Zacks Small-Cap Research

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Zalicus Inc.

(ZLCS-NASDAQ)

ZLCS: Chugging Along Under The Radar, But We're Watching Z160 Like A Hawk…

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 fourth quarter 2013. But now might be the time value biotech investors take a look at the stock. The currently market capitalization is only $75 million. That's less than 5X our projected 2013 revenues of $16.3 million, and 33% of the market capitalization is supported by the cash balance.

With Z160 a potential blockbuster and the top-line supporting the stock at today's price, Zalicus could be poised for a big second half of the year. Our rating is 'Neutral', but we are watching the stock like a hawk.

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	09/10/2012
Current Price (05/02/13)	$0.59
Target Price	**$1.00**

SUMMARY DATA

52-Week High	**$1.48**
52-Week Low	**$0.43**
One-Year Return (%)	**-43.92**
Beta	**2.30**
Average Daily Volume (sh)	**616,252**
Shares Outstanding (mil)	**127**
Market Capitalization ($mil)	**$76**
Short Interest Ratio (days)	**4.14**
Institutional Ownership (%)	**11**
Insider Ownership (%)	**2**
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 E	4.2 E	4.5 E	16.3 E
2014					18.0 E
2015					20.0 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$0.13 A	-$0.09 A	-$0.10 A	-$0.07 A	-$0.38 A
2013	-$0.06 A	-$0.06 E	-$0.07 E	-$0.06 E	-$0.25 E
2014					-$0.13 E
2015					-$0.11 E

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WHAT'S NEW

Financial Results

On May 2, 2013, Zalicus reported financial results for the first quarter 2013. Total revenues in the quarter were $3.7 million. Revenues consisted of $2.2 million in collaborative payments and $1.4 million in royalties on sales of Exalgo at partner Mallinckrodt. Both line items were $0.1 million shy of our modeling. We expect Exalgo sales at Mallinckrodt to slowly tick higher throughout the year (we model $7.0 million in royalties in 2013). Collaborative payments have been relatively consistent over the past three quarters, coming in at $2.1 million, $2.4 million, and $2.2 million for the third quarter 2012, fourth quarter 2012, and first quarter 2013, respectively.

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. For 2013, we model $9.2 million in collaborative payments.

We think the potential for Zalicus to strike additional alliances and collaborations is highly discounted by investors. Here's an interesting way to view Zalicus' valuation – the current market capitalization of $75 million is less than 5X our projected 2013 revenues of $16.3 million, and the company is sitting on $26.2 million in cash and investments.

Net loss for the first quarter 2013 was $8.1 million, or $0.06 per share. This was essentially in-line with our estimate for net loss of $0.06 per share, although we forecasted slightly higher R&D expense and slightly lower amortization expense on Exalgo. As noted above, Zalicus exited the quarter with $26.2 million in cash. We note the first quarter tends to be the highest quarter from a cash burn perspective. The company had a number of final payments on the Z944 phase 1 studies and upfront payments on the Z160 phase 2 studies. We expect operating burn over the next few quarter to average around $6-7 million per quarter. Meaning, we see the company's cash position as sufficient to fund operations into 2014.

The valuation of Zalicus remains attractive in our view. As noted above, the market capitalization of $75 million is less than 5X above our projected 2013 sales figure – a fair multiple for a growing biotech company, and we note that 33% of the market value is supported by the current cash balance of $26.2 million. On a net enterprise value, the market is only assigning $50 million to the company's growing royalty and collaborative revenues, and the company's two phase 2 candidates in Z160 and Z944. We provide a brief update on each candidate below.

