Zacks Small-Cap Research

May 9, 2014
Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Suite 1600 Chicago, IL 60606

Zalicus Inc.

(ZLCS-NASDAQ)

ZLCS: Zalicus To Be Acquired By Privately-Held Epirus Biopharmaceuticals…

UPDATE

On April 16, 2014, Zalicus Inc. (ZLCS) announced that it has entered into a definitive agreement with Epirus Biopharmaceuticals, a privately-held biopharma company focused on the global development and commercialization of biosimilar monoclonal antibodies. The merger will create a Nasdaq-listed, publicly traded company focused on building a global biosimilar enterprise. We discuss Epirus, its pipeline, and how Zalicus fits into the new organization in our report.

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	09/10/2012
Current Price (05/09/14)	$0.90
Target Price	**$1.00**

SUMMARY DATA

52-Week High	**$7.20**
52-Week Low	**$0.89**
One-Year Return (%)	**-75.38**
Beta	**1.56**
Average Daily Volume (sh)	**1,112,647**
Shares Outstanding (mil)	**26**
Market Capitalization ($mil)	**$25**
Short Interest Ratio (days)	**4.30**
Institutional Ownership (%)	**10**
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 2014 Estimate	**N/A**
P/E using 2015 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)
2013	3.7 A	3.9 A	3.4 A	3.2 A	14.7 A
2014	1.6 A	1.5 E	1.5 E	1.5 E	6.1 E
2015					6.0 E
2016					6.0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.38 A	-$0.49 A	-$0.46 A	-$0.37 A	-$1.68 A
2014	-$0.15 A	-$0.12 E	-$0.10 E	-$0.10 E	-$0.48 E
2015					-$0.38 E
2016					-$0.38 E

© Copyright 2014, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Merger With Epirus Biopharma

On April 16, 2014, Zalicus Inc. (ZLCS) announced that it has entered into a definitive agreement with Epirus Biopharmaceuticals, a privately-held biopharma company focused on the global development and commercialization of biosimilar monoclonal antibodies. The merger will create a Nasdaq-listed, publicly traded company focused on building a global biosimilar enterprise. We discuss Epirus, its pipeline, and how Zalicus fits into the new organization below. However, first let's discuss the terms of the agreement.

The percentage of the combined company that Zalicus stockholders will own as of the closing of the merger is subject to adjustment based on the level of Zalicus' net cash at the closing date. The ownership of current Zalicus stockholders will be:

- Approximately 19% of the combined company if Zalicus' net cash at closing is ≥ $12 million,
- Approximately 17% of the combined company if Zalicus' net cash at closing is between $9 and $12 million,
- Approximately 14% of the combined company if Zalicus' net cash at closing is < $9 million.

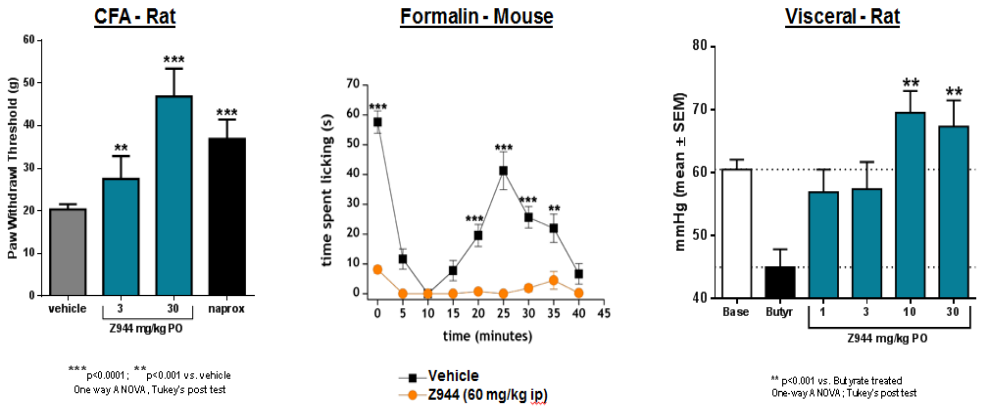
Epirus will adjust the number of shares of common stock to be issued to acquire Zalicus at the closing of the deal based solely on the cash Zalicus has on hand. This tells us Epirus has no interest in keeping T-type calcium channel blocker Z944 or Zalicus cHTS technology platform. This deal for Epirus is simply a way to go public and acquire Zalicus key executive leadership and expertise in the rheumatology area.

