Zacks Small-Cap Research

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

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

Zalicus Inc.

(ZLCS-NASDAQ)

ZLCS: SYNERGY Fails, management to discontinue Synavive development, but don't sleep on the pipeline.

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	09/10/2012
Current Price (09/11/12)	$0.78
Target Price	**$1.50**

UPDATE

On September 10, 2012, Zalicus announced results from the phase 2b SYNERGY trial. Results showed that patients on Synavive achieved a -0.9 change from baseline on the DAS28 endpoint for Synavive (approximately 17% improvement) compared to a -0.5 change from baseline for placebo (approximately 10% improvement). However, Synavive was not statistically superior to 2.7 mg or 5 mg prednisolone. As a result, management has discontinued development of Synavive. Zalicus will also halt the ongoing one-year extension study which was designed to investigate the long-term safety and durability of response for Synavive.

Our rating is 'Neutral' and our new target is $1.50.

SUMMARY DATA

52-Week High	**$1.48**
52-Week Low	**$0.76**
One-Year Return (%)	**-41.91**
Beta	**2.23**
Average Daily Volume (sh)	**3,847,599**
Shares Outstanding (mil)	**127**
Market Capitalization ($mil)	**$100**
Short Interest Ratio (days)	**0.54**
Institutional Ownership (%)	**17**
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					12.5 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	-$0.07 E	-$0.37 E
2013					-$0.19 E
2014					-$0.21 E

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WHAT'S NEW

Phase 2b SYNERGY Fails – Management to Discontinue

On September 10, 2012, Zalicus announced top-line results from the phase 2b SYNERGY trial. SYNERGY (SYNavivE for Reducing signs and sYmptoms of rheumatoid arthritis trial) was 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 conducted at over 50 centers in the U.S., Europe, and Latin America (ClinicalTrials.gov identifier: NCT01369745). Enrollment in SYNERGY completed on April 30, 2012.

The primary endpoint was efficacy measured by the Disease Activity Score in 28 Joints (DAS28) at 12 weeks. DAS28 is a common, patient specific, outcome tool used in therapeutic trials to assess disease improvement or response. The trial was designed to show the efficacy of Synavive compared to its individual components (2.7 mg of prednisolone and 360mg of dipyramidamole) as well as how Synavive performs in comparison to 5 mg of prednisolone alone.

Results showed that patients on Synavive achieved a -0.9 change from baseline on the DAS28 endpoint for Synavive (approximately 17% improvement) compared to a -0.5 change from baseline for placebo (approximately 10% improvement). However, Synavive was not statistically superior to 2.7 mg or 5 mg prednisolone. As a result, management has discontinued development of Synavive. Zalicus will also halt the ongoing one-year extension study which was designed to investigate the long-term safety and durability of response for Synavive.

We believe discontinuing Synavive is the right thing to do, and applaud management for showing the discipline necessary to make the call. Zalicus spent $9.9 million on R&D in the second quarter 2012. Synavive accounted for $2.8 million of this figure. The company spent a total of $6.1 million on Synavive development during the first six months of 2012. In 2011, Zalicus spent $11.8 million on Synavive research and development. We expect a savings of around $3 million in the third and fourth quarter of 2012 now that Synavive has been discontinued. We are lowering our 2013 R&D expense by $5 million as well.

Moving To Neutral

We are disappointed in the failure of SYNERGY and the discontinuation of Synavive. We had previously believed the drug had $250 million potential as a treatment of moderate to severe RA in patients failing high doses of the glucocorticoid prednisolone due to poor tolerability and/or side effects. Our previous price target was $3.00 per share. We are moving our rating to 'Neutral' while we wait for additional data on the two phase 2a ion channel candidates, Z944 and Z160 (discussed below), and lowering our target to $1.50 per share.

We see significant value in these two ion channel candidates, each with novel mechanisms of action for the treatment of acute and chronic pain, respectively. We remind investors that Zalicus also received a royalty on sales of Exalgo at Covidien. Covidien recently received approval for a 32 mg dose of Exalgo, which we believe makes the product far more competitive in the crowded long-acting opioid space. Zalicus also has early-stage oncology and ion channel collaborations, and is eligible to receive both milestones and royalties on the advancement and commercialization of Prednisporin at Sanofi.

INVESTMENT THESIS

The Value Lies With The Ion Channel Pipeline

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 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 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. Preclinical data demonstrated efficacy in multiple animal models of neuropathic and inflammatory pain. 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.

…Phase 2a Initiated…

In September 2012, Zalicus initiated the first phase 2a study with Z160 in 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 see LSR has 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.

