Zacks Small-Cap Research

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Zalicus Inc.

(ZLCS-NASDAQ)

ZLCS: Waiting On Z160 Data…

UPDATE

Zalicus Stock is starting to look very interesting at this level. Traders are no doubt are waiting for the big phase 2 data on potential blockbuster drug Z160 coming in the next few weeks. Data on Z160 could be huge for Zalicus. If the company can show efficacy in both PHN and LSR, we believe Z160 could be a $1.5 billion drug. We believe the odds of success in PHN are higher than LSR, and PHN alone, now thanks to a recent orphan drug designation win, still represents a $300 million opportunity. Complete failure of Z160 probably sends the stock to $1.50, supported only by the current cash balance of around $0.85 per share and Z944 progressing into phase 2a studies in 2014. We remain Neutral while we wait for the data.

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	09/10/2012
Current Price (11/04/13)	$4.26
Target Price	**$6.00**

SUMMARY DATA

52-Week High	**$7.20**
52-Week Low	**$2.59**
One-Year Return (%)	**41.12**
Beta	**1.79**
Average Daily Volume (sh)	**1,279,190**
Shares Outstanding (mil)	**22**
Market Capitalization ($mil)	**$102**
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					12.5 E
2015					10.5 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					-$0.84 E
2015					-$0.82 E

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WHAT'S NEW

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 in November 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 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 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. We will have a better sense of the exact burn and cash generated through the Lincoln Park agreement when Zalicus files its Form 10Q next week.

Waiting On Z160 Data

Make no mistake about it; Zalicus has a potential blockbuster on its hands if eagerly awaited data on pain drug Z160 hits in a few weeks. Z160 is an N-type calcium channel (Cav2.2) blocker currently in two Phase 2a studies, one for post-herpetic neuralgia (PHN) and another for lumbosacral radiculopathy (LSR). These trials completed enrollment in early September 2013. Both are of similar design - 140 patients, 6-weeks, looking for signs of reductions in pain on a numeric rating scale, along with safety and tolerability. If we assume the company needs 4-5 weeks to analyze the data after the last patient enrolled, results should be coming by the middle of November.

In August, we wrote an article outlining the history of Z160, formerly Merck's MK6721, and how Zalicus has spent the last several years reformulating the drug. The mechanism of action for Z160 has been validated by ziconotide, marketed by Jazz Pharmaceuticals as Prialt; only Z160 is an oral tablet and Prialt is a direct injection into a patient's spinal cord. Preclinical data(spinal nerve ligation) on Z160 is suggestive of efficacy on par with ziconotide, gabapentin, and morphine. Positive Phase 1 data was released in March 2012.

Management describes their goal with Z160 as, "Lyrica-like efficacy with significantly improved safety and tolerability." Lyrica is a monster drug for Pfizer. The drug did $4.2 billion in sales in 2012. Lyrica's label includes neuropathic pain associated with diabetic peripheral neuropathy, post-herpetic neuralgia, fibromyalgia, and neuropathic pain associated with spinal cord injury. However, meaningful side-effects and tolerability issues include somnolence (13-16%) and dizziness (23-29%). We believe that Lyrica's side-effect profile, which is only modestly better than generic gabapentin, is due to the drug's non-selective binding at the alpha2-delta Type 1 protein.

Management believes Z160, however, is far more selective, and unlike the irreversible binding of ziconotide at Cav2.2, Z160 is state-dependent. This means the drug is designed to only target and modulate those neurons transmitting pain signals. Preclinical and clinical data to date with Z160 suggest that this state-dependent mechanism of action alleviates the severe psychiatric and neurological side effects, including akathsia. Additional data in this regard was presented in May 2013 at the 32nd Annual Meeting of the American Pain Society via a poster entitled, "Z160: A potent and state-dependent, small molecule blocker of N-type calcium channels effective in nonclinical models of neuropathic pain."

What Does This All Mean?

