Zacks Small-Cap Research

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Zalicus Inc.

(ZLCS-NASDAQ)

ZLCS: Z994 is the primary driver for 2014…

UPDATE

On March 13, 2014, Zalicus reported financial results for the fourth quarter and full year 2013. Total revenues for 2013 were $14.7 million with a net loss was $38.6 million, or $1.68 per share.

In February 2014, Zalicus announced the sale of all rights to future royalties on sales of Exalgo at Mallinckrodt Inc. in return for $7.2 million in cash. Zalicus immediately used the $7.2 million cash payment from Mallinckrodt to pay off an $8.65 million outstanding term loan with Oxford Finance LLC.

Given the failure of Z160 in November 2013, all eyes are now squarely focused on Z944 as the primary valuation driver in 2014 and beyond.

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	09/10/2012
Current Price (03/14/14)	$1.85
Target Price	**$1.50**

SUMMARY DATA

52-Week High	**$7.20**
52-Week Low	**$0.89**
One-Year Return (%)	**-52.16**
Beta	**1.69**
Average Daily Volume (sh)	**1,877,804**
Shares Outstanding (mil)	**26**
Market Capitalization ($mil)	**$50**
Short Interest Ratio (days)	**0.54**
Institutional Ownership (%)	**48**
Insider Ownership (%)	**3**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2014 Estimate	**N/A**
P/E using 2015 Estimate	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Blend**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	3.7 A	3.9 A	3.4 A	3.2 A	14.7 A
2014	1.8 E	1.8 E	1.7 E	1.7 E	7.0 E
2015					5.0 E
2016					5.0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.38 A	-$0.49 A	-$0.46 A	-$0.37 A	-$1.68 A
2014	-$0.28 E	-$0.26 E	-$0.25 E	-$0.21 E	-$0.99 E
2015					-$0.83 E
2016					-$0.72 E

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WHAT'S NEW

Financial Update

On March 13, 2014, Zalicus reported financial results for the fourth quarter and full year 2013. Total revenues for the fourth quarter and full year were $3.7 million and $14.7 million, respectively. The fourth quarter revenues consisted of $1.7 million in collaborative payments and $2.0 million in royalties on sales of Exalgo at partner Mallinckrodt. Full year revenues consisted of $8.0 million in collaborative payments and $6.7 million in royalties on sales of Exalgo at partner Mallinckrodt.

Net loss for the full year 2013 was $38.6 million, or $1.68 per share, which included $34.0 million in research and development expenses, $7.5 million in general and administrative expenses and $10.0 million in depreciation and amortization. Zalicus expects research and development expenses to decrease significantly for the year 2014 due to the terminated development activities related to the discontinuation of Z160. Zalicus exited 2013 with $19.8 million in cash, cash equivalents and restricted investments.

…Exalgo Royalties Monetized…

On February 3, 2014, Zalicus filed a Form 8K announcing the sale of all rights to future royalties on sales of Exalgo at Mallinckrodt Inc. in return for $7.2 million in cash. Zalicus originally entered into a licensing agreement with Mallinckrodt for Exalgo, an extended release formulation of hydromorphine hydrochloride, in June 2009. Exalgo was approved for sale in the U.S. in March 2010 and launched by Mallinckrodt in April 2010. To date, Zalicus has received $16.0 million in royalties relating to sales of Exalgo at Mallinckrodt.

We believe the transaction was a wise one for Zalicus because Exalgo's days of exclusivity are nearing an end. Pending final U.S. approval for the generic formulation, generic manufacturer Actavis, Inc. has already reached an agreement with Mallinckrodt allowing Actavis to launch a generic formulation of Exalgo for the 8, 12, and 16 mg dosage strengths. The agreement allows for Actavis to launch a generic 32 mg dosage strength on May 15, 2014. Under terms of the previous agreement with Mallinckrodt, Zalicus royalties in net sales of the approved dosage strengths are reduced by 50% upon the introduction of generic versions of the drug.

...Uses Cash to Strengthen Balance Sheet...

