Zafgen, Inc. (ZFGN)

Beloranib Pivotal Trial for Prader-Willi Syndrome Ahead of Schedule

MARKET OUTPERFORM | Price: $34.23 | Target Price: $50.00

MARKET DATA

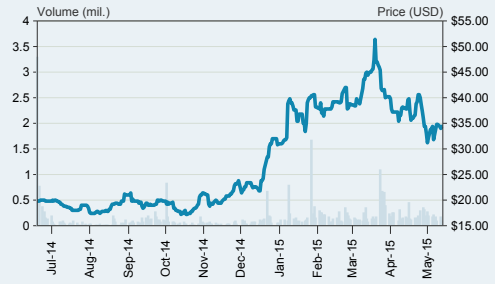
Price	$34.23
52-Week Range:	$16.01 - $55.36
Shares Out. (M):	26.9
Market Cap ($M):	$920.8
Average Daily Vol. (000):	92.0
Cash (M):	$234
Cash/Share:	$8.70
Enterprise Value (M):	$695
LT Debt (M):	$8

Source: Thomson Reuters and JMP Securities LLC

FY DEC		2014A	2015E	2016E
Revenue ($M)	1Q	$0.3	$0.0A	--
	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)	($0.53)A	--
	2Q	($2.96)	($0.72)	--
	3Q	($0.65)	($1.00)	--
	4Q	($0.48)	($1.25)	--
	FY	**($9.91)**	**($3.50)**	**($3.42)**
Previous FY		NC	($3.56)	($3.48)

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE



INVESTMENT HIGHLIGHTS

Enrollment acceleration moves up timing for PWS Phase 3 readout; we reiterate our Market Outperform rating on Zafgen and reinstate our $50 price target (previously under review). Zafgen reported 1Q15 earnings in line with our and consensus estimates. The company ended 1Q15 with ~$234MM in cash and guided to YE 2015 cash of at least $145MM. Most notably, the company announced completion of enrollment in the first Phase 3 trial for beloranib in patients with Prader-Willi syndrome (PWS) and top-line results are now anticipated in early 1Q16, ~3-6 months earlier than our expectations. The other focus for the conference call was the change in primary statistical analysis for the Phase 3 PWS trial and we believe the probability of success remains high. Development of beloranib in additional indications (HIAO and severe obesity) remains on track. Our $50 price target is derived through a sum-of-the-parts NPV analysis of beloranib in PWS, and in hypothalamic injury associated obesity.

Change to statistical plan for Phase 3 PWS trial incrementally changes risk profile, in our view. The company announced that, based on continued dialogue with the FDA, it has changed the primary statistical analysis to a co-primary endpoint where both improvements in body weight and hyperphagia-related behaviors are required to achieve success (vs. prior dual-primary endpoints where either/or could be met to achieve success). Offsetting this change, the alpha has increased to a p value of 0.05 for the co-primary endpoints (vs. a more stringent p value of 0.025 for each dual-primary endpoint). The power of the study remains at 95% to detect a 1.5% difference in body weight and a 4.5 unit difference in the hyperphagia metric. The number of patients in this trial is unchanged (n>102) and management noted that retention in the trial to date has been higher than predicted, increasing the power of the trial, and further increasing the probability of success, in our view. While we believe the probability of success in this trial remains predominantly unchanged, and high, we believe the statistical analysis change may incrementally increase risk. This is due to having relatively less clinical experience with the behavior endpoint vs. weight change. However, we remain confident that the improvements in hyperphagia-related behaviors in the Phase 2 trial were robust and provide validation for the endpoint.

Second PWS Phase 3 trial remains on track to begin in Europe in mid-2015. This trial is designed to enroll ~150 patients randomized to receive beloranib (2.4mg) or placebo. This trial includes only one dose of beloranib vs. the first Phase 3 trial that includes two doses (1.8mg and 2.4mg) and patients will be treated for ~12 months (vs. ~6 months in the first trial). We expect the trial to use the same co-primary endpoints as the U.S.-based trial. While ZFGN had planned to wait for results from the European trial prior to submitting the NDA, the FDA indicated that with compelling data, an NDA submission would be possible based on only the U.S.-based best PWS trial data.

