Zacks Small-Cap Research

November 2, 2011
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Zalicus Inc.

(ZLCS-NASDAQ)

ZLCS: SYNERGY Trial Underway, Expecting Z160 and Z944 To Enter The Clinic Before Year End…

UPDATE

We use a Sum-Of-Parts valuation methodology to determine fair-value for Zalicus. Out work shows the company is under-valued at the current stock price. We see a market capitalization of $350 million, or $3.50 per share, as more fairly valuing the company's core assets, which include royalties from Exalgo, phase 2b candidate Synavive, and a growing early-stage pipeline through in-house and external research collaborations. We see upside to this figure based on positive developments or updates on prednisporin at Sanofi, Exalgo, or the ion channel partnering efforts.

We rate the shares 'Outperform'.

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	09/13/2010
Current Price (11/02/11)	$1.33
Target Price	**$3.50**

SUMMARY DATA

52-Week High	**$3.19**
52-Week Low	**$0.84**
One-Year Return (%)	**-4.62**
Beta	**2.14**
Average Daily Volume (sh)	**1,169,320**
Shares Outstanding (mil)	**99**
Market Capitalization ($mil)	**$123**
Short Interest Ratio (days)	**4.90**
Institutional Ownership (%)	**34**
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					17.7 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					-$0.27 E
2013					-$0.13 E

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WHAT'S NEW

Recent Financials

On November 2, 2011, Zalicus reported financial results for the third quarter 2011. Total revenues in the quarter were $2.4 million, of which $0.8 million was royalties on sales of Exalgo at Covidien. This was slightly ahead of our expectations for royalties of $0.7 million. Covidien continues to say that Exalgo is on track for peak sales of around $250 million. Reported sales are still being impacted by multiple rebate programs associated with inventory and to create demand for the product. We note that Zalicus receives its royalty on net Exalgo sales at Covidien after these rebate and co-pay assistance programs are recorded. Revenues also consisted of $1.6 million in collaborations, government contracts, and grants. During the third quarter 2011, this included payments from Novartis, Amgen and Eisai, and a grant from the U.S. Army Medical Research Institute for Infectious Diseases.

Operating expenses in the third quarter totaled $12.7 million. Enrollment in the phase 2b SYNERGY trial continues on plan. This trial initiated in June 2011 and will seek to enroll 250 patients at 60 centers around the U.S., Europe, and South America. We expect R&D to tick up in the fourth quarter if management can initiate phase 1 trials on Z160 and/or Z944. SG&A costs remain in check. Net loss reported for the quarter was $9.3 million, or $0.09 per diluted share. This was slightly better than our expectations for a loss of $0.11 per share on lower royalties from Covidien and higher R&D costs.

…Cash Position Solid…

Zalicus exited the third quarter ended September 30, 2011 with $49.0 million in cash and investments. We view this to be sufficient cash to fund operations well into 2013. We expect that management will continue to look to generate non-dilutive cash in the next few quarters through signing additional collaborations for its combination high throughput screening (cHTS) platform, as well as seek early-stage development partnerships for clinical and pre-clinical ion channel candidates.

Upcoming Catalysts

Event	Timeline
Initiate Phase 2b (SYNERGY) trial with Synavive in RA	June 2011
Initiate Phase 1 on Z160	*Q4-2011*
Initiate Phase 1 on Z944	*Q4-2011*
Sign one collaboration agreement around cHTS	*Q4-2011*
Sign one collaboration agreement around ion channel	*Q4-2011*
Sanofi Moves Prednisporin into Phase 3	*2012*

INVESTMENT OVERVIEW

Phase 2b SYNERGY Initiated

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*		

…Previous Data Supports Optimism…

We are optimistic on the outcome of the trial based on results from the previous phase 2 (n=59) studies with Synavive in RA. As a reminder, in November 2006, management presented positive data from a phase 2a program studying Synavive in patients with RA. The trial compared Synavive plus a disease-modifying antirheumatic drug (DMARD) to placebo plus DMARD (control) in subjects with RA over a 6-week treatment period. The primary endpoint was reduction in C-reactive protein (CRP) levels comparing drug plus DMARD to placebo plus DMARD from baseline at day 42. Secondary endpoints of the trial included ACR-20 responses and DAS-28 scores.

