Zacks Small-Cap Research

May 21, 2014
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ULURU Inc. (ULUR-OTCQB)

ULUR: Expecting A Big Revenue Ramp In The Coming Quarters…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	10/21/2013
Current Price (05/21/14)	$1.00
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.

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	**$0.32**
One-Year Return (%)	**162.35**
Beta	**1.86**
Average Daily Volume (sh)	**55,353**
Shares Outstanding (mil)	**18**
Market Capitalization ($mil)	**$16**
Short Interest Ratio (days)	**0.12**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**12**
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	0.43 E	0.70 E	1.05 E	2.27 E
2015					5.25 E
2016					10.35 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	-$0.02 E	-$0.01 E	-$0.00 E	-$0.07 E
2015					-$0.00 E
2016					$0.11 E

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WHAT'S NEW

First Quarter Financial & Business Update

…Scale-Up Issues Impact Revenue Ramp…

On May 16, 2014, ULURU, Inc. (ULUR) reported financial results for the first quarter ending March 31, 2014. Revenues during the quarter totaled only $102k, comprised of $87k in products sales and $15k in licensing and royalty income. Revenues came in below expectations; we had expected revenues to be around $200k. The company noted production issues, as discussed in our last report, continue to delay shipments to distributors.

We remind investors that in the fourth quarter 2013, ULURU had to write off $60,000 in obsolete finished goods and raw materials. Management has been working through increased lead-times and logistical issues associated with ramping of production on Altrazeal. Last year the company changed packaging from foil package to a clear 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. Nevertheless, according to CEO Kerry Gray, the company still has significant back orders due to these delays in packaging and finish goods labeling. We believe once finally ironed-out, these changes will lead to dramatically improved gross margin for the company. For example, the company has already reduced cost by 33% on manufacturing compared to a year ago. With a fully optimized process by year end, we believe another 33% cost savings is possible in 2015.

…But Revenue Ramp Coming…

Mr. Gray expects the company will be able to eliminate substantially all back orders before the end of the second quarter 2014, with a goal of shipping product into 10 new markets in June. By the end of June 2014, Altrazeal should be on the market in 20 countries around the world. Revenues of $87k in the first quarter 2014 came from only 9 countries and one major distributor. Markets include parts of Latin America, Georgia, Turkmenistan, Ukraine, Czech Republic, Slovakia, South Africa, Croatia, and Slovenia. The company should double that number in the second quarter, and then double it again before the end of the year. Each country ULURU launches Altrazeal in comes with an upfront order, fully recognized as sales by the company. ULURU classifies countries into four sizes:

Country Size	Min. Order
Small	$20,000
Medium	$40,000
Major	$80,000
Super Major	$160,000

On the first quarter conference call, Mr. Gray noted that the 10 countries the company plans to launch Altrazeal to in the second quarter include a mix of small, medium, and major markets. For example, in early May 2014, ULURU presented at the European Wound Management Association (EWMA) meeting in Madrid, Spain, and used that meaning as the kick-off to launch Altrazeal in Spain. If we assume an average of $40,000 per country in the second quarter, launching Altrazeal into 10 countries should generate $400,000 in revenues.

…2014 Should Be A Big Year…

By the end of 2014, the company expects to be on the market with Altrazeal in 50 countries. That assumes launching in 30 more markets during the third and fourth quarters of the year. Again, based on an average of $40,000 per country, we could be looking at $1.2 million in revenues between the third and fourth quarter. That's a heck of a ramp from only $87k in the first quarter.

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.

