Zacks Small-Cap Research

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ULURU Inc. (ULUR-OTCQB)

ULUR: Looking For 2014 To Be A Breakout Year for Altrazeal…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	10/21/2013
Current Price (04/03/13)	$1.42
Target Price	**$2.50**

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, leading to peak sales potential around $100 million in our view. We have conducted a discounted cash flow analysis on this potential and believe the shares are worth $2.50.

SUMMARY DATA

52-Week High	**$1.80**
52-Week Low	**$0.29**
One-Year Return (%)	**288.89**
Beta	**1.74**
Average Daily Volume (sh)	**85,487**
Shares Outstanding (mil)	**18**
Market Capitalization ($mil)	**$26**
Short Interest Ratio (days)	**0.12**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**10**
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	0.24 E	0.50 E	0.81 E	1.07 E	2.62 E
2015					5.25 E
2016					10.35 E

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

	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 E	-$0.02 E	-$0.01 E	-$0.01 E	-$0.07 E
2015					-$0.00 E
2016					$0.10E

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WHAT'S NEW

Fourth Quarter Financial & Business Update

…Scale-Up Issues Impact Revenue Ramp…

On March 31, 2014, ULURU, Inc. reported financial results for the fourth quarter and full year ending December 31, 2013. Revenues for the fourth quarter totaled $129k, comprised of $94k in products sales, $15k in licensing fees, and $20k in royalty income. Revenues of $129k decreased 22% from the fourth quarter 2012. Product sales of $94k declined 38% from the fourth quarter 2012. On the fourth quarter earnings call, CEO Kerry Gray noted that sales were impacted by two events in the quarter. Firstly, in late December 2013, a sizable order was stranded at the company's sterilization facility in New York due to bad weather. As a result, this order that was supposed to ship in the fourth quarter 2013 had to be pushed into the first quarter 2014. Secondly, Mr. Gray noted equipment instillation and production scheduling made the company unable to fulfill another two orders during the quarter.

Mr. Gray noted that a typical order from a distributor can range between $40k (small) to $80k (average) to as high as $160k (large). As such, we believe the company missed out on booking another potential $120k to $160k during the quarter. It seems the company is having some production issues that lead to delayed fulfillment of orders. There are a number of factors that result in such issues, including manufacturing time, production scheduling, equipment installation, and equipment modifications. It seems ULURU is not immune to the challenges of scale-up manufacturing, with further equipment modification still required to optimize some of the production process. In fact, the company has begun working with outside consultants to handle some of the issues inherent with a major production campaign, including the added paper work required to comply with ISO quality control standards. However, Mr. Gray tells us most issues have now been overcome, and in his prepared remarks, stated that he is hopeful revenue should start to reflect order flow by the end of the second quarter.

…But 2014 Should Be A Big Year…

Despite the manufacturing and production issues note above, we remain optimistic on the potential for Altrazeal on a global basis. Through 2013 the company was very active in signing new distribution agreements and launching Altrazeal in various countries around the world. In September 2013, ULURU executed an Exclusive License and Supply Agreement with Altrazeal AG to market Altrazeal in several territories, to include new parts of Africa, Latin America, Georgia, Turkmenistan, Ukraine, and the Commonwealth of Independent States. Through these agreements, the company receives an up-front licensing payment and royalties on product sales. ULURU also supplies Altrazeal to its partners at an agreed upon transfer price, which we believe incorporates a smaller margin amounting to an additional single-digit royalty.

In October 2013, ULURU completed the initial shipment of Altrazeal for distribution in South Africa. In October 2013 and February 2014, the company executed amendments to the agreement with Altrazeal AG for the purpose of expanding the territories to include Asia and the Pacific (excluding China, Hong Kong, Macau, Taiwan, South Korea, Japan, Australia, and New Zealand), Jordan, and Syria. Mr Gray anticipates that Altrazeal AG will be launching Altrazeal in a number of these markets in 2014.

