

ULURU INC.

2014 Annual Report

COMPANY MISSION

We are a diversified specialty pharmaceutical company committed to developing and commercializing a broad range of innovative wound care and muco-adhesive film products based on our patented Nanoflex™ and OraDisc™ technologies, with the goal of improving outcomes for patients, healthcare professionals and health care payers.



PRESIDENTS LETTER TO STOCKHOLDERS

To Our Stockholders:

During 2014, we continued to execute on our primary objective, the global commercialization of Altrazeal[®], our innovative wound care product. We now have in place the systems and organizations to support the accelerated commercialization of Altrazeal[®] into new markets while servicing our existing markets. By year end 2014, Altrazeal[®] was commercially available in approximately 25 markets.

Progress has been made in the past 18 months to achieve our commercialization objectives and to establish an international marketing network. Now that significantly more clinical and pharmacoeconomic data is available to support the many benefits of Altrazeal[®], this gives strong support for the expansion of our marketing network and attracting highly qualified companies as potential commercialization partners.

In addition, there have been significant efforts during the past year devoted to achieving regulatory approval in markets not covered by the CE Mark authorization. Registration activities are ongoing throughout the Middle East, India, Egypt, and a number of other markets. Registration approvals have recently been received in numerous markets including Saudi Arabia, Russia, Kuwait, Afghanistan, and Singapore.

Achievements in 2014 and 2015

- Entered an agreement to purchase the 75% ownership of Altrazeal Trading GmbH, not currently owned by the Company. This will more than double European revenue and immediately be accretive to our operating results.*
- Extended and expanded the option granted to OraDisc GmbH for the development of prescription pharmaceuticals using our patented muco-adhesive film technology. The therapeutic categories were extended to include anti-psychotics, neurologics, and erectile dysfunction.*

- *Announced interim data on 43 patients from the European Pharmacoeconomic Study. Compared with competitive advanced moist wound dressings, Altrazeal[®] reduced healing times almost 50% and the cost to wound closure by 73%. For 50 days of treatment, due to Altrazeal[®] being able to remain in place up to 14 days (average 9 days in the study), Altrazeal[®] is almost 50% less expensive compared with competitive advanced moist wound healing dressings.*
- *Extended our international marketing network to include among other countries, Germany, Russia, the Middle East, Greece, Egypt, and Northern Africa.*
- *Launched Altrazeal[®] in approximately 15 new markets including Germany, Italy, Spain, Portugal, and numerous Middle Eastern countries.*
- *Extensive participation at the European Wound Management Association Conference, including a podium presentation on the benefits of Altrazeal[®] for patients and caregivers, poster presentations, and a clinical expert meeting.*

Objectives for 2015:

- *Continuing the expansion the commercialization of Altrazeal[®] with the objective of having Altrazeal[®] available in 50 markets.*
- *Further expand the global marketing network to include 75 markets by year end.*
- *Advance strategic partnering discussions in key markets including, USA, Canada, United Kingdom, Japan, Korea, and Latin America.*
- *Improve operating margins through economies of scale, reduction in average fill weights and increased filling speeds.*
- *Utilize our patented muco-adhesive film technology to advance the development of products incorporating the active drug in numerous high-volume prescription pharmaceuticals.*
- *Continue to develop additional clinical and pharmacoeconomic data to support the commercialization of Altrazeal[®].*

I would like to thank our strategic partners, suppliers, consultants, the Board of Directors and our loyal dedicated employees for all the contributions they have made to our progress and success. The continued support of our loyal investors is greatly appreciated.

We look forward to further establishing Altrazeal[®] in the global wound care market, providing benefits to patients, reducing the cost burden to those funding health care, and achieving the associated increment in shareholder value.

Sincerely,

A handwritten signature in black ink on a light gray background. The signature reads "Kerry P. Gray" in a cursive, flowing script.

Kerry P. Gray
President and Chief Executive Officer

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-K

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2014
- OR
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission File No. 001-336180

ULURU Inc.

(Exact name of registrant as specified in its charter)

Nevada
*(State or other jurisdiction of incorporation or
organization)*

41-2118656
(I.R.S. Employer Identification No.)

4452 Beltway Drive
Addison, Texas
(Address of principal executive offices)

75001
(Zip Code)

(214) 905-5145
(Registrant's telephone number, including area code)

Securities registered under Section 12(b) of the Exchange Act:

None

Securities registered under Section 12(g) of the Exchange Act:

Common Stock, \$0.001 par value

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

As of June 30, 2014 (the last business day of the most recently completed second fiscal quarter), the aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates of the registrant (without admitting that any person whose shares are not included in the calculation is an affiliate) was approximately \$19,745,635 based on the closing price of the registrant's common stock as reported on the OTCQB™ marketplace on such date.

As of March 31, 2015, there were 24,458,018 shares of the registrant's Common Stock, \$0.001 par value per share, and nil shares of Series A Preferred Stock, \$0.001 par value per share, issued and outstanding.

Documents Incorporated by Reference

The information required by Part III of this Report, to the extent not set forth herein, is incorporated herein by reference from the registrant's definitive proxy statement relating to the Annual Meeting of Stockholders to be held in 2015, which definitive proxy statement shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Report relates.

ULURU Inc.

FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2014

TABLE OF CONTENTS

| <u>Item</u> | | <u>Page</u> |
|-----------------|--|-------------|
| Part I | | |
| 1. | Business | 4 |
| 1A. | Risk Factors | 19 |
| 1B. | Unresolved Staff Comments | 32 |
| 2. | Properties | 32 |
| 3. | Legal Proceedings | 32 |
| 4. | Mine Safety Disclosures | 32 |
| Part II | | |
| 5. | Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities | 33 |
| 6. | Selected Financial Data | 34 |
| 7. | Management's Discussion and Analysis of Financial Condition and Results of Operations | 35 |
| 7A. | Quantitative and Qualitative Disclosures about Market Risk | 50 |
| 8. | Financial Statements and Supplementary Data | 50 |
| 9. | Changes In and Disagreements With Accountants on Accounting and Financial Disclosure | 50 |
| 9A. | Controls and Procedures | 51 |
| 9B. | Other Information | 52 |
| Part III | | |
| 10. | Directors, Executive Officers and Corporate Governance | 53 |
| 11. | Executive Compensation | 54 |
| 12. | Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters | 54 |
| 13. | Certain Relationships and Related Transactions and Director Independence | 54 |
| 14. | Principal Accountant Fees and Services | 54 |
| Part IV | | |
| 15. | Exhibits and Financial Statement Schedules | 55 |
| | Signatures | 56 |
| | Index to Exhibits | 57 |
| | Index to Financial Statements | 58 |

Part I

FORWARD-LOOKING INFORMATION IS SUBJECT TO RISK AND UNCERTAINTY

This Annual Report on Form 10-K (including documents incorporated by reference) (this “Report”) and other written and oral statements we make from time to time contain certain “forward-looking” statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. You can identify these forward-looking statements by the fact that they use words such as “should”, “expect”, “anticipate”, “estimate”, “target”, “may”, “project”, “guidance”, “will”, “intend”, “plan”, “believe” and other words and terms of similar meaning and expression in connection with any discussion of future operating or financial performance. One can also identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes to differ materially from current expectations. These statements are likely to relate to, among other things, the Company’s goals, plans and projections regarding its financial position, statements indicating that the Company has cash and cash equivalents sufficient to fund our operations in the future, results of operations, cash flows, market position, product development, product approvals, sales efforts, expenses, performance or results of current and anticipated products and the outcome of contingencies such as legal proceedings, acquisitions, and financial results, which are based on current expectations that involve inherent risks and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years. We have included important factors in the cautionary statements included in this Report, particularly under “Risk Factors”, that we believe could cause actual results to differ materially from any forward-looking statement.

Although the Company believes it has been prudent in its plans and assumptions, no assurance can be given that any goal or plan set forth in forward-looking statements can be achieved, and readers are cautioned not to place undue reliance on such statements, which speak only as of the date made. We undertake no obligation to release publicly any revisions to forward-looking statements as a result of new information, future events or otherwise.

Altrazeal®, Aphthasol®, Nanoflex®, OraDisc™, the ULURU logo and other trademarks or service marks of ULURU Inc. appearing in this Report are the property of ULURU Inc. This Report contains additional trade names, trademarks and service marks of other companies, which belong to such companies.

ITEM 1. BUSINESS

Company Mission and Strategy

ULURU Inc. (together with our subsidiaries, “we”, “our”, “us”, “ULURU”, or the “Company”) is a Nevada corporation. We are a diversified specialty pharmaceutical company committed to developing and commercializing a broad range of innovative wound care and mucoadhesive film products based on our patented Nanoflex® and OraDisc™ technologies, with the goal of improving outcomes for patients, health care professionals and health care payers.

Our strategy is twofold:

- Establish a market leadership position in wound management by developing and commercializing a customer focused portfolio of innovative wound care products based on our Nanoflex® technology to treat the various phases of wound healing; and
- Develop our oral mucoadhesive film technology (OraDisc™) and for systemic drug delivery and delivery of actives to the oral cavity.

Core Technology Platforms

Nanoflex® Technology

The Nanoflex® technology platform provides the ability to formulate a variety of unique materials through the aggregation of hydrogel-like particles. This concept takes advantage of the inherent biocompatibility of hydrogels. Unlike bulk hydrogels, these aggregates are shape retentive, can be extruded or molded, and offer properties suitable for use in a variety of in-vivo medical devices, and in novel drug delivery systems. The polymers used in our Nanoflex® technology have been extensively researched and commercialized into several major medical products including contact lenses and other FDA-approved implants. They are generally accepted as safe, non-toxic and biocompatible.

Our Nanoflex® technology system has at its core a system of hydrogel-like nanoparticles composed of a polymer used in manufacturing contact lenses and other FDA-approved implants. When applied to a wound the polymer particles aggregate immediately and irreversibly upon contact with physiological fluid, such as wound exudate or blood, forming a flexible, nano-porous, non-resorbable film material.

