Zacks Small-Cap Research

November 17, 2014
Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

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

ULURU Inc. (ULUR-OTCQB)

ULUR: Thesis Remains Intact, But Sales Rollout Taking Longer Than Expected…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	10/21/2013
Current Price (11/17/14)	$1.03
Target Price	**$1.50**

UPDATE

We believe ULURU's wound care product, Altrazeal®, has the potential to dramatically change the way physicians treat chronic wounds. Altrazeal® is a Transforming Powder Dressing built on the company's Nanoflex® technology. We see a dramatic change coming in how physicians treat chronic wounds in the next few years, primarily driven by CMS mandated packaging of skin substitutes and a move toward a pay for performance model. Altrazeal's simple application procedure and low cost should allow for sizable market share gains in the coming years.

We have conducted a discounted cash flow analysis on this potential and believe the shares are worth $1.50.

SUMMARY DATA

52-Week High	**$1.80**
52-Week Low	**$0.49**
One-Year Return (%)	**112.25**
Beta	**2.01**
Average Daily Volume (sh)	**45,133**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$26**
Short Interest Ratio (days)	**0.12**
Institutional Ownership (%)	
Insider Ownership (%)	
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-14.9**
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-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	0.10 A	0.03 A	0.11 A	0.13 A	0.37 A
2014	0.10 A	0.21 A	0.32 A	0.45 E	1.08 E
2015					3.24 E
2016					6.35 E

Earnings per Share
(In USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.06 A	-$0.06 A	-$0.05 A	-$0.05 A	-$0.21 A
2014	-$0.03 A	-$0.03 A	-$0.03 A	-$0.02 E	-$0.11 E
2015					-$0.06 E
2016					$0.00 E

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

WHAT'S NEW

Third Quarter Financial & Business Update

On November 17, 2014, ULURU, Inc. (ULUR) reported financial results and filed its Form 10-Q for the third quarter 2014, which corresponded to the three month period ending September 30, 2014. Revenues during the quarter totaled $323k, comprised of $283k in products sales and $39k in licensing and royalty income. Product sales grew by 219% from the third quarter 2013 and 59% sequentially from the second quarter 2014. These are impressive numbers, but still below expectations. We had expected revenue from product sales in the $500k range. We believe our thesis remains intact, but is taking longer than expected to play out.

As of mid-November 2014, the product has launched in 24 countries, slightly behind schedule. However, distribution agreements are in place for 64 countries. We believe logistical issues associated with Altrazeal manufacturing and product labeling is slowing the launch of the product. For example, production of Altrazeal is a complicated process, with manufacturing, sterilization, and final packaging take place at four different locations. Plus, as ULURU, Inc. launches the product around the global, packaging and labeling must meet regional specifications for that specific country. For instance, Altrazeal product labeling is available in 17 different languages. The Altrazeal product label for Switzerland alone contains four different languages.

The company recently received final inventory of 100,000 blister packs. On the third quarter conference call, CEO Kerry Gray noted that he expects to ship 40% of these by the end of the year, with another 40% to be shipped in the first quarter 2015. If we assume an average distributor price per blister pack of $25, then shipping 40,000 units in the fourth quarter would correspond to revenues of $1.0 million. The company is aggressively targeting areas of Europe, including Italy, Spain, and Portugal. The company was active at the May 2014 European Wound Management Association (EWMA) meeting in Madrid, Spain, and used that meaning as the kick-off to launch Altrazeal in Spain. Efforts are also underway to roll-out Altrazeal in Germany, Europe's largest market for chronic wounds.

Outside of Europe, the company is making progress expanding distribution in the Middle East, Asia, and Latin America. For example, earlier in November, ULURU, Inc. signed up an exclusive distribution agreement for 17 Middle East and North African markets. Together with previously signed agreements for Saudi Arabia, Afghanistan, and the United Arab Emirates these agreements cover a population of approximately 475 million people. The large markets of Egypt, Iraq, Algeria, Morocco and Sudan are covered by the most recent agreements. Approval was also recently received to market Altrazeal in Singapore, providing the company with its first entry into Asia. Key areas for targeting in Asia include Russia, China, and India. ULURU is also aggressively pursuing launching the product in Korea and Japan in 2015. Affluent countries like Korea and Japan are an exciting opportunity because procedures can be quickly put into place to allow for expansion of existing infrastructure, and countries like India and China are exciting on the sheer population basis. The minimum order size for a country like India or China could drive ULURU to profitability in a single quarter.