	Synavive	Placebo	p-value
Primary Endpoint – CRP Level	-50%	-19%	p=0.024
Secondary Endpoint – ACR-20 Response	63%	30%	p=0.025
Secondary Endpoint – DAS-28 Level	-1.6	-0.7	p=0.016

During the trial, Synavive was generally well-tolerated with no serious adverse events (SAE). The most common side effect was headache, with gastro-intestinal symptoms and dizziness also reported. These are all common side effects of the dipyridamole.

We note that Zalicus has also conducted a phase 2b study testing Synavive in patients with knee osteoarthritis (OA). COMET was a large-scale study in 279 patients with knee OA, with a standard flare design where subjects with active disease needed to demonstrate an increase in knee pain as determined by the WOMAC question #1 (related to pain while walking on a flat surface) upon withdrawal of their NSAID/COXIB therapy to be eligible. Subjects were dosed for a total of 14 weeks (98 days) including an initial two-week dipyridamole titration phase. The data shows a dose-related improvement in baseline change, however, the results were not significant for any cohort tested. We believe this was due to the high discontinuation rate (32%), mainly the result of adverse events and subject requests. In follow-up analysis, management identified a number of protocol violators, including use of restricted or prohibited medications during the trial. It is important to note, over half of the protocol violators were in the placebo or prednisolone alone cohort. This dramatically impacted the statistical analysis when compared to the studied doses of Synavive.

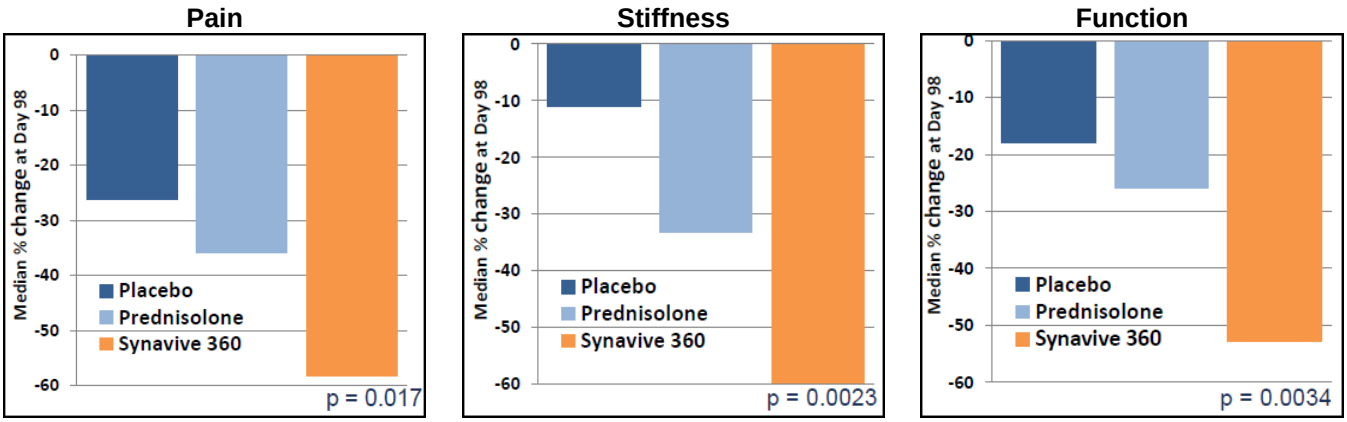
Management conducted a modified ITT analysis using the last observation carried forward for these non-compliant patients. Under the mITT analysis, the highest dose of Synavive (2.7/360mg) did demonstrate clinically meaningful benefits in WOMAC Pain, Stiffness, Physical Function, and Hand Pain VAS. The data also showed an improved dose response curve for the low and middle-dose Synavive cohorts.