Utilizing our proprietary Nanoflex® technology, we have developed two separate development platforms:

- Nanoflex® Powder
- Nanoflex® Injectable Liquid

Materials from either platform are composed of polymer particles which are stabilized to prevent aggregation prior to application to a physiological environment. We can control the physic-chemical characteristics to affect the rate of aggregation, the final material properties such as fluid content and strength of the resulting aggregate, and if desired, the drug delivery profile for actives trapped in the aggregate.

Nanoflex® Powder

Our Nanoflex® Powder is a novel wound treatment technology used to promote the healing of exuding wounds. The scientifically engineered material is unique among all other dressings currently available in terms of properties and performance, and can be used in chronic, acute, surgical and traumatic wounds. It is formulated as a two-polymer blend in a specific ratio. In the presence of wound exudate, the particles hydrate and irreversibly aggregate to conform to the contours of the wound bed, transforming into a moist, flexible, moisture-permeable film. This film not only provides an optimal moist wound environment which supports cellular function and tissue repair, but it is also of appropriate pore size to prevent intrusion by exogenous bacteria. After application to the wound bed, Nanoflex® Powder exhibits mechanical properties which are similar to soft tissue. The stable, non-resorbable film flakes off at the edges as the wound heals, like a scab. It can remain in place for up to 14 days if exudate is present and can be painlessly removed without additional trauma, leaving no residue in the wound bed. Nanoflex® Powder can also serve as a drug delivery matrix for antiseptics, and there is significant potential for its use as a delivery platform for anti-inflammatory drugs such as corticosteroids, pro-angiogenic agents, and other actives such as growth factors to accelerate wound healing.

Nanoflex® Injectable Liquid

A suspension of hydrogel nanoparticles containing a small percentage of hyaluronic acid, when injected into tissue, immediately and irreversibly aggregates. With time, the hyaluronic acid portion of the aggregate is resorbed, leaving behind a porous, Nanoflex® scaffold which provides the basis for cellular infiltration and acts as the anchor for collagen attachment.

This injectable system has been studied extensively for safety and for applications as a dermal filler to provide a family of soft tissue filler materials with different degrees of permanency.

Hyaluronic acid is a nonspecies-specific hydrophilic coiled polysaccharide that is present in all connective tissue. In dermal and sub-dermal tissue, hyaluronic acid binds with water and provides volume and elasticity. As a dermal filler, hyaluronic acid provides superb biocompatibility, but applications of this material can be limiting because the material is resorbed in a four to twelve month period requiring repeat injections. Our potential dermal filler and sub-dermal filler can be composed of between 1% and 95% hyaluronic acid. Materials for facial sculpting containing a lower amount of hyaluronic acid result in a higher degree of permanence.

Mucoadhesive OraDisc™ Technology

Treatment of oral conditions generally relies upon the use of medications formulated as gels and pastes, which are applied to lesions in the mouth. The duration of effectiveness of these medications is typically short because the applied dose is worn away through the mechanical actions of speaking, eating, and tongue movement, and is washed away by saliva flow. To address these problems, we developed a novel erodible mucoadhesive film product. This technology, known as OraDisc™, comprises a multi-layered film having an adhesive layer, a pre-formed film layer, and a coated backing layer. Depending upon the intended application, a pharmaceutically active compound can be formulated within any of these layers, providing a wide range of potential applications. The disc stays in place eroding over a period of time, so that subsequent removal is unnecessary. The drug delivery rate is pre-determined by the rate of erosion of the disc, which is in turn controlled by the composition of the backing layer.

Our adhesive film technology has multiple applications, including the localized delivery of drug to a mucosal site, use as a transmucosal delivery device for delivering drugs into the systemic circulation, and incorporating the drug in the outer layer for delivery into the oral cavity. The adhesive film will adhere to any wet mucosal surface. Additionally, the adhesive film has been formulated to adhere to the surface of teeth and gums for the delivery of dental health and cosmetic dental actives.

Initial drug delivery studies using our adhesive film technology indicate the potential to achieve significantly higher drug exposure and higher blood level concentrations.

OraDisc™ was initially developed as a drug delivery system to treat canker sores with the same active ingredient (amlexanox) that is used in our Aphthasol® paste. We have continued to develop the OraDisc™ technology and we have generated or are exploring additional prototype drug delivery products, including those for pain palliation in the oral cavity, breath freshener, and other dental applications. Work has commenced on the development of a range of prescription products, including products to treat migraine, erectile dysfunction, neurological conditions, and asthma.

Marketed Products

We have used our drug delivery technology platforms to develop the following products and product candidates:

Altrazeal®

Altrazeal® Transforming Powder Dressing, based on our Nanoflex® technology, has the potential to change the way health care providers approach the treatment of wounds. Launched in June 2008, the product is indicated for exuding wounds such as partial thickness burns, donor sites, abrasions, non-healing surgical wounds, trauma and chronic wounds including diabetic foot ulcers, venous leg ulcers, and pressure ulcers. The powder fills and seals the wound to provide an optimal moist wound healing environment. The wound exudate is controlled through the high moisture vapor transpiration rate (MVTR) of the material. Intimate contact at the wound bed supports cellular function and tissue repair. Other characteristics of Altrazeal® that promote healing are oxygen permeability and bacteria impermeability. Patient comfort is enhanced with the easy application and removal of our wound dressing, where no granulating tissue is harmed during the removal procedure. In a randomized clinical study Altrazeal® demonstrated a statistically significant improvement in patient pain and comfort compared to Aquacel® AG, a market leading product, in the treatment of skin graft donor sites. Also, in numerous clinical settings, including venous leg ulcers, arterial ulcers and second degree burns, significant pain reduction has been reported by patients, enabling increased compliance to therapy and improved clinical outcomes. The dressing is flexible and adherent and is designed to allow greater range of motion. In addition, the ability of Altrazeal® to manage wound exudates extends the wear time between dressing changes, which offers a significant pharmaco-economic benefit. This feature is considered an extremely important marketing advantage in countries where there are socialized medical programs.

The regulatory status of Altrazeal® is a 510(k) exempt product. The FDA was notified and the product was registered in June 2008.

Since the roll-out of Altrazeal® in June 2008, there have been many outstanding clinical results. Positive clinical experiences have been documented through the completion of one randomized clinical trial, the publishing of more than 40 poster presentations, two peer reviewed articles being published in an international indexed journal, and multiple publications in the international literature. The extensive clinical data supporting the benefits of Altrazeal® has been further enhanced by the clinical experience in Europe and Australia. To further improve the cost effectiveness of Altrazeal®, we now offer a 0.75 gram blister pack along with our original 2 gram and 5 gram pouches. We believe the 0.75 gram blister pack contains a quantity of product more appropriate for treating smaller chronic wounds.

The focus of our commercial activities is introducing Altrazeal® globally through our network of distribution partners. Due to the efforts of our licensees, Altrazeal Trading GmbH and Altrazeal AG, Altrazeal® is now available in twenty three international territories. During 2015, we are expecting the launch and availability of Altrazeal® in an additional twenty five new international markets. The clinical and economic benefits that can be derived using Altrazeal® are important marketing features in socialized medical programs throughout Europe and many global markets. We believe that short-term revenue growth will be maximized by focusing on international markets. Consequently, our limited resources are being allocated to international expansion rather than growth in the United States.

Currently, we do not have sufficient human or financial resources to effectively compete in the U.S. market. Utilizing predominately independent sales representatives over which we have no control has proven ineffective. Accordingly, our plan is to first attempt to develop a strong presence internationally. By adopting this strategy we believe we will improve our ability to engage a significant marketing partner with the necessary experience and financial resources to effectively compete in the U.S. market. We continue to have successes with a limited number of healthcare institutions in the U.S., which indicates the potential in the U.S. market.

In June 2010, we entered into a licensing and supply agreement with Jiangxi Aiqilin Pharmaceuticals Group Company, a corporation in China (“Aiqilin”), for the development and commercialization of Altrazeal® in China, including Hong Kong, Macau, and Taiwan. Under the terms of the agreement, we received an upfront licensing payment, will receive a royalty based on product sales and milestone payments based on certain regulatory approvals and on the achievement of certain cumulative product sales performance. Aiqilin has also been granted certain manufacturing rights. The agreement covers Altrazeal®, Altrazeal® Silver, and Altrazeal® Collagen.

In July 2010, we received notification that Altrazeal® Transforming Powder Dressing had been granted CE Mark Certification. The issuance of a CE Mark for Altrazeal® represents a significant milestone for the commercial expansion as this enables us to market in all European Union member states and other countries that recognize the CE Mark. Additionally, registration has been received in Saudi Arabia, Singapore, Australia, and numerous other international markets. Registration is ongoing in other important markets including India and Russia.

In September 2010, we entered into a worldwide distribution agreement appointing Novartis Animal Health, Inc. as the exclusive distributor of a veterinary version of Altrazeal® for marketing to the animal health sector. Under the terms of the agreement, we will supply Novartis Animal Health, Inc. with finished product for marketing in the global markets. The agreement further states that other wound care products developed by us may also be covered by the agreement upon the mutual agreement of the parties. In November 2012, we completed the initial shipment of the veterinary version of Altrazeal® to Novartis Animal Health, Inc.

In January 2012, we executed a License and Supply Agreement with Melmed Holding AG (the “Melmed Agreement”) for the marketing of Altrazeal® throughout the European Union, Australia, New Zealand, North Africa, and the Middle East. Currently, such marketing efforts are being performed by Altrazeal Trading GmbH and Altrazeal AG. Under the terms of the Melmed Agreement, we received a licensing fee in 2012, will receive certain royalties on product sales within the territories, and will supply Altrazeal® at an agreed sales price. In addition, Melmed is required to meet certain minimum sales obligations in the years 2014, 2015 and 2016. Contemporaneous with the execution of the Melmed Agreement, we also executed a shareholders’ agreement for the establishment of Altrazeal Trading Ltd., a single purpose entity to be used for the exclusive marketing of Altrazeal® throughout the European Union, Australia, New Zealand, North Africa, and the Middle East. We received a non-dilutable 25% ownership interest in Altrazeal Trading Ltd. In February 2014, we executed an amendment to the Melmed Agreement for the purpose of expanding the territories to include Albania, Bosnia, Croatia, Kosovo, Macedonia, Montenegro, and Serbia.