Zalicus cash on hand as of March 31, 2014 was $12.9 million. However, cash burn in the first quarter alone totaled $7.0 million, or around $2.3 million per month. We expect operating burn to drop in the second quarter as Zalicus winds down operations, but we still only project Zalicus cash on hand at June 30, 2014 to be $7.5 million.

…Zalicus Focused Asset Sales…

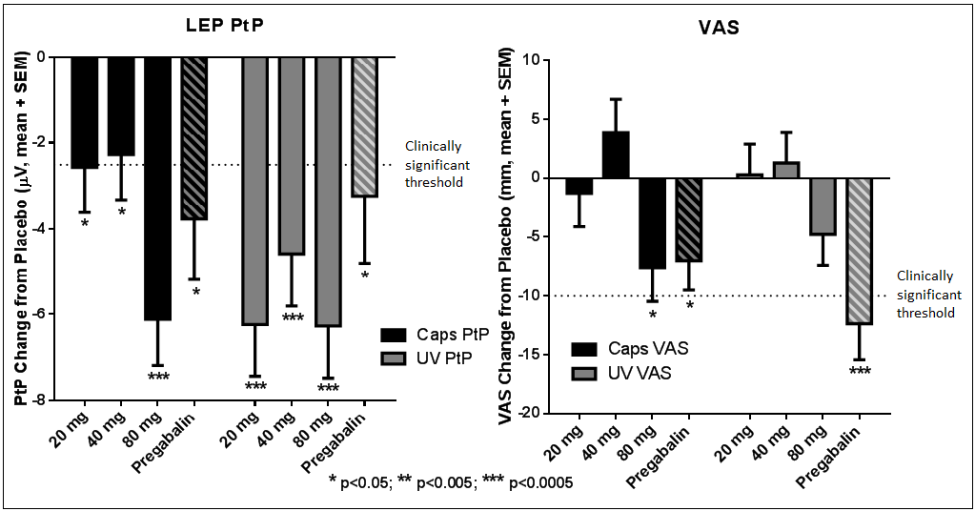
Zalicus is exploring different alternatives to increase its level of net cash. We spoke briefly with Zalicus CFO, Justin Renz the day the deal was announced. Mr. Renz told us the company's goal is to increase cash, but they would not be selling any more shares. Quite simply, Zalicus has four core assets: 1) Its Nasdaq listing, 2) Its senior management, 3) Z944, and 4) Its combination High-throughput screening (cHTS) technology platform. Epirus is interested in items 1 and 2. That means Z944 and cHTS are up for sale. If Zalicus can sell these assets prior to the closing of the Epirus transaction, then they can raise current stockholders ownership in the combined company.

Z944: Preclinical data generated to date with Z944 is encouraging. In February 2012, the company published a paper in Science Translational Medicine identifying Z944 as a potential therapy for seizure and generalized epilepsy. In May 2013, the company presented Poster #383 at the American Pain Society highlighting the mechanism of action for Z944 and its potential utility in various nonclinical models of acute and inflammatory pain. Below we highlight some of this data showing how Z944 compared well to naproxen in rat complete freund's adjuvant (CFA) model, mouse formalin model, and in a model of rat visceral pain.