Ultimately, we believe ULURU is well-positioned to see a meaningful acceleration in revenues over the next several quarters. As noted above, simply distributing 100,000 blister packs over the next 2-3 quarters could generate revenues in excess of $1 million. That would dwarf the $323k reported in the third quarter. We believe it is imperative that the company start showing some meaningful financial progress over the next few quarters for our investment thesis to remain intact.

Specifically, we'd like to see the gross margin line improve. Gross margin in the third quarter 2014 was a meager 21%, impacted negatively by inventory write-offs and use of older, far more expensive raw materials. The company has secured newer dry powder material to make Altrazeal. On the third quarter conference call Mr. Gray noted this new dry powder is 50% the cost of the old material. In addition, as production ramps up Mr. Gray believes costs can be reduced another 40% based on sheer efficiencies of scale. We note the company also just recently completed a successful ISO Compliance Audit. Improved manufacturing and packaging capabilities will lead to dramatically improved gross margin for the company in the coming quarters. Having a gross margin line back above 50% in 2015 is an important and necessary step toward driving ULUR to profitability.

Outside of the gross margin line, operating expenses were in-line with expectations in the third quarter. Net loss for the quarter totaled $679k, or $0.03 per share. Cash burn with similar at $680k. The company has been funding operations through the sale of equities – so called, "drip financings" for the past several quarters.

...Data To Drive Uptake…

ULURU was fairly active at EWMA meeting in May in Madrid, Spain. Below we highlight two abstracts and e-posters that were published on Altrazeal.

- A team from the University Medical Centers Ljubljana, Slovenia co-authored an e-poster entitled, "Application of the Transforming Powder Acrylate Wound Dressing and Their Positive Effects." Results from the 8 patient case studies included all major wound types. The goal was to assess the utility of Altrazeal in treating highly exudating wounds that require frequent changes to the dressing. Data show that use of Altrazeal resulted in significant growth of new granulation tissue, allowing for improved healing and earlier use of transplantation grafting. The researchers concluded that use of Altrazeal resulted in reduced cross infections and minimized nursing times, both of which saved significant cost to the healthcare system.

- A team from the University Hospital 'Puerta de Hierro' in Madrid, Spain, co-authored a second abstract and e-poster entitled, "Challenges in Wound Care: The Benefits of Hydration Response Technology (HRT) on Cost Considerations in Clinical Practice." The goal of this analysis was to evaluate the fundamental properties of a hydrokinetic fibre dressing based on HRT on a range of patients with different wounds. Results show that, despite the differences of the patients' medical conditions, their wound history, and their wound status, all cases had in common an immediate and sustained improvement of the wound situation once the HRT dressing was applied. These effects support the hypothesis that exudate absorption and retention help reduce inflammation and aid in wound healing. The data also show that improving wound situation through dressing changes improves patient quality of life. However, for the product to be practical and cost-effective, dressing changes must be quick and simple. The authors concluded that the application of HRT dressings had a positive effect on the cost-benefit-ratio of the already tight budgets within the public health care sector. A product like Altrazeal, with high water absorption and retention fits this model.

Beside the two above abstracts, Altrazeal was the subject of a podium presentation from a nurse from the Czech Republic. The basis of the presentation was a survey conducted in which 12 nurses were interviewed. For a nurse to participate, the nurse had to have treated at least 5 patients with Altrazeal (meaning the total number of patients in the survey data was >60). Areas investigated and reported on included the benefits to the patient, the benefits to the caregivers, and obstacles for the use of Altrazeal.