Also during the third quarter 2013, Altrazeal was shipped to five new markets: Czech Republic, Slovakia, South Africa, Croatia, and Slovenia. Since the middle of 2013, the company has announced the further expansion of the Altrazeal international marketing network to include 16 additional countries including, Scandinavia, Finland, South Africa, and Portugal, along with the aforementioned five countries above. Management expects to have Altrazeal® available in over 50 markets by the end of 2014 and have distribution agreements in place for another 20 countries – truly an impressive roll-out!

Existing Distribution Agreements

Altrazeal®	
Altrazeal Trading GmbH	▪ European Union, Australia, New Zealand, Middle East (excluding Jordan and Syria), North Africa, Albania, Bosnia, Kosovo, Macedonia, Montenegro, and Serbia
Altrazeal AG	▪ Africa (markets not already licensed), Latin America, Georgia, Ukraine, Turkmenistan, the Commonwealth of Independent States, Jordan, Syria, Asia and the Pacific (excluding China, Hong Kong, Macau, Taiwan, South Korea, Japan, Australia, and New Zealand)
Jiangxi Aiqilin Pharmaceuticals Group	▪ China, Hong Kong, Macau, and Taiwan

We remind investors that ULURU, Inc. owns 25% of key distributors Altrazeal AG and Altrazeal GmbH, and has the right to acquire the remaining 75% ownership at an agreed upon price should the company look to consolidate distributors in the future. This is something that we would not be surprised to see happen later in 2014 or in 2015.

Opportunities in the EU Big-5 (namely UK, Italy, Spain, and Germany) are the most exciting from a near-term revenue generating position because these countries have standardized protocols and existing wound care infrastructure in place to facilitate rapid uptake of Altrazeal. 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.

…Gross Margin Hiccup…

Gross margin in the fourth quarter was -25%, resulting from a $60,000 write-off of obsolete finished goods and raw materials. At this time we are unsure if the write-off is associated with the delayed shipments in the quarter due to bad weather or related to the equipment installations noted above. Either way, backing-out this charge and gross margin would have been 39%. This is still below historic rates based on a number of factors, including increased lead-times and logistical issues associated with ramping of production on Altrazeal (discussed above) and challenges with respect to moving from a foil package to a blister pack. The clear blister pack includes an applicator and allows for easier administration by the wound care professional vs. the opaque foil package. Product filling logistic issues associated with the uniqueness of Altrazeal's density (5% that of water) have also been overcome by moving from a volumetric to a weight-based fill system. As these inventory and logistical issues are resolved, we expect the gross margin line to approach 65% in the second half of 2014.

….R&D Activities To Expand…

Operating expenses were generally in-line with expectations during the quarter. Despite the significant roll-out of Altrazeal in a number of countries throughout Europe and Africa, costs have been held in check by management. The company spent $374k on SG&A and $211k R&D during the quarter.

R&D expense is being driven by an ongoing pharmaco-economic study in Germany, with planned submission to the EU regulatory authorities on pricing and reimbursement later this year, and the wrapping-up of a 100-person venous leg ulcer (VLU) study in Europe. Management expects to have pharmaco-economic data on Altrazeal to present publicly in the second quarter of 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.

- ***If you had a diabetic foot ulcer, would you pay $10,000 to have it heal in six weeks? Or would you rather pay $250 and have it heal in seven weeks?***

We are expecting performance data from the European VLU study around the middle of 2014. ULURU also has plans to conduct a large diabetic foot ulcer (DFU) study in 2014, as well as several smaller studies in highly regard State sites in Europe. Mr. Gray believes the cost-effectiveness of doing this small site-specific work in Europe is superior to that of a large-scale program in the U.S. However, at some point the company is going to have to conduct clinical studies in the U.S. in both DFU's and VLU's to gain a fee schedule. Altrazeal is reimbursed in the U.S., but the lack of a fee schedule makes billing and invoicing a challenge.

