Zacks Small-Cap Research

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ULURU Inc. (ULUR-OTCQB)

ULUR: Production Issues Being Resolved, Revenue Ramp Imminent…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	10/21/2013
Current Price (08/22/14)	$1.30
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	**$0.38**
One-Year Return (%)	**145.28**
Beta	**2.11**
Average Daily Volume (sh)	**35,039**
Shares Outstanding (mil)	**24**
Market Capitalization ($mil)	**$32**
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	0.21 A	0.70 E	1.05 E	2.06 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	-$0.03 A	-$0.01 E	-$0.00 E	-$0.07 E
2015					-$0.00 E
2016					$0.11 E

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WHAT'S NEW

Second Quarter Financial & Business Update

…Working Through Production Issues…

On August 14, 2014, ULURU, Inc. (ULUR) reported financial results and filed its Form 10-Q for the second quarter ending June 30, 2014. Revenues during the quarter totaled $209k, comprised of $178k in products sales and $32k in licensing and royalty income. Product sales grew by 908% from the second quarter 2013 and 105% sequentially from the first quarter 2014. These are impressive numbers, but still below expectations. We had expected revenue from product sales in the $300k range. Production issues continue to negatively impact revenue growth.

For example, management's guidance after the first quarter conference call in May 2014 was to have launched Altrazeal in 24 countries by the end of June 2014. As of mid-August 2014, the product has launched in 22 countries, slightly behind schedule. On the second quarter call, CEO Kerry Gray noted that supply issues are still resulting in the company not being able to meet demand. Production of Altrazeal is a complicated process, and 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 instance, Altrazeal product labeling is available in 17 different languages for 29 targeting countries.

The company recently received final inventory of 100,000 blister packs, with another 40,000 schedule to be received soon. In September 2014, management expects to initiate product for another 160,000 units. This equates to final goods of $1.4 million at international distributor prices. As such, we believe the company is working through production issues and should be able to fully-meet growing distributor demand by the fourth quarter 2014.

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. 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.

…Revenue Ramp Coming…

By the end of 2014, Altrazeal should be on the market in 40-50 countries around the world. Existing markets include parts of Latin America, Georgia, Turkmenistan, Ukraine, Czech Republic, Slovakia, South Africa, Serbia, Macedonia, Montenegro, Croatia, Slovenia, and Afghanistan. New targets for the second half of the year include areas of the Middle East, Asia, and Russia. 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

New major markets recently launched include Italy, Spain, and Portugal in May 2014. 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.

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 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.

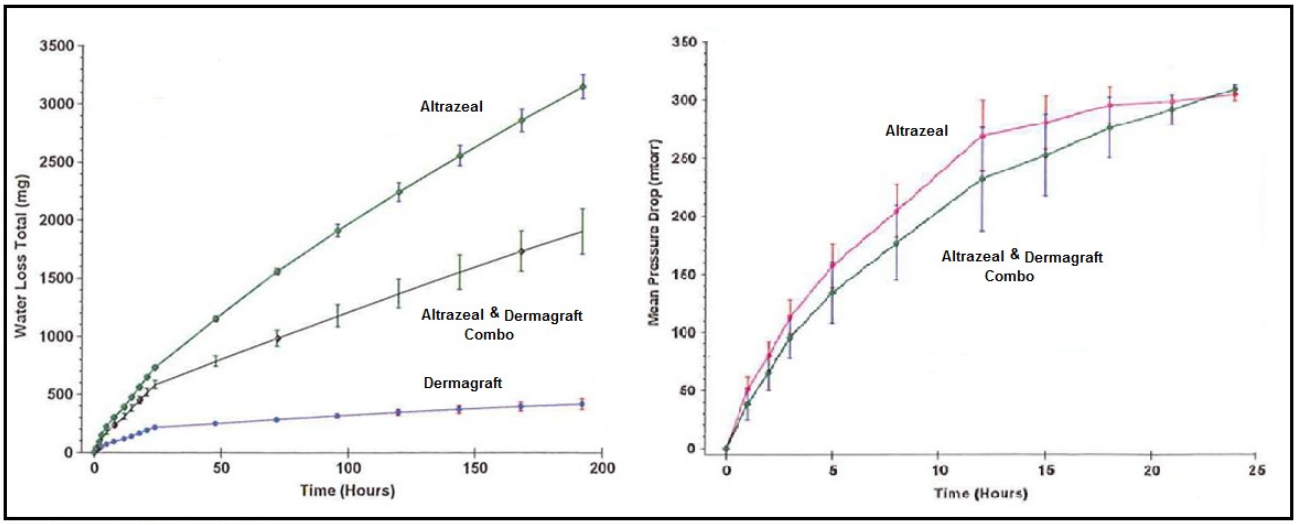
- In terms of the issues with Altrazeal, there is a need to educate physicians on when to use the secondary dressing, when to use additional sealing and to educate the physician not to be impatient and not to change the dressing so regularly. On average in these patients, the dressings will change every 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 later this year. Management expects to have pharmaco-economic data on Altrazeal to present publicly very soon. 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 $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