Change in Baseline…	placebo	prednisolone (2.7mg)	Synavive (2.7/360mg)
…WOMAC Pain	-19.1mm	-31.0mm	-37.2mm
…WOMAC Stiffness	-15.5mm	-29.5mm	-35.0mm
…Physical Function	-13.2mm	-21.8mm	-30.4mm
…Hand Pain VAS	-18.0mm	-17.5mm	-34.0mm

The high dose of Synavive (2.7/360mg) demonstrated an 18.1mm improvement over placebo and a 6.2mm improvement over prednisolone alone on the primary WOMAN Pain endpoint.

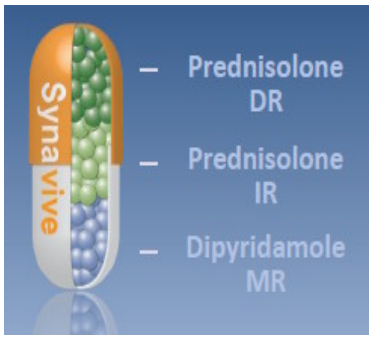
…WOMAC Pain (%)	~ 28%	~ 50%	**~ 57%**
			p=0.030

Subjects who completed the 14-week core study were eligible to participate in a 12-month, open-label extension study designed to investigate the long-term safety and durability of response for Synavive. This data was presented in October 2009 at the American College of Rheumatology (ACR) 2009 annual meeting. The data demonstrated that Synavive subjects maintained efficacy levels throughout the 12 month extension trial. These findings further support the mITT data that demonstrated efficacy for the highest dose of Synavive. In addition, subjects on placebo were able to cross-over to Synavive for the 12 month extension study. These patients also experienced statistically significant improvements in all WOMAC measurement subscales upon crossing over.



Importantly, no treatment-related increase in glucocorticoid associated adverse events was observed in any Synavive treated subjects. This includes no worsening of vision, adrenal glucose, infection rate, hypotension, hyperglycemia, or osteoporosis (as measured by bone mineral density).

…New Formulation Should Reduce Discontinuations…



COMET failed due to the high discontinuation rate of 32%. A significant number of patients in the trial reported headaches. This is most likely the result of the dipyridamole component, which has been known to cause significant headache due to its vasodilating properties. Management has re-formulated the dipyridamole in Synavive from an immediate release to a modified release. The new formulation of Synavive provides time-release co-exposure to both prednisolone and dipyridamole. It also offers a significantly improved tolerability and side-effect profile, as demonstrated in a small (n=24) patient study in which 0% of the subjects experienced headache vs. 41% for conventional dipyridamole. The modified release formulation also allows for a once daily dosing format. We note this new formulation is what Zalicus is studying in SYNERGY discussed above.

…A Big Opportunity…

Rheumatoid Arthritis (RA) is among the most common degenerative joint diseases and a frequent cause of physical disability among older adults. In the U.S. more than 100 million people suffer from RA and OA, combined. The disease affects the hands, lower back, neck, and weight-bearing joints such as the knees, hips, and feet. Symptoms range from stiffness and intermittent mild pain to severe joint pain and impaired biomechanical function.

Over the past year, management has been conducting a series of interviews with key opinion leaders, practicing rheumatologists, primary care doctors and managed care personnel to fully explore the potential for Synavive in RA. Based on their feedback, management believes that RA is attractive on a number of fronts, including current medical practice in which there is already a high prevalence of glucocorticoid use in RA to combat inflammation and restore function, as well as the unmet need for less expensive, easier to access options to biologic therapy.

The SYNERGY trial is set up to demonstrate that Synavive superiority to placebo and the individual components, and offer non-inferiority to the higher dose of 5mg prednisolone. The ultimate goal of Synavive would be to replicate a 5mg dose of prednisolone, albeit without the side-effects commonly associated with high doses of corticosteroids. This would allow RA patients to take Synavive daily as a maintenance therapy to prevent flare-ups.

The current treatment paradigm is for patients to manage pain by using non-steroidal anti-inflammatory drugs (NSAIDS) and Cox-II inhibitors, local analgesics, opioids, oral steroids, disease modifying antirheumatic drugs, intra-articular corticosteroid injection and surgery. The withdrawal of two high-profile Cox-II drugs, Merck's Vioxx and Pfizer's Bextra, has created a significant void the prescription NSAID market. These two drugs were annualizing at sales over $6 billion worldwide before they were pulled from the market for cardiovascular safety concerns. As such, the market has dramatically shifted toward over-the-counter (OTC) NSAIDs such as naproxen and ibuprofen to management pain.

