

# Zafgen, Inc. (ZFGN)

Presentation at ENDO Highlights Additional Positive Phase 2 Results for Beloranib in HIAO Patients

MARKET DATA	
Price	\$38.75
52-Week Range:	\$16.01 - \$43.03
Shares Out. (M):	22.7
Market Cap (\$M):	\$879.6
Average Daily Vol. (000):	104.0
Cash (M):	\$127
Cash/Share:	\$5.59
Enterprise Value (M):	\$852
LT Debt (M):	\$0
Source: Thomson Reuters and JMP Securities LLC	

FY DEC		2013A	2014E	2015E
Revenue (\$M)	1Q	\$0.0	\$0.3A	
	2Q	\$0.0	\$0.0A	
	3Q	\$0.0	\$0.0A	
	4Q	\$0.0	\$0.0	
	FY	\$0.0	\$0.3	\$0.0
EPS	1Q	(\$4.94)	(\$5.82)A	
	2Q		(\$2.96)A	
	3Q		(\$0.65)A	
	4Q		(\$0.86)	
	FY	(\$19.53)	(\$10.28)	(\$2.13)
Source: Company reports and JMP Securities LLC				



MARKET OUTPERFORM | Price: \$38.75 | Target Price: \$50.00

# **INVESTMENT HIGHLIGHTS**

Presentation of HIAO Phase 2 results at ENDO provide further support of the broad opportunity for beloranib; reiterate our Market Outperform rating and \$50 price target on Zafgen. This weekend, Zafgen presented additional data from its Phase 2 proof-of-concept trial evaluating beloranib in patients with hypothalamic injury associated obesity (HIAO) at the Endocrine Society Annual Meeting (ENDO). The new data presented at ENDO included further details on the weight loss efficacy of beloranib demonstrated in this trial, as well as improvements in cardiovascular risk parameters such as LDL-C, total cholesterol, triglycerides, and hsCRP. Additionally, the results provided signals that beloranib may positively impact feeding/hunger related behaviors (food intake), which may inform the design of additional studies in this patient population. In our view, these results provide further support for the benefits of beloranib in a broad range of patient populations, including HIAO, with high unmet medical needs and limited/no available treatment options. Our \$50 price target is derived through a sum-of-the-parts NPV analysis of beloranib in PWS, and in hypothalamic injury associated obesity.

**Weight loss efficacy remains impressive.** Baseline body weight was 128kg and 125kg in beloranib and placebo patients, and BMI was 43 and 42, respectively. As previously disclosed, treatment with beloranib resulted in mean weight loss of 3.4kg after four weeks, significantly greater than the 0.3kg mean weight loss in patients treated with placebo for four weeks (p=0.01). Weight loss with beloranib persisted during the open label extension, with no indication of plateau, to a total of 6.2kg at eight weeks.

Additional benefits included significant improvements in cardiometabolic risk biomarkers. The trial demonstrated statistically significant improvements in LDL-C, total cholesterol, and triglycerides (P<0.05 vs. baseline).

Behavioral endpoints provide encouraging signals of efficacy and may inform the design of the development program in HIAO patients. Hunger and appetite using an eight-question Visual Analog Scale (Flint 8Q-VAS). While there were no changes in perceived hunger in the trial, significant reductions in food intake were reported (38-55% reductions). The company hypothesizes that hypothalamic injury in HIAO patients may impact a patient's ability to sense hunger or respond to hunger with treatment. However, the drive to eat may be controlled, at least in part, by areas of the brain outside of the hypothalamus.

**Safety profile continues to look favorable.** There were no severe or serious adverse events in patients treated with beloranib, and no adverse events leading to study withdrawal. The only mild adverse events occurring in more than one patient (n=2) were dizziness, headache, and nasopharyngitis.

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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 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.

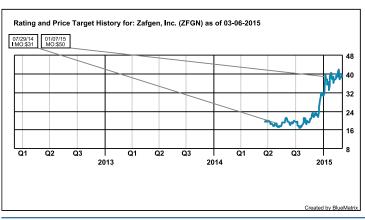
Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

JMP Securities Research Ratings and Investment Banking Services: (as of March 9, 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	283	63.03%	Buy	283	63.03%	86	30.39%
MARKET PERFORM	Hold	156	34.74%	Hold	156	34.74%	23	14.74%
MARKET UNDERPERFORM	Sell	8	1.78%	Sell	8	1.78%	0	0%
COVERAGE IN TRANSITION		1	0.22%		1	0.22%	0	0%
TOTAL:		449	100%		449	100%	109	24.28%

## **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 9, 2015

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