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 second quarter totaled $710k, or $0.03 per share based on 24.1 million shares outstanding. Net operating cash burn during the quarter totaled roughly $745k. The company exited June 2014 with $721k 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 all remaining debt has been eliminated.

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.

…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.

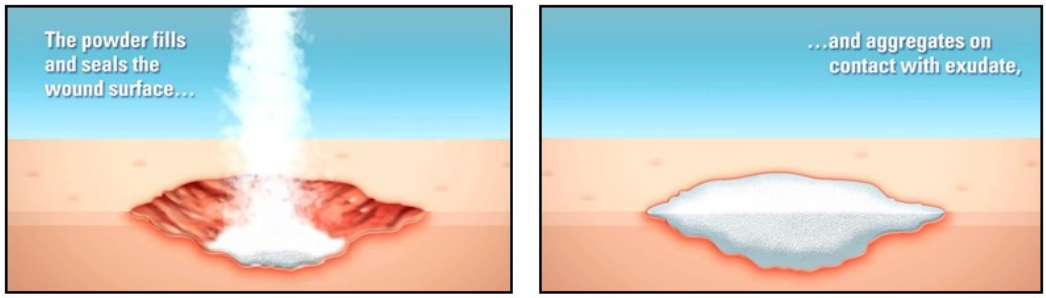
…An Uplist On The Horizon…

Earlier this year, 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 $1.30 per share, ULURU still has a long-way to go before this minimum requirement is achieved. As of June 30, 2014, the company reported $2.95 million in positive shareholder equity – close to where they need to be to qualify for an uplisting.

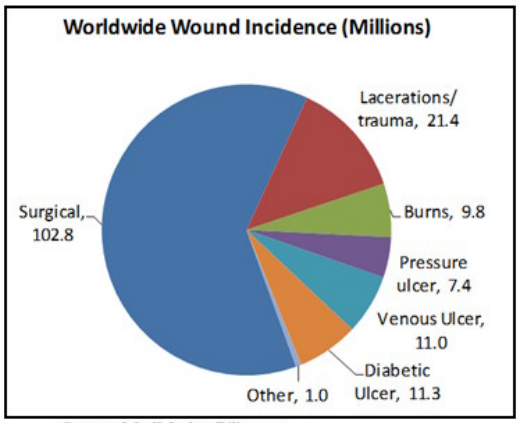
With business fundamentals improving and the global roll-out of Altrazeal planned in full-force for 2014, we would not be surprised to see the shares significantly closer to this goal by year end 2014.

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.