Lycia posted worldwide sales of $4.2 billion in 2012. Gabapentin, marketed by Pfizer as Neurontin until generics arrived in 2004, posted worldwide sales at peak of over $2.7 billion. The reason Zalicus did two Phase 2a studies is to potentially show efficacy in a classic model of neuropathic pain (i.e. PHN) and compression / irritation neuropathic pain (i.e. LSR). We think that's smart, because it makes the molecule highly attractive to larger pharmaceutical partners if both trials succeed. And, Zalicus is doing all the right things to attract big pharma, like gaining patent extensions and orphan drug indications for the compound.

Going 2-for-2 in these Phase 2a studies means the drug can probably capture 25% of the market from Lyrica and generic gabapentin. That pegs peak worldwide sales in the area of $1.5 billion. Under that scenario, we think Zalicus' stock will skyrocket on the news. Specifically, if we peg Z160 sales at $1.5 billion in 10 years (assumes 6 years to approval and then 4 years to peak sales), give the drug a 30% chance at success, apply a conservative 3.0x price-to-sales multiple to that figure, discount back to present day at 15%, and then divide that number by the current fully diluted share count of 24.6 million, we get a stock price of $14.

If only the PHN trial hits, which may not be a big surprise to those familiar with how difficult clinical trials in LSR are, then we peg Z160 peak sales at around $400 million. The figure is so much lower than $1.5 billion (on going 2-for-2) because if we assume if Z160 works in PHN and LSR, then it probably works in diabetic neuropathy and fibromyalgia as well. If LSR fails, the company may conduct additional studies to qualify the efficacy in expanded neuropathic pain indications. Under that scenario, with similar metrics to the above methodology, we believe Zalicus' stock is worth $5. If only the LSR trial hits, management scratches their heads a little with respect to the mechanism for Z160, but in the end moves forward expeditiously because LSR - essentially lower back pain - is a huge market. A label for LSR alone probably gets Z160 sales to $600 million. Under that scenario, the stock is worth $6. Therefore, going 1-for-2 probably nets investors a 25% to 50% return.

If Zalicus goes 0-for-2, we think the stock drops below $2 per share. This would be based on the residual cash on the books of around $0.85 per share and the potential of the acute pain drug Z944 (more on Z944 below). Therefore, if Z160 bombs, you probably lose 65% of your money.

Moving Forward With Z944

On November 1, 2013, Zalicus reported positive results of a phase 1b clinical study with Z944, a novel oral T-type calcium channel modulator in development for the treatment of pain. The 16 patient, single-center phase 1b study is 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. 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.

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.

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.