In this regard, the company has three initiatives designed to drive growth in 2014. 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, over the next 90 days, 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. We believe these types of quality-of-life measure marry well with the company's pharmaco-economic data-based strategy noted above. The marketing message with Altrazeal is simple – it's low-cost and highly effective.

…On The Road To Profitability…

Net loss during the fourth quarter totaled $858k, or $0.05 per share based on 18.1 million shares outstanding. Loss for the full year 2013 totaled $3.1 million, or $0.21 per share. Loss improved approximately $0.5 million from 2012. Net cash burn during the quarter totaled roughly $481k. Burn for the full year totaled $1.8 million. Operations during 2013 were funded by financing activities totaling a similar $1.8 million. The company exited 2013 with only $5k in cash – on the cusp looking like a major concern. However, we note several recent events to strengthen the financial position over the past several months:

- During the third quarter 2013 the company took steps to improve the balance sheet by converting all outstanding Series A preferred stock. The conversion price for this stock was fixed at $0.70 per share with no adjustment mechanisms, resets, ratchets, or anti-dilution covenants. We believe this created an overhang that limited the ability of the company to enter into new financings at favorable terms.

- On August 15, 2013, ULURU, Inc. provided notice to Ironridge for the redemption of all Series A Shares held by Ironridge, totaling $969,000. With the preferred stock not eliminated, the company will save on dividend payments and is now unencumbered from entering into favorable financing transactions in 2014.

- On January 3, 2014, warrants vested with respect to 3.0 million shares of common stock and were exercised by an assignee of IPMD GmbH. Exercise is taking place over the first four months of the year ending on January 31, 2014, February 28, 2014, March 31, 2014, and April 30, 2014 in exchange for the payment of $450,000 on each such date. So in total, ULURU will receive $1.8 million from this transaction.

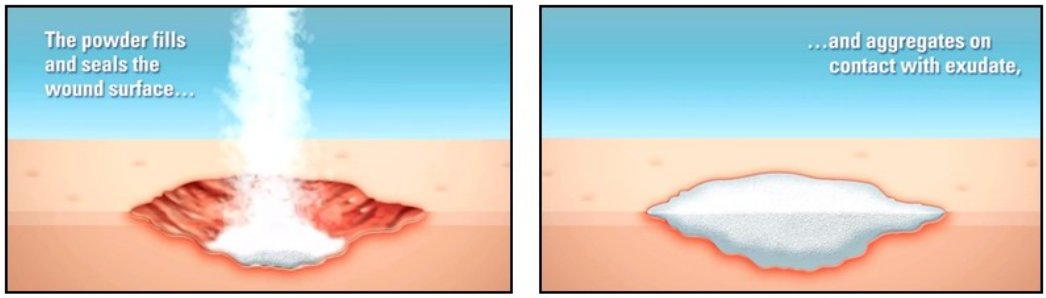
- On April 1, 2014, the company announced that it has made the final payment on the Inter-Mountain Capital Corp. Secured Convertible Note. Under the terms of the Convertible Note, ULURU exercised their option to offset the principal and interest of the Buyer Notes received from Inter-Mountain against the principal and interest outstanding on the Convertible Note. Inter-Mountain then converted the remaining outstanding balance of the Convertible Note in accordance with the conversion provisions. During this prepared remarks, CEO Kerry Gray noted that Inter-Mountain has been a significant seller of the stock over the past two years. We believe retiring the debt to Inter-Mountain, similar to the conversion of the preferred stock noted above, greatly improves the balance sheet and frees up the company for potential new financings on far more favorable terms at some point in 2014.