Rheumatologists typically start patients with RA out on steroids or disease modifying anti-rheumatic drugs (DMARDs) such as cyclosporine and methotrexate (MTX). Rheumatologists do not like to prescribe high doses of prednisolone as a maintenance therapy to control flare-ups due to the potential for serious side-effects such as high blood sugar, dyslipidemia, weight gain, insomnia, and weakening immune system. Failure of these pain and steroid medications leads to the use of stronger DMARDs such as TNF-alpha molecules and biologics. These drugs carry potential serious metabolic, gastrointestinal, renal, and liver risks. The biologics are also injectable drugs, offering less convenience than a once-daily oral medication. Accordingly, a safer alternative such as Synavive could be a blockbuster product in the hands of a major pharmaceutical company.

The treatment paradigm for osteoarthritis (OA) plays out in a similar fashion. In the U.S. more than 100 million people suffer from RA and OA combined. We encourage investors to view our research report from November 2010 that discusses the previous phase 2 data with Synavive in the phase 2a RA program and the phase 2b COMET-1 OA program. Beyond RA and OA, we believe Synavive has potential in other steroid-responsive diseases such as polymyalgia rheumatica (PMR), lupus (SLE) and ulcerative colitis (Crohn's).

In the hands of a capable marketing and promotion partner, we see Synavive as a $300+ million drug in the U.S., with another $200-300 million peak potential outside the U.S. We expect that Zalicus will look to partner for phase 3 in 2013-2014.

…IP Position Solid…

In April 2011, Zalicus announced that it has been granted a composition-of-matter patent by the U.S. Patent and Trademark office covering Synavive. U.S. patent number 7,915,265 entitled "Combinations for the Treatment of Immunoinflammatory Disorders" provides broad coverage for Synavive through August 2025. This key patent, along with the existing issued method-of-use patent (US patent 7,253,155), fortifies the Synavive patent estate, which includes several patents and patent applications, granted and pending worldwide which collectively provide coverage of Synavive through 2028.

Prednisporin

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 in 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.