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**	**$10.0**	**$10.0**
YOY Growth	*-87.3%*	*28.2%*	*83.8%*	*34.1%*	*-10.8%*	*-16.2%*	*13.1%*	*20.3%*	*0.0%*
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%*
Prednisporin Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Z160	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-					-	-	-
Z944	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-					-	-	-
Total Revenues	**$8.2**	**$12.6**	**$3.7**	**$3.9**	**$3.4**	**$3.2**	**$14.2**	**$12.5**	**$10.5**
YOY Growth	*-82.5%*	*53.3%*	*58.4%*	*33.1%*	*-3.4%*	*-15.5%*	*12.9%*	*-11.8%*	*-16.0%*
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%*	*64.0%*	*85.7%*
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%*	*160.0%*	*190.5%*
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%*	*60.0%*	*57.1%*
Operating Income	($42.7)	($42.8)	($7.6)	($10.2)	($10.2)	($9.0)	($37.0)	($23.0)	($24.5)
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)	($23.2)	($24.7)
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)	($23.2)	($24.7)
YOY Growth	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-
Reported EPS	**($2.61)**	**($2.27)**	**($0.38)**	**($0.49)**	**($0.46)**	**($0.40)**	**($1.72)**	**($0.84)**	**($0.82)**
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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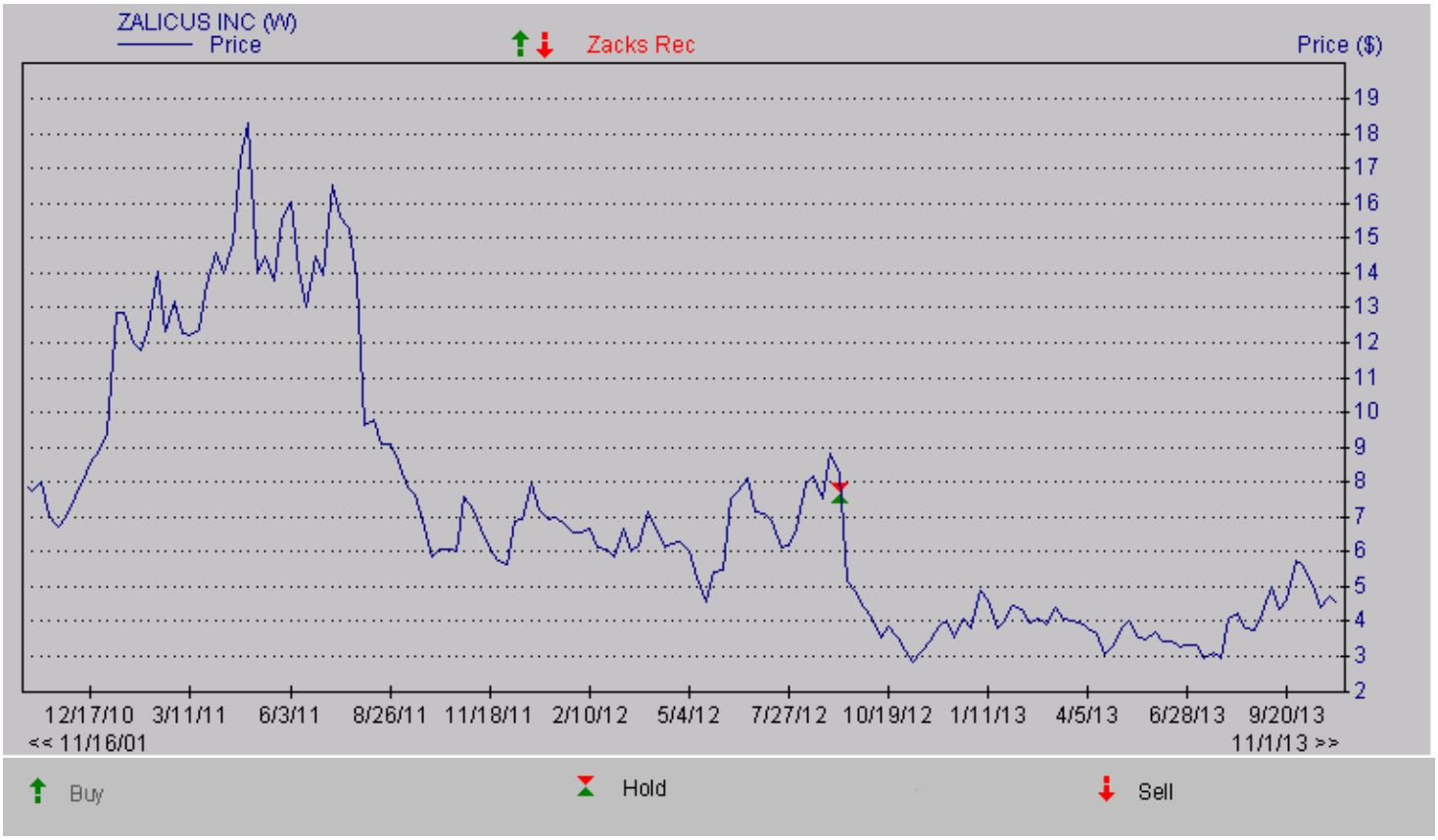

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