Zacks Small-Cap Research

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Zalicus Inc.

(ZLCS-NASDAQ)

ZLCS: Insights From Meeting With Management…

UPDATE

On Sunday, January 12, 2014, we arrived in San Francisco, CA for the annual JP Morgan Healthcare Conference, as well as the parallel Biotech showcase and OneMedForum Conferences. This was the eighth year in a row that we made the trip to San Francisco for these events, which are a must-attend for serious healthcare investors.

During my three days in San Francisco, I conducted 25 one-on-one meetings with various managements of small and mid-cap biotechnology and specialty pharmaceutical companies. Below are some "notes" from our meeting with Zalicus Inc.

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	09/10/2012
Current Price (01/22/14)	$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 2013 Estimate	**N/A**
P/E using 2014 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)
2012	2.3 A	2.9 A	3.5 A	3.8 A	12.6 A
2013	3.7 A	3.9 A	3.4 A	3.2 E	14.2 E
2014					10.0 E
2015					5.5 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$0.78 A	-$0.55 A	-$0.59 A	-$0.39 A	-$2.27 A
2013	-$0.38 A	-$0.49 A	-$0.46 A	-$0.40 E	-$1.72 E
2014					-$0.93 E
2015					-$0.99 E

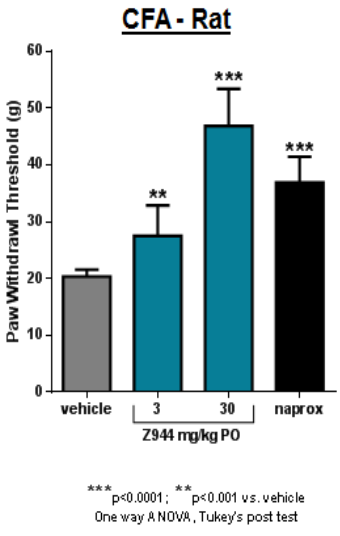
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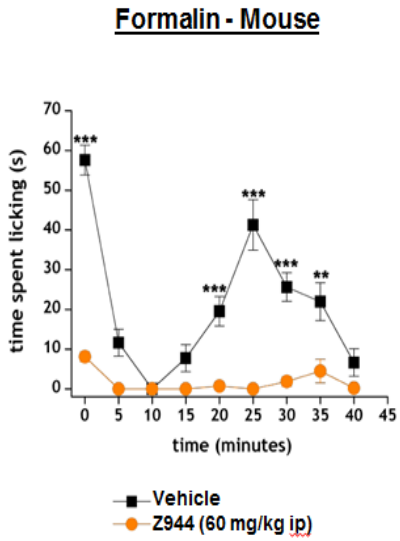
Zalicus (ZLCS)
Meeting took place with Dr. Mark Corrigan, MD, CEO, and Justin Renz, CFO

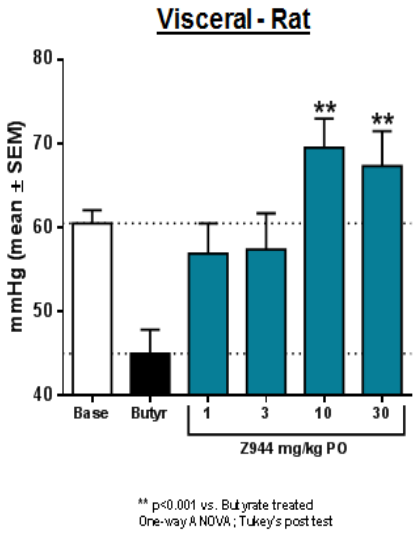
Going into the our meeting with Zalicus management we had one major goal – find out as much as we could about Z944 and why it has a chance to succeed where Z160 failed. Z944 is the company's novel, oral T-type calcium channel (Ca_v 3.1, Ca_v 3.2, and Ca_v 3.3) modulator for chronic, acute, or visceral 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.