Our financial model assumed only limited royalties on sales of Exalgo to Zalicus in 2014, so the $7.2 million in cash received by Zalicus on January 31, 2014 was a nice positive surprise. Zalicus immediately used the $7.2 million cash payment from Mallinckrodt to pay off an $8.65 million outstanding term loan with Oxford Finance LLC. The original $20 million loan was entered into back in December 2010 with Oxford. Zalicus paid both principal and interest payments on the loan in 2013, with another $6.7 million due in 2014 and $2.1 million scheduled for 2015 assuming full interest payments were made. Paying down the loan in its entirety not only improves the company's working-capital position, but also reduces future cash burn associated with the principal and interest payments.

As a result of paying back the loan, Oxford has released all security interests in Zalicus' tangible and intangible property. This should allow the company to enter into future equity or debt financings unencumbered by the terms of the Oxford transaction.

Zalicus reported cash and equivalents at December 31, 2013 of $19.8 million. We note net cash burn in the fourth quarter 2013 was only $0.2 million, as the company raised $7.7 million in cash through sales of securities to Lincoln Park Capital in October 2013. As of October 24, 2013, Zalicus has sold $19.8 million of the $25.0 million allowed through the securities purchase agreement with Lincoln Park. We believe the company's goal is to keep cash and cash equivalents of - at least - six months of operating burn. For the first half of 2014, we model cash usage from operations of roughly $10 million, meaning Zalicus should tap the remaining $5.2 million from Lincoln Park here in the first or second quarter 2014 (assuming they haven't already done so). We model cash at March 31, 2014, the end of the first quarter, to still be above $17.5 million.

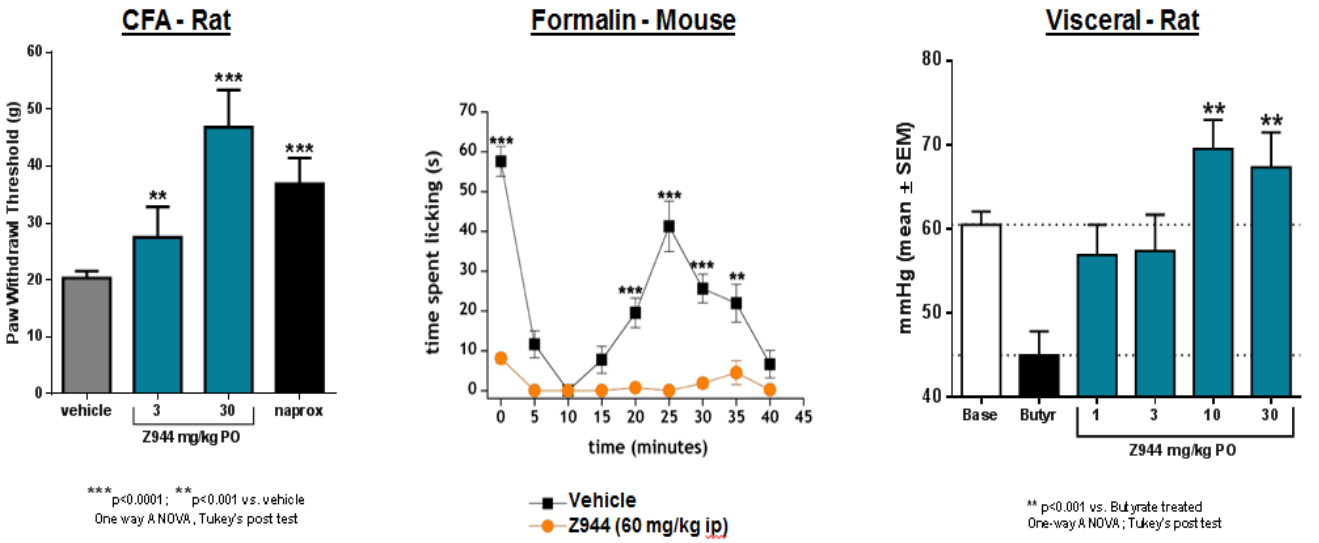
INVESTMENT UPDATE

Z944 Is the Primary Driver In 2014

Given the failure of Z160 in November 2013, all eyes are now squarely focused on Z944 as the primary valuation driver in 2014 and beyond. Z944 is the company's novel, oral T-type calcium channel (Cav 3.1, Cav 3.2, and Cav 3.3) modulator for chronic, acute, or visceral pain. The profile of the drug candidate clearly has enormous potential for Zalicus, but it is early stage, having only just recently completed a Phase 1b study in November 2013.

