Zacks Small-Cap Research

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Zalicus Inc.

(ZLCS-NASDAQ)

ZLCS: Z160 Fails – Company to Discontinue And Focus on Z944…

UPDATE

This morning Zalicus, Inc. announced that Z160 did not meet the primary endpoint in either phase 2a clinical study. The company will discontinue development of Z160 and focus all resources on Z944, the company's phase 2a ready oral, T-type calcium channel blocker for the treatment of pain.

It's been a rough year for Zalicus, dating back to the failure of Synavive in September 2012. As of recently, Sanofi no longer reports prednisporin in its pipeline, and generic manufactures will be allowed to launch a generic version of Exalgo 8, 12, and 16mg on November 15, 2013. The company does hold over $20 million in cash however.

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	09/10/2012
Current Price (11/11/13)	$1.45
Target Price	**$1.50**

SUMMARY DATA

52-Week High	**$7.20**
52-Week Low	**$2.59**
One-Year Return (%)	**62.88**
Beta	**1.79**
Average Daily Volume (sh)	**1,288,497**
Shares Outstanding (mil)	**22**
Market Capitalization ($mil)	**$105**
Short Interest Ratio (days)	**0.47**
Institutional Ownership (%)	**50**
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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WHAT'S NEW

Z160 Fails – Management Will Discontinue

This morning, Zalicus, Inc. (ZLCS) released some very unfortunate news for investors holding the stock. Top-line results from the two Phase 2 clinical studies of Z160 in chronic pain failed to meet the primary endpoint. As a result of the double-failure, management will discontinue development of Z160 and focus all clinical resources on Phase 2 ready, Z944.

As a reminder, Z160 was an oral N-type calcium channel (Cav2.2) blocker that management hoped would offer efficacy on par with drugs like gabapentin and Lyrica (pregabalin), only with significantly less side-effects and greater tolerability. The two Phase 2 studies, one in post-herpetic neuralgia (PHN) and another in lumbosacral radiculopathy (LSR), were designed to show utility in a classical and more visceral manifestation of neuropathic pain, respectively. We noted in the past the enormous potential for a drug like Z160 if successful, but warned investors as recently as two weeks ago that the risks here were high.

Management did not give an explanation for the failure in the press release, only noting that the drug was found to be safe and generally well-tolerated, yet failed to demonstrate a difference in effect from placebo on any endpoint. In our experience, there are several reasons why neuropathic pain drugs fail. The majority of time, unexpectedly high placebo response plays a negative role in making separation of drug and control difficult, or nearly impossible to achieve from a statistical standpoint. Other typical reasons for pain drug failures include unacceptably high side-effects, poor tolerability, or poor bioavailability.

We spoke briefly with Zalicus CEO, Mark H.N. Corrigan, MD, this morning. Dr. Corrigan noted that both trials were well designed and that the placebo response was generally in-line with historical neuropathic pain drugs such as gabapentin or pregabalin. Unexpectedly high placebo response does not seem to be the issue here. We remind investors that the target for Z160 has been validated by ziconotide, marketed by Jazz Pharmaceuticals as Prialt. Privately-held Convergence Pharmaceuticals is going after the same target with CNV2197944. Therefore, we doubt that the target was the issue. The idea behind Z160 vs. Prialt was that Z160 was an oral tablet and Prialt is a direct injection into a patient's spinal cord. This dosing advantage was supposed to be the key differentiator from Prialt, an effective but difficult to use drug.

In fact, the goal of Z160 was to offer efficacy on par with molecules like gabapentin or pregabalin, only with less side-effects. Z160 was designed to be state dependent – meaning it only targeted receptors firing pain signals. This more specific and reversible targeting leads to less side-effects than the irreversible Prialt. Preclinical and clinical data to date with Z160 suggested that this state-dependent mechanism of action alleviates the severe psychiatric and neurological side effects, including akathisia.

The press release notes Z160 was safe and generally well-tolerated. In fact, throughout the drugs history it has always shown to be a highly tolerable drug. Perhaps this was a clue that the efficacy would struggle, because as of yet scientists have struggled to develop a powerful, yet highly tolerable drug for neuropathic pain. Or perhaps Zalicus could never overcome the poor bioavailability issues that dogged Z160 several years ago. We remind investors that Z160 was formerly Merck's MK6721, and that Zalicus spent the last several years reformulating the drug after Merck discontinued development due to poor bioavailability.