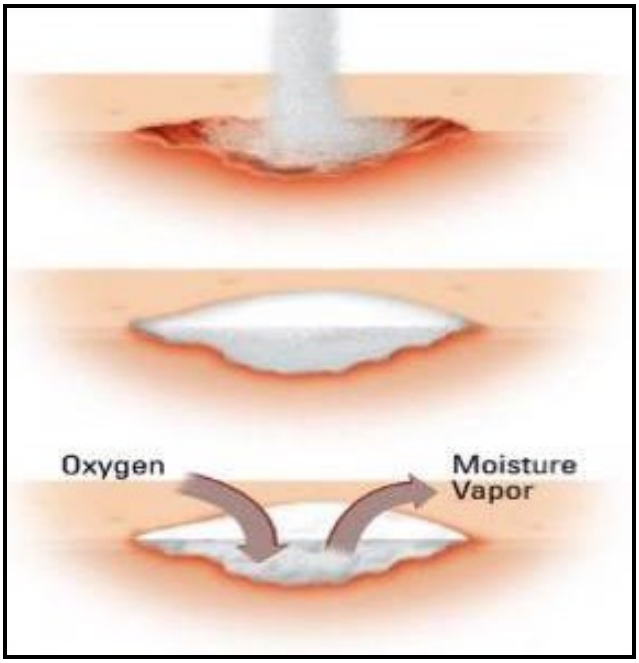


Altrazeal is U.S. FDA / EU CE Mark approved for sale. The product is supplied as a sterile dressing suitable for the covering and protection of exuding wounds such as burns, abrasions, skin graft donor sites, surgical wounds, and chronic wounds including venous leg ulcers and diabetic foot ulcers. It 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 40 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 in the coming months 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 $2.0 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 $1.30 because the stock is significantly under-valued and offers a very attractive return to investors over the next several years.