The phase 2a trial is a multicenter, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of Z160 in approximately 140 subjects with LSR (Clinicaltrials.gov Identifier: NCT01655849). We expect enrollment will take place at approximately 20 centers around the U.S. Patients will be randomized to receive either 375 mg Z160 BID or placebo. We expect enrollment to take six to eight months, with data expected in the third quarter 2013.

The primary endpoint will be change in average daily pain score assessed via a numeric rating scale (PI-NRS) at week 6. Secondary endpoints will include PI-NRS at weeks 1, 2, 3, 4, and 5, patient global impression of change (PGIC), modified Roland-Morris disability scale, use of rescue medication, profile of mood states, sleep interference, and safety and tolerability. We expect Zalicus to also conduct a responder analysis looking at time to and the number of patients achieving a 30% and 50% reduction in average daily pain scores.

…Another phase 2a Soon…

Other possible indications for Z160 include post-herpetic neuralgia (PHN), diabetic peripheral neuropathy (DPN), fibromyalgia, and peripheral nerve pain. Zalicus plans to initiate a second phase 2a study in PHN in the fourth quarter 2012. PHN is a painful neuropathic condition resulting from an outbreak of the herpes zoster virus, otherwise known as shingles.

Successful competition of both trials will allow management to attract development and commercialization partners with a phase 2b ready drug with proven efficacy in multiple models of neuropathic pain. We suspect that Zalicus will leave larger indications such as DPN and fibromyalgia for a potential development and commercialization partner to push forward. We note the new formulation being developed by Zalicus improves patent protection of Z160. If concept is demonstrated in these two phase 2a programs, we believe the company will sign a deal with big pharma partner in the second half of 2013 or 2014. In our view, Z160 has blockbuster potential given the novel mechanism of action and potential for multiple indications in the neuropathic pain market.

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, 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. 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.

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

Zalicus receives a royalty on sales of Exalgo (hydromorphone HCl) from Mallinckrodt, a division of Covidien. 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, but Exalgo does provide pure cash to Zalicus bottom-line. Exalgo was approved at 8, 12, and 16 mg doses in March 2010.

That being said, we have reason to be optimistic on the future of Exalgo. In August 2012, Covidien announced the U.S. FDA had granted approval for a 32mg dose tablet of Exalgo. This was an important approval because the 32 mg dose is the dose post patients stabilized on in the pivotal trial. Until this, Exalgo was competitively disadvantaged versus other long-acting opioids, like Opana-ER. We note that gaining approval of a 32mg dose for Exalgo also extends the exclusivity 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 believe there is significant value remaining in shares of Zalicus after the failure of SYNERGY and the discontinuation of Synavive. We would not be selling the stock at this price. In fact, we believe long-term investors should be holding or adding to their position. That being said, we are reducing our rating to 'Neutral' to allow for the lack of near-term catalysts and re-set of expectations in the stock. We see Z160 and Z944 as more significant drivers of valuation in the long-run for Zalicus. With positive phase 2a data in hand, we believe both Z160 and Z944 could command multi-hundred million dollar licensing and collaborative deals in late 2013 or early 2014.

Zalicus exited the second quarter 2012 with $44.1 million. Factoring in burn for the third quarter and the recently completed at the market (ATM) financing that raised $14.7 million in proceeds, and we see nearly $50 million in cash still on the books at the end of the third quarter 2012. We see Zalicus trading side-ways for the near-term, but then trending higher in 2013 in anticipation of the phase 2a data on Z160 in the third quarter 2013. We would be buyers below $0.75 per share. Our target is $1.50 per share.