…An Uplist On The Horizon…

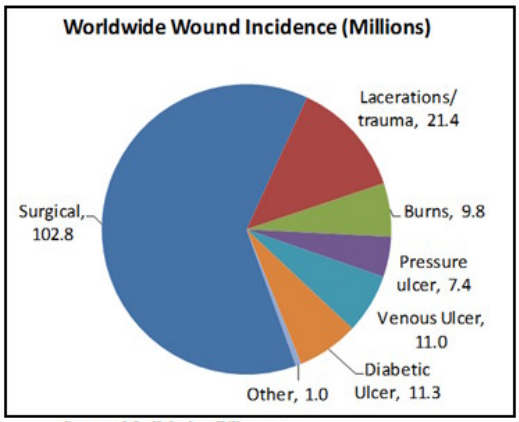
On the company's fourth quarter earnings call, CEO Kerry Gray noted that ULURU has started working with an investment bank on the possibility of listing the common stock on a national exchange; we suspect either the NYSE-MKT or NASDAQ-CM are the target. To achieve this there are three requirements that would need to be addressed, a minimum net equity of $4.0 million, a stock price above $3 share price, and an expansion of the company's Board of Directors. We believe that the company is in compliance with corporate governance requirements. As of now, Mr. Gray's plan is to achieve the minimum share price through market forces (i.e. no reverse split). With the stock currently at $1.40 per share, ULURU still has a long-way to go before this minimum requirement is achieved. Nevertheless, with business fundamentals improving and the global roll-out of Altrazeal planned in full-force for 2014, we would not be surprised to see the shares significantly closer to this goal by year end 2014.

BACKGROUD MATERIAL / INVESTMENT THESIS

In October 2013, we initiated coverage of ULURU, Inc. with a Buy rating. We believe the company'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. When applied to the wound surface, the fine powder dressing hydrates and transforms by mixing with exudate to form a flexible film over the surface of the open wound that provides an ideal moist wound environment supporting cellular function and tissue repair. Specifically, the aggregation of the polymer particles creates a dressing with a porosity that enables moisture vapor transport and the transport of oxygen to the wound surface, but which is too small for exogenous bacteria to penetrate. The film matrix is strong but flexible and elastic which prevents cracking or flaking under normal movement. The outflow of exudate and moisture vapor creates capillary action against the wound surface and a low-pressure environment believed to stimulate cell growth and fibroblast mobility, thus promoting the formation of healthy granulation tissue. As the wound heals, Altrazeal will dry up and flake off, similar to a scab.

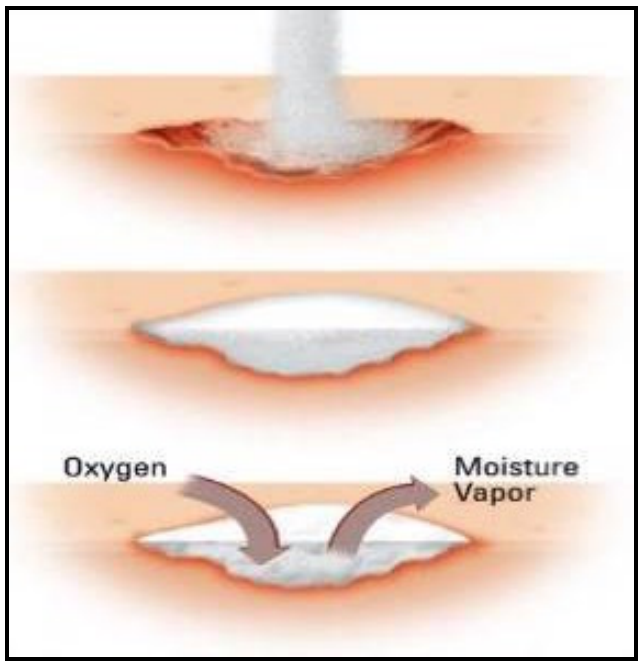


Altrazeal is U.S. FDA / EU CE Mark approved for sale. The product is supplied as a sterile dressing suitable for the covering and protection of exuding wounds such as burns, abrasions, skin graft donor sites, surgical wounds, and chronic wounds including venous leg ulcers and diabetic foot ulcers. It is available in a single-use, 0.75g blister back, or in 2g or 5g sterile foil laminate pouches. The global chronic wound market exceeds $10 billion and is growing rapidly given an aging population and the accelerating rate of obesity and diabetes.