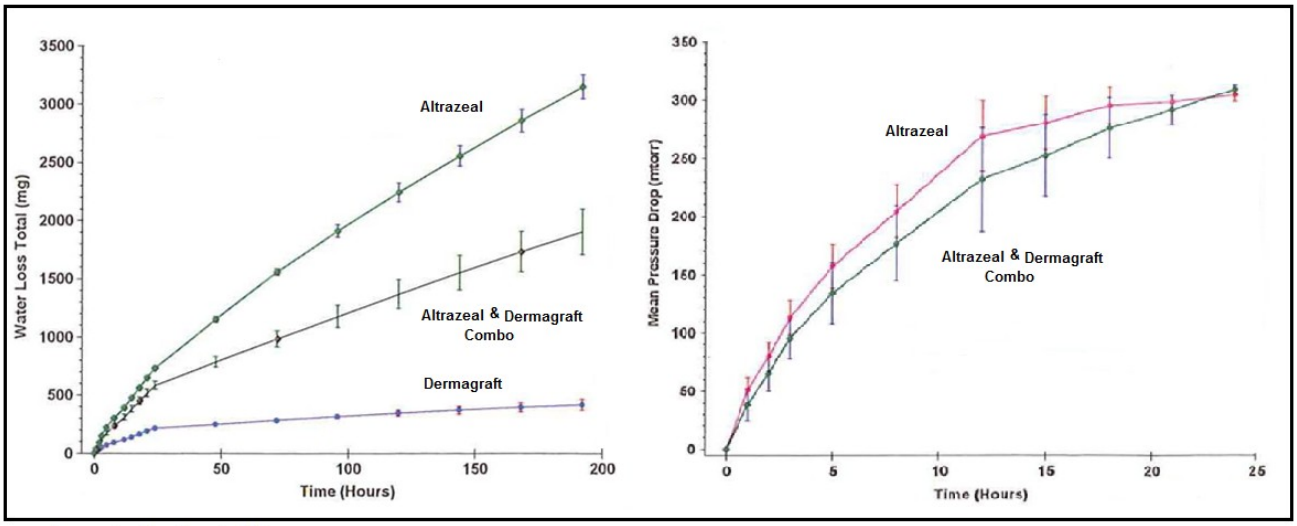
- Benefits for the patients included lower pain after application. For example, the average patient pain prior to application ranged between 5 and 8 on a 10 point scale. Pain after application was reduced to a range of 1 to 3. Additionally, lower sensitivity and irritation at the wound bed was reported by all patients, along with reduced bleeding and accelerated healing.

- Benefits to the care giver included the simplicity of the application and removal, along with fewer dressing changes and reduction in the negative patient clinical symptoms.

- In terms of the issues with Altrazeal, there is a need to educate physicians on when to use the secondary dressing, when to use additional sealing and to educate the physician not to be impatient and not to change the dressing so regularly. On average in these patients, the dressings will change every 7 days. All of the above could be overcome with education. Despite a small learning curve, nurses concluded that Altrazeal was easy to use, allowed total wound coverage, and gave the ability to continually inspect the wound and allowed for few dressing changes.

ULURU, Inc. anticipates that this important study will be published in the peer-review journal. Publishing of the study data should allow for expanding awareness of the product through targeting marketing campaigns and peer-to-peer networking. ULURU is also working on a pharmaco-economic study in Germany, with planned submission to the EU regulatory authorities on pricing and reimbursement once completed. Preliminary data was released in April 2014. Pharmaco-economics remains the backbone of the company's global commercialization strategy, as Mr. Gray believes wound healing physicians and outpatient clinics are more focused on cost-benefit analysis that simply time-to-healing. Mr. Gray frequently makes reference to expensive skin substitute products that cost $1,500 to $2,000 per application and offer median healing times of six weeks with a cost upwards of $10,000 total. Altrazeal cost roughly $50 per application and has median healing times of seven weeks. This type of data will be particularly instrumental in gaining access to large markets like India noted above.

ULURU is also wrapping-up of a 100-person venous leg ulcer (VLU) study in Europe. We are expecting performance data from the European VLU study in 2015. On the first quarter conference call, the company noted increasing use and interest for the product in conjunction with negative pressure wound therapy (NPWT). There is evidence that use of Altrazeal provides increased negative pressure on the wound, drawing out exudate and speeding healing time. The following graphs below were presented in poster form at EWMA last week in Spain. The graph to the left shows the improved exudate absorption of Altrazeal, a $50 product, when compared to Dermagraft, a $1,650 product with sales in excess of $100 million at one point. The graph to the right shows the potential for Altrazeal use in conjunction with NPWT or Dermagraft given the products ability to create a high mean pressure drop once applied to the wound.



Source: Assadian O. et al, 2014

The company has three initiatives designed to drive growth in the coming quarters. These include a pilot Accountable Care Organization (ACO) project, an alternative reimbursement pilot study, and partnering with a large wound care management company to rapidly accumulate clinical data. We discuss these in greater detail below:

- ACO's are stand-alone organizations that partner with insurance companies who offer an extensive bonus program to its members and physicians. The goal is to facilitate treatment of chronic wounds by enrolling wound care centers and even primary care physician into a cost-effective program that includes use of Altrazeal with their prospective patients.

- ULURU is also looking at an alternative reimbursement system for Altrazeal. For example, this might include approaching an insurance company and offering to heal a particular wound type for set fees, where all parties benefit – the insurance company, the wound care center and the patient. This motivates the physician to use the most cost effective approach to wound treatment.

- Finally, the company is looking to partner with a large wound management company that controls approximately 100 would care centers to conduct clinical studies and to more rapidly accumulate data. This could certainly accelerate timelines for U.S. reimbursement if completed successfully. For example, the planned DFU study noted above might be conducted with the assistance of a large wound management company. This would reduce time and cost to ULURU if an agreement can be made.