Ion Channel Programs

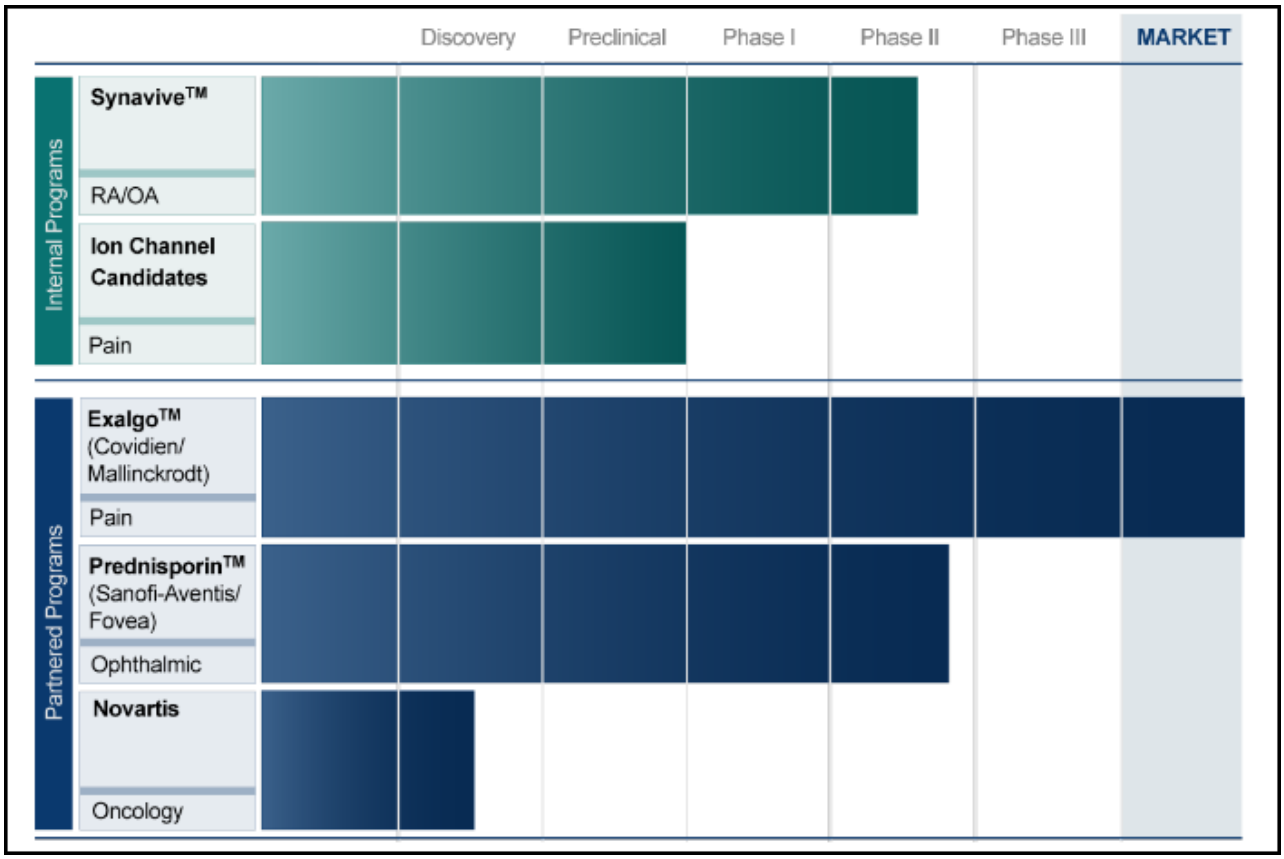
Zalicus plans to move Z160 (formerly NMED-160), a novel oral N-type calcium channel blocker, into phase 1 trials by the end of the year. Z160 has been reformulated to address previous solubility and bioavailability issues that stalled the candidate despite promising early-stage data in over 200 subjects to date. The goal is to move quickly from this phase 1 trial into a phase 2a trial during the first half of 2012. The profile of Z160 should provide for utility in patient suffering from chronic pain such as with PHN, DPN, or fibromyalgia.

Zalicus also plans to advance Z944, a novel T-type calcium channel blocker under development for the treatment of acute pain, into phase 1 either later this year or in early 2012. Preclinical data from inflammatory pain models suggests the candidate has excellent efficacy. 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 2012.

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 Na1.7 sodium channel blockers. In fact, Zalicus published a paper on the preclinical data from Z212 in the Journal of Pain in February 2011. The paper describes the activity of Z212, a novel proprietary small organic compound that acts to modulate Nav1.7 and Nav1.8 sodium channels and to reduce neuropathic pain by targeting the hyper-excitability associated with chronic pain signaling pathways. Through its unique mechanism of action, Z212 has been shown to both reduce the excitability of neurons and reverse pain hypersensitivity in preclinical models. We expect an update from Zalicus on additional ion channel programs similar to Z212 in 2012.

Between the above three candidates we believe Zalicus has the potential to sign either one broad-scale Ion Channel development partnership in 2011, or three 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 expect that Zalicus will look to complete phase 1 trials on each of the above candidates before individually out-licensing. A broad scale platform collaboration, however, could come sooner.

PIPELINE



VALUATION

Zalicus is in an enviable position within the biotechnology industry. The company has an approved product on the market in Exalgo, and is collecting royalties from a strong partner in Covidien. The company's pipeline contains Synavive, a mid-stage candidate with proof-of-concept data in a significant market opportunity with rheumatoid arthritis (RA) and osteoarthritis (OA). Zalicus also possess one of the market's leading research and discovery programs in calcium channel programs. Management is focusing the company's early-stage discovery efforts into the development of a new class of analgesics for the treatment of both acute and chronic pain. Finally, the cash position is strong, with an estimated $49 million on hand as of the end of the third quarter 2011. Zalicus has the potential to raise additional funds through the sale or out-license of non-core candidates for psoriasis (CRx-191) and diabetes (CRx-401), or exercising Term-C on its loan with Oxford. Accordingly, we believe the best valuation methodology for Zalicus is a sum-of-parts analysis that takes into account the strong cash flows from Exalgo and the upside in future development from Synavive, the ion channel programs, and potential out-licensing opportunities.