Source: MedMarket Diligence

Altrazeal is applied to an exuding wound by sprinkling the powder on the open wound. The particles then hydrate and aggregate to a final moisture content of approximately 65% by weight. This transformation occurs without any chemical reaction and the particles adhere and remain bound together as a dressing through hydrophilic / hydrophobic interaction, hydrogen bonding and Van der Waals forces. The aggregated powder becomes a moist, flexible film over the surface of the open wound that provides an ideal moist wound environment supporting cellular function and tissue repair.



Specifically, the aggregation of the polymer particles creates a dressing with a porosity that enables moisture vapor transport and the transport of oxygen to the wound surface, but which is too small for exogenous bacteria to penetrate. The film matrix is strong but flexible and elastic which prevents cracking or flaking under normal movement. As the wound heals, in most cases Altrazeal will dry up and flake off, similar to a scab.

…Data To Date Supports Uptake…

An ULURU, Inc. funded randomized clinical study and several investigator sponsored case studies have demonstrated clinical utility in treating serious chronic non-healing wounds such as diabetic foot ulcers and venous legs ulcers. Data shows Altrazeal is comparable to carboxymethylcellulose-silver (CMC-Ag) dressing with reduced pain and higher patient and physician satisfaction. The product can be used in combination with standard of care, including additional dressings, off-loading, and negative-pressure wound therapy. Case studies clearly demonstrate that Altrazeal® is complementary to living and synthetic skin substitutes, extracellular matrix growth factors, can aid in the anchoring of split-thickness skin grafts, and can be used with contact casting.

…A Sizable Market Opportunity…

We think Altrazeal provides certain advantages in terms of ease of use, cost-effectiveness, improved compliance, and accelerated healing that the product can become a significant player in the global wound care market. We particularly think Altrazeal is well-positioned given a changing reimbursement environment in the U.S. and a move toward packaging and potentially “pay-for-performance” in the near future. With just 3% of the DFU or VLU chronic wounds treated in the U.S. and EU each year, we see Altrazeal as a $100 million product.

Altrazeal is approved for over-the-counter use, but the company recommends use under the supervision of a health care professional. In Europe, Altrazeal has CE Mark for sale as of July 2010. In March 2009, ULURU, Inc. was notified by the PDAC Medicare Pricing, Data Analysis and Coding, from the Centers for Medicare & Medicaid Services that the Medicare HCPCS code(s) to bill the four DME Medicare Administrative Contractors for Altrazeal. This allows for negotiated reimbursement but the product has yet to be covered under a fee schedule. To gain reimbursement under the physician’s fee schedule (PFS), the company must conduct additional clinical studies.

In Europe, ULURU is currently conducting a trial studying Altrazeal in approximately 100 patients with VLUs to facilitate pricing and reimbursement. Management believes data from this trial will be available around the middle of 2014. In the U.S., the company plans to initiate a pivotal DFU study in approximately 80 patients in of 2014. We believe this trial will take approximately 6-9 months to report interim analysis and 12 months from initiation to report full analysis. Accordingly, we believe ULURU will be in position to present pivotal DFU and VLU data to CMS in 20156 for reimbursement under the PFS. We believe this will dramatically facilitate uptake of the product in both the U.S. and Europe.

Conclusion & Valuation

There are three major catalysts coming that lead us to believe Altrazeal® will see a significant ramp in sales over the next few years:

- ✓ The first is launching the product around the world over the next one to two years. We believe the company is making great progress in this regard given the launch of over two dozen new countries since the start of the third quarter 2013. Management anticipates having Altrazeal on the market in over 50 countries around the world by the end of 2014, which includes almost all of Europe.

- ✓ The second is gaining reimbursement in the U.S. by CMS under the PFS in 2015. We believe the data that ULURU, Inc. plans to generate with respect to the 100-person VLU study currently being conducted in Europe with data expected around the middle of 2014, the 80-person DFU study to start later in 2014, and the pharmaco-economic analysis to be presented this summer 2014 should all help the company drive reimbursement and coding in the U.S. over the next several years.