In September 2013, we executed an Exclusive License and Supply Agreement with Altrazeal AG (the “AG Agreement”) to market Altrazeal® in several territories, to include Africa (markets not already licensed), Latin America, Georgia, Turkmenistan, Ukraine, and the Commonwealth of Independent States. Under the terms of the AG Agreement, we received an up-front licensing payment, will receive certain royalties on product sales within the territories, and will supply Altrazeal® at an agreed upon price. We also received a non-dilutable 25% ownership interest in Altrazeal AG. In October 2013 and February 2014, we executed amendments to the AG Agreement 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.

Aphthasol® (Amlexanox 5% Paste)

Aphthasol®, amlexanox 5% paste, is the first drug approved by the FDA for the treatment of canker sores. Extensive clinical studies have shown that Aphthasol® accelerates the healing of canker sores which results in a statistically significant reduction in the level of pain a patient experiences over the duration of the ulcer episode. Additionally, a Phase IV clinical study conducted in Northern Ireland was completed in November 2000 and results confirmed that amlexanox 5% paste was effective in preventing the formation of an ulcer when used at the first sign or symptom of the disease.

International activities related to amlexanox are now being devoted to OraDisc™ A as we considered it to be a superior formulation and delivery system as compared to the Aphthasol® product.

OraDisc™ A

Treatment of oral conditions generally relies upon the use of medications formulated as gels and pastes that are applied to lesions in the mouth. The duration of effectiveness of these medications is typically short because the applied dose is worn away through the mechanical actions of speaking, eating, and tongue movement, and is washed away by saliva flow. To address these problems, we have developed a novel, cost-effective, adhesive film product that is bioerodible. This technology, known as OraDisc™, comprises a multi-layered film having an adhesive layer, an optional pre-formed film layer, and a coated backing layer.

OraDisc™ A was developed as a drug delivery system to treat canker sores using the same active ingredient (amlexanox) that is used in Aphthasol® paste. We anticipate that higher amlexanox concentrations will be achieved at the disease site, increasing the effectiveness of the product. OraDisc™ A was approved by the FDA in September 2004.

This successful development was an important technology milestone which supports the development of an OraDisc™ range of products. To achieve OraDisc™ A approval, in addition to performing the necessary clinical studies to prove efficacy, an irritation study, a 28-day safety study and drug distribution studies were conducted which support the development of additional products. Patients in a 700 patient clinical study and a 28-day safety study completed a survey which produced very positive results with regard to perceived effectiveness, ease of application, ability of the disc to remain in place and purchase intent. These data give strong support to our overall development program. The survey data confirms market research studies which indicate a strong patient acceptance of this delivery device.

In June 2008, we executed a Licensing and Supply Agreement with KunWha Pharmaceutical Co., Ltd, for OraDisc™ A and Aphthasol (5% amlexanox) paste in South Korea. KunWha Pharmaceutical Co., Ltd paid us an upfront licensing fee and further milestone payments are to be made on regulatory approval and achievement of certain commercial milestones.

In November 2008, we executed an expanded European Agreement with Meda, Sweden for OraDisc™ A and Aphthasol® (5% amlexanox) paste for distribution into most major European markets. Meda paid us an upfront licensing fee and additional milestone payments will be made upon regulatory approval and achievements of commercial milestones. Prior to commercialization by Meda, regulatory approval is required throughout the territory.

OraDisc™ B

A second mucoadhesive disc product has also been successfully developed for the treatment and management of oral pain. This product contains 15 milligrams of benzocaine which is the maximum allowable strength that falls under the classification of an OTC monograph product in the United States. This classification allows for an easier regulatory pathway to market. The product has been optimized and is ready for commercial scale-up.

In October 2012, we executed a License and Supply Agreement (the “Ora-D Agreement”) with ORADISC GmbH (“Ora-D”) to market worldwide all applications of our OraDisc™ erodible film technology for dental applications including but not limited to benzocaine (OraDisc™ B). Currently, negotiations are ongoing to appoint marketing partners for OraDisc™ B.

OraDisc™ – Other Applications

In October 2012, we executed a License and Supply Agreement with Ora-D to market worldwide all applications of our OraDisc™ erodible film technology for dental applications including benzocaine (OraDisc™ B), re-mineralization dental strips, fluoride dental strips, long-acting breath freshener, and amlexanox (OraDisc™ A). The marketing rights for OraDisc™ A granted to Ora-D exclude territories held by Meda, EpiTan Pharmaceuticals, KunWha Pharmaceutical, Laboratories del Dr. Esteve SA, Orient Europharma, Co., Ltd., and Pharmascience Inc. We have also granted to Ora-D a twenty-four month option to utilize the OraDisc™ erodible film technology for drug delivery for migraine, nausea and vomiting, cough and cold, and pain. Under the terms of the Ora-D Agreement, we received a licensing fee in 2012, will receive certain royalties on product sales within the territories, and will supply OraDisc™ products. Contemporaneous with the execution of the Ora-D Agreement, we also executed a shareholders’ agreement for the establishment of ORADISC GmbH, a single purpose entity to be used for the exclusive development and marketing of OraDisc™ erodible film technology products. We received a non-dilutable 25% ownership interest in ORADISC GmbH. The initial twenty-four month option to utilize the OraDisc™ erodible film technology by Ora-D has been extended until December 31, 2015. In addition this option has been expanded to include anti-psychotics, neurologic products, and actives for the treatment of erectile dysfunction. Recently, pre-clinical development has commenced with four actives.

Marketing Relationships

For our commercialized products, we currently rely upon the following relationships in the following marketing territories for sales, manufacturing and/or regulatory approval efforts:

Altrazeal®

- | | |
|---------------------------------------|--|
| Altrazeal Trading GmbH | ▪ European Union, Australia, New Zealand, Middle East (excluding Jordan and Syria), North Africa, Albania, Bosnia, Croatia, Kosovo, Macedonia, Montenegro, and Serbia |
| Altrazeal AG | ▪ Africa (markets not already licensed), Latin America, Georgia, Ukraine, Turkmenistan, the Commonwealth of Independent States, Jordan, Syria, Afghanistan, Russia, 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 |

Nanoflex® technology - Veterinary

- | | |
|------------------------|-------------|
| Novartis Animal Health | ▪ Worldwide |
|------------------------|-------------|

Amlexanox 5% paste and OraDisc™ A

- | | |
|--------------------------------|---|
| ORADISC GmbH | ▪ Worldwide (excluding territories held by Meda AB, KunWha Pharmaceutical, Laboratories del Dr. Esteve SA, Orient Europharma, Co., Ltd., and Pharmascience Inc.) |
| Meda AB | ▪ United Kingdom, Ireland, Scandinavia, the Baltic states, Iceland, Belgium, France, Germany, Italy, Luxembourg, Netherlands, Switzerland, Austria, Bulgaria, Cyprus, Czech Republic, Hungary, Malta, Poland, Romania, and Slovenia |
| KunWha Pharmaceutical | ▪ South Korea |
| Laboratories del Dr. Esteve SA | ▪ Spain, Portugal, Greece, and Andorra |
| Orient Europharma, Co., Ltd. | ▪ Taiwan and Hong-Kong |
| Pharmascience Inc. | ▪ Canada |

OraDisc™ B

- | | |
|--------------|-------------|
| ORADISC GmbH | ▪ Worldwide |
|--------------|-------------|

Patents

We believe that the value of technology both to us and to our potential corporate partners is established and enhanced by our broad intellectual property positions. Consequently, we have already been issued and seek to obtain additional U.S. and foreign patents for products under development and for new discoveries. Patent applications are filed for our inventions and prospective products with the U.S. Patent and Trademark Office and, when appropriate, with authorities in countries that are part of the Paris Convention's Patent Cooperation Treaty ("PCT") (most major countries in Western Europe and the Far East) and with other authorities in major markets not covered by the PCT.

With regards to our Nanoflex® technology, three patents have issued in the U.S. and multiple patents have been issued in international countries. There are also four PCT patent applications that have been filed and nine patent applications filed in nine international countries. The granted patents and patent applications have a variety of potential applications, such as wound management, burn care, dermal fillers, artificial discs and tissue scaffold.

We have one U.S. patent and have filed one PCT patent application for our OraDisc™ technology. This oral delivery vehicle potentially overcomes the difficulties encountered in using conventional paste and gel formulations for conditions in the mouth. Utilizing this technology, we anticipate that higher drug concentrations will be achieved at the disease site, increasing the effectiveness of the product. Our patent applications cover the delivery of drugs through or into any mucosal surface. The patent and patent applications cover our ability to control the erosion time of the adhesive film and the subsequent drug release by adjusting the ratio of hydrophobic to hydrophilic polymers in the outer layer of the composite film.

The United States patents for our technologies and products expire in the years indicated below:

| | <u>Year of Expiration</u> |
|--|---------------------------|
| Nanoflex® technology | |
| ▪ Hydrogel – Shape retentive hydrogel particle aggregate | 2022 |
| ▪ Altrazeal® Injectable | 2024 |
| ▪ Altrazeal® wound dressing and biomaterials | 2028 |
| OraDisc™ technology | |
| ▪ Mucoadhesive erodible drug delivery device | 2021 |

Manufacturing and Supply

We currently rely on a limited number of contract manufacturers, monitored by our internal management, to manufacture, package, and finish our products in conformance with current good manufacturing practices (cGMP) and do not currently have relationships with alternate suppliers. We believe that there are other contract manufacturers that can satisfy our production requirements, but should it be necessary to change suppliers this could result in a delay while they are qualified and validated.