What is surprising about the failure of Z160 is how effective the drug was in preclinical animal models. The drug previously demonstrated robust efficacy across a wide range of animal pain models, including the L5/L6 spinal nerve ligation (Chung) model, the chronic constriction injury (Bennett) model, and the Carrageenan model. Zalicus was unable to transition these effective animal model findings into humans. Perhaps because of poor bioavailability, or mode of administration, or dose level, we do not know. What we do know is that moving Z160 into two phase 2 studies totaling 280 patients was a gamble, and for Zalicus management it did not pay off.

Focus Turns To Z944

When we spoke with Zalicus management this morning, we asked them what the failure of Z160 meant for Z944, or at the very least, what the company learned that could help them when moving forward with Z944 into the next stage in development. A bit of caution about moving forward from animal studies into large-scale human trials was

the answer. As noted above, the preclinical data for Z160 was great, but for whatever reason that animal data did not transition to humans. Z944 also has impressive preclinical animal data. Plus, the company just recently completed a Phase 1b study with Z944, and on November 1, 2013 reported positive results.

Z944 has a different mechanism from Z160. Z944 is an oral T-type calcium channel modulator in development for the treatment of acute and chronic pain. The successful 16 patient, single-center Phase 1b study was an experimental clinical model utilizing Laser-Evoked-Potentials (LEP) to provide both objective and subjective assessments of the activity of Z944 in induced pain states. Highlights of the results of the Z944 Phase 1b LEP study results include:

- Statistically significant and meaningful reductions at each of the three doses compared to placebo of overall peak-to-peak amplitude of LEPs in models of both inflammatory ($p \leq 0.0002$) and neuropathic ($p < 0.05$) pain.
- Consistent trends in reduction of subjective pain scores compared to placebo using a visual analog scale in both pain models.
- Meaningful trends in effects based on dose and concentration, providing important insights into the potential therapeutic window and effective plasma concentrations of Z944.
- Z944 was generally well tolerated with dose dependent CNS side effects and no serious adverse events.

Based on these results, Zalicus is planning to advance a modified-release formulation of Z944 into Phase 2 clinical development in an appropriate pain indication in 2014. However, given the failure of Z160, investors may need to temper their expectations on the size of this Phase 2 study. We think management will start much smaller with Z944 and attempt to demonstrate proof-of-concept in a handful of individuals, rather than the two studies and 280 patients attempted with Z160. We think a slower and more cautious development with Z944 is okay. The drug has good intellectual property protection so there is no need to rush.

For example, in addition to the positive Phase 1b data, Zalicus also noted a second United States patent for Z944 (U.S. Patent number 8,569,344) covering methods of treating pain was issued on October 29, 2013, providing additional patent protection for Z944 in the United States until at least 2029. Given that long patent life of the drug, there's no reason to dive head-first into a large-scale Phase 2 program. Ultimately, Zalicus may benefit more from demonstrating proof-of-concept, conserving cash, and then seeking a partner for the drug step in Z944 development.

Third Quarter Financial Results

On November 4, 2013, Zalicus reported financial results for the third quarter 2013. Total revenues in the quarter were $3.4 million. Revenues consisted of $1.9 million in collaborative payments and $1.5 million in royalties on sales of Exalgo at partner Mallinckrodt. Both line items were lighter than expected, although we note reported Exalgo royalties tend to bounce around from quarter to quarter based on net sales at Mallinckrodt and not actual prescriptions.

Beginning on November 15, 2013, third party manufacturers will have the right to sell generic version of 8 mg, 12 mg, and 16 mg dosages of Exalgo. In May 15 2014, this will be expanded to the 32 mg dose. We believe this will have a material negative impact on Zalicus top-line starting in the fourth quarter 2013. Mallinckrodt noted in its third quarter Form 10Q filing that they expect sales of Exalgo to decrease in fiscal 2014. We have slashed our royalty income at Zalicus down to $2.5 million in 2014 and $0.5 million in 2015.

Collaborative revenue was shy of our forecast by $0.3 million. Collaborative payments have been relatively consistent over the past three quarters, coming in $2.2 million for the last four quarter in a row before the slight dip to $1.9 million in the third quarter. Earlier this year, Zalicus announced that the company's combination High Throughput Screening (cHTS) discovery collaboration with Novartis has been extended through October 2014. This is clearly positive news for the company, as it not only validates the platform – Zalicus and Novartis are using the cHTS discovery technology to advance novel treatments of cancer – but it also provides $3 million in sponsored research funding to the company over the next 18 months.

Net loss for the third quarter 2013 was $10.5 million, or $0.46 per share. This was $1.0 million greater than our estimate due to higher R&D expense and slightly lower revenues. We note R&D expense in the third quarter totaled $9.3 million, driven by management desire to accelerated enrollment in the phase 2a PHN study so that it caught up to the phase 2a LSR study – thus facilitating releasing data from both studies at the same time.