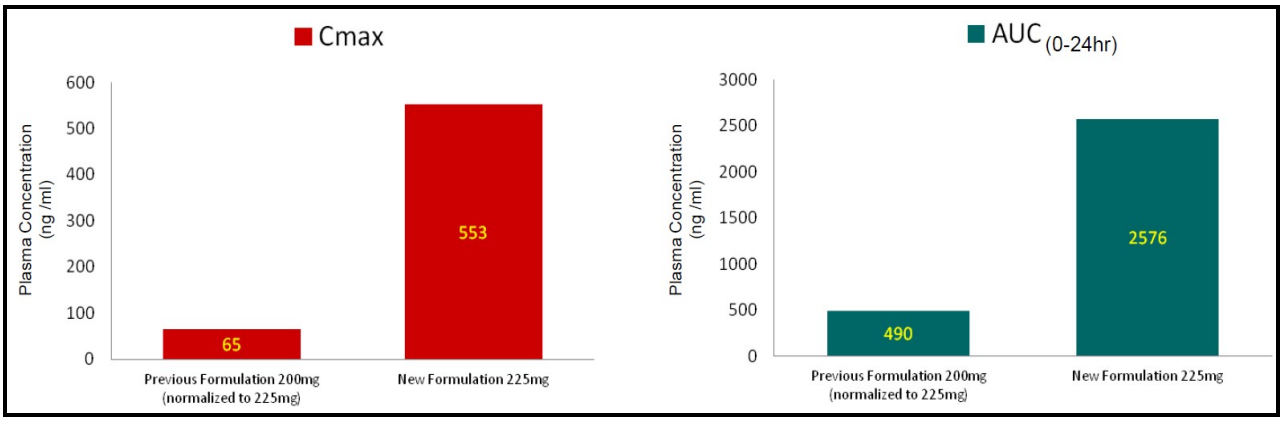
INVESTMENT THESIS

Update On Z160 For Chronic Pain

On March 5, 2012, Zalicus announced it had successfully completed a phase 1 (n=16) pharmacokinetic and safety study with new formulations of Z160 (formerly MK6721), a first in class, oral, state dependent, selective N-type calcium channel (Cav2.2) blocker. Management noted that Z160 has been reformulated to overcome bioavailability and food effect challenges from previous studies. One formulation demonstrated a 6-fold increase in bioavailability based on the PK/PD analysis from the phase 1 program.

We remind investors that Z160 was formerly known as MK6721 through a partnership with Merck and privately-held Neuromed. Neuromed merged with CombinatoRx in December 2009 to form Zalicus. Back in March 2006, Merck licensed the compound (originally named NMED-160) from Neuromed for $25 million upfront and potentially as much as $450 million in milestones and royalties on sales. Unfortunately, Merck returned the rights to NMED-160 back to Neuromed in August 2007 because phase 2 clinical studies, "Did not demonstrate the ideal pharmaceutical characteristics considered necessary to advance the compound further into development." Interestingly enough, Merck did note that no serious adverse events with NMED-160 were observed in clinical trials testing the safety and effectiveness even at doses as high as 1600 mg per day.

Despite Merck walking from the collaboration, scientists at Neuromed knew they had an effective drug if they could improve the formulation. That is exactly what Zalicus spent the past several years doing. Phase 1 data was released in March 2012. The data below shows a greater than 8-fold improvement in CMax and 5-fold improvement in AUC for the new formulation of Z160 vs. the old NMED-160 compound that Merck previously believed was a blockbuster drug.

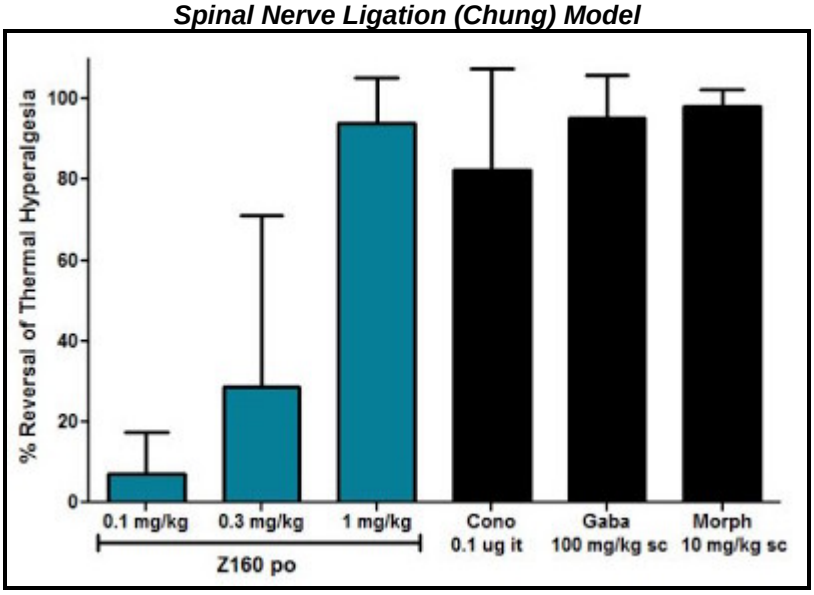


The mechanism of action for Z160 has been validated by ziconotide, marketed by Jazz Pharmaceuticals as Prialt. Prialt has well-documented clinical efficacy. The product is the only non-opioid analgesic (synthetic peptide) approved for the management of severe chronic pain in patients who are intolerant of or refractory to other treatment options. The problem with Prialt is that it must be given through intrathecal injections - or directly into the sub-arachnoid area of the spinal canal so it reaches the cerebrospinal fluid. The Prialt label also includes a boxed warning that severe psychiatric and neurological impairment may occur during treatment with ziconotide intrathecal infusion. Therefore, patients with history of psychosis should not be treated with Prialt. As a result, we estimate that Jazz sold only around $21 million of Prialt in 2012.