Significant Customers

A significant portion of our revenues are derived from a few major customers. Customers with greater than 10% of total revenues, along with their relative percentage of total revenues, for the year ended December 31 are represented on the following table:

| <u>Customers</u> | <u>Product</u> | <u>2014</u> | <u>2013</u> |
|------------------|----------------|-------------|-------------|
| Customer A | Altrazeal® | 80% | 8% |
| Customer B | Altrazeal® | 11% | 67% |
| Total | | <u>91%</u> | <u>75%</u> |

Research and Development

We are continuously engaged in research and development activities. During the years ended December 31, 2014 and 2013 approximately \$771,000 and \$788,000, respectively, were expended for research and development. The costs incurred for each of the two years are primarily attributable to the development and commercialization of Altrazeal®. We continue to perform activities to develop new products and to improve existing products utilizing our proprietary technologies.

Government Regulation

We are subject to extensive regulation by the federal government, principally by the United States Food and Drug Administration (“FDA”), and, to a lesser extent, by other federal and state agencies as well as comparable agencies in foreign countries where registration of products will be pursued. Although a number of our formulations incorporate extensively tested drug substances, because the resulting formulations make claims of enhanced efficacy and/or improved side effect profiles, they are expected to be classified as new drugs by the FDA.

The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern the testing, manufacturing, safety, labeling, storage, shipping, and record keeping of our products. The FDA has the authority to approve or not approve new drug applications and/or new medical devices and inspect research, clinical and manufacturing records and facilities.

For a medical device in Europe, a Technical File Dossier is submitted to a Notified Body for review. Once approved the medical device receives a CE mark which allows commercialization of the product in the European Union. There are separate processes in each European Union jurisdiction governing additional approvals including reimbursement for medical devices.

Among the requirements for drug and medical device approval and testing is that the prospective manufacturer's facilities and methods conform to the Code of Good Manufacturing Practices ("cGMP") regulations, which establish the manufacturing and quality requirements, and the facilities or controls to be used during the production process. Such facilities and manufacturing process are subject to ongoing FDA and notified body inspection to insure compliance.

The steps required before a pharmaceutical product or medical device product may be produced and marketed in the U.S. can include preclinical tests, the filing of an Investigational New Drug application ("IND") or an Investigational Device Exemption ("IDE") with the FDA, which must become effective pursuant to FDA regulations before human clinical trials may commence. Numerous phases of clinical testing and the FDA approval of a New Drug Application ("NDA"), a Product Marketing Authorization ("PMA"), or a 510(k) application ("510(k)") is also required prior to commercial sale.

Preclinical tests are conducted in the laboratory, usually involving animals, to evaluate the safety and efficacy of the potential product. The results of preclinical tests are submitted as part of the IND and IDE application and are fully reviewed by the FDA prior to granting the sponsor permission to commence clinical trials in humans. All trials are conducted under International Conference on Harmonization, good clinical practice guidelines. All investigator sites and sponsor facilities are subject to FDA inspection to insure compliance. Clinical trials typically involve a three-phase process. In the case of a pharmaceutical product, Phase I, the initial clinical evaluations, consists of administering the drug and testing for safety and tolerated dosages. Phase II involves a study to evaluate the effectiveness of the drug for a particular indication and to determine optimal dosage and dose interval and to identify possible adverse side effects and risks in a larger patient group. When a product is found safe and an initial efficacy is established in Phase II, the product is then evaluated in Phase III clinical trials. Phase III trials consist of expanded multi-location testing for efficacy and safety to evaluate the overall benefit to risk index of the investigational drug in relationship to the disease treated. The results of preclinical and human clinical testing are submitted to the FDA in the form of an NDA, PMA, or 510(k) for approval to commence commercial sales.

The process of performing the requisite testing, data collection, analysis and compilation of an IND, IDE, NDA, PMA, or 510(k) is labor intensive and costly and may take a protracted time period. In some cases, tests may have to be redone or new tests instituted to comply with FDA requests. Review by the FDA may also take considerable time and there is no guarantee that an NDA, PMA, or 510(k) will be approved. Therefore, we cannot estimate with any certainty the length of the approval cycle.

The regulatory status of our principal products is as follows:

- Altrazeal® is been cleared or approved for sale in the U.S., the European Union (together with countries that recognize the CE mark), Australia, New Zealand, and a number of additional international markets;
- Other Altrazeal® products are currently in development phases;
- 5% amlexanox paste is a product approved for sale in the U.S. (Aphthasol®); approved in Canada and a number of EU countries but not yet sold;
- OraDisc™ A is a product approved for sale in the U.S., and
- Our other OraDisc™ products are currently in the development phase.

We are also governed by other federal, state and local laws of general applicability, such as laws regulating working conditions, employment practices, as well as environmental protection.

Competition

The medical device and pharmaceutical industry is characterized by intense competition, rapid product development and technological change. Competition is intense among manufacturers of prescription pharmaceuticals, medical devices, and other product areas where we may develop and market products in the future. Most of our potential competitors in the wound care market such as Smith & Nephew plc, Systagenix Wound Management Limited, ConvaTec Inc., 3M Company, and Molnlycke Health Care are large, well established medical device or healthcare companies with considerably greater financial, marketing, sales and technical resources than are available to us. Additionally, many of our potential competitors have research and development capabilities that may allow such competitors to develop new or improved products that may compete with our product lines. Our potential products could be rendered obsolete or made uneconomical by the development of new products to treat the conditions to be addressed by our developments, technological advances affecting the cost of production, or marketing or pricing actions by one or more of our potential competitors. Our business, financial condition and results of operation could be materially adversely affected by any one or more of such developments. We cannot assure you that we will be able to compete successfully against current or future competitors or that competition will not have a materially adverse effect on our business, financial condition and results of operations. We are aware of certain developmental projects for products to treat or prevent certain disease targeted by us. The existence of these potential products or other products or treatments of which we are not aware, or products or treatments that may be developed in the future, may adversely affect the marketability of products developed by us.

In the area of wound management and burn care, which are the focus of our development activities, a number of companies are developing or evaluating new technology approaches. We expect that technological developments will occur at a rapid rate and that competition is likely to intensify as various alternative technologies achieve similar, if not identical, advantages.

Wound care products developed from our Nanoflex® technology, including Altrazeal®, will compete with numerous well established products including Aquacel® marketed by ConvaTec Inc., Silvercel® and Promogran® marketed by Systagenix Wound Management Limited, Acticoat® and Allevyn® marketed by Smith and Nephew plc, and Mepitel® and Meplix® marketing by Molnlycke Health Care.

Our product, Aphthasol®, is the only product clinically proven to accelerate the healing of canker sores. There are numerous products, including prescription steroids such as Kenalog in OraBase, and many over-the-counter pain relief formulations that incorporate a local anesthetic used for the treatment of this condition.

Products developed from our OraDisc™ erodible film technology, for the controlled release of prescription pharmaceuticals, will compete with numerous alternative drug delivery technologies including fast release film technology, transdermal drug delivery, and other mucoadhesive film technologies.

Even if our products are fully developed and receive the required regulatory approval, of which there can be no assurance, we believe that our products that require extensive sales efforts directed both at the consumer and the medical professional can only compete successfully if marketed by a company having expertise and a strong presence in the therapeutic area or in direct to consumer marketing. Consequently, our business model is to form strategic alliances with major or regional pharmaceutical companies for products to compete in these markets.

Employees

As of December 31, 2014, we had 7 full-time employees, including 1 in research and development, 3 in general and administration and 3 in manufacturing and quality. In addition, we use contract consultants for business development, quality control and quality assurance, clinical administration, and regulatory affairs. Our employees are not represented by a labor union and are not covered by a collective bargaining agreement. Management believes that we maintain good relations with our personnel. At times, we may compliment our internal expertise with external scientific consultants, university research laboratories and contract manufacturing organizations that specialize in various aspects of drug development including clinical development, regulatory affairs, toxicology, preclinical testing and process scale-up.

Executive Officers

The following table sets forth the executive officers of the Company, as of the date hereof, along with their respective ages and positions. Each of the officers listed below has been appointed to hold the office listed opposite his respective name until the earlier to occur of the death or resignation of such officer or until a successor has been duly appointed by the board of directors of the Company.

| <u>Name</u> | <u>Age</u> | <u>Position</u> |
|----------------------|------------|---|
| Kerry P. Gray | 62 | President, Chief Executive Officer, Chairman |
| Terrance K. Wallberg | 60 | Vice President, Chief Financial Officer, Secretary, Treasurer |

Set forth below is certain employment and biographical information with respect to each executive officer of the Company.

Kerry P. Gray has served as one of our directors since March 2006 and currently has served as our President and Chief Executive Officer from January 2006 to March 2009 and since June 2010. Previously, Mr. Gray was the President and CEO and a director of Access Pharmaceuticals, Inc. from June 1993 until May 2005. Previously, Mr. Gray served as Chief Financial Officer of PharmaScience, Inc., a company he co-founded to acquire technologies in the drug delivery area. From May 1990 to August 1991, Mr. Gray was Senior Vice President, Americas, Australia and New Zealand for Rhone-Poulenc Rorer, Inc. Prior to the Rhone-Poulenc Rorer merger, he had been Area Vice President Americas of Rorer International Pharmaceuticals. From January 1986 to May 1988, he was Vice President, Finance of Rorer International Pharmaceuticals, having served in the same capacity at the Revlon Health Care Group of companies before the acquisition by Rorer Group. Between 1975 and 1985, he held various senior financial positions with the Revlon Health Care Group.

Terrance K. Wallberg has served as our Vice President and Chief Financial Officer since March 2006. Mr. Wallberg is a Certified Public Accountant and possesses an extensive and diverse background with over 30 years of experience with entrepreneurial/start-up companies. Prior to joining ULURU Inc., from 2004 to 2005 Mr. Wallberg was Chief Financial Officer with Alliance Hospitality Management and from 2000 to 2004 was Chief Financial Officer for DCB Investments, Inc., a Dallas, Texas based diversified real estate holding company from 2000 to 2004. During his five year tenure at DCB Investments, Mr. Wallberg acquired valuable experience with several successful start-up businesses and dealing with the external financial community. Prior to DCB Investments, Mr. Wallberg spent 22 years with Metro Hotels, Inc., serving in several finance/accounting capacities and culminating his tenure as Chief Financial Officer. Mr. Wallberg is a member of the American Society of Certified Public Accountants and the Texas Society of Certified Public Accountants and is a graduate of the University of Arkansas, Little Rock.