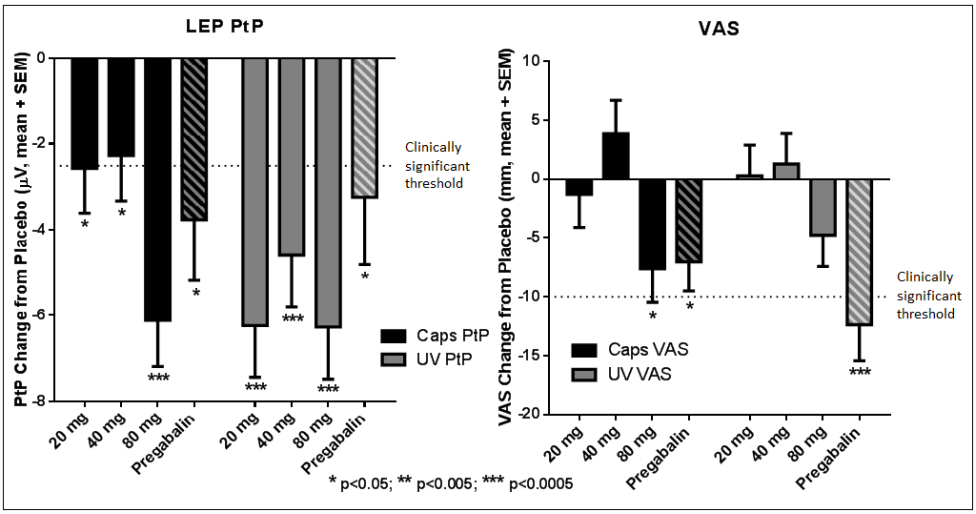






The Phase 1b data has some good nuggets of information. Firstly, Zalicus saw dose proportional pharmacokinetics with similar exposure to preclinical doses where efficacy was achieved. The data show rapid absorption and a pk profile that supports twice daily dosing. The drug was also well tolerated, but 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.