Zalicus exited the quarter with $20.0 million in cash, restricted cash, and short-term investments. We estimate burn during the quarter totaled $6 to $7 million. Therefore, it looks like management has been tapping the committed equity financing (CEF) with Lincoln Park Capital during the third quarter. This agreement provides management the right to sell up to $25 million in shares of its common stock at prevailing market prices.

Based on the remaining available CEF with Lincoln Park Capital, we forecast that Zalicus will still have in excess of $20 million in cash on hand at the end of 2013. That's around $0.85 per share. The company does have around $10 million in debt (in the form of a loan with Oxford Finance LLC). At this stage, we think Z944 is worth around $1.00 in value, and with the net cash position around $0.50, we see fair-value at $1.50 per share.

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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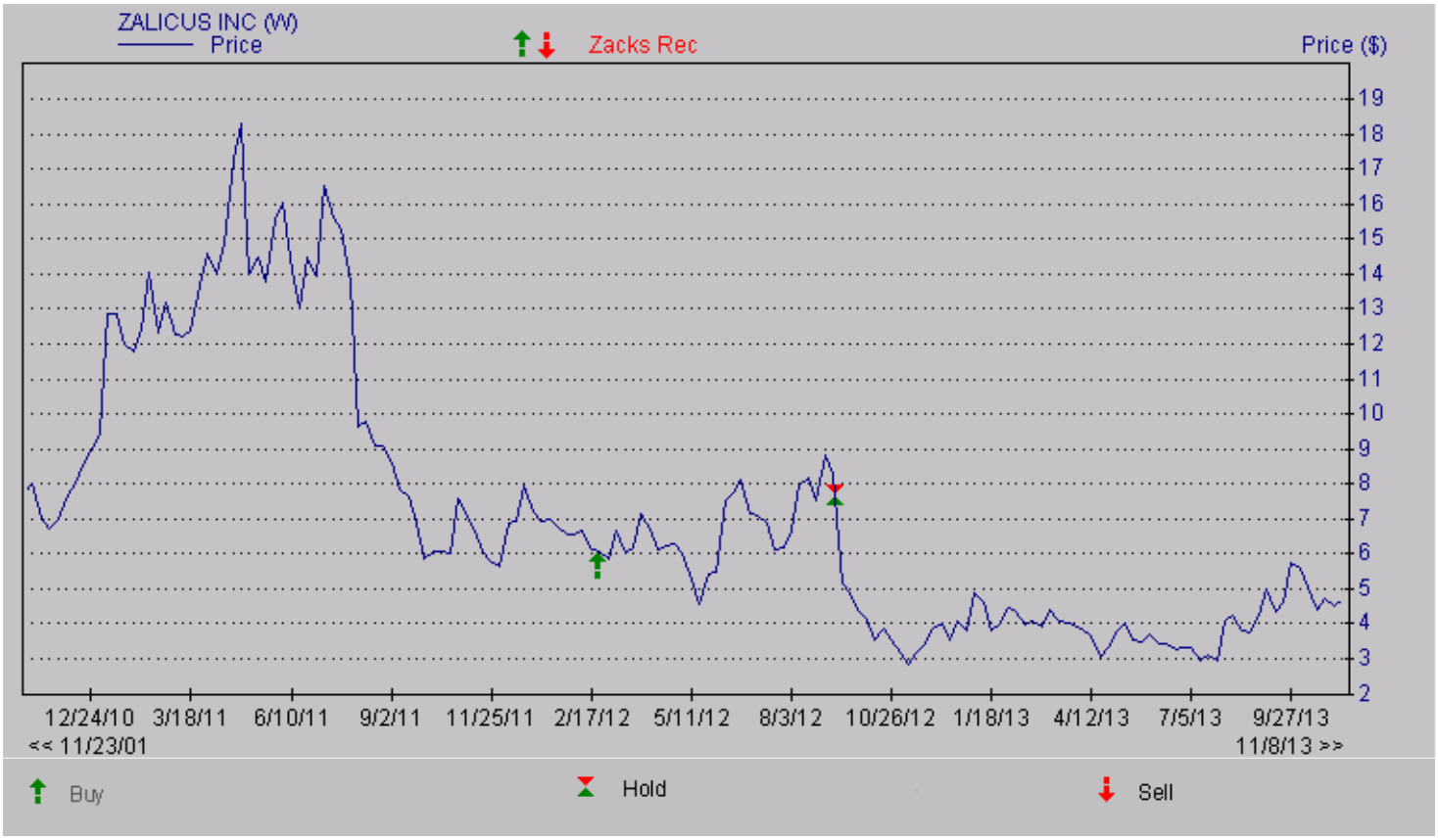

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