Organizational History

We were incorporated on September 17, 1987 under the laws of the State of Nevada, originally under the name Casinos of the World, Inc. From April 1993 to January 2002, the Company changed its name on four separate occasions, with Oxford Ventures, Inc. being the Company's name on January 30, 2002.

On March 29, 2006, we effected a 400:1 reverse stock split and, at the same time, authorized a decrease in authorized shares of common stock from 400,000,000 shares to 200,000,000 shares, and authorized up to 20,000 shares of Preferred Stock.

On March 31, 2006, a subsidiary of the Company, which had acquired, among other things, the net assets of the Nanoflex® and Mucoadhesive OraDisc™ technologies from Access Pharmaceuticals, Inc., merged with and into ULURU Inc., a Delaware corporation ("ULURU Delaware"), and ULURU Delaware became a wholly-owned subsidiary of the Company. On March 31, 2006, we changed our name from "Oxford Ventures, Inc." to "ULURU Inc." On the same date, we moved our executive offices to Addison, Texas.

On June 29, 2011, we effected a 15:1 reverse stock split.

On September 13, 2011, we filed a certificate of designation creating the Series A Preferred Stock, all of which has been redeemed.

Corporate Information

Our principal executive offices are located at 4452 Beltway Drive, Addison, Texas 75001, and our telephone number is (214) 905-5145.

Available Information

Our internet address is www.uluruinc.com. We are not including the information contained on our website as part of, or incorporating it by reference into, this annual report on Form 10-K. We make available free of charge through our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, as soon as reasonably practicable after we electronically file such materials with the Securities and Exchange Commission.

ITEM 1A. RISK FACTORS

You should carefully consider the following risk factors before you decide to invest in our Company and our business because these risk factors may have a significant impact on our business, operating results, financial condition, and cash flows. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. If any of the following risks actually occurs, our business, financial condition and results of operations could be materially and adversely affected.

Risks Related to Our Operations

We do not have significant operating revenue and we may never have sufficient revenue to be profitable.

Our ability to achieve significant revenue or profitability depends upon our ability to successfully commercialize existing products, particularly Altrazeal®. Historically, none of our existing products have had significant sales and all of our products compete in a competitive marketplace. We may not generate significant revenues or profits from the sale of Altrazeal® or other products in the future. If we are unable to generate significant revenues over the long term, we will not be profitable and may need to discontinue our operations.

We are dependent upon financings to fund our operations and may be unable to continue as a going concern.

We do not generate sufficient cash flows from operations to meet the cash requirements of our operations and other commitments without raising funds through the sale of debt and equity securities. We do not expect to generate enough cash from operations to meet our requirements in the near term. Proceeds raised from funding activities are required for us to have capital to meet our obligations for the foreseeable future. In their report on our most recently audited financial statements, our auditors expressed substantial doubt as to our ability to continue as a going concern because we did not have sufficient cash to fund operations for at least the following year. A going concern qualification could impair our ability to finance operations through the sale of debt or equity securities. Our ability to continue as a going concern will depend, in large part, on our ability to obtain additional financing and generate positive cash flow from operations, neither of which is certain. If we are unable to achieve these goals, our business would be jeopardized and we may not be able to continue operations.

A failure to obtain additional capital when and as needed could jeopardize our operations and the cost of capital may be high.

We believe existing and contemplated arrangements for additional capital or debt should provide us with adequate financial resources to continue to fund our business plan and meet our operating requirements through 2015. If we have unanticipated costs, our revenues are less than expected, or existing commitments do not yield anticipated capital, we may need to obtain additional capital earlier than anticipated. In any case, absence a significant increase in revenue, we will need to raise additional capital to fund our operations over the longer term.

As we go to market to raise capital, we may be unable to obtain the necessary financing on terms acceptable to us, or at all. If we are unable to raise capital when needed, we would be unable to continue our operations. Even if we are able to raise capital, we may raise capital by selling equity securities, which will be dilutive to existing shareholders. If we incur additional indebtedness, costs of financing may be extremely high, and we will be subject to default risks associated with such indebtedness, which may harm our ability to continue our operations.

Our financial condition limits our ability to borrow funds as may be required to fund our future operations.

We rely on capital from loans and the sale of equity securities to fund our operations due to our limited revenue. Our ability to borrow funds is limited by our financial condition. If we do not experience a significant increase in revenue, and are unable to raise additional capital, we may be required to discontinue operations. Any capital we are able to raise will generally be on terms that are disadvantageous to the Company.

Existing contractual restrictions held by IPMD GmbH may limit or delay our ability to obtain required financing.

In a securities purchase agreement with IPMD GmbH, we granted IPMD the right to appoint two directors to our board of directors and agreed that unanimous board approval would be required for any equity-based financings. In addition, IPMD has a right of first refusal, to be exercised within one month of written notice, to take over all, or part, of any equity-based financing. As a result of the unanimous approval requirement, the determination of a director not to approve any financing, or that director's unavailability when approval is requested, would prevent or delay the financing. In addition, the existence of the right of first refusal may deter potential financing sources and may lead to delays in our ability to close necessary financings. To the extent of any failure to approve, or delay in approving, any financing that is required for us to execute our business plan or continue as a going concern, our business and financial position may be harmed. If such failures or delays continue over an extended period of time, we will eventually be unable to continue as a going concern.

Sales of our products are dependent upon the efforts of commercial partners and other third parties over which we have no or little control.

The right to market and sell our key products has been licensed to third parties and to entities in which we have a minority equity stake. This presents certain risks, including the following:

- our commercial partners and licensees may not place the same priority on sales of our products as we do, may fail to honor contractual commitments, may not have the expertise, market strength or other characteristics necessary to effectively market our products, may dedicate only limited resources to, and/or may abandon, marketing of a product for reasons, including reasons such as a shift in corporate focus, unrelated to its merits;
- our commercial partners may be in the early stages of development and may not have sufficient liquidity to effectively obtain approvals for and market our products consistent with contractual commitments or our expectations;
- we may have disputes with our commercial partners, which may inhibit development, lead to an abandonment of our arrangements, lead to a protracted dispute or have other negative consequences;
- our commercial partners may fail to honor the terms of our agreements with them, with respect to payment, compliance with law or other terms, which may lead to liquidity issues, reputational harm with end customers and other issues; and
- even if the commercialization and marketing of products is successful, our revenue share may be limited and may not exceed our associated development and operating costs.

If any of these risks are realized, our revenues are unlikely to be sufficient to support our operations over the long terms, and we may have to discontinue operations.

We may not successfully commercialize our product candidates.

Our product candidates are subject to the risks of failure inherent in the development of pharmaceuticals based on new technologies. Our failure to develop safe, commercially viable products would severely

limit our ability to become profitable or to achieve significant revenues. We may be unable to successfully commercialize our product candidates because:

- some or all of our product candidates may be found to be unsafe or ineffective or otherwise fail to meet applicable regulatory standards or receive necessary regulatory clearances;
- our product candidates, if safe and effective, may be too difficult to develop into commercially viable products;
- it may be difficult to manufacture or market our product candidates on a large scale;
- given our limited market presence, we may be unable, directly or indirectly through licensees, to effectively market and distribute our products or establish a strong brand;
- proprietary rights of third parties may preclude us from marketing our product candidates; and
- third parties may market superior or equivalent products.

If we are unable to maintain effective sales, marketing and distribution capabilities, or to enter into agreements with third parties to do so, we will be unable to successfully commercialize Altrazeal® and OraDisc™ related products.

If we are unable to establish the capabilities to sell, market, and distribute Altrazeal® and OraDisc™ related products by entering into agreements with others, or to maintain such capabilities in countries where we have already commenced commercial sales, we will be unable to successfully sell Altrazeal® and OraDisc™. In that event, we will be unable to generate significant revenues. We may be unable to enter into and maintain any marketing or distribution agreements with third-parties on acceptable terms, if at all. Even if we enter into marketing and distribution agreements with third parties on acceptable terms, such agreements may contain terms that are disadvantageous to us, and licensees under such agreements may not expend sufficient resources to effectively market our products. In addition, parties to such agreements may fail to perform their obligations under such agreements, which may lead to costly and distracting disputes and periods of uncertainty. We may not be successful in commercializing Altrazeal® and OraDisc™ related products.

We may be unable to successfully develop, market, or commercialize our products or our product candidates without establishing new relationships and maintaining current relationships.

Our strategy for the development and commercialization of our potential pharmaceutical products requires us to enter into various arrangements with corporations, collaborators, licensees and others in order to develop, produce and market our products. Our business depends upon our ability to enter into agreements for the development, production and marketing of our products on reasonable terms, which we may be unable to do. Even if we enter into such agreements, we are subject to the risk that the counterparty to the agreement will not fulfill their obligations under such agreements. Our ability to successfully commercialize, and market our products and product candidates will be harmed if our existing relationships are terminated, we are unable to enter into new relationships or our partners fail to fulfill their obligations under the agreements.

We are dependent upon contract manufacturers to safely and timely manufacture our products.