Also, ULURU plans to commence a number of studies looking at the ability of Altrazeal to impact pathways known to cause pain and to inhibit healing. This is a part of the company's overall publication strategy to provide fundamental scientific support for Altrazeal. Management is frequently asked for "method of action" data supporting patient feedback and experience noting an almost immediate relief of pain once Altrazeal is applied to an exuding wound. Scientific data backing up these anecdotal patient claims would provide credibility and enhanced marketing support for the product. We believe peer-reviewed publications documenting improvement in quality-of-life measures marries well with the company's pharmaco-economic data-based strategy noted above. The marketing message with Altrazeal is simple – it's a low-cost and highly effective product.

As noted above, net cash burn in the third quarter totaled $680k. The company exited September 30, 2014 with only $40k in cash. Obviously management is going to need to raise funds in the near future to keep the Altrazeal roll-out moving forward. Several balance sheet improvements have been made over the past few quarters designed to facilitate better financing terms going forward. For example, all outstanding debt was eliminated in July 2014.

…Roll-Up Strategy Provides Meaningful Upside For Investors…

ULURU, Inc. is a major shareholder in its two leading international distributors, Altrazeal AG and Altrazeal Trading GmbH. The company owns a 25% non-dilutable ownership in these two entities. ULURU sells Altrazeal to these entities who in turn sell to country licensees capturing an undisclosed margin in these entities. Both of these entities have a relatively small expense base. Consequently, as revenue expands, management believes they will quickly become profitable entities.

ULURU reserved the right to purchase the 75% it currently does not own. On the second quarter conference call, CEO Kerry Gray noted that the company does not intend to exercise the option to acquire both Altrazeal AG and Altrazeal Trading GmbH until they are accretive to earnings. As a purchase price is formula based, we believe a transaction can be structured to provide significant upside to existing shareholders. Obviously, such an acquisition will also provide a sizable revenue increase to the company.

Valuation

We have conducted a discounted cash flow (DCF) analysis on future revenues based on our $60 million sales forecast – peaking in 2021. For 2015, we model over $3.0 million in revenues, growing to $6 million in 2016 before a “hockey stick” like ramp starting thereafter. We note the product is patent protected until 2029. Our DCF model calculates fair value at $1.50 per share. Accordingly, we are recommending purchase of the shares today at $1.05 because the stock is significantly under-valued and offers a very attractive return to investors over the next several years.

