Zacks Small-Cap Research

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Zalicus Inc.

(ZLCS-NASDAQ)

ZLCS: Pipeline Expanding With Ion Channel Candidates…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	09/13/2010
Current Price (01/12/12)	$1.21
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. We're expecting that if these phase 1 programs go according to plan, both candidates will be in phase 2a by the end of the year. In the meantime, the phase 2b SYNERGY trial continues on plan with data expected this summer.

We rate the shares 'Outperform' and have adjusted our price target to $3 per share to account for the planned increased shares outstanding and debt.

SUMMARY DATA

52-Week High	**$3.19**
52-Week Low	**$0.84**
One-Year Return (%)	**-38.12**
Beta	**2.15**
Average Daily Volume (sh)	**845,406**
Shares Outstanding (mil)	**99**
Market Capitalization ($mil)	**$124**
Short Interest Ratio (days)	**5.70**
Institutional Ownership (%)	**33**
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 2011 Estimate	**N/A**
P/E using 2012 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)
2010	41.3 A	2.9 A	1.2 A	1.3 A	46.7 A
2011	1.3 A	1.8 A	2.4 A	2.5 E	8.0 E
2012	2.7 E	3.1 E	3.6 E	4.7 E	14.1 E
2013					27.8 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.05 A	-$0.10 A	-$0.13 A	-$0.13 A	-$0.42 A
2011	-$0.12 A	-$0.11 A	-$0.09 A	-$0.11 E	-$0.44 E
2012	-$0.12 E	-$0.11 E	-$0.08 E	-$0.08 E	-$0.39 E
2013					-$0.21 E

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WHAT'S NEW

Two Ion Channel Programs Enter The Clinic

On December 5, 2011, Zalicus announced the initiation of a phase 1 clinical trial evaluating the pharmacokinetic and safety of new formulations of Z160 (formerly NMED-160), a novel oral N-type calcium channel blocker. The new formulations of Z160 are designed to address previous solubility and bioavailability issues that stalled the candidate despite promising early-stage data in over 200 subjects to date. Zalicus plans to conduct this phase 1 trial in approximately 16 patients, and then select the best formulation candidate to move quickly into a phase 2a trial during the second half of 2012. The profile of Z160 should provide for utility in patient suffering from chronic pain such as with PHN, DPN, or fibromyalgia.

On December 19, 2011, Zalicus announced the initiation of a phase 1 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. Based on what we have seen with previous phase 2a programs in pain / inflammation, this study can move rather quickly (at low cost), which would put Zalicus in position to seek out-licensing partners for Z944 in 2013.

We note that management has several additional preclinical ion channel candidates following behind Z160 and Z944. These include other T-type and N-type calcium channel blockers and Nav1.7 sodium channel blockers. Between the above two candidates and the preclinical pipeline, we believe Zalicus has the potential to sign either one broad-scale Ion Channel development partnership in 2012, or separate smaller deals. It really comes down to each products differentiation and how much of a commitment a larger organization is seeking to make in ion channel. We find it interesting that on January 10, 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.

Phase 2b SYNERGY Continues Enrollment

In June 2011, Zalicus announced it has 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 250 subjects with moderate to severe disease. The trial will be conducted in up to 50-60 centers throughout the U.S., Europe, and Latin America. We expect enrollment to be evenly split between the three regions. We estimate the program will take approximately 10 months to complete (looking for enrollment to complete in March 2012), thus we are expecting top-line data in the middle of 2012 (best guess is July 2012). Full data should be available later in 2012. If timelines hold, management should be able to sit down with the FDA for a post-phase 2 meeting late 2012.

The primary objective of the trial is to evaluate Synavive efficacy compared to placebo. The primary endpoint will be 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.

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*		

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 the second half of 2012.

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.

32mg Exalgo Filing Soon

We have learned that Covidien plans to file for approval of a 32mg dose tablet with Exalgo by the end of the second quarter 2012. 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).

In December 2011, Covidien announced it would spin-out its pharmaceutical division to shareholders. We think this is good news for Zalicus, as the new stand-alone pharmaceutical company will be seeking to expand its top-line and provide growth through new products. We think driving Exalgo growth with a 32mg tablet will be key to this goal for the new pharma division once independent.