...Data To Drive Uptake…

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

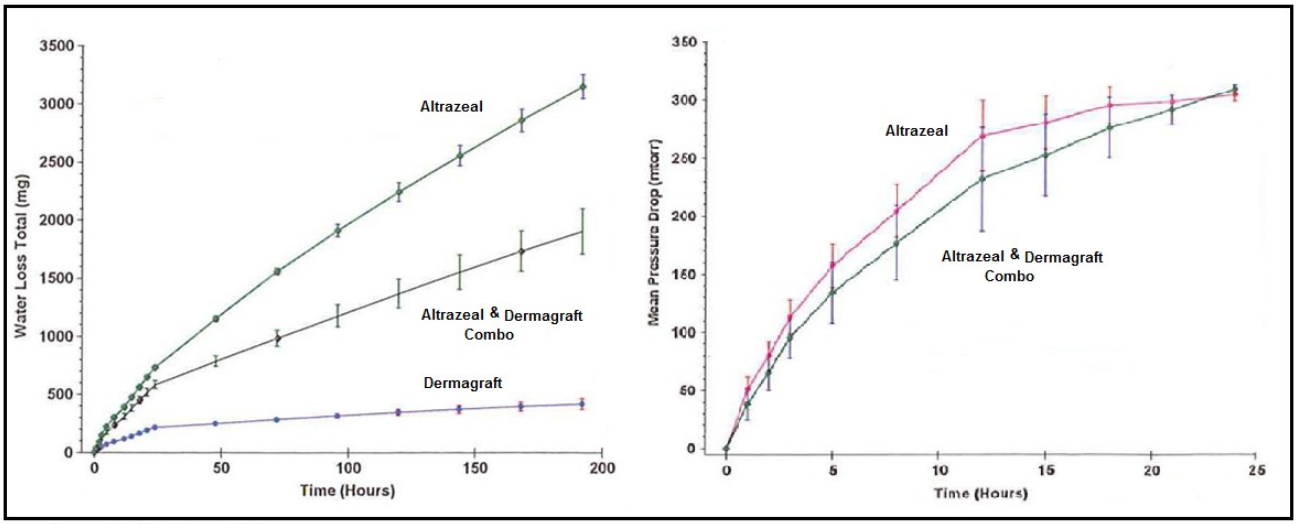
- A team from the the University Medical Centers Ljubljana, Slovenia co-authored an e-poster entitled, "Application of the Transforming Powder Acrylate Wound Dressing and Their Positive Effects." Results from the 8 patient case studies included all major wound types. The goal was to assess the utility 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.

The pharmaco-economic study in Germany continues, with planned submission to the EU regulatory authorities on pricing and reimbursement later this year. Management expects to have pharmaco-economic data on Altrazeal to present publicly in the second quarter of 2014. 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.

- ***If you had a diabetic foot ulcer, would you pay $10,000 to have it heal in six weeks? Or would you rather pay $200 and have it heal in seven weeks?***

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 the third quarter of 2014. 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 $1650 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

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. 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.

…On The Road To Profitability…

Net loss during the first quarter totaled $691k, or $0.03 per share based on 21.4 million shares outstanding. However, net operating cash burn during the quarter totaled roughly $160k. The company exited March 2014 with just over $1.0 million in cash. Several balance sheet improvements have been made over the past few quarters.

Since the end of the third quarter 2013, stockholders equity increased approximately $1.3 million, total liabilities have been reduced by $1.3 million, and cash position has improved by over $1 million.

These improvements in the balance sheet are an important for numerous reasons: it increases the investor audience due to the improved financial stability, it positions the company for a possible up-listing to an exchange due to improved shareholder equity position, it provides management with the resources to implement the business strategy, and it eliminates one uncertainly that can deter potential investors.

With the significant improvement in the balance sheet and the potential for soaring revenues over the next few quarters, we believe ULURU is clearly on the road to profitability. We expect operating loss to decline each subsequent quarter in 2014, with profitability to be achieved in 2015. However, because a sizable portion of the company's operating loss is non-cash amortization, depreciation, and warrant liability, we believe it is very likely that ULURU reports positive cash flow from operations later this year. Mr. Gray has stated that this is a clear goal for the company over the near future.

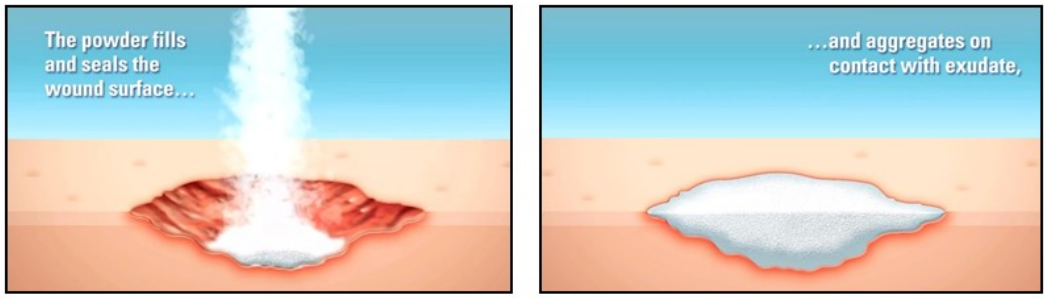
…An Uplist On The Horizon…

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 $1.00 per share, ULURU still has a long-way to go before this minimum requirement is achieved. As of March 31, 2014, the company reported $3.1 million in positive shareholder equity – close to where they need to be to qualify for an uplisting.