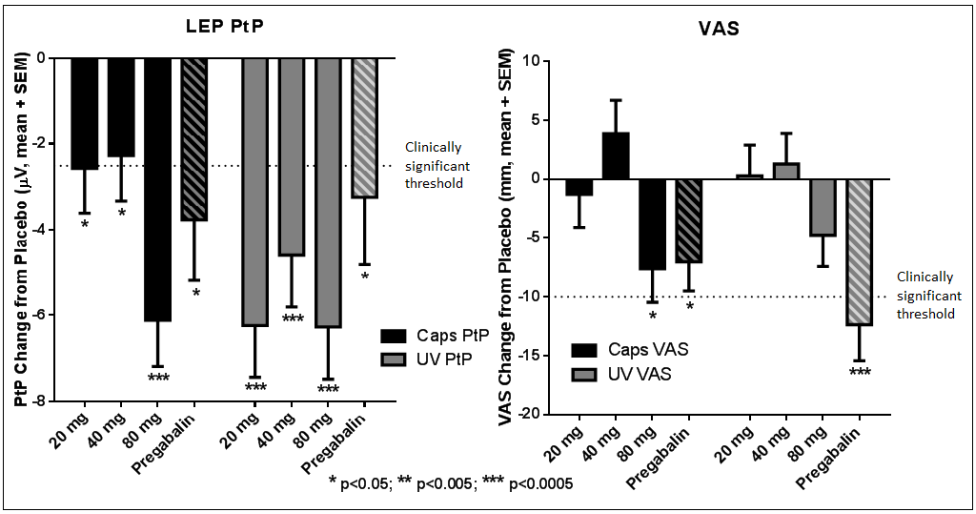
There are a number of things management plans to do different from the development of Z160 to Z944. Namely, Zalicus will proceed slower and more cautiously into clinical development with Z944. With Z160, management took the initial proof-of-concept data from Phase 1 and jumped right into two large-scale Phase 2b studies, one for PHN and another for LSR. With Z944, we expect Zalicus to do several smaller and more focused pilot efficacy studies. This is not because management doesn't believe the potential with Z944 is large, it's more a factor of things like cash burn and making sure the company fully understands the mechanism and utility of the drug before they invest heavily in its future.

The preclinical data generated to date with Z944 is very encouraging. In February 2012, the company published a paper in Science Translational Medicine identifying Z944 as a potential therapy for seizure and generalized epilepsy. In May 2013, the company presented Poster #383 at the American Pain Society highlighting the mechanism of action for Z944 and its potential utility in various nonclinical models of acute and inflammatory pain. Below we highlight some of this data showing how Z944 compared well to naproxen in rat complete freund's adjuvant (CFA) model, mouse formalin model, and in a model of rat visceral pain.



The Phase 1b data has some good nuggets of information. Firstly, Zalicus saw dose proportional pharmacokinetics with similar exposure to preclinical doses where efficacy was achieved. The data show rapid absorption and a pk profile that supports twice daily dosing. The drug was also well tolerated, but the company did identify a maximum tolerated dose. In fact, when doses got too high there were limiting CNS side effects. This is in contrast to Z160 where Zalicus saw very limited side effects and incredible tolerability. It's important to note companies *want* to see dose-limiting CNS side effects. That confirms the drug is hitting the target organ. With Z160, no dose-limiting side effects should have been a clue that the efficacy wasn't there. Water has no dose-limiting CNS side effects!