PROJECTED INCOME STATEMENT

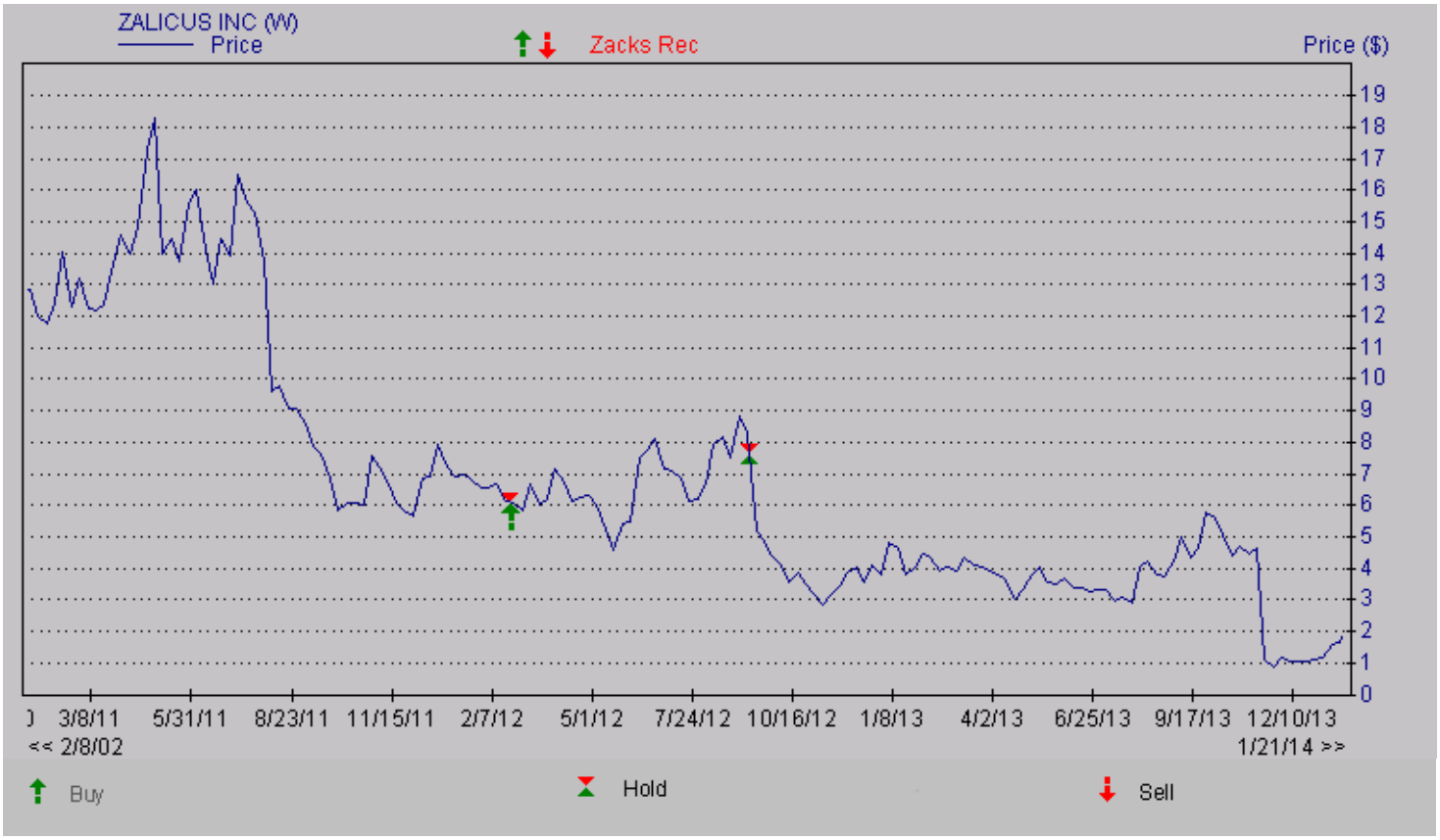
Zalicus, Inc.
Income Statement

Zalicus, Inc.	2011 A	2012 A	Q1 A	Q2 A	Q3 A	Q4 E	2013 E	2014 E	2015 E
Collaborations & Grants	**$5.7**	**$7.4**	**$2.2**	**$2.2**	**$1.9**	**$2.0**	**$8.3**	**$7.5**	**$5.0**
YOY Growth	*-87.3%*	*28.2%*	*83.8%*	*34.1%*	*-10.8%*	*-16.2%*	*13.1%*	*-9.7%*	*-33.3%*
Exalgo Royalty	**$2.5**	**$5.2**	**$1.4**	**$1.7**	**$1.5**	**$1.2**	**$5.9**	**$2.5**	**$0.5**
YOY Growth	*54.2%*	*112.2%*	*30.2%*	*31.8%*	*7.9%*	*-14.3%*	*12.6%*	*-57.3%*	*-80.0%*
Z944	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-					-	-	-
Total Revenues	**$8.2**	**$12.6**	**$3.67**	**$3.89**	**$3.40**	**$3.20**	**$14.2**	**$10.0**	**$5.5**
YOY Growth	*-82.5%*	*53.3%*	*58.4%*	*33.1%*	*#REF!*	*-15.5%*	*12.9%*	*-29.4%*	*-45.0%*
General & Administrative	$10.4	$9.0	$2.0	$2.1	$2.1	$2.0	$8.2	$8.0	$9.0
% SG&A	*127.1%*	*71.5%*	*55.6%*	*52.9%*	*61.1%*	*62.5%*	*57.7%*	*80.0%*	*163.6%*
Research & Development	$35.3	$41.4	$7.1	$9.8	$9.3	$8.0	$34.3	$20.0	$20.0
% R&D	*431.3%*	*330.1%*	*192.7%*	*253.0%*	*274.8%*	*250.0%*	*241.9%*	*200.0%*	*363.6%*
Amort & Restruct	$5.1	$5.0	$2.2	$2.2	$2.2	$2.2	$8.7	$7.5	$6.0
% Other	*62.8%*	*39.7%*	*59.5%*	*56.0%*	*64.1%*	*68.8%*	*61.8%*	*75.0%*	*109.1%*
Operating Income	($42.7)	($42.8)	($7.6)	($10.2)	($10.2)	($9.0)	($37.0)	($25.5)	($29.5)
Operating Margin	-	-	-	-	-	-	-	-	-
Interest & Other Net	($0.8)	($2.0)	($0.4)	($0.4)	($0.3)	($0.3)	($1.4)	($0.2)	($0.2)
Pre-Tax Income	($43.5)	($44.8)	($8.1)	($10.6)	($10.5)	($9.3)	($38.4)	($25.7)	($29.7)
Taxes	($1.2)	($0.4)	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Discontinued Operations	$0.0	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	($42.3)	($44.4)	($8.1)	($10.6)	($10.5)	($9.3)	($38.4)	($25.7)	($29.7)
YOY Growth	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-
Reported EPS	**($2.61)**	**($2.27)**	**($0.38)**	**($0.49)**	**($0.46)**	**($0.40)**	**($1.72)**	**($0.93)**	**($0.99)**
YOY Growth	-	-	-	-	-	-	-	-	-
Weighted Ave. Shares	16.2	19.5	21.2	21.7	22.9	23.5	22.3	27.5	30.0

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

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