The Phase 1b data has some good nuggets of information. Firstly, Zalicus saw dose proportional pharmacokinetics with similar exposure to preclinical doses where efficacy was achieved. The data show rapid absorption and a pk profile that supports twice daily dosing. The drug was also well tolerated, but the company did identify a maximum tolerated dose. In fact, when doses got too high there were limiting CNS side effects. This is in contrast to Z160 where Zalicus saw very limited side effects and incredible tolerability. It's important to note companies *want* to see dose-limiting CNS side effects. That confirms the drug is hitting the target organ. With Z160, no dose-limiting side effects should have been a clue that the efficacy wasn't there.

The Phase 1b study utilized state-of-the-art experimental clinical model measuring Laser-Evoked Potentials (LEP) following administration of capsaicin or exposure to UV light. The trial was designed to efficiently provide objective and subjective data on a drug's ability and modulate neuropathic pain signaling. This provided management with better sense of the efficacy signal than with Z160. Data shows that Z944 reduced peak-to-peak amplitudes in both neuropathic (capsaicin) and inflammatory (UV) pain models (see graphs below taken from the company's investor presentation). The drug also reduced subjective VAS pain scores for both models, with the highest dose of 80mg comparing well to preclinical data on Pfizer's Lyrica (pregabalin).



The company's goal is to now sell this asset to another pharmaceutical company interested in taking Z944 into Phase 2 studies. Based on the data we've presented above, and the potential for Z944 to offer "Lyrica-like" efficacy with improved side-effects and dosing, we find it possible that Zalicus can sell Z944 for $10 million in cash. This may be low to some investors, but given that Z944 is no longer a core asset and time is of the essence prior to the closing of the merger with Epirus, we think $10 million would be a fair price.

cHTS: Zalicus reported revenues in 2013 of $8.1 million through its cHTS technology platform. Revenues in the first quarter 2014 from cHTS totaled $1.6 million. Earlier this year, Zalicus presented preclinical data at the American Association for Cancer Research (AACR) 2014 Annual Meeting including a poster developed in collaboration with colleagues from Eisai Inc. and a podium presentation with collaborators from Sanofi which were generated in separate studies by leveraging the cHTS technology platform. The data demonstrating the potential to identify synergistic activity of the Eisai non-taxane eribulin and the Sanofi antibody drug conjugate SAR3419, through drug combinations.

Similarly to Z944, cHTS clearly has value in the market. Zalicus has noted in the past that cHTS revenues tend to be lumpy based on project work, so the fact that revenues in the first quarter 2014 totaled only $1.6 million does not concern us. In previous conversations with the company management believed they could do $10 million in revenues with cHTS in 2014. We find it possible that another organization would be willing to pay 2x these revenues to acquire this technology platform. If a deal is completed, this could provide $20 million in cash to Zalicus and would clearly boost the current stockholders ownership in Epirus.

…Epirus Focused on Biosimilars…

Not much is known about Epirus Biopharmaceuticals because they are privately held and we have yet to see their S/1 or super-8K filing. What we know of Epirus is taken from their website:

Epirus is building a global biosimilar enterprise to improve patient access to important medicines. The Company's strategy for commercial success relies on targeted approaches for diverse global markets. For emerging markets with accessible regulatory frameworks for biosimilars, Epirus develops partnerships with local companies to accelerate regulatory approval and commercialize its products. For high-growth global markets where local manufacturing confers strategic and operational advantages, Epirus intends to use its SCALE™ platform to deliver an In Market, For Market™ manufacturing solution with local partners. For large markets with an established biosimilar regulatory framework, such as Europe, Epirus plans to commercialize its products using a combination of direct sales and local distributors.

The leading pipeline candidate is BOW015, a biosimilar infliximab (sold by J&J as Remicade®). Infliximab is a monoclonal antibody against tumor necrosis factor alpha (TNF-α). It is used to treat autoimmune diseases. Epirus has previously reported positive Phase 1 and Phase 3 clinical data for BOW015. The Phase 3 trial met its predefined endpoint and demonstrated the comparability of BOW015 to Remicade®, as measured by ACR20 response in severe rheumatoid arthritis (RA) patients. The study also showed no meaningful differences between BOW015 and Remicade® with regard to safety or immunogenicity.