The Phase 1b study utilized state-of-the-art experimental clinical model measuring Laser-Evoked Potentials (LEP) following administration of capsaicin or exposure to UV light. The trial was designed to efficiently provide objective and subjective data on a drug's ability and modulate neuropathic pain signaling. This provided management with better sense of the efficacy signal than with Z160. Data shows that Z944 reduced peak-to-peak amplitudes in both neuropathic (capsaicin) and inflammatory (UV) pain models (see graphs below taken from the company's investor presentation). The drug also reduced subjective VAS pain scores for both models, with the highest dose of 80mg comparing well to preclinical data on Pfizer's Lyrica (pregabalin).



Heading into Phase 2 Zalicus has a better sense of the objective and subjective endpoints and complete profile of Z944 compared to Z160. As noted above, management will proceed into smaller Phase 2a studies to further qualify the efficacy. We note that the 80mg dose cohort of Z944, the one that compared the best with pregabalin on neuropathic pain signals, did have four serious adverse events. In total, 16 patients in the 80mg cohort had 47 total adverse events, 21 mild, 22 moderate, and four severe. One patient had to discontinue due to a severe CNS-related SAE. Therefore, before Zalicus can truly proceed forward with Z944 they will need to modify the formulation from the current profile to an extended-release profile. Management believes this "smoother" pk curve should eliminate many of the adverse events and allow them to push forward into future clinical studies with the drug.

We believe Zalicus will spend the next several months working on the new Z944 formulation before filing the U.S. IND application to begin a Phase 2 trial in the "indication of choice" during the second half of 2014. We value the shares at $1.50 based on the potential for Z944 and the opportunity to sign-up additional early-stage research collaborations similar to the ongoing programs with Novartis and Amgen. We expect investor attention to return to the story upon filing of the U.S. IND application in the next several months.

