Zacks Small-Cap Research

August 7, 2012
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Zalicus Inc.

(ZLCS-NASDAQ)

ZLCS: SYNERGY Data In Q3-2012 Could Be The Catalyst…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	09/13/2010
Current Price (08/07/12)	$1.17
Target Price	**$3.00**

UPDATE

Zalicus has been making significant progress over the past few months in bringing new candidates into the clinic. In December 2011, management initiated phase 1 trials on both Z160, a novel oral N-type calcium channel blocker, and Z944, a novel oral T-type calcium channel blocker. Z160 has successfully completed its trial and Z944 is now in its second phase 1 program. In the meantime, the phase 2b SYNERGY trial continues on plan with data expected around mid-September 2012.

We rate the shares 'Buy' and have a price target of $3 per share.

SUMMARY DATA

52-Week High	**$1.78**
52-Week Low	**$0.76**
One-Year Return (%)	**-19.42**
Beta	**2.19**
Average Daily Volume (sh)	**2,627,505**
Shares Outstanding (mil)	**113**
Market Capitalization ($mil)	**$127**
Short Interest Ratio (days)	**0.46**
Institutional Ownership (%)	**24**
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 2012 Estimate	**N/A**
P/E using 2013 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)
2011	1.3 A	1.8 A	2.4 A	2.6 A	8.2 A
2012	2.3 A	2.9 A	3.1 E	3.1 E	11.4 E
2013					18.0 E
2014					11.1 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.12 A	-$0.11 A	-$0.09 A	-$0.11 A	-$0.43 A
2012	-$0.13 A	-$0.09 A	-$0.09 E	-$0.08 E	-$0.37 E
2013					-$0.25 E
2014					-$0.25 E

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WHAT'S NEW

Financial Results

On August 7, 2012, Zalicus reported financial results for the second quarter 2012. Total revenues in the quarter were $2.9 million. Revenues consisted of $1.6 million in collaborative payments and $1.3 million in royalties on sales of Exalgo at partner Covidien. Both line-items exceeded our expectations. Exalgo royalties were up 12% from the first quarter 2012; and at $1.3 million were just above our forecast at $1.2 million. However, the nice surprise in the top-line was the collaborative payments totaling $1.6 million, nicely above our estimate of $1.4 million. We think management is making a strong push to bring in new collaborative revenues on the combination high throughput screening (cHTS) platform. We are expecting the ramp to continue in the second half of 2012 for both Exalgo royalties and collaborative payments.

Net loss for the second quarter 2012 was $10.4 million, or $0.09 per share. This was slightly better than our estimate for net loss of $0.11 per share on the higher revenues noted above. Net loss was driven by $2.3 million in SG&A, $9.9 million R&D, and $1.0 million in amortization and restructuring. We are expecting R&D costs to be consistent in the third quarter with the first half of the year, as Zalicus is still conducting the phase 2b SYNERGY trial, recently initiated a phase 1b multiple ascending dose study with Z944, and plans to start a phase 2a program with Z160 before the end of the quarter. SG&A declined in the quarter thanks to management closing down operations at the Vancouver facility in February 2012.

Zalicus exited the second quarter ended June 30, 2012 with $44.1 million in cash, investments, and restricted cash. On August 2, 2012, Zalicus filed an 8K noted it had completed its planned equity distribution agreement with Wedbush Securities, issuing a total of 13,091,957 shares to raise net proceeds of $14.7 million. The "ATM" went effective back in June 2012. This was the second such ATM of the year for Zalicus. Back in March 2012, Zalicus completed an equity distribution agreement with Wedbush first enacted in January 2012. Under that plan, Zalicus sold a total of 14.058 million shares into the public market to raise net proceeds of $14.6 million. We find the current cash balance to be sufficient to fund operations into the middle of 2013.

INVESTMENT THESIS

We are expecting Zalicus to offer-up a steady flow of news over the next several months, with the key event being the release of top-line data from the phase 2b SYNERGY trial expected in the third quarter 2012.

Top-Line Data From Phase 2b SYNERGY Expected Mid-September 2012

In June 2011, Zalicus announced it had initiated a phase 2b clinical trial evaluating Synavive for the treatment of rheumatoid arthritis (RA). The trial, SYNERGY (SYNavivE for Reducing signs and sYmptoms of rheumatoid arthritis trial), is a 12-week, 5-arm, double-blind, placebo-controlled study to evaluate the safety and efficacy of Synavive as a treatment for the signs and symptoms of rheumatoid arthritis (RA) in approximately 259 subjects with moderate to severe disease (ClinicalTrials.gov identifier: NCT01369745).