We have limited experience in the manufacture of medical devices and pharmaceutical products in commercial quantities. As a result, we have established, and in the future intend to establish, arrangements with contract manufacturers to manufacture, package, label, and deliver our medical devices and pharmaceutical products. Our business will suffer if there are delays or difficulties in establishing relationships with manufacturers to manufacture, package, label, and deliver our products or if the prices charged by such manufacturers are higher than anticipated. Moreover, contract manufacturers that we may use must adhere to current Good Manufacturing Practices, as required by FDA and other regulatory agencies. If any such manufacturers fail to comply with FDA requirements and similar requirements of other nations, the manufacturers may be unable to manufacture our products. In addition, such manufacturers may fail to manufacture our products in accordance with specifications, or the manufacturing specifications may be fail to produce products that comply with functional, technical, cosmetic or other requirements. For example, we recently discovered that the adhesive by which we attach a label to our Altrazeal® blister product may break down when exposed to extremes of heat and cold. The peeling of the label does not affect the function of the product but may be important for tracking of the product. We have replaced the adhesive with a new product and are offering to substitute replacement product to our distributors. We estimate the cost of such replacement at \$30,000. We have granted extended payments terms on approximately \$310,000 in receivables that are included in our 2014 revenues to a related-party distributor that received shipments in 2014 of our Altrazeal® blister products with this label issue. We have not been able to determine the exact number of units affected by this label issue. In addition, third party manufacturers may fail to meet delivery timelines, which may cause problems in our customer or distributor relationships and potentially lead to defaults or an obligation to pay damages. If we are unable to obtain or retain third party manufacturing on commercially acceptable terms, we may not be able to commercialize our products as planned. Our dependence upon third parties for the manufacture of our products may harm our ability to generate significant revenues or acceptable

profit margins and our ability to develop and deliver such compliant products on a timely and competitive basis.

We may incur substantial product liability expenses due to manufacturing or design defects, or the use or misuse of our products.

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing and marketing of medical devices and pharmaceutical products. We may face liability to our distributors and customers if our products are not manufactured as per specifications or if such specifications cause the products to spoil, become unsafe or fail to function as marketed. We may also face substantial liability for damages if our products produce adverse side effects or defects are identified with any of our products that harm patients and other users. Any such failures or defects may lead to a breakdown in our relationships with distributors and purchasers, leading to a substantial decline in or collapse of our market. In addition, if any judgments or liabilities are material in size, we may be unable to satisfy such liabilities. Any product liability could harm our operations, and a large judgment could force us to discontinue our operations.

We may incur significant liabilities if we fail to comply with stringent environmental regulations.

Our development processes involve the controlled use of hazardous materials. We are subject to a variety of federal, state and local governmental laws and regulations related to the use, manufacture, storage, handling, and disposal of such material and certain waste products. If we experience an accident with hazardous materials or otherwise mishandle them, we could be held liable for any damages. Any such liability could exceed our resources and force us to discontinue operations.

Additional federal, state, foreign and local laws and regulations affecting our operations may be adopted in the future, including laws related to climate change. We may incur substantial costs to comply with these laws or regulations. Additionally, we may incur substantial fines or penalties if we violate any of these laws or regulations.

Our ability to successfully commercialize our drug or device candidates could substantially depend upon the availability of reimbursement for the costs of the resulting drugs or devices and related treatments.

The successful commercialization of, and the interest of potential collaborative partners to invest in the commercialization of our drug or device candidates, may depend substantially upon the reimbursement prices paid being at acceptable levels by government authorities, private health insurers and other organizations, including health maintenance organizations, or HMOs. The amount of such reimbursement in the United States or elsewhere may be decreased in the future or may be unavailable for any drugs or devices that we are currently marketing or may develop in the future. Limited reimbursement for the cost of any drugs or devices that we develop will reduce the demand for, or may reduce the price of such drugs or devices, which would hamper our ability to obtain collaborative partners to commercialize our drugs or devices, or to obtain a sufficient financial return on our own manufacture and commercialization of any future drugs or devices.

Intense competition may limit our ability to successfully develop and market commercial products.

The pharmaceutical industry is intensely competitive and subject to rapid and significant technological change. Our competitors in the United States and elsewhere are numerous and include, among others, major multinational pharmaceutical, device, and chemical companies.

In the area of wound management and burn care, which is the primary focus of our commercialization and development activities, a number of companies are developing or evaluating new technology approaches. Significantly larger companies compete in this marketplace including Smith & Nephew plc, Systagenix Wound Management Limited, ConvaTec Inc., 3M Company, Molnlycke Health Care, and numerous other companies. We expect that technological developments will occur at a rapid rate and that competition is likely to intensify as various alternative technologies achieve similar if not identical or superior advantages.

Prescription steroids such as Kenalog in OraBase, developed by Bristol-Myers Squibb, may compete with our Aphthasol® product. OTC products including Orajel (Church & Dwight, Inc.) and Anbesol (Pfizer Consumer Healthcare) also compete in the aphthous ulcer market.

These competitors have and employ greater financial and other resources, including larger research and development, marketing and manufacturing organizations. As a result, our competitors may successfully develop technologies and drugs that are more effective or less costly than any that we are developing or which would render our technology and future products obsolete and noncompetitive.

In addition, most of our competitors have greater experience than we do in conducting preclinical and clinical trials and may obtain FDA and other regulatory approvals for product candidates more rapidly than we do. Companies that complete clinical trials obtain required regulatory agency approvals and commence commercial sale of their products before their competitors may achieve a significant competitive advantage. Products resulting from our development efforts or from our joint efforts with collaborative partners therefore may not be commercially competitive with our competitors' existing products or products under development.

The market may not accept any medical device or pharmaceutical products that we successfully develop.

The drugs and devices that we are attempting to develop may compete with a number of well-established drugs and devices manufactured and marketed by major pharmaceutical companies. The degree of market acceptance of any drugs or devices developed by us will depend on a number of factors, including the establishment and demonstration of the clinical efficacy and safety of our product candidates, the potential advantage of our product candidates over existing therapies and the reimbursement policies of government and third-party payers, and the effectiveness of our marketing efforts and those of our partners. Physicians, patients or the medical community in general may not accept or use any drugs or devices that we may develop independently or with our collaborative partners and if they do not, our business could suffer.

Our future financial results could be adversely impacted by asset impairments or other charges.

Accounting Standards Codification (“ASC”) Topic 350-30, *Intangibles Other than Goodwill* requires that we test goodwill and other intangible assets determined to have indefinite lives for impairment on an annual, or on an interim basis if certain events occur or circumstances change that would reduce the fair value of a reporting unit below its carrying value or if the fair value of intangible assets with indefinite lives falls below their carrying value. In addition, under ASC Topic 350-30, long-lived assets with finite lives are tested for impairment whenever events or changes in circumstances indicate that its carrying value may not be recoverable. A significant decrease in the fair value of a long-lived asset, an adverse change in the extent or manner in which a long-lived asset is being used or in its physical condition or an expectation that a long-lived asset will be sold or disposed of significantly before the end of its previously estimated life are among several of the factors that could result in an impairment charge.

We evaluate intangible assets determined to have indefinite lives for recoverability whenever events or changes in circumstances indicate that their carrying amounts may not be recoverable. These events or circumstances could include a significant change in the business climate, legal factors, operating performance indicators, competition, sales or disposition of a significant portion of the business, or other factors such as a decline in our market value below our book value for an extended period of time.

We evaluate the estimated lives of all intangible assets on an annual basis, to determine if events and circumstances continue to support an indefinite useful life or the remaining useful life, as applicable, or if a revision in the remaining period of amortization is required. The amount of any such annual or interim impairment charge could be significant, and could have a material adverse effect on reported financial results for the period in which the charge is taken.

We may not timely receive financial results from our unconsolidated subsidiaries, and any financial results we receive may not conform with U.S. GAAP.

We rely on our unconsolidated subsidiaries to provide reliable and timely financial statement information so that we may include such financial results in our financial reports. In preparation of our financial reports for the year ended December 31, 2014, our unconsolidated subsidiaries have not provided us with financial statements for the year ended December 31, 2014, and financial statements received for the year ended December 31, 2013 were unaudited. Any failure of our unconsolidated subsidiaries to provide timely or accurate financial reports to us may adversely affect the accuracy of our financial statements. If we subsequently receive timely, updated or audited financial statements for the unconsolidated subsidiaries, we may be forced to correct or revise our financial statements.

Failure to achieve and maintain effective internal controls could have a material adverse effect on our business.

Effective internal controls are necessary for us to provide reliable financial reports. If we cannot provide reliable financial reports, we may be subject to legal actions by shareholders, regulators or other parties. All internal control systems, no matter how well designed, have inherent limitations. These inherent limitations include the realities that judgments in decision-making can be faulty, and breakdowns can occur because of simple error or mistake. Therefore, even those systems determined to be effective can only provide reasonable assurance with respect to financial preparation and presentation.

While we continue to evaluate and improve our internal controls, we cannot be certain that these measures will ensure that we implement and maintain adequate controls over our financial processes and reporting in the future. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations. Failure to achieve and maintain an effective internal control environment could also cause investors to lose confidence in our reported financial information, which could have a material adverse effect on our stock price and lead to disruptions, litigation and liabilities.

Our business is subject to increasingly complex corporate governance, public disclosure, and accounting requirements and regulations that could adversely affect our business and financial results and condition.

We are subject to changing rules and regulations of various federal and state governmental authorities. These entities, including the Public Company Accounting Oversight Board and the Securities and Exchange Commission, or SEC, have issued a significant number of new and increasingly complex requirements and regulations over the course of the last several years and continue to develop additional requirements and regulations in response to laws enacted by Congress, including the Sarbanes-Oxley Act of 2002 and, most recently, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act. Our efforts to comply with these requirements and regulations have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management's time from other business activities. We also may incur liability if we fail to comply with such laws.

Our business could suffer if we lose the services of, or fail to attract, key personnel.

We are highly dependent upon the efforts of our senior management and scientific team, all of which are employed on an at-will basis. The loss of the services of one or more of these individuals could delay or prevent the achievement of our development or product commercialization objectives. We do not maintain any "key-man" insurance policies on any of our senior management and we do not intend to obtain such insurance. In addition, due to the specialized scientific nature of our business, we are highly dependent upon our ability to attract and retain qualified scientific and technical personnel. There is intense competition among major pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions for qualified personnel in the areas of our activities and we may be unsuccessful in attracting and retaining these personnel.

Significant disruptions of information technology systems or breaches of information security could adversely affect our business.