PROJECTED INCOME STATEMENT

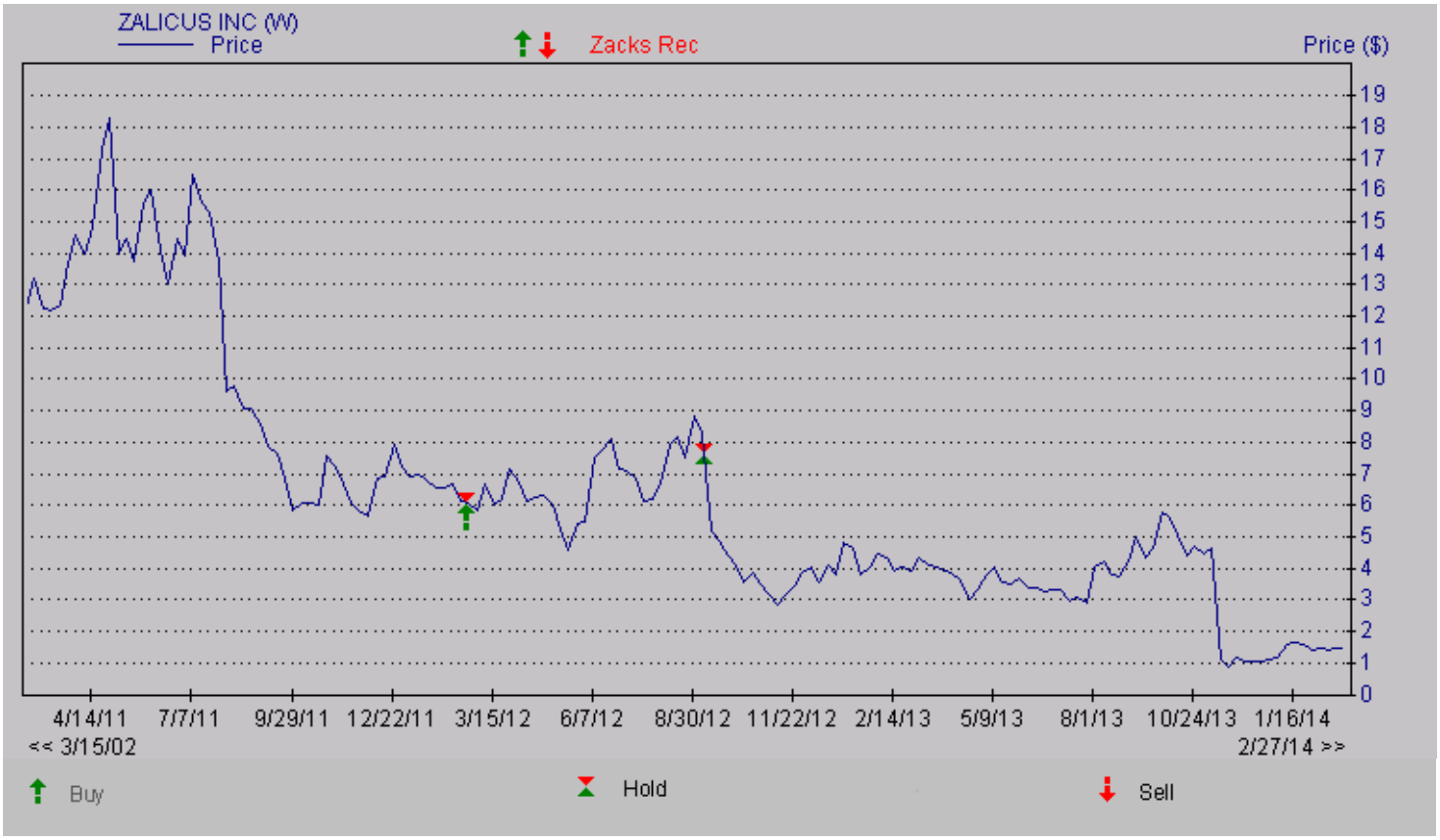
Zalicus, Inc.
Income Statement

Zalicus, Inc.	2013 A	Q1 E	Q2 E	Q3 E	Q4 E	2014 E	2015 E	2016 E
Collaborations & Grants	**$8.1**	**$1.8**	**$1.8**	**$1.7**	**$1.7**	**$7.0**	**$5.0**	**$5.0**
YOY Growth	*9.8%*	*-19.7%*	*-17.4%*	*-10.1%*	*-3.4%*	*-13.3%*	*-28.6%*	*0.0%*
Exalgo Royalty	**$6.7**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	*28.1%*	-	-	-	-	-	-	-
Z944	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$14.7**	**$1.8**	**$1.8**	**$1.7**	**$1.7**	**$7.0**	**$5.0**	**$5.0**
YOY Growth	*17.4%*	*-51.0%*	*-53.7%*	*-50.0%*	*-54.9%*	*-52.5%*	*-28.6%*	*0.0%*
General & Administrative	$7.5	$2.0	$2.1	$2.1	$1.1	$7.3	$8.0	$8.5
% SG&A	*51.1%*	*113.4%*	*114.4%*	*122.2%*	*66.0%*	*104.3%*	*160.0%*	*170.0%*
Research & Development	$34.0	$5.5	$5.6	$5.5	$5.4	$22.0	$20.0	$20.0
% R&D	*230.6%*	*305.6%*	*311.1%*	*323.5%*	*317.6%*	*314.3%*	*400.0%*	*400.0%*
Amort & Restruct	$10.5	$1.9	$1.7	$1.7	$1.8	$7.1	$6.0	$5.0
% Other	*71.0%*	*105.6%*	*94.4%*	*100.0%*	*105.9%*	*101.4%*	*120.0%*	*100.0%*
Operating Income	($37.2)	($7.6)	($7.6)	($7.6)	($6.6)	($29.4)	($29.0)	($28.5)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Net	($1.4)	($0.1)	($0.1)	($0.1)	($0.1)	($0.4)	($0.2)	($0.2)
Pre-Tax Income	($38.6)	($7.7)	($7.7)	($7.7)	($6.7)	($29.8)	($29.2)	($28.7)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Discontinued Operations	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	($38.6)	($7.7)	($7.7)	($7.7)	($6.7)	($29.8)	($29.2)	($28.7)
YOY Growth	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.68)**	**($0.28)**	**($0.26)**	**($0.25)**	**($0.21)**	**($0.99)**	**($0.83)**	**($0.72)**
YOY Growth	-	-	-	-	-	-	-	-
Weighted Ave. Shares	22.9	28.0	29.2	30.5	32.5	30.1	35.0	40.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

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