Zafgen, Inc. (ZFGN)

3Q14 Earnings Update: Clinical Progress Continues In Line with Expectations

MARKET DATA

Price	$19.43
52-Week Range:	$16.01 - $21.96
Shares Out. (M):	22.7
Market Cap ($M):	$441.1
Average Daily Vol. (000):	35.0
Cash (M):	$127
Cash/Share:	$5.59
Enterprise Value (M):	$304
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)**
Previous FY		NC	($10.29)	($2.15)

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

MARKET OUTPERFORM | Price: $19.43 | Target Price: $31.00

INVESTMENT HIGHLIGHTS

Clinical timelines remain on-track; reiterate Market Outperform rating and $31 price target on Zafgen. Zafgen reported 3Q14 earnings roughly in line with our estimates, and ahead of consensus on lower than expected operating expenses. The company ended the quarter with $127M in cash, and guided to YE 2015 cash of greater than $100M. Zafgen is continuing to advance development of its lead candidate beloranib in severe/orphan obesity populations, and data read-outs remain on-track for the Phase 3 trial in Prader-Willi syndrome in 2H15, as well as the Phase 2a proof-of-concept trial in patients with hypothalamic injury-associated obesity (1Q15E) and the Phase 2b trial in severe obesity (2H15E). Our $31 price target is derived though a sum-of-the-parts NPV analysis of beloranib in PWS, and in hypothalamic injury-associated obesity.

Enrollment in the Phase 3 PWS trial is progressing in line with expectations. As previously announced, the Phase 3 trial (bestPWS) for beloranib in patients with Prader-Willi syndrome (PWS) began enrolling patients in September. Management stated that recruitment has gone well so far, and interest from the community has been strong. In order to ensure a robust outcome, and acknowledging patient demand, the company is increasing target enrollment to 100 from 85 patients. The trial is powered at >90% to show efficacy on both the body mass (DEXA) and hyperphagia-related behavior endpoints with an alpha of 0.025, and success will be achieved by meeting either or both endpoints. Zafgen still expects to complete enrollment with an ~six-month time period, and results are expected in 2H15. In our view, results from bestPWS represent the primary value driving catalyst for the stock in 2015.

HIAO Phase 2a results anticipated in 1Q15. The company announced in September that it had completed enrollment in the Phase 2a trial (ZAF-221) evaluating beloranib in patients with hypothalamic injury-associated obesity (HIAO). As a reminder, the trial enrolled 14 obese patients with radiographically confirmed hypothalamic damage at four centers (two in the United States and two in Australia). Patients were randomized to receive beloranib (1.8mg) twice weekly or placebo for a four-week double-blind treatment period, followed by an optional four-week open-label extension. The primary endpoint for this trial is change in body weight, and additional endpoints include metabolic risk markers (cholesterol, triglycerides, CRP), assessments of hunger, and quality of life. The trial is still expected to be completed in 4Q15, with top-line results from the randomized portion anticipated in 1Q15.

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Phase 2b trial in patients with severe obesity set to begin in 4Q14. Zafgen remains on-track to initiate the Phase 2b trial (ZAF-203) for beloranib in patients with severe obesity and type 2 diabetes by YE 2014. The trial is designed to enroll ~100 patients, and initial six-month results are anticipated in 2H15. The company also reiterated that it plans to file an IND in 1H15 for ZGN-839, its next-generation MetAP2 inhibitor, and advance the program into clinical development.

3Q14 FINANCIAL SUMMARY

Zafgen reported 3Q14 net income of ($14.7M), roughly in line with our estimate of ($15.1M). The company reported no revenue, which was in line with our expectations. Total operating expenses were $14.4M, slightly lower than our estimate of $15.1M. R&D expenses were $12.1M, compared to our estimate of $13.1M. SG&A expenses were $2.3M, versus our estimate of $1.9M. Cash and equivalents totaled $127M as of September 30, 2014, and the company guided to YE 2014 cash in excess of $100M. Management stated that current cash is sufficient to fund operations for ~24 months.

We have updated our model (Figure 1) to reflect the 3Q14 financial results.

FIGURE 1. 3Q14 Earnings Summary and Changes to Our Model

ZFGN	3Q14			2014 est			2015 est		
	JMP old	Cons	Actual	JMP old	Cons	JMP new	JMP old	Cons	JMP new
Revenue	**0.0**	**0.0**	**0.0**	**0.3**	**0.1**	**0.3**	**0.0**	**0.0**	**0.0**
R&D	13.1		12.1	38.2		35.7	42.0		39.3
SG&A	1.9		2.3	6.7		7.4	8.0		8.9
Total operating expense	15.1		14.4	44.9		43.2	50.1		48.3
Net income (loss)	**(15.1)**	**(19.8)**	**(14.7)**	**(45.1)**	**(47.6)**	**(43.7)**	**(50.0)**	**(65.3)**	**(48.2)**
Shares outstanding (diluted)	22.8		22.7	12.1		12.1	23.3		23.3
EPS (diluted)	**($0.66)**	**($0.92)**	**($0.65)**	**($10.3)**	**($3.12)**	**($10.2)**	**(2.1)**	**(2.5)**	**($2.4)**

Source: JMP Securities LLC, Company Reports

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

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 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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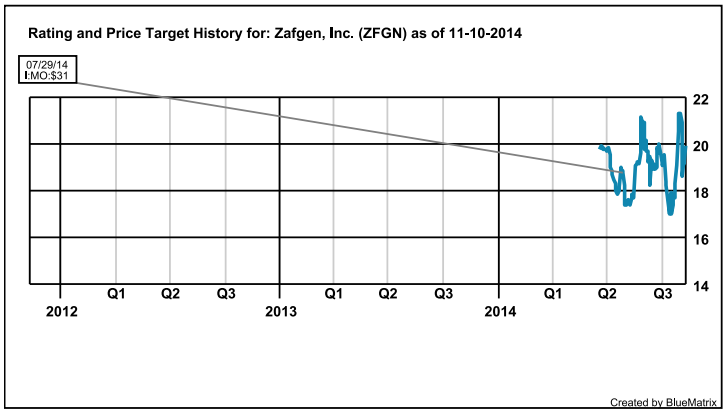
JMP Rating	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	# Co's Receiving IB Services in Past 12 Months	*% of Co's With This Rating*
MARKET OUTPERFORM	Buy	285	*61.03%*	Buy	285	*61.03%*	102	*35.79%*
MARKET PERFORM	Hold	141	*30.19%*	Hold	141	*30.19%*	14	*9.93%*
MARKET UNDERPERFORM	Sell	2	*0.43%*	Sell	2	*0.43%*	0	*0%*
COVERAGE IN TRANSITION		36	*7.71%*		36	*7.71%*	0	*0%*
TOTAL:		467	*100%*		467	*100%*	118	*25.27%*

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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