On April 30, 2012, the company announced enrollment has been completed and top-line data is expected around mid-September 2012. Full data should be available later in 2012, perhaps as a late-breaker session of the American College of Rheumatology (ACR) meeting in November 2012. If timelines hold, management should be able to sit down with the FDA for a post-phase 2 meeting early 2013.

…About SYNERGY…

The trial was conducted in up to 60 centers throughout the U.S., Europe, and Latin America. Enrollment should be evenly split between the three regions. The primary endpoint is efficacy measured by the Disease Activity Score in 28 Joints (DAS28). DAS28 is a common, patient specific, outcome tool used in therapeutic trials to assess disease improvement or response.

Key secondary objectives include evaluating the efficacy of Synavive compared to its individual components (2.7mg of prednisolone and 360mg of dipyramidamole) as well as how Synavive performs in comparison to 5mg of prednisolone. We expect the typical patient will have moderate-to-severe RA, over the age of 60, currently on stable doses of methotrexate (MTX) but not yet progressed to biologics. We expect management to report ACR-20 scores as part of the secondary analysis when they release top-line results in mid-September. Full data in November 2012 may also include ACR-50 and ACR-70 scores.

Subjects who complete the core SYNERGY trial (or at least 6 weeks on drug) will be eligible to participate in a one-year extension study designed to investigate the long-term safety and durability of response for Synavive. Key safety and tolerability issues will be weight gain and glucose levels, along with cataract formations or changes in visual acuity. Besides demonstrating efficacy on par with the 5mg prednisolone cohort, we believe it is paramount that Synavive demonstrate meaningful improvements in overall tolerability vs. 5mg prednisolone and 360mg dipyridamole (immediate release).

DAS28	placebo	dipyridamole (360mg)	prednisolone (2.7mg)	Synavive (2.7/360mg)	prednisolone (5mg)
Baseline					
Change at Week-12					
p-value					
	NEGATIVE CONTROLS		*TEST SUBJECTS*		

Ion Channel Pipeline Rolling Forward

Beyond Synavive, Zalicus is developing an attractive suite of ion channel candidates for both acute and chronic pain. These include T-type and N-type calcium channel blockers and Nav1.7 sodium channel blockers. In early February 2012, Zalicus and Hydra Biosciences, Inc., a leader in the discovery and development of novel ion channels, announced that they have entered into a collaboration to advance development of Zalicus' preclinical ion channel modulator product candidates for the treatment of pain. We like the deal from a cost-savings and development standpoint.

This collaboration brings together the Zalicus portfolio of novel, preclinical ion channel product candidates, representing multiple calcium and sodium channel modulators, with Hydra's expertise in ion channel discovery and preclinical drug development. The goal of the collaboration is to advance ion channel drug candidates into clinical development for the treatment of acute and chronic pain. The collaboration does not include Z160 or Z944, already in human clinical trials.

Under the terms of the agreement, Zalicus paid Hydra an upfront payment (undisclosed) and will fund research and development activities at Hydra for a two-year period. Hydra will perform the preclinical development activities necessary and Zalicus will retain all intellectual property and commercial rights to its product candidates. In connection with the collaboration agreement, Zalicus also announced it closed its Vancouver, British Columbia-based ion channel discovery research operations, resulting in a workforce reduction of 16 employees (approximately 28% of the workforce).

We note that Zalicus recorded a $1.1 million restructuring charge in the first quarter 2012 financials. However, the costs savings from closing down Vancouver, the old Neuromed headquarters, should be in the area of $3 to $4 million for 2012 alone. Reductions in overhead were evident in the second quarter financials. The upfront payment to Hydra was undisclosed, but we are modeling the deal to be cash neutral in 2012. In 2013, Zalicus will continue to fund preclinical activities at Hydra, but the costs will be more variable as opposed to fixed costs associated with owning the Vancouver facility. If Zalicus is having success, they will spend more. If things aren't going so well they can pull back. We think this was a wise move for management.

…Z160 Nearing Phase 2…

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 novel oral N-type calcium channel blocker (Cav2.2). 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 Merck paid Neuromed $25 million upfront to license MK6721 (then called NMED160) back when the molecules was still in preclinical testing. The agreement between Merck and Neuromed called for an additional $450 million in potential development and commercialization milestones and royalties on sales. Unfortunately, the poor bioavailability of NMED160 resulted in Merck walking-away from the collaboration following a disappointing phase 1 trial in August 2007. Zalicus has since reformulated Z160 to where the bioavailability is now attractive. Management has reported a six-fold increase in bioavailability from the NMED160 candidate.