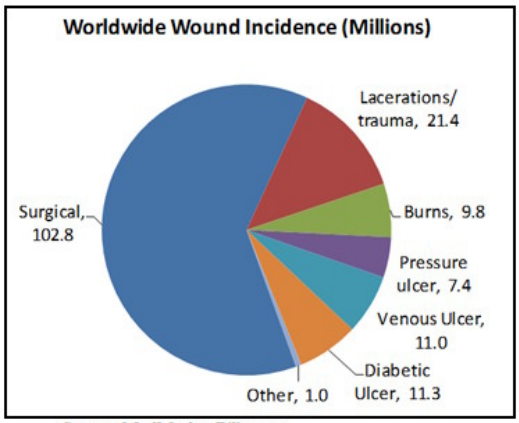
With business fundamentals improving and the global roll-out of Altrazeal planned in full-force for 2014, we would not be surprised to see the shares significantly closer to this goal by year end 2014.

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.

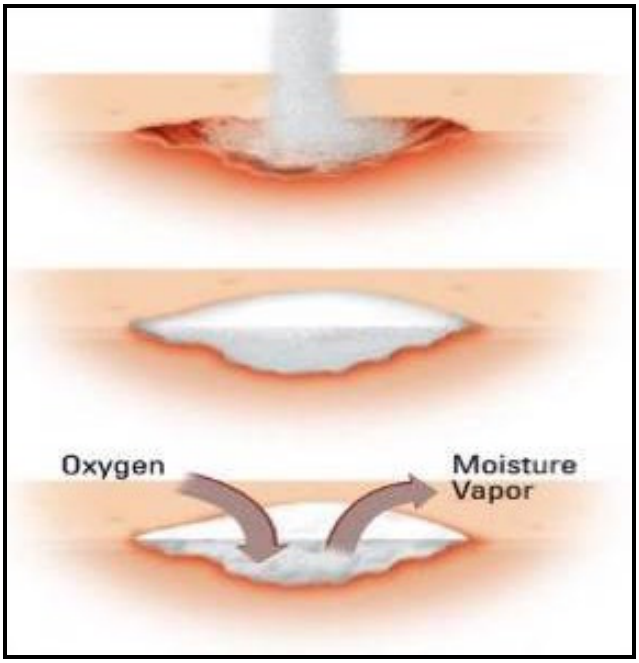


Altrazeal is U.S. FDA / EU CE Mark approved for sale. The product is supplied as a sterile dressing suitable for the covering and protection of exuding wounds such as burns, abrasions, skin graft donor sites, surgical wounds, and chronic wounds including venous leg ulcers and diabetic foot ulcers. It 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 $1.00 because the stock is significantly under-valued and offers a very attractive return to investors over the next several years.