The key difference between Z160 and Prialt, is that Z160 is an oral tablet with proposed dosing at around 375 mg BID; that's less than half of the dose that Merck noted was well-tolerated without conveying serious adverse events in previous clinical studies. Prialt is also an irreversible binder of Cav2.2, whereas Z160 is state-dependent - meaning it 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. The drug also seems to lack the somnolence and dizziness associated with calcium channel blocker, gabapentin, which Pfizer turned into a blockbuster with Neurontin. Neurontin sales peaked at over $2.7 billion worldwide in 2004 before the patient expired.

Preclinical data on Z160 is suggestive of efficacy on par with ziconotide, gabapentin, and morphine. The data below is from a spinal serve ligation (Chung) model, one of the most commonly used neuropathic pain models for preclinical testing. Zalicus has confirmed that Z160 exposure in humans exceeds the minimum efficacy levels for this neuropathic pain model.

Spinal Nerve Ligation (Chung) Model



...Patent Validates Reformulation…

On April 2, 2013, Zalicus announced it has been granted a patent by the U.S. Patent and Trademark office (USPTO # 8,409,560) entitled, "Solid Dispersion Formulations and Methods of Use Thereof." The announcement went largely unnoticed by investors; however, we see the patent was a key win for Zalicus and its shareholders. Often we are asked, "If Z160 has such significant potential, then why did Merck walk-away so quickly?"

Merck could not fix the formulation issues that dogged MK6721 (formerly NMED-160) back in 2007. Zalicus spent the last half decade working on it – a commitment Merck was not willing to make. The clinical data above clearly demonstrates that Zalicus fixed the problem. But news that the USPTO has now granted a formulation patent that does not expire until 2032 is proof of a structural change. Z160 may have always had the efficacy that Merck believed it had back when it was called MK6721, but this new patent locks up protection around this new formulation and opens the doors back up to potential partners post phase 2a data later this year.

…Clinical Studies Underway…

In September 2012, Zalicus initiated the first phase 2a study (Clinicaltrials.gov Identifier: NCT01655849) with Z160 in 140 patients with chronic neuropathic pain associated with lumbosacral radiculopathy (LSR). LSR is a common neuropathic pain condition resulting from the compression or irritation of the nerve roots exiting the lumbar region of the spine. Common symptoms include pain radiating from the lower back and down the legs, as well as numbness and tingling in the lower extremities. We expect enrollment will take place at approximately 20-30 centers around the U.S. Patients will be randomized to receive either 375 mg Z160 BID or placebo for six weeks. The primary endpoint of the study is change in weekly mean pain scores on the pain intensity - numeric rating scale (PI-NRS). Secondary endpoints including other pain and functional measures, a responder analysis at 30% and 50% pain reduction in pain scores, and safety will also be reported.

On January 3, 2013, Zalicus initiated the second phase 2a study (Clinicaltrials.gov Identifier: NCT01757873) with Z160 in 140 patients with post-herpetic neuralgia (PHN). The design of the study is similar to the previously initiated program in LSR. The primary endpoint is the change from baseline to week six in the weekly average pain score based on PI-NRS. Clinical trials in PHN are an industry-accepted standard condition for establishing clinical proof-of-concept in neuropathic pain. It is also a potential orphan indication because the prevalence is less than 200,000 patients in the U.S.

Data from the LSR study is expected early in the fourth quarter 2013. Data from the PHN study is expected late in the fourth quarter 2013. These data have the potential to dramatically re-value the company. We see LSR as a significant unmet medical need and an attractive market opportunity. The prevalence of LSR is high, affecting 3-5% of the global population, and to date there are no drug treatments specifically approved to treat the condition. In LSR alone, Z160 could have $500 million or more peak sales potential. Other possible indications for Z160 include post-herpetic neuralgia (PHN), and off-label uses in diabetic peripheral neuropathy (DPN), fibromyalgia, and peripheral nerve pain. PHN is a painful neuropathic condition resulting from an outbreak of the herpes zoster virus, otherwise known as shingles. We see a $250 million opportunity in PHN for Z160. Larger indications such as DPN and fibromyalgia may offer another $250 million or more peak potential.