PROJECTED INCOME STATEMENT

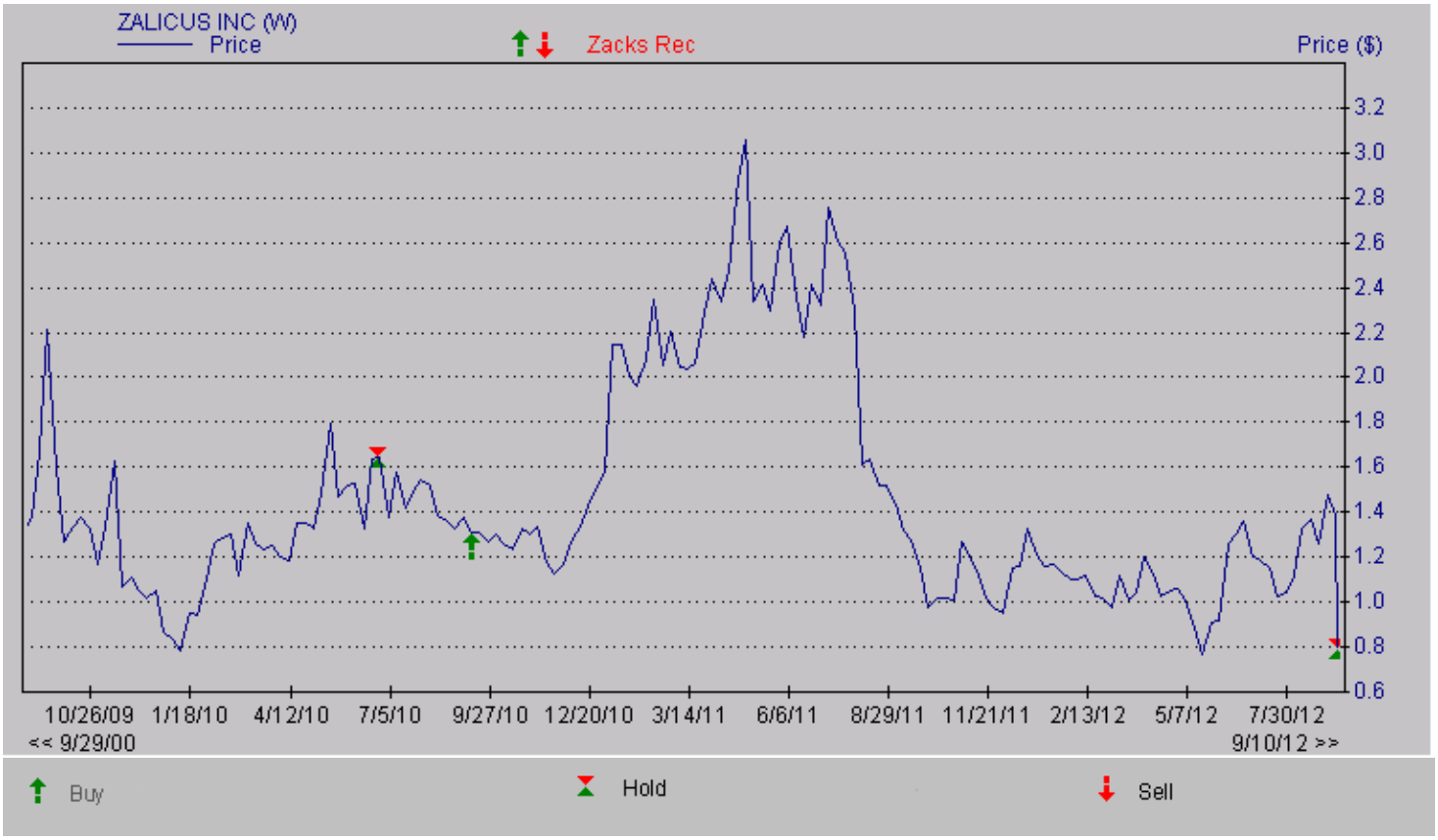
Zalicus, Inc.
Income Statement

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**	**$2.5**	**$1.4**
YOY Growth	-	*54.2%*	*214.3%*	*160.0%*	*75.0%*	*75.0%*	*112.2%*	*101.9%*	*-76.7%*	*-42.9%*
Prednisporin Royalty	**$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**	**$12.5**	**$16.4**
YOY Growth	*170.6%*	*-82.5%*	*82.5%*	*58.2%*	*27.7%*	*17.6%*	*39.8%*	*57.3%*	*-30.8%*	*31.7%*
General & Administrative	$12.1	$10.4	$2.7	$2.3	$2.4	$2.5	$9.9	$10.5	$11.0	$11.5
% SG&A	*25.9%*	*127.1%*	*114.8%*	*78.9%*	*77.4%*	*80.6%*	*86.3%*	*58.3%*	*88.4%*	*70.1%*
Research & Development	$23.0	$35.3	$10.6	$9.9	$11.0	$8.0	$39.4	$27.5	$25.0	$25.0
% R&D	*49.2%*	*431.3%*	*456.1%*	*337.2%*	*354.8%*	*258.1%*	*344.7%*	*152.8%*	*200.8%*	*152.4%*
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%*	*32.1%*	*24.4%*
Operating Income	($7.1)	($42.7)	($13.0)	($10.2)	($11.3)	($8.4)	($42.9)	($24.5)	($27.6)	($24.1)
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)	($11.5)	($8.6)	($43.1)	($24.7)	($27.8)	($24.3)
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)	($11.5)	($8.6)	($43.1)	($24.7)	($27.8)	($24.3)
YOY Growth	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-
Reported EPS	**($0.42)**	**($0.43)**	**($0.13)**	**($0.09)**	**($0.09)**	**($0.07)**	**($0.37)**	**($0.19)**	**($0.21)**	**($0.17)**
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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