Our sum of parts / NPV analysis for Zalicus yields a total firm value of roughly $350 million, or $3.50 per share. We see Exalgo worth $0.50 per share. We note the current cash balance is over $0.50 per share. At the current value of only $195 million we believe the company is under-valued. We see upside beyond the $3.50 level based on positive news from Sanofi on prednisporin, or partnering of the early-stage ion channel program. We rate the shares 'Outperform'.

PROJECTED INCOME STATEMENT

Zalicus, Inc.
Income Statement

	2009 A	2010 A	Q1 A	Q2 A	Q3 A	Q4 E	2011 E	2012 E	2013 E
Collaborations & Grants	**$17.3**	**$45.2**	**$0.9**	**$1.3**	**$1.6**	**$1.5**	**$5.4**	**$10.0**	**$15.0**
YOY Growth	*22.3%*	*161.4%*	*-97.8%*	*-26.7%*	*52.7%*	*63.6%*	*-88.0%*	*85.3%*	*50.0%*
Exalgo Royalty	**$0**	**$1.6**	**$0.4**	**$0.5**	**$0.8**	**$1.0**	**$2.7**	**$7.7**	**$12.8**
YOY Growth	-	-	-	-	-	-	*66.8%*	*190.6%*	*66.2%*
Synavive (CRx-102)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	**$17.3**	**$46.7**	**$1.3**	**$1.8**	**$2.4**	**$2.5**	**$8.0**	**$17.7**	**$27.8**
YOY Growth	*22.3%*	*170.6%*	*-96.9%*	*-36.9%*	*108.2%*	*89.8%*	*-82.8%*	*120.0%*	*57.1%*
General & Administrative	$17.1	$12.1	$2.7	$2.7	$2.6	$2.7	$10.7	$12.0	$12.5
% SG&A	*98.9%*	*25.9%*	*215.9%*	*147.3%*	*105.6%*	*108.0%*	*133.3%*	*67.8%*	*45.0%*
Research & Development	$21.2	$23.0	$7.8	$9.0	$8.9	$9.5	$35.2	$30.0	$25.0
% R&D	*123.0%*	*49.2%*	*615.0%*	*486.5%*	*365.4%*	*380.0%*	*437.2%*	*169.5%*	*89.9%*
Amort & Restruct	($0.4)	$18.7	$1.3	$1.3	$1.3	$1.3	$5.2	$5.0	$4.0
% Other	*-2.6%*	*40.1%*	*101.1%*	*69.5%*	*52.9%*	*52.0%*	*64.1%*	*28.2%*	*14.4%*
Operating Income	($20.6)	($7.1)	($10.6)	($11.2)	($10.3)	($11.0)	($43.0)	($29.3)	($13.7)
Operating Margin	-	-	*-832.0%*	-	-	-	-	-	-
Interest & Other Net	$21.8	($29.2)	($0.1)	($0.2)	($0.2)	($0.2)	($0.7)	($0.2)	($0.2)
Pre-Tax Income	$1.2	($36.3)	($10.7)	($11.3)	($10.5)	($11.2)	($43.7)	($29.5)	($13.9)
Taxes	($0.1)	($1.2)	$0.0	$0	($1.2)	$0	($1.2)	($1.0)	$0
Tax Rate	*-6%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Discontinued Operations	$14.1	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	$15.4	($35.0)	($10.7)	($11.3)	($9.3)	($11.2)	($42.5)	($28.5)	($13.9)
YOY Growth	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-
Reported EPS	**$0.41**	**($0.42)**	**($0.12)**	**($0.11)**	**($0.09)**	**($0.11)**	**($0.44)**	**($0.27)**	**($0.13)**
YOY Growth	-	-	-	-	-	-	-	-	-
Weighted Ave. Shares	37.3	82.6	92.0	98.9	99.2	99.5	97.4	105.0	110.0