Therefore, on a conservative basis, we think Z160 is a $500 to $750 million product, with significant upside depending on the efficacy and tolerability Zalicus or a development partner can show in pivotal trials. The peak market opportunity for the drug may be more in-line with what Pfizer was able to do with Neurontin (gabapentin), peaking at $2.7 billion worldwide in 2004, or what they are currently doing with Lyrica (pregablin), a drug most believe is no better than generic gabapentin. Pfizer sold $4.2 billion of Lyrica in 2012.

We suspect that Zalicus will look to partner Z160 in a deal similar to the previous collaboration with Merck following results of the two ongoing phase 2a trials. Management told us partners are already knocking on the door for Z160. We think with two positive Phase 2a trials in hand, Zalicus will be able to secure a very lucrative deal. For the sake of argument, let's assume Z160 is a $1 billion drug, with a 20% chance to make it to the market in 2018. That could be worth $50 million upfront to a big pharmaceutical company in early 2014, along with $250 million in reasonable back-end potential plus a mid-teen to low-twenty percent royalty on sales. With a current market capitalization of only $82 million, we think it is fair to say that this sort of transaction is certainly not priced into the shares today.

Z944 For Acute Pain

On December 19, 2011, Zalicus announced the initiation of a phase 1a single ascending dose clinical trial evaluating the pharmacokinetics and safety of Z944, a novel oral T-type calcium channel blocker with demonstrated preclinical potential for the treatment of acute and inflammatory pain in animal pain models. The phase 1 trial took place in the United Kingdom. In June 2012, management reported that the trial was a success and that a maximum tolerated dose (MTD) has been identified.

In July 2012, Zalicus initiated a phase 1b multiple ascending dose clinical trial looking to better identify the therapeutic window with Z944. Management is keeping the dosing and indication for Z944 quiet for now, as this is a highly competitive area of pharmaceutical research. Through on conversations with management, we get the sense that Zalicus really thinks they have something special with Z944. There are no approved T-Type calcium channel blockers on the market. Z944 represents a potentially new and revolutionary way to treat acute pain.

T-type calcium channels have been recognized as key targets in the therapeutic inhibition of a broad range of cell functions and have been implicated in the frequency and intensity of pain signals. During the first quarter 2012, Zalicus published preclinical data in the journal Science Translational Medicine, describing the activity of Z944 to potently suppress seizures. This data reinforces the potential biologic activity of Z944, as it is generally understood that conditions of neuronal hyper-excitability, such as epilepsy and pain, are mechanistically linked.

In February 2013, Zalicus announced it had been granted a patent by the U.S. Patent and Trademark office (USPTO) covering Z944. United States patent number 8,377,968 entitled "N-Piperidinyl Acetamide Derivatives as Calcium Channel Blockers" provides broad coverage for Z944 including compositions of matter and certain therapeutic methods of use through April 2029. If Z944 is safe and well tolerated in the ongoing phase 1b program, we expect Zalicus to file an IND in the U.S., and advance the molecule into a phase 2a clinical trial in 2013. Following proof-of-concept, we expect the company to look to strike a development and collaboration alliance with a large pharmaceutical company. The patent granted in February 2013 was an excellent step in the right direction for monetizing Z944. Phase 2a data will be the second step. We expect management to provide an update on the plans for Z944 in the next month or two.

Pipeline Undervalued

Between the above two candidates and the preclinical pipeline now being developed at Hydra, we believe Zalicus has the potential to sign ion channel development partnership in 2013 and 2014. There are several ion-channel deals that investors can view as precedent for what we can expect in the future.

- In January 2012, Roche announced a collaboration agreement with privately-held Xenon Pharmaceuticals to discover and develop compounds for the treatment of pain. Under terms of the agreement, Xenon could earn up to $646 million in research, development, and commercialization related milestones plus royalties from Roche. Xenon's most advanced candidate, XEN402, is an oral Nav1.7 inhibitor currently in phase 2 trials.

- In October 2011, Pfizer acquired Icagen, Inc. for $56 million in cash. Prior to the deal, Pfizer had already held an 11% stake in Icagen through a research collaboration originally signed in 2007. Pfizer and Icagen are developing ICA-105665, a novel opener of the KCNQ potassium ion channel which has demonstrated a broad spectrum of activity in preclinical models of both epilepsy and pain. The 2007 deal between Pfizer and Icagen gave Pfizer worldwide rights to commercialize the drug and could have awarded Icagen nearly $360 million in development, regulatory and commercialization milestones. Icagen's pipeline also possessed compounds addressing inflammatory disorders and asthma, as well as a library of about 250,000 small molecules ion channel targets at the time of the Pfizer acquisition.