- ✓ Finally, we see a dramatic shift in how chronic wounds are treated and paid for by government and private insurance coming in 2014. We think CMS is heading toward packaging and, eventually, a pay-for-performance model much like the rest of the world. We think this will drive use away from the more expensive skin-substitute products like Dermagraft and Apligraf, and to cheaper, equally-effective products like Altrazeal.

We have conducted a discounted cash flow (DCF) analysis on future revenues based on our $100 million sales forecast – peaking in 2020. For 2014, we model over $2.5 million in revenues, growing to $10 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 $2.50 per share. Accordingly, we are recommending purchase of the shares today at $0.51 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.	2012 A	2013 A	Q1 E	Q2 E	Q3 E	Q4 E	2014 E	2015 E	2016 E
Product Sales	$0.280	$0.292	$0.200	$0.450	$0.750	$1.000	$2.400	$5.000	$10.000
YOY Growth	*-28.7%*	*4.2%*	*120.0%*	*2455.4%*	*743.6%*	*958.7%*	*722.3%*	*108.3%*	*100.0%*
Licenses Fees / Royalty Income	$0.090	$0.079	$0.040	$0.050	$0.060	$0.075	$0.225	$0.250	$0.350
Total Revenues	**$0.371**	**$0.371**	**$0.240**	**$0.500**	**$0.810**	**$1.075**	**$2.625**	**$5.250**	**$10.350**
YOY Growth	*-23.5%*	*0.0%*	*135.2%*	*1631.1%*	*632.5%*	*732.9%*	*608.4%*	*100.0%*	*97.1%*
Cost of Goods Sold	$0.244	$0.222	$0.120	$0.225	$0.263	$0.350	$0.958	$1.500	$2.500
Product Gross Margin	*13%*	*24%*	*40%*	*50%*	*65%*	*65%*	*60%*	*70%*	*75%*
Research & Development	$0.833	$0.788	$0.220	$0.240	$0.260	$0.280	$1.000	$1.250	$1.500
Sales, General & Admin	$1.791	$1.288	$0.350	$0.350	$0.350	$0.350	$1.400	$1.650	$1.850
Amtz & Dep	$0.768	$0.720	$0.180	$0.180	$0.180	$0.180	$0.720	$0.720	$0.720
Operating Income	($3.265)	($2.648)	($0.630)	($0.495)	($0.243)	($0.085)	($1.453)	$0.130	$3.780
Operating Margin	-	-	-	-	-	-	-	-	-
Interest & Other Income	($0.267)	($0.433)	($0.100)	($0.050)	($0.050)	($0.050)	($0.250)	($0.200)	($0.150)
Pre-Tax Income	($3.531)	($3.081)	($0.730)	($0.545)	($0.293)	($0.135)	($1.703)	($0.070)	$3.630
Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Preferred Stock Dividends	($0.047)	($0.030)	$0	$0	$0	$0	$0	$0	$0
Net Income	($3.579)	($3.081)	($0.730)	($0.545)	($0.293)	($0.135)	($1.703)	($0.070)	$3.630
Net Margin	-	-	-	-	-	-	-	-	-
Reported EPS	**($0.42)**	**($0.21)**	**($0.03)**	**($0.02)**	**($0.01)**	**($0.01)**	**($0.07)**	**($0.00)**	**$0.10**
YOY Growth	-	-	-	-	-	-	-	-	-
Basic Shares Outstanding	8.494	14.773	23.000	24.000	25.000	26.000	24.500	30.000	35.000

