Zacks Small-Cap Research

March 7, 2012
Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

scr.zacks.com
111 North Canal Street, Chicago, IL 60606

Zalicus Inc.

(ZLCS-NASDAQ)

ZLCS: Pipeline Rolling Forward, But All Eyes Are On Synavive Top-Line Data Expected In The Q3-12…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	09/13/2010
Current Price (03/07/12)	$1.01
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 we are expecting news on Z944 shortly. In the meantime, the phase 2b SYNERGY trial continues on plan with data expected in the third quarter 2012.

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

SUMMARY DATA

52-Week High	**$3.19**
52-Week Low	**$0.84**
One-Year Return (%)	**-52.58**
Beta	**2.08**
Average Daily Volume (sh)	**768,601**
Shares Outstanding (mil)	**99**
Market Capitalization ($mil)	**$100**
Short Interest Ratio (days)	**3.14**
Institutional Ownership (%)	**28**
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 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	2.7 E	3.0 E	3.2 E	3.6 E	12.5 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 E	-$0.10 E	-$0.11 E	-$0.12 E	-$0.45 E
2013					-$0.28 E
2014					-$0.29 E

© Copyright 2012, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Financial Results

On March 7, 2012, Zalicus reported financial results for the fourth quarter and full year ended December 31, 2011. Total revenues in the fourth quarter were $2.6 million, in-line with our estimate for revenues of $2.5 million. Revenues consisted of $1.8 million in collaborative payments and $0.8 million in royalties on sales of Exalgo at partner Covidien. For the full year 2011, revenues were $8.2 million, consisting of $5.7 million in collaborative payments and $2.5 million in royalties on Exalgo.

Net loss for the fourth quarter 2011 was $11.0 million, or $0.11 per share. This was in-line with our estimate for net loss of $0.11 per share. For the full year 2011, net loss totaled $42.3 million, or $0.43 per share. Net loss was driven by $10.4 million in SG&A and $35.3 million R&D. Zalicus exited 2011 with $49.7 million in cash, investments, and restricted cash. We find this to be sufficient to fund operations into early 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 Q3-2012

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 April 2012), thus we are expecting top-line data in the third quarter 2012 (August 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 early 2013.

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.

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 pain.

Under the terms of the agreement, Zalicus will pay Hydra an upfront payment (undisclosed) and 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 will discontinue its Vancouver, British Columbia-based ion channel discovery research operations, resulting in a workforce reduction of 16 employees (approximately 28% of the workforce).

We expect Zalicus to record a one-time restructuring charge of $1.1 million in the first quarter 2012. 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. 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. We note that Zalicus has provided written notice of termination of the sublease agreement to the facility in Vancouver. Additionally, Dr. Christopher Gallen, Zalicus' Executive Vice President, Research and Development, resigned effective March 1, 2012, as part of the announcement.

…Z160 Successfully Completes Phase 1…

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 NMED-160), a novel oral N-type calcium channel blocker. Management noted that Z160 has been reformulated to overcome bioavailability and food effect challenges from previous studies. One formulation demonstrated substantially improved bioavailability based on the PK/PD analysis.

Additional formulation studies continue, but we expect that Zalicus should be in position to commence a phase 2 trial in neuropathic pain during the second half of 2012. We remind investors that preclinical data suggests Z160 is effective across multiple models of inflammation and neuropathic pain. We believe the new formulations being developed by Zalicus may also improve patent protection. With position phase 2 data in neuropathic pain, we believe Z160 will be an attractive in-licensing candidate for a larger specialty pharmaceutical company. The profile of Z160 should provide for utility in patient suffering from chronic pain such as with PHN, DPN, or fibromyalgia.

…Z944 To Complete Phase 1 Soon…

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. We are expecting results from the trial to be announced in the second quarter 2012. This is a maximum-tolerated-dose (MTD) program, so conceivably, the longer it runs the better. Based on 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.

…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 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 sometime in the first half of 2012. Covidien has been tight-lipped on the status of Exalgo – perhaps it has been filed already. 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. Cash on hand at the end of 2011 was 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 $3.00 price target on shares of Zalicus. The biggest driver of the stock in 2012 will be the results of the SYNERGY trial in the third quarter 2012.