The two deals above provide a good valuation road-map for Zalicus in 2014 when it seeks to partner or out-licenses its phase 2 candidates. Clearly this is an area that big pharma is interested in, attractive marquee names like Merck, Roche and Pfizer to the table. Although Icagen was taken-out relatively cheap by Pfizer, Pfizer did so to save the potential for backend milestones of $360 million. Merck offered up the potential for $450 million on Z160 and Roche has offered $646 million up to Xenon.

It is clear to us that both Z160 and Z944 could attract sizable upfront payments in the $25 to $40 million range, with backend payments near $500 million in total. We point investors to keep an eye on two smaller companies developing ion channel agents, Tau Therapeutics and Convergence Pharmaceuticals. Deals by these companies could further clarify the market opportunity for Zalicus.

Novartis Collaboration Renewed

In May 2009, Zalicus entered into a strategic alliance and research collaboration with Novartis for the discovery of novel anti-cancer combinations. Under the agreement, each party will contribute compounds and evaluate the anti-cancer effects by utilizing Zalicus' proprietary cHTS platform and Chalice analyzer software to screen a unique library of molecules, including Novartis compounds in multiple cell lines representing a broad spectrum of cancers. Zalicus received an upfront payment of $4 million, plus $3 million per year for two years in research support funding. The company is also eligible to receive up to $58 million in clinical, regulatory and commercial milestones for each combination that is commercialized under the collaboration. In April 2012, Zalicus announced that Novartis has exercised its second option to extend its oncology discovery research collaboration with Zalicus for an additional contract year, through April 2013. On May 2, 2013, management announced the collaboration has been extended again, this time going until October 2014.

PROJECTED INCOME STATEMENT

Zalicus, Inc.
Income Statement

Zalicus, Inc.	2011 A	2012 A	Q1 A	Q2 E	Q3 E	Q4 E	2013 E	2014 E	2015 E
Collaborations & Grants	**$5.7**	**$7.4**	**$2.2**	**$2.3**	**$2.3**	**$2.4**	**$9.2**	**$12.5**	**$15.0**
YOY Growth	*-87.3%*	*28.2%*	*83.8%*	*41.6%*	*8.6%*	*0.5%*	*25.7%*	*35.3%*	*20.0%*
Exalgo Royalty	**$2.5**	**$5.2**	**$1.4**	**$1.6**	**$1.9**	**$2.1**	**$7.0**	**$5.5**	**$5.0**
YOY Growth	*54.2%*	*112.2%*	*30.2%*	*23.1%*	*35.7%*	*50.0%*	*35.2%*	*-21.8%*	*-9.1%*
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**	**$4.2**	**$4.5**	**$16.3**	**$18.0**	**$20.0**
YOY Growth	*-82.5%*	*53.3%*	*58.4%*	*33.4%*	*19.4%*	*18.8%*	*29.7%*	*10.6%*	*11.1%*
General & Administrative	$10.4	$9.0	$2.0	$1.9	$1.9	$1.9	$7.7	$8.0	$9.0
% SG&A	*127.1%*	*71.5%*	*55.6%*	*48.7%*	*45.2%*	*42.2%*	*47.6%*	*44.4%*	*45.0%*
Research & Development	$35.3	$41.4	$7.1	$7.8	$8.5	$7.5	$30.9	$20.0	$20.0
% R&D	*431.3%*	*330.1%*	*192.7%*	*200.0%*	*202.4%*	*166.7%*	*189.7%*	*111.1%*	*100.0%*
Amort & Restruct	$5.1	$5.0	$2.2	$2.2	$2.2	$2.2	$8.8	$7.5	$6.0
% Other	*62.8%*	*39.7%*	*59.5%*	*56.4%*	*52.4%*	*48.9%*	*54.0%*	*41.7%*	*30.0%*
Operating Income	($42.7)	($42.8)	($7.6)	($8.0)	($8.4)	($7.1)	($31.1)	($17.5)	($15.0)
Operating Margin	-	-	-	-	-	-	-	-	-
Interest & Other Net	($0.8)	($2.0)	($0.4)	($0.3)	($0.3)	($0.3)	($1.3)	($0.2)	($0.2)
Pre-Tax Income	($43.5)	($44.8)	($8.1)	($8.3)	($8.7)	($7.4)	($32.5)	($17.7)	($15.2)
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)	($8.3)	($8.7)	($7.4)	($32.5)	($17.7)	($15.2)
YOY Growth	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-
Reported EPS	**($0.43)**	**($0.38)**	**($0.06)**	**($0.06)**	**($0.07)**	**($0.06)**	**($0.25)**	**($0.13)**	**($0.11)**
YOY Growth	-	-	-	-	-	-	-	-	-
Weighted Ave. Shares	97.3	117.3	127.2	129.0	130.0	131.0	129.3	135.0	140.0