We rely to a large extent upon sophisticated information technology systems to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personally identifiable information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have also outsourced elements of our information technology infrastructure, and as a result we are managing independent vendor relationships with third parties who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, make such systems potentially vulnerable both to service interruptions and to security breaches from inadvertent or intentional actions. We may be susceptible to third-party attacks on our information security systems, which attacks are of ever increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise. Service interruptions or security breaches could result in significant financial, legal, business or reputational harm.

Our current strategy focuses on certain international markets, particularly those in Europe, which are experiencing a recession or slow financial growth.

In recent years, our strategy has been to focus on international markets where we believe our products may be better received. This includes markets in Europe and other parts of the world that remain in, or have slid back into, recession and are harmed by the continuing European sovereign debt crisis. Continuing worldwide economic instability, including challenges faced by the Eurozone and certain of the countries in Europe, may lead to slower than expected revenue growth and collection issues as potential customers, or payors, continue to be harmed by slow economic growth.

Fluctuation in foreign currency exchange rates may adversely affect our financial statements and our ability to realize projected sales.

Although our financial statements are denominated in U.S. dollars, a significant portion of our revenues are realized in Euros. Our revenues are affected by movement of the U.S. dollar against the Euro. Fluctuations in exchange rates between the U.S. dollar and the Euro may also affect the reported value of our unconsolidated subsidiaries, as well as our cash flows. Currently, we do not employ forward contracts or other financial instruments to mitigate foreign currency risk.

Risks Related to Development, Clinical Testing and Regulatory Approval

We may be unable to obtain government approvals required to market our products and, even if we do, that approval may subsequently be withdrawn or limited.

Government regulation affects the manufacturing and marketing of pharmaceutical and medical device products. Government regulations may delay marketing of our potential drugs or potential medical devices for a considerable or indefinite period of time, impose costly procedural requirements upon our activities and furnish a competitive advantage to larger companies or companies more experienced in regulatory affairs. Delays in obtaining governmental regulatory approval could prohibit us from marketing our products in affected markets. Our drug or device candidates may not receive FDA or other regulatory approvals on a timely basis or at all. Even if our drug or device candidates receive marketing approval in the U.S. and other markets, our sales may be harmed by the absence of, or limits on, reimbursement by insurance companies, government health organizations and others in those markets.

Moreover, if regulatory approval of a drug or device candidate is granted, such approval may impose limitations on the indicated use for which such drug or device may be marketed. Even if we obtain initial regulatory approvals for our drug or device candidates, our drugs or devices and our manufacturing facilities would be subject to continual review and periodic inspection, and later discovery of previously unknown problems with a drug, or device, manufacturer or facility may result in restrictions on the marketing or manufacture of such drug or device, including withdrawal of the drug or device from the market. The FDA and other regulatory authorities stringently apply regulatory standards, and failure to comply with regulatory standards can, among other things, result in fines, denial or withdrawal of regulatory approvals, product recalls or seizures, operating restrictions and criminal prosecution.

The uncertainty associated with preclinical and clinical testing may affect our ability to successfully commercialize new products.

Before we can obtain regulatory approvals for the commercial sale of our potential products, the product candidates may be subject to extensive preclinical and clinical trials to demonstrate their safety and efficacy in humans. In this regard, for example, adverse side effects can occur during the clinical testing of a new drug on humans which may delay ultimate FDA or other agency approval or even lead us to terminate our efforts to develop the product for commercial use. Companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after demonstrating promising results in earlier trials. The failure to adequately demonstrate the safety and efficacy of a product candidate under development could delay or prevent regulatory approval of the product candidate. A delay or failure to receive regulatory approval for any of our product candidates could prevent us from successfully commercializing such candidates, and we could incur substantial additional expenses in our attempts to further develop such candidates and obtain future regulatory approval.

Trends toward managed health care and downward price pressure on medical products and services may limit our ability to profitably sell any drugs or devices that we develop.

Lower prices for health care products may result from:

- Third-party payers' increasing challenges to the prices charged for medical products and services;
- The trend toward managed health care in the United States and the concurrent growth of HMOs and similar organizations that can control or significantly influence the purchase of healthcare services and products; and
- The Affordable Care Act (a/k/a Obama care) and other proposals to reform healthcare or reduce government insurance programs.

The cost containment measures that healthcare providers are instituting, including practice protocols and guidelines and clinical pathways, and the effect of any healthcare reform, could limit our ability to profitably sell any drugs or devices that we may successfully develop. Moreover, any future legislation or regulation, if any, relating to the healthcare industry or third-party coverage and reimbursement, may cause our business to suffer.

Risks from the improper conduct of employees, agents or contractors or collaborators could adversely affect our business or reputation.

We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including without limitation, healthcare, employment, foreign corrupt practices, environmental, competition, and privacy laws. Such improper actions could subject us to civil or criminal investigations, monetary and injunctive penalties and could adversely impact our ability to conduct business, results of operations, and reputation.

Risks Related to Our Intellectual Property

We may not be successful in protecting our intellectual property and proprietary rights.

Our success depends, in part, on our ability to obtain U.S. and foreign patent protection for our drug and device candidates and processes, preserve our trade secrets and operate our business without infringing the proprietary rights of third parties. Legal standards relating to the validity of patents covering pharmaceutical inventions and the scope of claims made under such patents are still developing. We cannot assure you that any existing or future patents issued to, or licensed by, us will not subsequently be challenged, infringed upon, invalidated or circumvented by others. As a result, although we, together with our subsidiaries, are the owner of U.S. patents and U.S. patent applications now pending, and international patents and international patent applications, we cannot assure you that any additional patents will issue from any of the patent applications owned by us. Furthermore, any rights that we may have under issued patents may not provide us with significant protection against competitive products or otherwise be commercially valuable.

In addition, patents may have been granted to third parties or may be granted covering products or processes that are necessary or useful to the development of our product candidates. If our product candidates or processes are found to infringe upon the patents or otherwise impermissibly utilize the intellectual property of others, our development, manufacture and sale of such product candidates could be severely restricted or prohibited. In such event, we may be required to obtain licenses from third parties to utilize the patents or proprietary rights of others. We cannot assure you that we will be able to obtain such licenses on acceptable terms, if at all. If we become involved in litigation regarding our intellectual property rights or the intellectual property rights of others, the potential cost of such litigation, regardless of the strength of our legal position, and the potential damages that we could be required to pay could be substantial and harm our ability to continue as a going concern.

Risks Related to Our Common Stock

Our stockholders may experience substantial dilution in the value of their investment if we issue additional shares of our capital stock.

Our charter allows us to issue up to 200,000,000 shares of our common stock and to issue and designate the rights of, without stockholder approval, up to 20,000 shares of preferred stock. In the event we issue additional shares of our capital stock, dilution to our stockholders could result. In addition, if we issue and designate a new class of preferred stock, these securities may provide for rights, preferences or privileges senior to those of holders of our common stock.

Substantial sales of our common stock could lower our stock price.

Trading in our common stock is limited, and daily trading volumes are low. As a result, the market price for our common stock could drop as a result of sales of a large number of our presently outstanding shares of common stock or shares that we may issue or be obligated to issue in the future.

Future sales of our common stock may depress the market price of our common stock and cause stockholders to experience dilution.

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market. We may issue additional shares of common stock through one or more equity transactions in the future to satisfy our capital and operating needs; however, such transactions will be subject to market conditions and will likely include sales at a discount from our market prices. Sales of equity securities by a company at a discount from market price are often associated with a decrease in the market price of the common stock and will dilute the percentage interest owned by existing shareholders.

An investment in our common stock may be less attractive because it is not listed on a national stock exchange.

On April 2, 2012, we began quotation and trading on the OTCQB™ marketplace, operated by the OTC Markets Group. The OTCQB is a market tier for over-the-counter-traded companies that are registered and reporting with the SEC. The OTCQB is viewed by most investors as a less desirable, and less liquid, marketplace than a national stock exchange. As a result, an investor may find it more difficult to purchase, dispose of or obtain accurate quotations as to the value of our common stock.

Our common stock is a “low-priced stock” and subject to regulations that limits or restricts the potential market for our stock.

Shares of our common stock are “low-priced” or “penny stock,” resulting in increased risks to our investors and certain requirements being imposed on some brokers who execute transactions in our common stock. In general, a low-priced stock is an equity security that:

- Is priced under five dollars;
- Is not traded on a national stock exchange, such as NASDAQ or the NYSE;
- Is issued by a company that has less than \$5 million in net tangible assets (if it has been in business less than three years) or has less than \$2 million in net tangible assets (if it has been in business for at least three years); and
- Is issued by a company that has average revenues of less than \$6 million for the past three years.

We believe that our common stock is presently a “penny stock.” At any time the common stock qualifies as a penny stock, the following requirements, among others, will generally apply:

- Certain broker-dealers who recommend penny stock to persons other than established customers and accredited investors must make a special written suitability determination for the purchaser and receive the purchaser’s written agreement to a transaction prior to sale.
- Prior to executing any transaction involving a penny stock, certain broker-dealers must deliver to certain purchasers a disclosure schedule explaining the risks involved in owning penny stock, the broker-dealer’s duties to the customer, a toll-free telephone number for inquiries about the broker-dealer’s disciplinary history and the customer’s rights and remedies in case of fraud or abuse in the sale.
- In connection with the execution of any transaction involving a penny stock, certain broker-dealers must deliver to certain purchasers the following:
 - bid and offer price quotes and volume information;
 - the broker-dealer’s compensation for the trade;
 - the compensation received by certain salespersons for the trade;
 - monthly accounts statements; and
 - a written statement of the customer’s financial situation and investment goals.

We do not expect to pay dividends in the foreseeable future.

We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Accordingly, you will have to rely on appreciation in the price of our common stock, if any, to earn a return on your investment in our common stock. Furthermore, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends.

Provisions of our charter documents could discourage an acquisition of our Company that would benefit our stockholders and may have the effect of entrenching, and making it difficult to remove, management.