PROJECTED INCOME STATEMENT

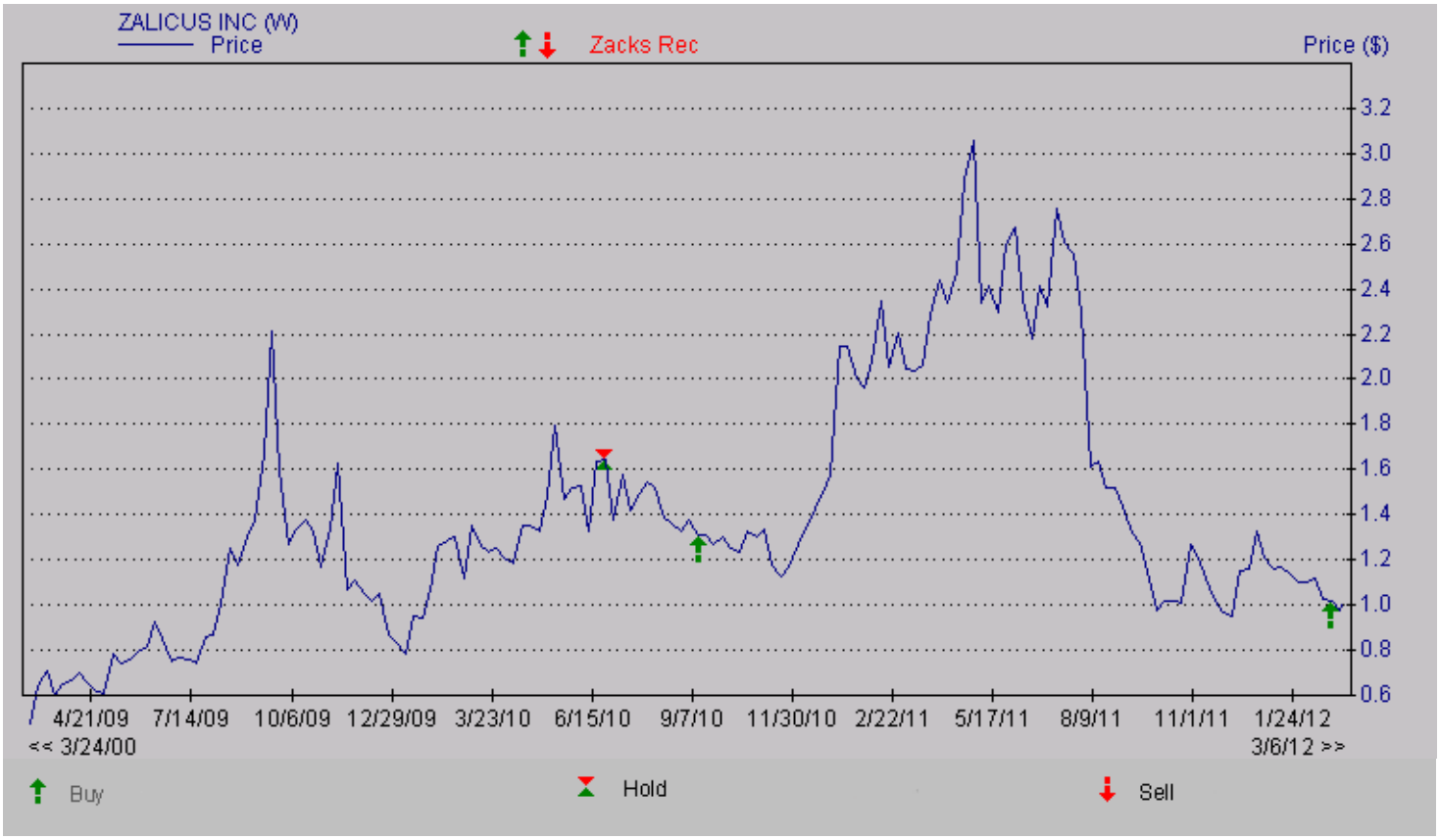
Zalicus, Inc.
Income Statement

Zalicus, Inc.	2010 A	2011 A	Q1 E	Q2 E	Q3 E	Q4 E	2012 E	2013 E	2014 E	2015 E
Collaborations & Grants	**$45.2**	**$5.7**	**$1.8**	**$1.8**	**$1.8**	**$1.8**	**$7.2**	**$7.5**	**$10.0**	**$15.0**
YOY Growth	*161.4%*	*-87.3%*	*95.4%*	*33.5%*	*10.6%*	*-2.0%*	*25.6%*	*4.2%*	*33.3%*	*50.0%*
Exalgo Royalty	**$1.6**	**$2.5**	**$0.9**	**$1.2**	**$1.4**	**$1.8**	**$5.3**	**$10.5**	**$1.1**	**$0.8**
YOY Growth	-	*54.2%*	*157.1%*	*140.0%*	*75.0%*	*125.0%*	*116.3%*	*98.1%*	*-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**	**$2.7**	**$3.0**	**$3.2**	**$3.6**	**$12.5**	**$18.0**	**$11.1**	**$15.8**
YOY Growth	*170.6%*	*-82.5%*	*112.4%*	*62.3%*	*31.8%*	*36.5%*	*52.7%*	*44.0%*	*-38.4%*	*42.8%*
General & Administrative	$12.1	$10.4	$2.4	$2.1	$2.2	$2.3	$9.0	$9.5	$10.0	$11.0
% SG&A	*25.9%*	*127.1%*	*88.9%*	*70.0%*	*68.8%*	*63.9%*	*72.0%*	*52.8%*	*90.2%*	*69.5%*
Research & Development	$23.0	$35.3	$10.5	$10.0	$11.5	$12.5	$44.5	$35.0	$30.0	$30.0
% R&D	*49.2%*	*431.3%*	*388.9%*	*333.3%*	*359.4%*	*347.2%*	*356.0%*	*194.4%*	*270.7%*	*189.6%*
Amort & Restruct	$18.7	$5.1	$2.4	$1.3	$1.2	$1.2	$6.1	$4.5	$4.0	$4.0
% Other	*40.1%*	*62.8%*	*88.9%*	*43.3%*	*37.5%*	*33.3%*	*48.8%*	*25.0%*	*36.1%*	*25.3%*
Operating Income	($7.1)	($42.7)	($12.6)	($10.4)	($11.7)	($12.4)	($47.1)	($31.0)	($32.9)	($29.2)
Operating Margin	-	-	-	-	-	-	-	-	-	-
Interest & Other Net	($29.2)	($0.8)	($0.2)	($0.2)	($0.2)	($0.2)	($0.2)	($0.2)	($0.2)	($0.2)
Pre-Tax Income	($36.3)	($43.5)	($12.8)	($10.6)	($11.9)	($12.6)	($47.3)	($31.2)	($33.1)	($29.4)
Taxes	($1.2)	($1.2)	$0	$0	$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)	($12.8)	($10.6)	($11.9)	($12.6)	($47.3)	($31.2)	($33.1)	($29.4)
YOY Growth	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-
Reported EPS	**($0.42)**	**($0.43)**	**($0.13)**	**($0.10)**	**($0.11)**	**($0.12)**	**($0.45)**	**($0.28)**	**($0.29)**	**($0.26)**
YOY Growth	-	-					-	-	-	-
Weighted Ave. Shares	82.6	97.3	102.0	104.0	106.0	108.0	105.0	110.0	115.0	115.0

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

© Copyright 2012, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



DISCLOSURES

The following disclosures relate to relationships between Zacks Investment Research ("ZIR") and Zacks Small-Cap Research ("Zacks SCR") and the issuers covered by the Zacks SCR analysts in the Small-Cap Universe.

ZIR or Zacks SCR Analysts do not hold or trade securities in the issuers which they cover. Each analyst has full discretion on the rating and price target based on their own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for non-investment banking services. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or blog.

ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Zacks SCR has never received compensation for investment banking services on the small-cap universe. Zacks SCR does not expect received compensation for investment banking services on the small-cap universe. Zacks SCR has received compensation for non-investment banking services on the small-cap universe, and expects to receive additional compensation for non-investment banking services on the small-cap universe, paid by issuers of securities covered by Zacks SCR. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, investment research, and investment management.

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Because of individual objectives, the report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change. Reports are not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned. Zacks SCR uses the following rating system for the securities it covers. Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters. Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters. Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution of Zacks Ratings is as follows on the 1025 companies covered: Buy/Outperform- 16.8%, Hold/Neutral- 76.4%, Sell/Underperform – 6.0%. Data is as of midnight on the business day immediately prior to this publication.

© Copyright 2012, Zacks Investment Research. All Rights Reserved.