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

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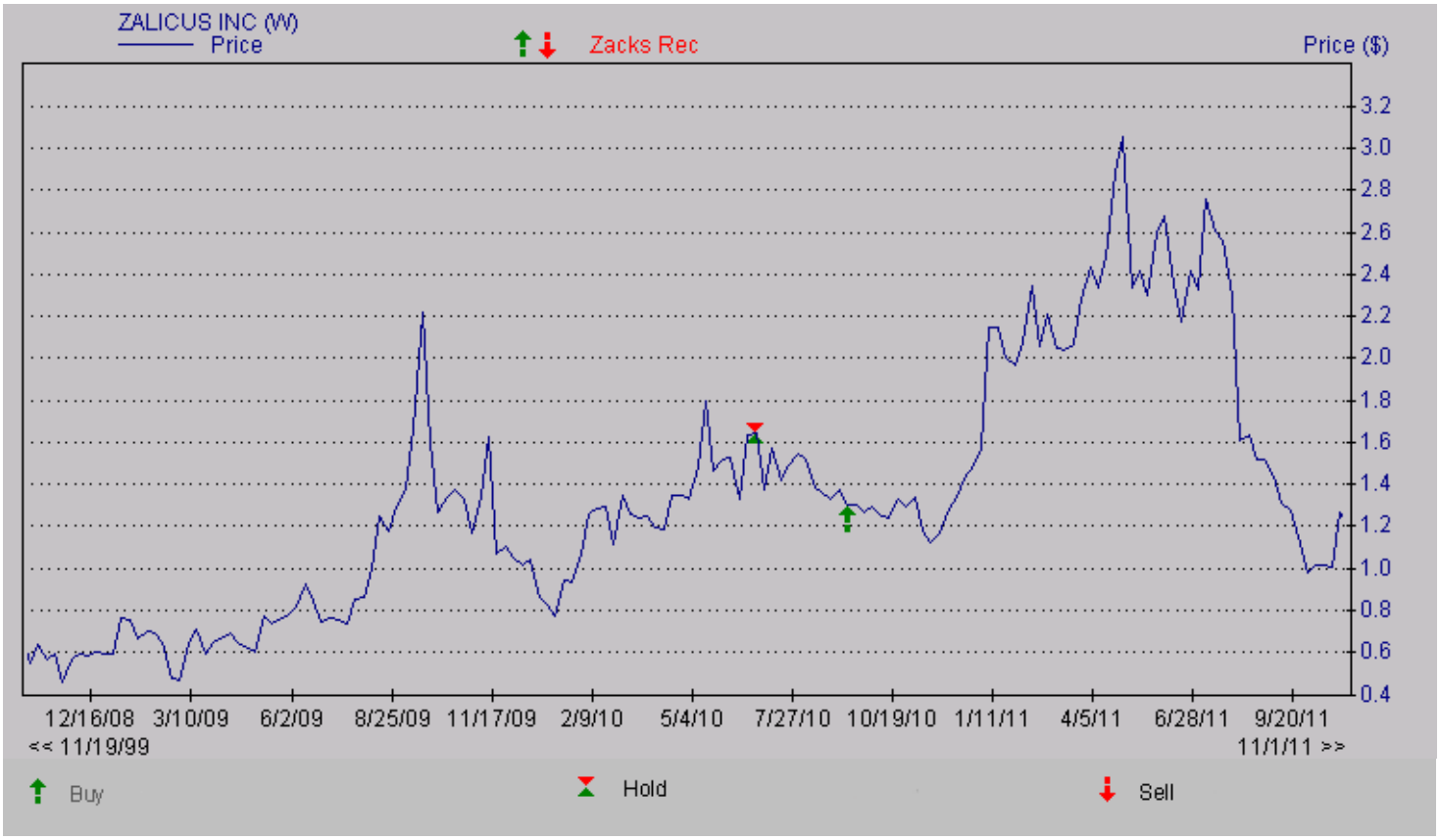
HISTORICAL ZACKS RECOMMENDATIONS



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