Zalicus should be in position to commence a phase 2a trial in neuropathic pain during the third quarter of 2012. We remind investors that preclinical data suggests Z160 is effective across multiple models of inflammation and neuropathic pain. Management plans to conduct the initial proof-of-concept study in lumbosacral radiculopathy (LSR). LSR is a type of lower-back pain caused by nerve irritation due to damage to the discs between the vertebrae. LSR represents an attractive proof-of-concept program for Zalicus because the trial can be conducted relatively quickly and at a reasonable cost.

Other possible indications for Z160 include post-herpetic neuralgia (PHN), diabetic peripheral neuropathy (DPN), fibromyalgia, and peripheral nerve pain, but we suspect that Zalicus will leave those larger indications for a potential development and commercialization partner. The plan is to prove concept in LSR, and then seek a partner for the next wave of clinical studies. The new formulations being developed by Zalicus should improve patent protection. If concept is demonstrated, we believe the company will sign a deal with big pharma partner in 2013.

…Z944 Moving Forward…

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, 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.

If Z944 is safe and well tolerated in the ongoing phase 1b program, we expect Zalicus to quickly file an IND in the U.S., and advance the molecule into a phase 2a clinical trial in early 2013. Following proof-of-concept, we expect the company to look to strike a development and collaboration alliance with a large pharmaceutical company.

…Out-Licensing To Come…

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. We find it interesting that 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 clinical trials. This could provide a good valuation road-map for Zalicus in 2013 when it seeks to partner or out-licenses its phase 2 candidates.

Prednisporin Still Alive At Sanofi

Sanofi continues its formulation scale-up work on Prednisporin. We remind investors that Sanofi initiated a phase 2b clinical program testing Prednisporin in subjects with persistent allergic conjunctivitis in June 2010. This trial has completed in December 2010, but Sanofi has not shared the results. However, the fact that Sanofi has moved into scale-up for a commercial formulation is a clear sign that the data was positive. We are expecting Sanofi to conduct a bridging study with this new formulation later this year, and then move into a phase 3 program sometime during late 2012 or early 2013.

Zalicus is eligible for $3 million milestone payment from Sanofi when the phase 3 trial initiates. If commercialized, Zalicus is eligible to receive milestone payments of up to approximately $65 million and tiered royalty payments of up to 12% on the development and commercialization of certain products generated from the Zalicus platform. The milestone $65 million schedule includes: $25 million in development and regulatory milestones, $25 million in sales-related milestones, and $15 million in additional indication approval milestones. We note prednisporin may have potential for the treatment of dry eyes as well.

Exalgo Royalties Chugging Along

Exalgo royalties during the first quarter 2012 totaled $1.1 million, up 33% sequentially from the fourth quarter 2011. Exalgo royalties during the second quarter 2012 totaled $1.3 million, up 12% sequentially from the first quarter 2012. Neither of those are big sexy numbers, Exalgo does provide pure cash to Zalicus bottom-line. Upside comes when Covidien can gain approval for the 32mg dose tablet.

Covidien has been very tight lipped about the status of the 32mg dose tablet with Exalgo – perhaps trying to keep generic companies in the dark. As noted in our previous reports, the 32mg dose of Exalgo will make the product more competitive with Endo's Opana-ER. We note that gaining approval of a 32mg dose for Exalgo will also extend the intellectual property protection for Covidien, as Watson has not challenged the 32mg dose (as of yet).

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.

Much like the company's preclinical ion channel platform, we think that Zalicus' preclinical discovery in oncology is vastly under-valued by investors. The company has been active in publishing papers over the past few months, aiming to increase investor attention and awareness of the oncology discovery platform.

- ✓ Published preclinical data in the journal Molecular Cancer Therapeutics, in which Zalicus researchers, in collaboration with the Jerome Lipper Multiple Myeloma Center, Dana-Farber Cancer Institute, Harvard Medical School, have discovered that adenosine A2A and beta-2 adrenergic receptor agonists are highly synergistic and selective novel agents that enhance glucocorticoid activity in B-cell malignancies such as multiple myeloma and, importantly, can synergize in combination with current multiple myeloma treatment regimens such as melphalan, lenalidomide, bortezomib and doxorubicin.

- ✓ Published an editorial in a special Targeted Oncology issue of the journal Future Medicinal Chemistry in which Dr. Lee discusses the promise and progress to date of the biopharmaceutical industry to adopt a systematic, high-throughput approach to identify selective and synergistic cancer combination therapies to provide meaningful clinical benefit to cancer patients.

