Initial development of beloranib is targeting obesity and hyperphagia, or insatiable life-threatening hunger and hunger-related behaviors, in patients with Prader-Willi Syndrome (PWS) and craniopharyngioma-associated obesity. Additional indications for beloranib, and second generation MetAP2 inhibitors, include severe obesity in the general population, NASH, and Type 2 diabetes. The company is lead by an experienced management team with proven success in the cardiovascular and metabolic disease arenas.

Zafgen completed its IPO in June 2014 and raised net proceeds of ~\$103MM. We believe the IPO proceeds provide sufficient cash to fund operations into 2017, which include full clinical development of beloranib in Prader-Willi Syndrome.

Investment Risks

Potential risks to our price target include, but are not limited to, clinical, regulatory, commercial and competitive factors.

Clinical risk. We note that positive results from early trials cannot always be replicated and that the drug may fail in later trials. We note that the Phase 2a proof-of-concept trial was conducted in a small number of patients (n=14), although we believe the likelihood of replicating these positive results in a Phase 3 trial is high. Zafgen may not be successful in the full development and launch of its product candidate, beloranib. There may be dosing, efficacy, or safety issues related to product candidates undergoing clinical trials that could preclude continued development. In addition, there may be manufacturing issues including challenges with the scale-up to commercial quantities. Any of these issues could pose a risk to success.

Regulatory risk. The company's potential regulatory filing for its NDA may not receive approval from the FDA or ex-U.S. agencies. The FDA may request further studies, in which case the approval pathway will likely take longer and cost significantly more. Zafgen relies on third parties to conduct future clinical trials of beloranib and there is risk that they may not carry out their contractual duties or meet deadlines, either of which would result in delays and adverse consequences to the business.

Market risk. Market estimates of PWS patients, or patients eligible for beloranib treatment, may be overestimated. This would impact the ability to reach revenue and profitability projections. The company must retain its intellectual property rights. Other companies may file patent applications or may receive patents that claim the same methods or formulations. This competition would affect operations and potential business prospects.

Financial risk. Zafgen has funded operations to date through proceeds from sales of redeemable convertible preferred stock and convertible debt. Due to no incoming revenue as of yet, the company has incurred losses each year since inception due to research and development expenses. These expenses are expected to continue to incur in the near future. We anticipate that Zafgen will likely need to raise additional funds in the next 12 months to continue future operations. If there are any issues commercializing its product candidates and achieving sales revenue, the company may not reach profitability, which may jeopardize the business. Additionally, Zafgen shares are subject to market volatility risk.



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JMP Securities currently makes a market in the security of Zafgen, Inc.

JMP Securities was manager or co-manager of a public offering of securities for Zafgen, Inc. (ZFGN) in the past 12 months, and received compensation for doing so.

JMP Securities expects to receive OR intends to seek compensation for investment banking services from Zafgen, Inc. in the next 3 months.

JMP Securities Investment Opinion Definitions:

Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months.

Market Perform (MP): JMP Securities expects the stock price to perform in line with relevant market indices over the next 12 months.

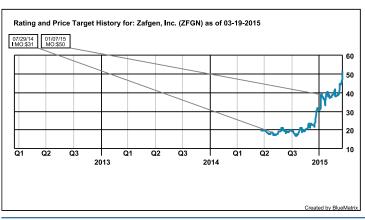
Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

JMP Securities Research Ratings and Investment Banking Services: (as of March 20, 2015)

						# Co's Receiving		
							IB	
		# Co's	%		# Co's	%	Services in	% of Co's
	Regulatory	Under	of	Regulatory	Under	of	Past 12	With This
JMP Rating	Equivalent	Coverage	Total	Equivalent	Coverage	Total	Months	Rating
MARKET OUTPERFORM	Buy	286	63.84%	Buy	286	63.84%	90	31.47%
MARKET PERFORM	Hold	152	33.93%	Hold	152	33.93%	22	14.47%
MARKET UNDERPERFORM	Sell	8	1.79%	Sell	8	1.79%	0	0%
COVERAGE IN TRANSITION		1	0.22%		1	0.22%	0	0%
TOTAL:		448	100%		448	100%	112	25.00%

Stock Price Chart of Rating and Target Price Changes:

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar guarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



March 20, 2015

Zafgen, Inc. (ZFGN)



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