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

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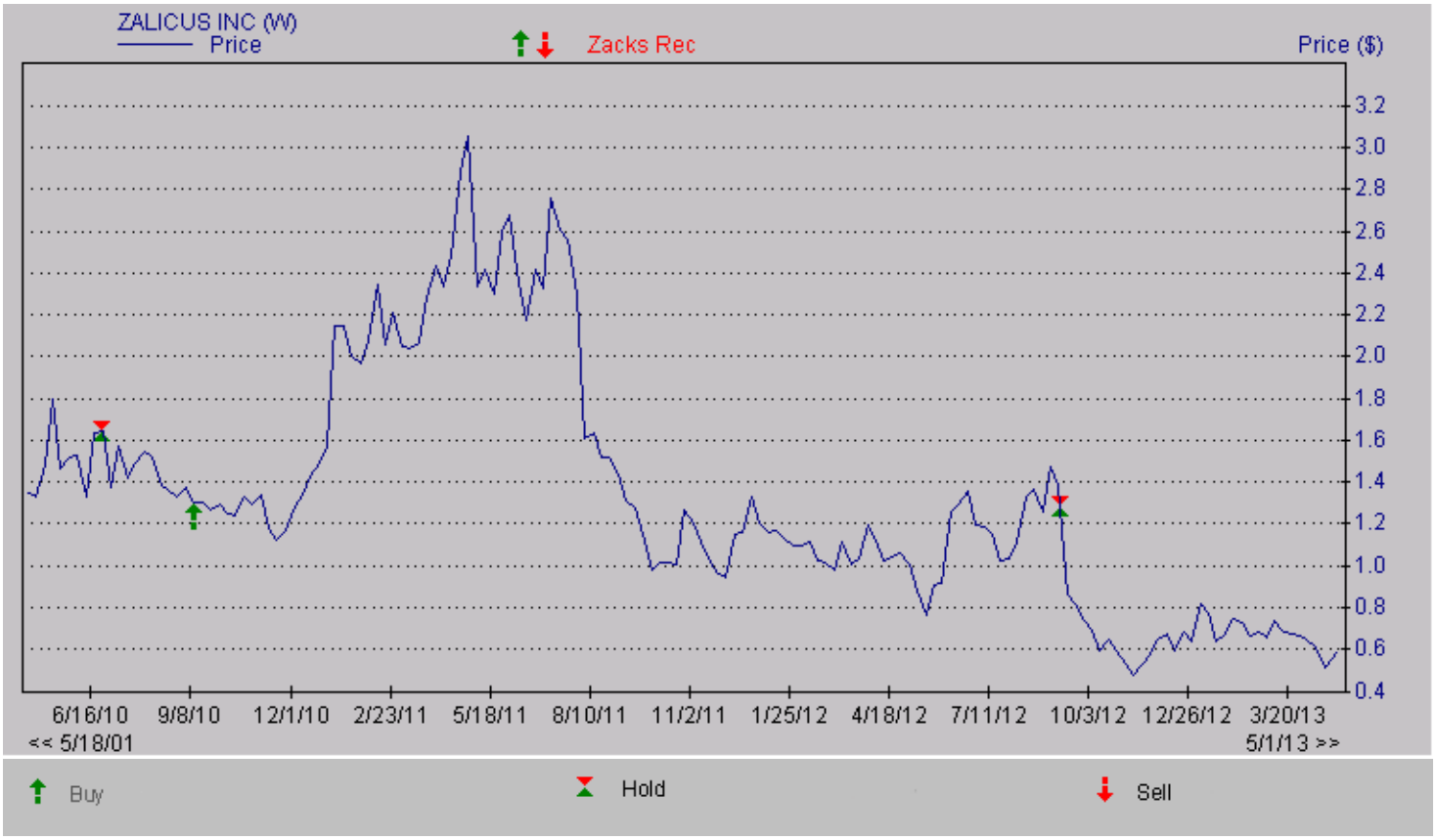

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