- ✓ Presented on the systematic discovery of novel cancer combination targets and therapeutics at the 3rd annual Cancer Targets and Therapeutics conference in Las Vegas, February 27-28, 2012.

RECOMMENDATION

We are maintaining our Buy rating, and $3.00 price target on shares of Zalicus. The biggest driver of the stock in 2012 will be the results of the SYNERGY trial in mid-September 2012. Besides this however, we see several potential catalysts that could drive the shares higher:

- ✓ Initiating a phase 2a program with Z160 in the third quarter 2012.
- ✓ Reporting phase 2b data on SYNERGY during the third quarter 2012.
- ✓ Reporting phase 1b results with Z944 in the fourth quarter 2012.
- ✓ Initiating a phase 2a program with Z944 in the first quarter 2013.
- ✓ Forming additional cHTS or ion channel collaborations during the second half of 2012.
- ✓ Sanofi initiating a phase 3 trial on Prednisporin late 2012 / early 2013.
- ✓ Covidien receiving approval for the 32mg Exalgo (anytime).
- ✓ Partnering Synavive for phase 3 trials in 2013.
- ✓ Partnering Z160 for phase 2b trials in 2013.
- ✓ Partnering Z944 for phase 2b trials in 2013.
- ✓ Moving additional ion channel candidates into the clinic in 2013.

PROJECTED INCOME STATEMENT

Zalicus, Inc.
Income Statement

Zalicus, Inc.	2010 A	2011 A	Q1 A	Q2 A	Q3 E	Q4 E	2012 E	2013 E	2014 E	2015 E
Collaborations & Grants	**$45.2**	**$5.7**	**$1.2**	**$1.6**	**$1.7**	**$1.7**	**$6.2**	**$7.5**	**$10.0**	**$15.0**
YOY Growth	*161.4%*	*-87.3%*	*32.5%*	*20.5%*	*4.4%*	*-7.5%*	*8.9%*	*20.1%*	*33.3%*	*50.0%*
Exalgo Royalty	**$1.6**	**$2.5**	**$1.1**	**$1.3**	**$1.4**	**$1.4**	**$5.2**	**$10.5**	**$1.1**	**$0.8**
YOY Growth	-	*54.2%*	*214.3%*	*160.0%*	*75.0%*	*75.0%*	*112.2%*	*101.9%*	*-89.7%*	*-24.3%*
Synavive	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Prednisporin	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-					-	-	-	-
Z160	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-					-	-	-	-
Z944	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-					-	-	-	-
Total Revenues	**$46.7**	**$8.2**	**$2.3**	**$2.9**	**$3.1**	**$3.1**	**$11.4**	**$18.0**	**$11.1**	**$15.8**
YOY Growth	*170.6%*	*-82.5%*	*82.5%*	*58.2%*	*27.7%*	*17.6%*	*39.8%*	*57.3%*	*-38.4%*	*42.8%*
General & Administrative	$12.1	$10.4	$2.7	$2.3	$2.4	$2.5	$9.9	$10.5	$11.0	$12.0
% SG&A	*25.9%*	*127.1%*	*114.8%*	*78.9%*	*77.4%*	*80.6%*	*86.3%*	*58.3%*	*99.3%*	*75.9%*
Research & Development	$23.0	$35.3	$10.6	$9.9	$10.5	$9.0	$39.9	$35.0	$30.0	$30.0
% R&D	*49.2%*	*431.3%*	*456.1%*	*337.2%*	*338.7%*	*290.3%*	*349.0%*	*194.4%*	*270.7%*	*189.6%*
Amort & Restruct	$18.7	$5.1	$2.1	$1.0	$1.0	$1.0	$5.1	$4.5	$4.0	$4.0
% Other	*40.1%*	*62.8%*	*89.4%*	*34.2%*	*32.3%*	*32.3%*	*44.3%*	*25.0%*	*36.1%*	*25.3%*
Operating Income	($7.1)	($42.7)	($13.0)	($10.2)	($10.8)	($9.4)	($43.4)	($32.0)	($33.9)	($30.2)
Operating Margin	-	-	-	-	-	-	-	-	-	-
Interest & Other Net	($29.2)	($0.8)	($0.5)	($0.6)	($0.2)	($0.2)	($0.2)	($0.2)	($0.2)	($0.2)
Pre-Tax Income	($36.3)	($43.5)	($13.5)	($10.8)	($11.0)	($9.6)	($43.6)	($32.2)	($34.1)	($30.4)
Taxes	($1.2)	($1.2)	$0	($0.4)	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Discontinued Operations	$0	$0.0	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	($35.0)	($42.3)	($13.5)	($10.4)	($11.0)	($9.6)	($43.6)	($32.2)	($34.1)	($30.4)
YOY Growth	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-
Reported EPS	**($0.42)**	**($0.43)**	**($0.13)**	**($0.09)**	**($0.09)**	**($0.08)**	**($0.37)**	**($0.25)**	**($0.25)**	**($0.22)**
YOY Growth	-	-	-		-	-	-	-	-	-
Weighted Ave. Shares	82.6	97.3	103.8	113.7	126.7	127.0	117.8	130.0	135.0	140.0