Epirus has worked to produce a robust data package supportive of both similarity and biosimilarity of BOW015 to Remicade®. The company's comparability data set, developed under a comparability and characterization protocol, addresses the physicochemical, biochemical and biological properties of infliximab and has been designed to assess biosimilarity between the innovator product (Remicade®) and BOW015. Epirus is actively progressing applications for marketing approval for BOW015 in targeted global markets. Epirus also plans to initiate an additional Phase 3 trial in Europe in early 2015. The logistics of this trial are where Epirus believes that Zalicus previous experience and expertise with Synavive can help.

Besides BOW015, Epirus has two other candidates under development, BOW050, a biosimilar to Humira® (adalimumab), and BOW030 a biosimilar to Avastin® (bevacizumab). These programs are in preclinical development.



We note in April 2014, Epirus announced that it has closed a $36 million Series B financing round led by Livzon Mabpharm, Inc. Other investors participating in this round include Adage Capital, Greenwoods Investment, Gibralt US, Inc., Monashee Capital Partners LP, and an investment affiliate of Mousse Partners, as well as existing investors TPG Biotech®, Montreux Equity Partners and 5AM Ventures. This should be sufficient cash to push BOW015 forward as well as bring new candidates into the clinic. By going public, Epirus will have access to additional capital through public offerings.

Why This Deal Makes Sense

Let's face it, Zalicus is struggling. After the failure of Synavive and Z160, Zalicus stock is down >90%. Cash on hand as of March 31, 2014 was only $12.9 million, and the share count was poised to double over the next year if management wanted to push forward into Phase 2a with Z944 alone. Z944 may have potential, but for Zalicus stockholders the rocky-road would have continued in 2014 and most likely 2015 without some sort of non-dilutive deal. So for Zalicus shareholders, owning 14%, 17%, or 19% of the new Epirus Biopharma may be better than owning 100% of just Zalicus alone. At least we know Zalicus management believes that is the case.

For Epirus, they get an expedited route to being a publicly-trading Nasdaq listed company. That allows the company to access additional capital later in 2014 and to execute on its biosimilar strategy in a timely manner. Acquiring Zalicus gives Epirus first-hand experience in running a global Phase 3 program in rheumatoid arthritis through the company's experience with Synavive. We note that Zalicus CEO, Mark Corrigan will serve as the new Chairman of the Board for the combined Epirus Biopharmaceuticals.

What's It Worth?

If we assume that Zalicus completes no asset sales prior to the closing of the deal, Zalicus stockholders will own 14% of the combined company. Zalicus current market capitalization is $25 million. That would put the market capitalization of the combined Epirus at around $180 million.

Biosimilars are an emerging growth area, particularly outside the U.S. where paths to approval are well-defined. For example, Epirus current focus is on brining BOW015 to the market in Europe. J&J posted peak sales with Remicade® over $6 billion. The opportunity in Europe is approximately $2 billion for all infliximab biosimilars (assumes biosimilars will be priced at 70% of the branded product). Unfortunately, Epirus will not be first to the market. Celltrion and Hospira have already gained approval for their biosimilar Remicade® product. Nevertheless, this is an enormous market and there are only a handful of companies in the world that can produce a biosimilar infliximab to scale.

Over the next few weeks we intend to take a deep look at the potential European market opportunity for a Remicade® biosimilar. However, for reference, if Epirus can capture just 10% of the peak market, BOW015 would have sales in the $200 million range. This would seem to suggest that Epirus Biopharmaceuticals is attractively valued at a "go-public" valuation of only $180 million. One might assume, even with a reasonable discount for time and risk to commercialization, trading at less than 1x peak sales is under-valued.