Cash Position & New ATM

On December 16, 2011, Zalicus borrowed an additional $8.5 million under Term-C of its existing loan agreement with Oxford Finance Corporation. As a result, we believe cash on hand at the end of 2011 is just shy of $50 million. On January 10, 2012, Zalicus entered into an equity distribution agreement with Wedbush Securities whereby Wedbush may make available up to $15 million in value of common stock. We expect that management will seek to use this At-The-Market (ATM) financing over the next several months to maintain a healthy cash position ahead of the phase 2b SYNERGY results and plan for the phase 2a programs on Z160 and Z944.

RECOMMENDATION

We are maintaining our Outperform rating and $3 price target on shares of Zalicus. The biggest drive of the stock in 2012 will be the results of the SYNERGY trial this summer.

PROJECTED INCOME STATEMENT

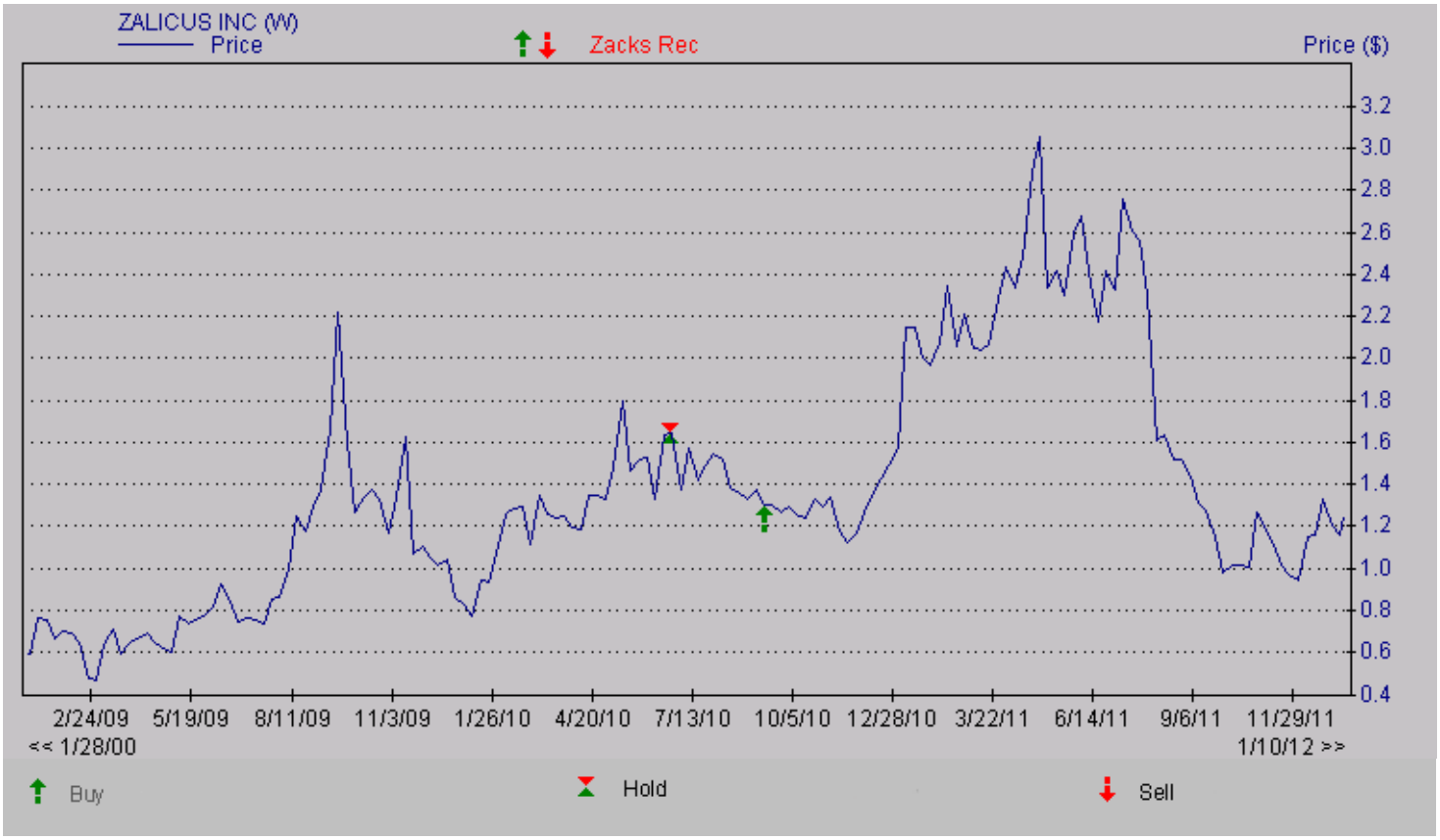
Zalicus, Inc.
Income Statement

	2010 A	Q1 A	Q2 A	Q3 A	Q4 E	2011 E	2012 E	2013 E	2014 E
Collaborations & Grants	**$45.2**	**$0.9**	**$1.3**	**$1.6**	**$1.5**	**$5.4**	**$6.5**	**$15.0**	**$20.0**
YOY Growth	*161.4%*	*-97.8%*	*-26.7%*	*52.7%*	*63.6%*	*-88.0%*	*20.4%*	*130.8%*	*33.3%*
Exalgo Royalty	**$1.6**	**$0.4**	**$0.5**	**$0.8**	**$1.0**	**$2.7**	**$7.6**	**$12.8**	**$16.5**
YOY Growth	-	-	-	-	-	*66.8%*	*186.8%*	*68.4%*	*28.9%*
Synavive (CRx-102)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	**$46.7**	**$1.3**	**$1.8**	**$2.4**	**$2.5**	**$8.0**	**$14.1**	**$27.8**	**$36.5**