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

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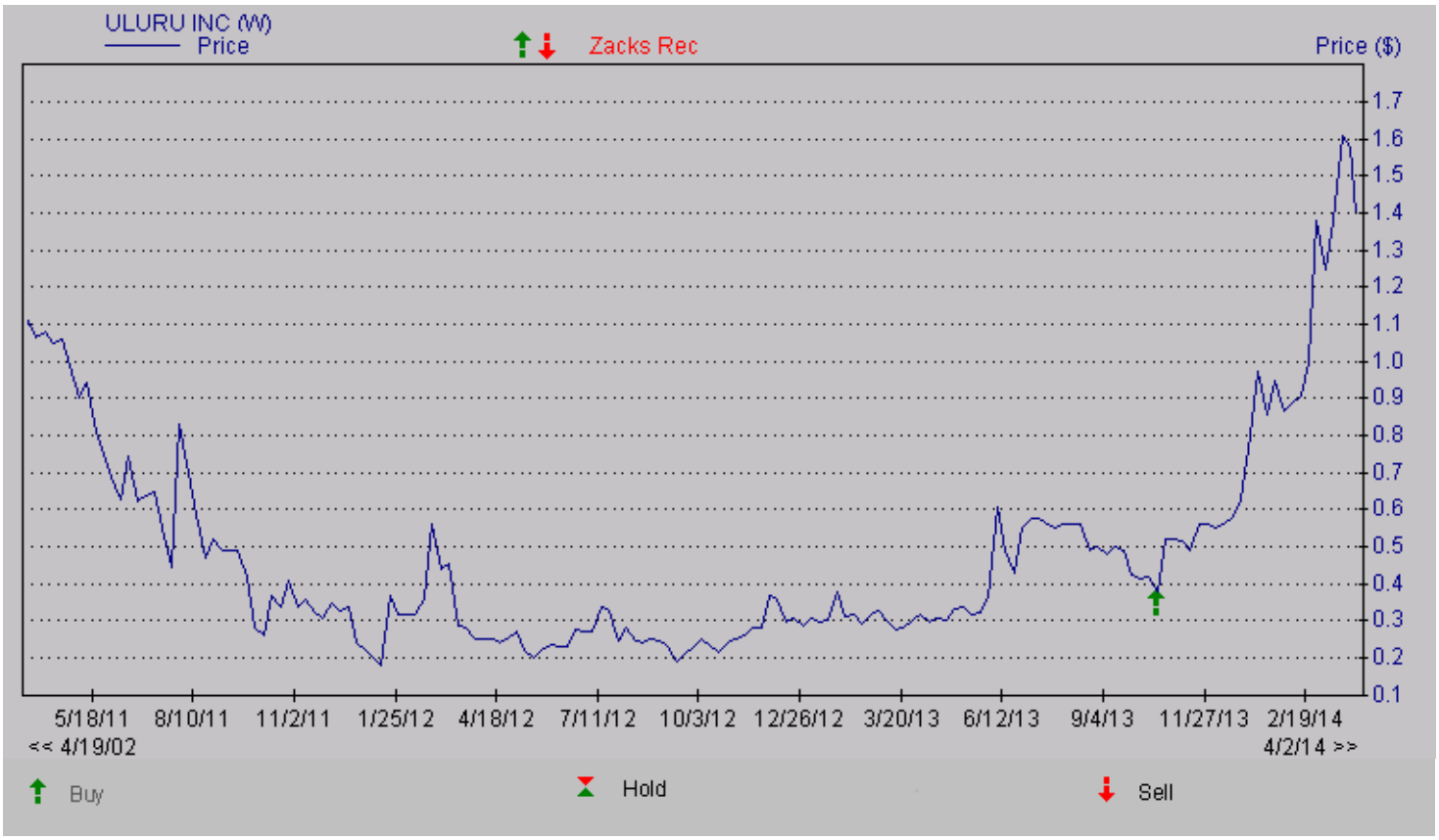
HISTORICAL ZACKS RECOMMENDATIONS



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The current distribution is as follows: Buy/Outperform- 17.0%, Hold/Neutral- 74.7%, Sell/Underperform – 7.5%. Data is as of midnight on the business day immediately prior to this publication.