PROJECTED FINANCIALS

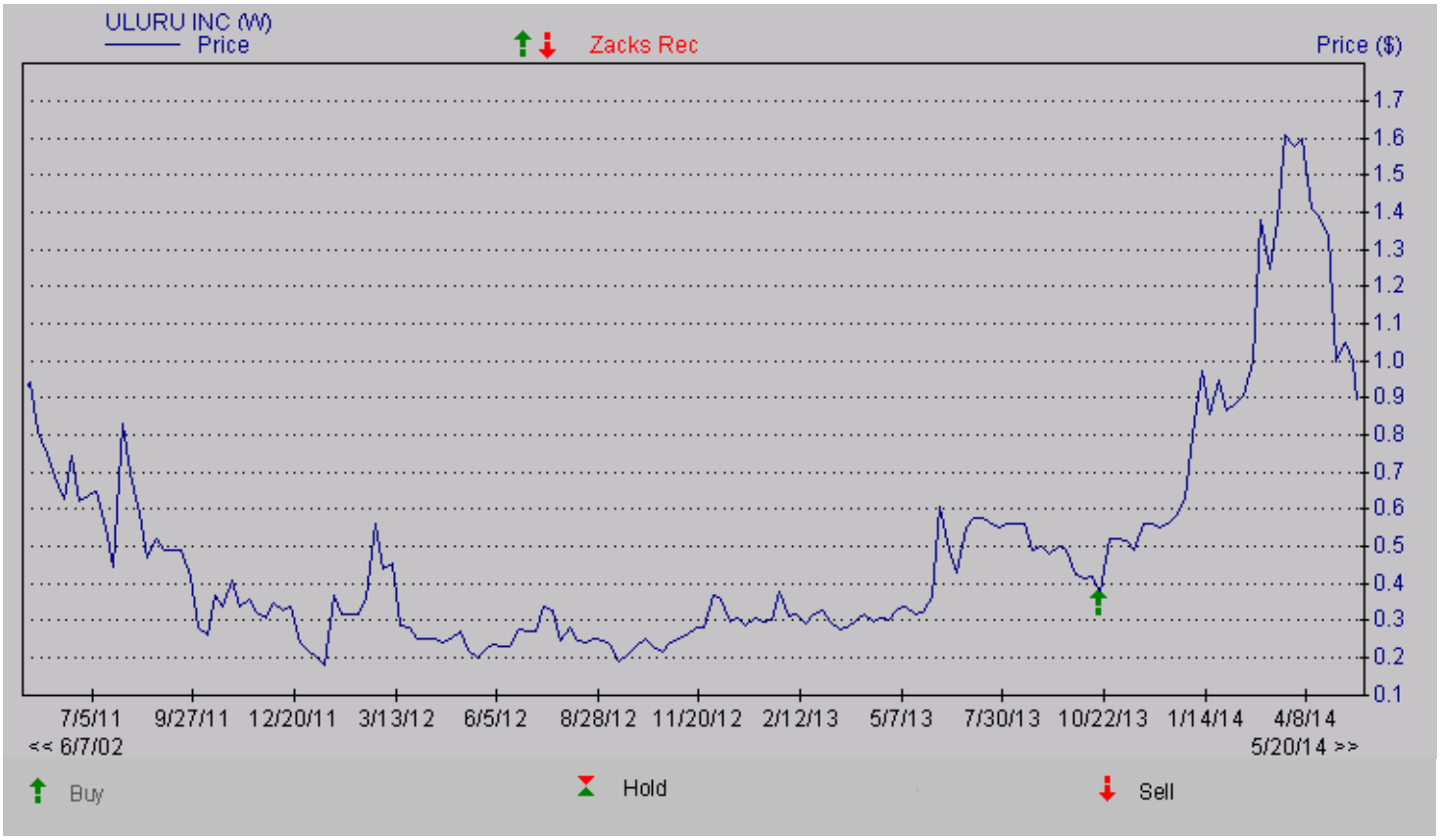
ULURU, Inc.
Income Statement

ULURU, Inc.	2012 A	2013 A	Q1 A	Q2 E	Q3 E	Q4 E	2014 E	2015 E	2016 E
Product Sales	$0.280	$0.292	$0.087	$0.400	$0.650	$1.000	$2.137	$5.000	$10.000
YOY Growth	*-28.7%*	*4.2%*	*-3.8%*	*2171.4%*	*631.1%*	*958.7%*	*632.3%*	*133.9%*	*100.0%*
Licenses Fees / Royalty Income	$0.090	$0.079	$0.015	$0.025	$0.050	$0.050	$0.140	$0.250	$0.350
Total Revenues	**$0.371**	**$0.371**	**$0.102**	**$0.425**	**$0.700**	**$1.050**	**$2.277**	**$5.250**	**$10.350**
YOY Growth	*-23.5%*	*0.0%*	*-0.1%*	*1371.4%*	*533.0%*	*713.6%*	*514.5%*	*130.6%*	*97.1%*
Cost of Goods Sold	$0.244	$0.222	$0.041	$0.200	$0.228	$0.350	$0.819	$1.500	$2.500
Product Gross Margin	*13%*	*24%*	*53%*	*50%*	*65%*	*65%*	*62%*	*70%*	*75%*
Research & Development	$0.833	$0.788	$0.188	$0.200	$0.220	$0.225	$0.833	$1.000	$1.250
Sales, General & Admin	$1.791	$1.288	$0.469	$0.400	$0.375	$0.400	$1.644	$1.650	$1.750
Amtz & Dep	$0.768	$0.720	$0.178	$0.180	$0.180	$0.180	$0.718	$0.720	$0.720
Operating Income	($3.265)	($2.648)	($0.773)	($0.555)	($0.303)	($0.105)	($1.736)	$0.380	$4.130
Operating Margin	-	-	-	-	-	-	-	-	-
Interest & Other Income	($0.267)	($0.433)	$0.082	$0.000	$0.000	$0.000	$0.082	($0.200)	($0.150)
Pre-Tax Income	($3.531)	($3.081)	($0.691)	($0.555)	($0.303)	($0.105)	($1.654)	$0.180	$3.980
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)	($0.691)	($0.555)	($0.303)	($0.105)	($1.654)	$0.180	$3.980
Net Margin	-	-	-	-	-	-	-	-	-
Reported EPS	**($0.42)**	**($0.21)**	**($0.03)**	**($0.02)**	**($0.01)**	**($0.00)**	**($0.07)**	**$0.01**	**$0.11**
YOY Growth	-	-	-	-	-	-	-	-	-
Basic Shares Outstanding	8.494	14.773	21.416	24.500	25.500	26.500	24.479	30.000	35.000

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

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The current distribution is as follows: Buy/Outperform- 16.9%, Hold/Neutral- 76.4%, Sell/Underperform – 6.0%. Data is as of midnight on the business day immediately prior to this publication.