PROJECTED INCOME STATEMENT

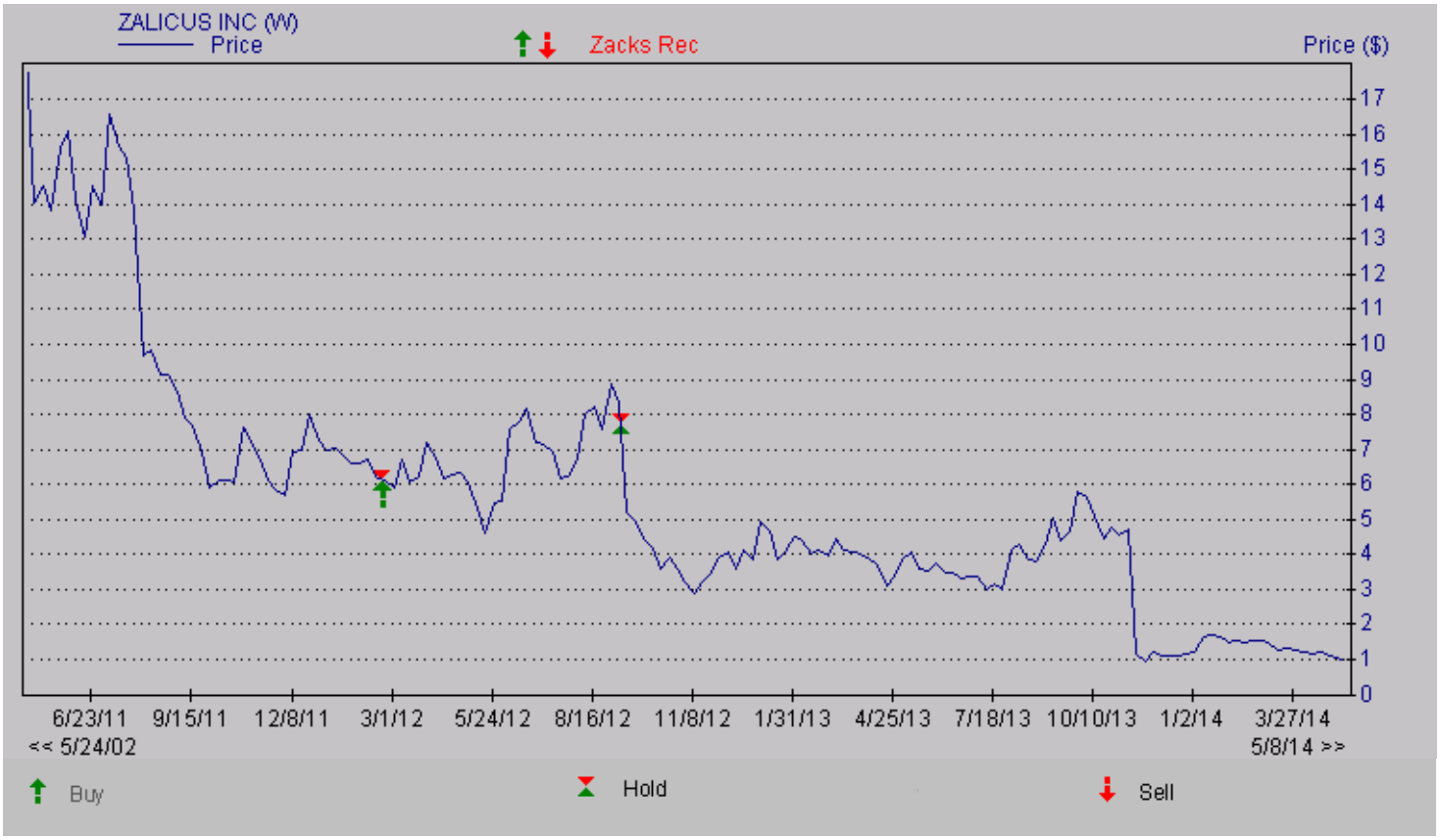
Zalicus, Inc.
Income Statement

Zalicus, Inc.	2013 A	Q1 A	Q2 E	Q3 E	Q4 E	2014 E	2015 E	2016 E
Collaborations & Grants	**$8.1**	**$1.6**	**$1.5**	**$1.5**	**$1.5**	**$6.1**	**$6.0**	**$6.0**
YOY Growth	*9.8%*	*-28.5%*	*-31.1%*	*-20.6%*	*-14.8%*	*-24.4%*	*-1.7%*	*0.0%*
Exalgo Royalty	**$6.7**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	*28.1%*	-	-	-	-	-	-	-
Z944	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$14.7**	**$1.6**	**$1.5**	**$1.5**	**$1.5**	**$6.1**	**$6.0**	**$6.0**
YOY Growth	*17.4%*	*-56.4%*	*-61.4%*	*-55.9%*	*-60.2%*	*-58.6%*	*-1.7%*	*0.0%*
General & Administrative	$7.5	$2.0	$1.8	$1.5	$1.5	$7.3	$6.0	$6.0
% SG&A	*51.1%*	*125.4%*	*120.0%*	*100.0%*	*100.0%*	*119.6%*	*100.0%*	*100.0%*
Research & Development	$34.0	$3.1	$2.9	$2.6	$2.5	$11.1	$10.0	$10.0
% R&D	*230.6%*	*192.2%*	*193.3%*	*173.3%*	*166.7%*	*181.6%*	*166.7%*	*166.7%*
Amort & Restruct	$10.5	$0	$0	$0	$0	$0	$0	$0
% Other	*71.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Operating Income	($37.2)	($3.5)	($3.2)	($2.6)	($2.5)	($12.3)	($10.0)	($10.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Net	($1.4)	($0.3)	($0.1)	($0.1)	($0.1)	($0.4)	($0.2)	($0.2)
Pre-Tax Income	($38.6)	($3.8)	($3.3)	($2.7)	($2.6)	($12.7)	($10.2)	($10.2)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Discontinued Operations	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	($38.6)	($3.8)	($3.3)	($2.7)	($2.6)	($12.7)	($10.2)	($10.2)
YOY Growth	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.68)**	**($0.15)**	**($0.12)**	**($0.10)**	**($0.10)**	**($0.48)**	**($0.38)**	**($0.38)**
YOY Growth	-	-	-	-	-	-	-	-
Weighted Ave. Shares	22.9	26.1	26.5	26.5	26.5	26.5	26.5	26.5

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

© Copyright 2014, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



© Copyright 2014, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

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

ANALYST DISCLOSURES

I, Jason Napodano, CFA, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESMENT BANKING, REFERRALS, AND FEES FOR SERVICE