YOY Growth	*170.6%*	*-96.9%*	*-36.9%*	*108.2%*	*89.8%*	*-82.8%*	*75.2%*	*97.2%*	*31.3%*
General & Administrative	$12.1	$2.7	$2.7	$2.6	$2.7	$10.7	$10.9	$12.0	$12.5
% SG&A	*25.9%*	*215.9%*	*147.3%*	*105.6%*	*108.0%*	*133.3%*	*77.3%*	*43.2%*	*34.2%*
Research & Development	$23.0	$7.8	$9.0	$8.9	$9.5	$35.2	$37.5	$30.0	$25.0
% R&D	*49.2%*	*615.0%*	*486.5%*	*365.4%*	*380.0%*	*437.2%*	*266.0%*	*107.9%*	*68.5%*
Amort & Restruct	$18.7	$1.3	$1.3	$1.3	$1.3	$5.2	$6.2	$8.5	$4.5
% Other	*40.1%*	*101.1%*	*69.5%*	*52.9%*	*52.0%*	*64.1%*	*44.0%*	*30.6%*	*12.3%*
Operating Income	($7.1)	($10.6)	($11.2)	($10.3)	($11.0)	($43.0)	($40.5)	($22.7)	($5.5)
Operating Margin	-	*-832.0%*	-	-	-	-	-	-	-
Interest & Other Net	($29.2)	($0.1)	($0.2)	($0.2)	($0.2)	($0.7)	($0.2)	($0.2)	($0.2)
Pre-Tax Income	($36.3)	($10.7)	($11.3)	($10.5)	($11.2)	($43.7)	($40.7)	($22.9)	($5.7)
Taxes	($1.2)	$0.0	$0	($1.2)	$0	($1.2)	$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
Net Income	($35.0)	($10.7)	($11.3)	($9.3)	($11.2)	($42.5)	($40.7)	($22.9)	($5.7)
YOY Growth	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-
Reported EPS	**($0.42)**	**($0.12)**	**($0.11)**	**($0.09)**	**($0.11)**	**($0.44)**	**($0.39)**	**($0.21)**	**($0.05)**
YOY Growth	-	-	-	-	-	-	-	-	-
Weighted Ave. Shares	82.6	92.0	98.9	99.2	99.5	97.4	105.0	110.0	115.0

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

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