PROJECTED FINANCIALS

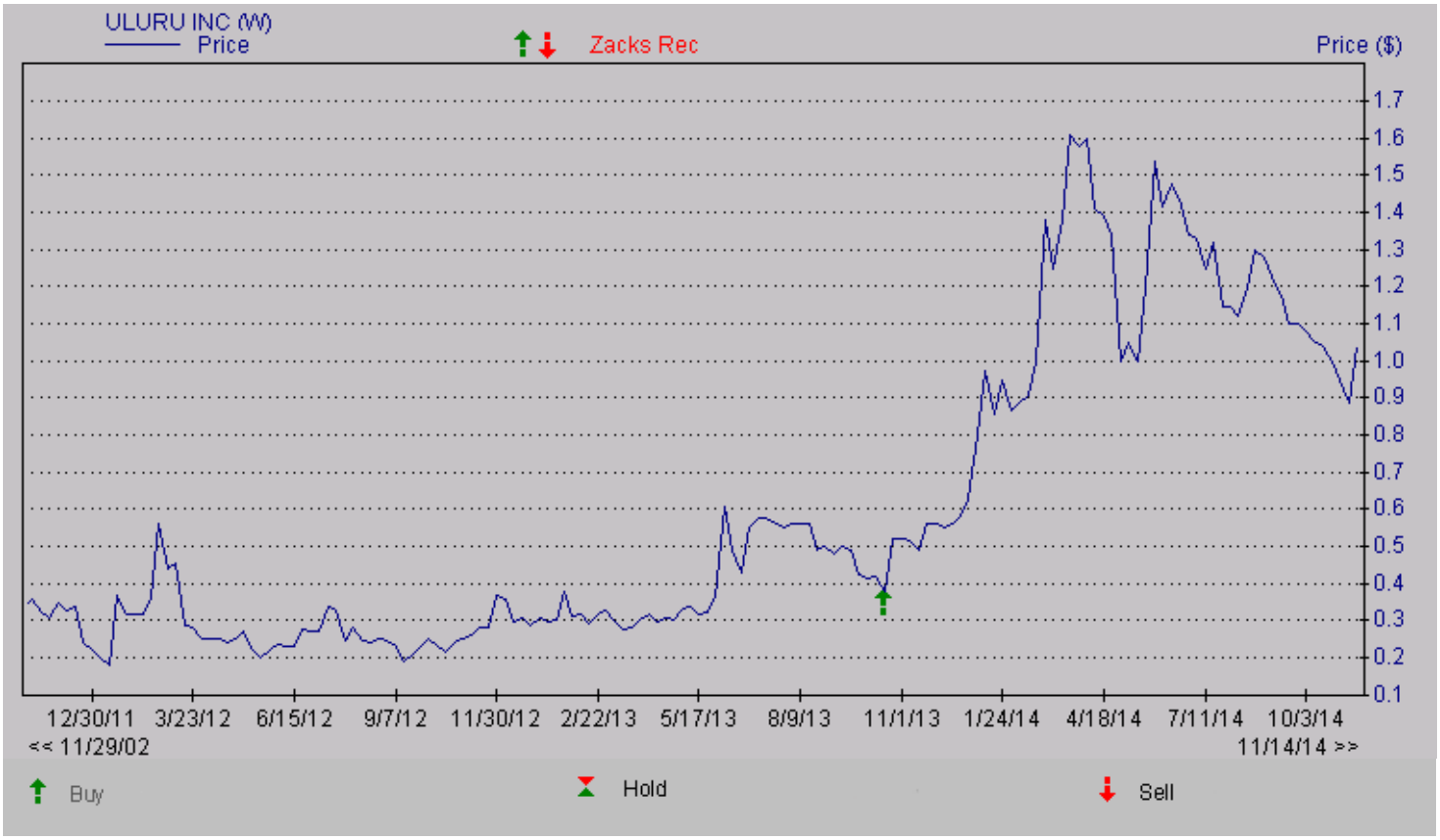
ULURU, Inc.
Income Statement

ULURU, Inc.	2013 A	Q1 A	Q2 A	Q3 A	Q4 E	2014 E	2015 E	2016 E
Product Sales	$0.292	$0.087	$0.178	$0.283	$0.400	$0.949	$2.950	$6.000
YOY Growth	*4.2%*	*-3.8%*	*908.4%*	*218.9%*	*323.5%*	*225.0%*	*211.0%*	*103.4%*
Licenses Fees / Royalty Income	$0.079	$0.015	$0.032	$0.039	$0.050	$0.136	$0.285	$0.350
Total Revenues	**$0.371**	**$0.102**	**$0.209**	**$0.323**	**$0.450**	**$1.084**	**$3.235**	**$6.350**
YOY Growth	*0.0%*	*-0.1%*	*624.6%*	*191.9%*	*248.7%*	*192.5%*	*198.4%*	*96.3%*
Cost of Goods Sold	$0.222	$0.041	$0.113	$0.224	$0.230	$0.608	$1.460	$2.650
Product Gross Margin	*24%*	*53%*	*36%*	*21%*	*43%*	*36%*	*51%*	*56%*
Research & Development	$0.788	$0.188	$0.184	$0.173	$0.190	$0.735	$0.800	$1.000
Sales, General & Admin	$1.288	$0.469	$0.411	$0.390	$0.400	$1.670	$1.660	$1.750
Amtz & Dep	$0.720	$0.178	$0.178	$0.178	$0.178	$0.712	$0.712	$0.712
Operating Income	($2.648)	($0.773)	($0.678)	($0.642)	($0.548)	($2.641)	($1.397)	$0.238
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	($0.433)	$0.082	($0.032)	($0.037)	($0.040)	($0.027)	($0.120)	($0.150)
Pre-Tax Income	($3.081)	($0.691)	($0.710)	($0.679)	($0.588)	($2.668)	($1.517)	$0.088
Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Preferred Stock Dividends	($0.030)	$0	$0	$0	$0	$0	$0	$0
Net Income	($3.081)	($0.691)	($0.710)	($0.679)	($0.588)	($2.668)	($1.517)	$0.088
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.21)**	**($0.03)**	**($0.03)**	**($0.03)**	**($0.02)**	**($0.11)**	**($0.06)**	**$0.00**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	14.773	21.416	24.122	24.518	25.000	23.764	26.625	32.500

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, 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, equity 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 USD per annum.

POLICY DISCLOSURES

Zacks SCR Analysts are restricted from holding or trading securities placed on the ZIR, SCR, or Zacks & Co. restricted list, which may include issuers in the Small-Cap Universe. 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 1116 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- 17.1%, Hold/Neutral- 76.3%, Sell/Underperform – 5.8%. Data is as of midnight on the business day immediately prior to this publication.