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

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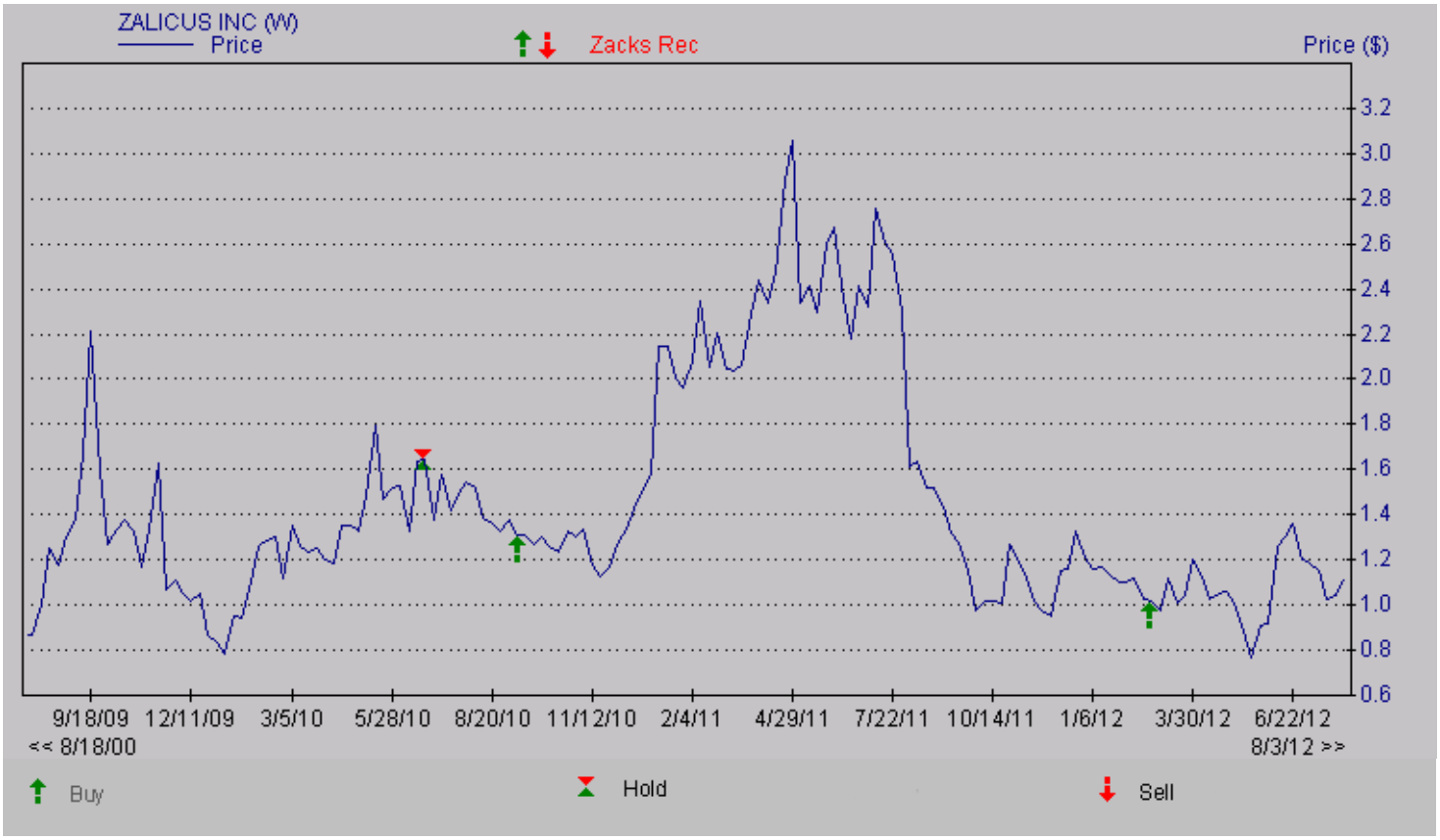

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