PROJECTED FINANCIALS

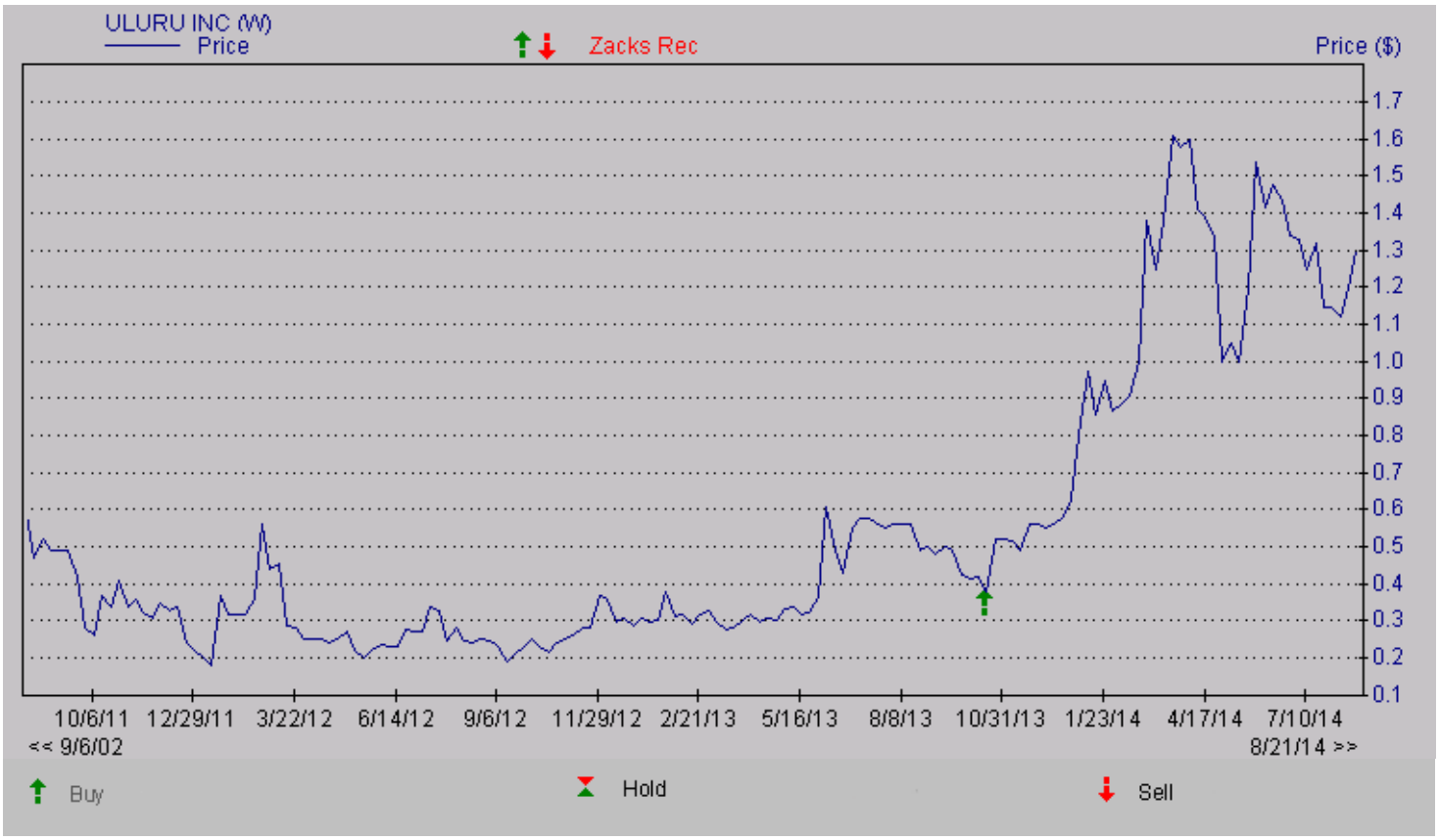
ULURU, Inc.
Income Statement

ULURU, Inc.	2013 A	Q1 A	Q2 A	Q3 E	Q4 E	2014 E	2015 E	2016 E
Product Sales	$0.292	$0.087	$0.178	$0.650	$1.000	$1.915	$5.000	$10.000
YOY Growth	*4.2%*	*-3.8%*	*908.4%*	*631.1%*	*958.7%*	*556.1%*	*161.1%*	*100.0%*
Licenses Fees / Royalty Income	$0.079	$0.015	$0.032	$0.050	$0.050	$0.146	$0.250	$0.350
Total Revenues	**$0.371**	**$0.102**	**$0.209**	**$0.700**	**$1.050**	**$2.061**	**$5.250**	**$10.350**
YOY Growth	*0.0%*	*-0.1%*	*624.6%*	*533.0%*	*713.6%*	*456.2%*	*154.7%*	*97.1%*
Cost of Goods Sold	$0.222	$0.041	$0.113	$0.228	$0.350	$0.732	$1.500	$2.500
Product Gross Margin	*24%*	*53%*	*36%*	*65%*	*65%*	*62%*	*70%*	*75%*
Research & Development	$0.788	$0.188	$0.184	$0.220	$0.225	$0.817	$1.000	$1.250
Sales, General & Admin	$1.288	$0.469	$0.411	$0.375	$0.400	$1.655	$1.650	$1.750
Amtz & Dep	$0.720	$0.178	$0.178	$0.180	$0.180	$0.716	$0.720	$0.720
Operating Income	($2.648)	($0.773)	($0.678)	($0.303)	($0.105)	($1.858)	$0.380	$4.130
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	($0.433)	$0.082	($0.032)	$0.000	$0.000	$0.050	($0.200)	($0.150)
Pre-Tax Income	($3.081)	($0.691)	($0.710)	($0.303)	($0.105)	($1.809)	$0.180	$3.980
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)	($0.303)	($0.105)	($1.809)	$0.180	$3.980
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.21)**	**($0.03)**	**($0.03)**	**($0.01)**	**($0.00)**	**($0.07)**	**$0.01**	**$0.11**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	14.773	21.416	24.122	25.500	26.500	24.385	30.000	35.000

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

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