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Beloranib's Phase 2 trial in severe obesity remains on track for data in late '15 or very early '16. The trial is progressing in line with our expectations and about two-thirds of the targeted 150 patients have been enrolled. Additionally, the company continues to establish a regulatory path for beloranib in HIAO with the positive data from the Phase 2 trial showing more body weight loss in the treatment group. Lastly, the company announced plans to advance ZGN-839 (a novel inhibitor of MetAP2) into the clinic this year for nonalcoholic steatohepatitis (NASH).

1Q15 FINANCIAL SUMMARY

Zafgen reported 1Q15 EPS of ($0.53), above our and consensus estimates of ($0.63) and ($0.58), respectively. Total operating expenses were lower than expected at $13.2MM, vs. our estimate of $16.1MM, with both lower R&D ($10.2MM vs. $12.5MM JMPe) and SG&A spending ($3.0MM vs. $3.7MM JMPe). R&D was driven by accelerated patient enrollment in the best PWS trial and the Phase 2b clinical trial of ZAF-203 as well as associated manufacturing and personnel costs. Zafgen expects to ramp R&D significantly as it conducts three clinical trials and increases headcount in the R&D team. Zafgen ended 1Q15 with $234MM, which includes the $130MM offering in January. Zafgen expects to end 2015 with more than $145MM in cash, which they expect to last ~18 months.

We have updated our model to reflect 1Q15 financial results as summarized in Figure 1.

FIGURE 1. 1Q15 Financial Summary

ZFGN	1Q15			2015 est			2016 est		
	JMP est	Cons	Actual	JMP est	Cons	JMP new	JMP est	Cons	JMP new
Revenue	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
R&D	12.5		10.2	77.3		75.5	85.0		83.1
SG&A	3.7		3.0	17.8		17.7	26.7		26.5
Total operating expense	16.1		13.2	95.1		93.2	111.8		109.6
Net income (loss)	**(16.1)**	**(16.6)**	**(13.5)**	**(95.1)**	**(80.8)**	**(94.0)**	**(111.8)**	**(88.3)**	**(110.4)**
Shares outstanding (diluted)	25.5		25.6	26.6		26.7	32.1		32.2
EPS (diluted)	**($0.63)**	**($0.58)**	**($0.53)**	**($3.56)**	**($2.99)**	**($3.50)**	**($3.48)**	**($3.14)**	**($3.42)**

Source: Company Reports and JMP Securities LLC

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.

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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.
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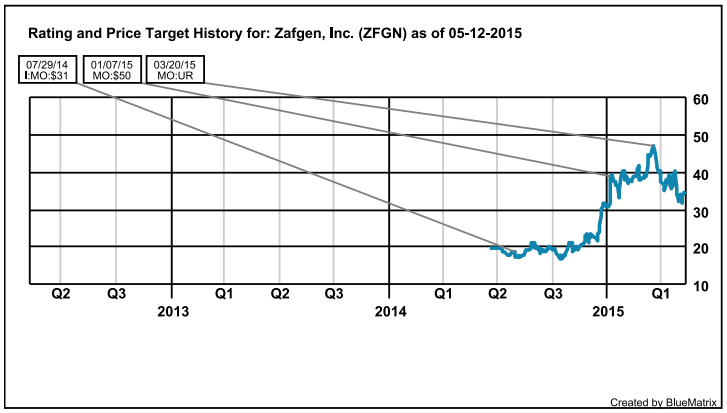
JMP Rating	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	# Co's Receiving IB Services in Past 12 Months	*% of Co's With This Rating*
MARKET OUTPERFORM	Buy	279	*62.00%*	Buy	279	*62.00%*	95	*34.05%*
MARKET PERFORM	Hold	140	*31.11%*	Hold	140	*31.11%*	17	*12.14%*
MARKET UNDERPERFORM	Sell	9	*2.00%*	Sell	9	*2.00%*	0	*0%*
COVERAGE IN TRANSITION		21	*4.67%*		21	*4.67%*	4	*19.05%*
TOTAL:		450	*100%*		450	*100%*	116	*25.78%*

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 quarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



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