Zacks SCR does not provide nor has received compensation for investment banking services on the securities covered in this report. Zacks SCR does not expect to receive compensation for investment banking services on the Small-Cap Universe. Zacks SCR may seek to provide referrals for a fee to investment banks. Zacks & Co., a separate legal entity from ZIR, is, among others, one of these investment banks. Referrals may include securities and issuers noted in this report. Zacks & Co. may have paid referral fees to Zacks SCR related to some of the securities and issuers noted in this report. From time to time, Zacks SCR pays investment banks, including Zacks & Co., a referral fee for research coverage.

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 Analysts. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, investment research, investment management, non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per client basis and are subject to the number of services contracted. Fees typically range between ten thousand and fifty thousand per annum.

POLICY DISCLOSURES

Zacks SCR Analysts are restricted from holding or trading securities in the issuers which they cover. ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Each Zacks SCR Analyst has full discretion on the rating and price target based on his or her 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 services described above. 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 article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but are not guaranteed as to be accurate nor do we purport to be complete. Because of individual objectives, this 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 without notice. Reports are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

ZACKS RATING & RECOMMENDATION

ZIR uses the following rating system for the 1047 companies whose securities it covers, including securities covered by Zacks SCR:
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 is as follows: Buy/Outperform- 16.5%, Hold/Neutral- 77.7%, Sell/Underperform – 5.1%. Data is as of midnight on the business day immediately prior to this publication.