Provisions of our Articles of Incorporation and Bylaws may make it more difficult for a third party to acquire control of our Company, even if a change in control would benefit our stockholders. In particular, shares of our preferred stock may be issued in the future without further stockholder approval and upon such terms and conditions, and having such rights, privileges and preferences, as our Board of Directors may determine, including for example, rights to convert into our common stock. The rights of the holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any of our preferred stock that may be issued in the future. The issuance of our preferred stock, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for a third party to acquire control of us. This could limit the price that certain investors might be willing to pay in the future for shares of our common stock and the likelihood of an acquisition.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

As of December 31, 2014, we did not own any real property. On January 31, 2006, we entered into a lease agreement for approximately 9,000 square feet of administrative offices and laboratories in Addison, Texas. Additional space is available in the complex for future expansion which we believe would accommodate growth for the foreseeable future. The lease commenced on April 1, 2006 and originally continued until April 1, 2013. The lease required a minimum monthly lease obligation of \$9,330, which was inclusive of monthly operating expenses, until April 1, 2011 and at such time increased to \$9,776, which was inclusive of monthly operating expenses. On February 22, 2013, we executed an Amendment to Lease Agreement (the "Lease Amendment") that renewed and extended our lease until March 31, 2015. The Lease Amendment required a minimum monthly lease obligation of \$9,193, which was inclusive of monthly operating expenses, until March 31, 2014 and at such time, increased to \$9,379, which was inclusive of monthly operating expenses. On March 17, 2015, we executed a Second Amendment to Lease Agreement (the "Second Amendment") that renewed and extended our lease until March 31, 2018. The Second Amendment requires a minimum monthly lease obligation of \$9,436, which is inclusive of monthly operating expenses.

We believe that our existing leased facilities are suitable for the conduct of our business and adequate to meet our growth requirements.

ITEM 3. LEGAL PROCEEDINGS

On or about August 22, 2014, Inter-Mountain Capital Corp (“Inter-Mountain”) filed a Complaint against ULURU in a matter now pending in the U.S. Federal Court for the District of Utah, Central Division. The Complaint relates to Inter-Mountain’s delivery of a notice of a cashless exercise with respect to its last remaining warrant to purchase Common Stock on or about May 1, 2014 purporting to exercise it with respect to the delivery of 782,284 shares of Common Stock under the non-standard cashless exercise or conversion provisions in the warrant. ULURU declined to honor the exercise on the basis that, as a result of an amendment to the warrant agreed to in December 2013, the warrant was exercisable, on a cashless basis, with respect to only 261,516 shares of Common Stock as of May 1, 2014. Inter-Mountain alleges that ULURU’s refusal to honor the exercise constitutes a breach of the warrant, breach of implied covenant of good faith and fair dealing, unjust enrichment, a violation of securities laws and common law fraud and seeks actual damages, consequential damages, treble damages, specific performance, attorneys’ fees and costs and other relief. Answers and counterclaims have been filed. A preliminary settlement has been reached and is in the process of being documented. All proceedings have been placed on hold pending documentation of the settlement.

On or about November 6, 2012, Discus Dental, LLC (“Discus”) and Philips Oral Healthcare Inc. (“Philips”) filed a Complaint against ULURU in the United States District Court, Central District of California (the “Action”). Discus, a subsidiary of Philips’ parent company, was party to a license agreement under which ULURU’s predecessor granted it a defined license. The license contractually required that Discus use commercially reasonable efforts to, market and sell Aphthasol® paste, a prescription pharmaceutical. Prior to the filing of the Action, ULURU sent a demand letter contending that Discus did not fulfill its obligations under the license agreement, including the obligation to retain an adequate selling organization and otherwise use commercially reasonable efforts to market and sell Aphthasol® paste. In response to ULURU’s demand letter, the Plaintiffs instituted the Action seeking a declaratory judgment that Discus did not breach the license agreement. On November 20, 2012, the Plaintiffs filed an Amended Complaint adding a claim requesting that ULURU be ordered to return certain royalty payments that Discus paid to ULURU after the expiration of the license period. On October 7, 2014, Discus filed a Second Amended Complaint, withdrawing Philips as a plaintiff and adding claims that ULURU breached the license by allegedly making a profit from the manufacture of Aphthasol® paste. ULURU denied liability with regard to Discus’s claims and asserted counterclaims for breach of contract against Discus, seeking compensatory damages and attorneys’ fees. On November 18, 2014, ULURU and Discus agreed to settle, resolve, and dismiss the claims asserted in the Action with the terms and conditions of the settlement subject to an agreement of confidentiality. The settlement included a release by each party in favor of the other and a settlement payment in favor of ULURU.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

Part II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market for Common Equity

Our common stock began quotation and trading on the OTCQB™ marketplace, operated by the OTC Markets Group, under the symbol "ULUR" on April 2, 2012.

From July 26, 2007 to April 1, 2012 our common stock was traded on the exchange currently known as the NYSE MKT NYSE Amex, LLC exchange under the symbol "ULU". From March 31, 2006 to July 25, 2007 our common stock was quoted on the OTC Bulletin Board under the symbol "ULUR.OB".

The following table sets forth, on a quarterly basis, the high and low per share closing prices of our common stock as reported on the OTCQB™ marketplace from January 1, 2013 through December 31, 2014.

| <u>Year Ended December 31, 2014</u> | <u>High</u> | <u>Low</u> |
|-------------------------------------|-------------|------------|
| First Quarter | \$1.80 | \$0.80 |
| Second Quarter | \$1.60 | \$0.89 |
| Third Quarter | \$1.35 | \$1.03 |
| Fourth Quarter | \$1.17 | \$0.81 |
| <u>Year Ended December 31, 2013</u> | | |
| First Quarter | \$0.38 | \$0.28 |
| Second Quarter | \$0.61 | \$0.29 |
| Third Quarter | \$0.65 | \$0.42 |
| Fourth Quarter | \$0.69 | \$0.38 |

Holder of Common Stock

As of March 31, 2015, there were approximately 56 shareholders of record holding our common stock based upon the records of our transfer agent which do not include beneficial owners of common stock whose shares are held in the names of various securities brokers, dealers, and registered clearing agencies. We believe the number of actual shareholders of our common stock exceeds the number of registered shareholders and estimate such number at approximately 4,000 shareholders. As of March 31, 2015, there were 200,000,000 shares of common stock authorized and 24,458,018 shares of common stock issued and outstanding.

The last sales price of our common stock on March 31, 2015 was \$0.715 per share as quoted and traded on the OTCQB™ marketplace.

Dividend Policy

To date, we have not declared or paid any cash dividends on our preferred stock or common stock and we do not anticipate paying any cash dividends on them in the foreseeable future. The payment of dividends, if any, in the future is within the discretion of our Board of Directors and will depend on our earnings, capital requirements, and financial condition and other relevant facts. We currently intend to retain all future earnings, if any, to finance the development and growth of our business.

Securities Authorized for Issuance Under Equity Compensation Plans

In March 2006, our board of directors (the “Board”) adopted and our stockholders approved our 2006 Equity Incentive Plan (the “Incentive Plan”), which initially provided for the issuance of up to 133,333 shares of our common stock pursuant to stock options and other equity awards. At the annual meetings of the stockholders held on May 8, 2007, December 17, 2009, June 15, 2010, June 14, 2012, June 13, 2013, and on June 15, 2014, our stockholders approved amendments to the Equity Incentive Plan to increase the total number of shares of common stock issuable under the Equity Incentive Plan pursuant to stock options and other equity awards by 266,667 shares, 200,000 shares, 200,000 shares, 400,000 shares, 600,000 shares, and 1,000,000 shares, respectively, to a total of 2,800,000 shares.

In December 2006, we began issuing stock options to employees, consultants, and directors. The stock options issued generally vest over a period of one to four years and have a maximum contractual term of ten years. In January 2007, we began issuing restricted stock awards to our employees. Restricted stock awards generally vest over a period of six months to five years after the date of grant. Prior to vesting, restricted stock awards do not have dividend equivalent rights, do not have voting rights, and the shares underlying the restricted stock awards are not considered issued and outstanding. Shares of common stock are issued on the date the restricted stock awards vest.

As of December 31, 2014, we had granted options to purchase 2,061,167 shares of Common Stock since the inception of the Equity Incentive Plan, of which 1,699,907 were outstanding at a weighted average exercise price of \$1.73 per share, and we had granted awards for 68,616 shares of restricted stock since the inception of the Equity Incentive Plan, of which none were outstanding. As of December 31, 2014, there were 1,030,647 shares that remained available for future grants under our Equity Incentive Plan.

The following table sets forth the outstanding stock options or rights that have been authorized under equity compensation plans as of December 31, 2014.

| Plan Category | Number of securities to be issued upon exercise of outstanding options, warrants and rights (a) | Weighted-average exercise price of outstanding options, warrants and rights (b) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c) |
|--|--|--|--|
| Equity compensation plans approved by security holders | | | |
| 2006 Equity Incentive Plan | 1,699,907 | \$ 1.73 | 1,030,647 |
| Equity compensation plans not approved by security holders | -0- | n/a | -0- |
| Total | 1,699,907 | \$ 1.73 | 1,030,647 |

ITEM 6. SELECTED FINANCIAL DATA

Smaller reporting companies are not required to provide the information required by this Item.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and other information in this Report contains forward-looking statements that are subject to significant risks and uncertainties. There are several important factors that could cause actual results to differ materially from historical results and percentages and results anticipated by the forward-looking statements. We have sought to identify significant risks to our business, but cannot predict whether or to what extent any of such risks may be realized nor can there be any assurance that we have identified all possible risks that might arise. Investors should carefully consider all of such risks before making an investment decision with respect to our stock.

The following contains certain statements that are forward-looking within the meaning of Section 27a of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, and that involve risks and uncertainties, including, but not limited to uncertainties regarding our ability to maintain costs, dependence on others to market our licensed products, the timing and receipt of licensing and milestone revenues, our ability to achieve licensing and milestone revenues, the future success of our marketed products and products in development, our ability to raise additional financing to sustain our operations, and other risks described below as well as those discussed elsewhere in this Report, documents incorporated by reference and other documents and reports that we file periodically with the Securities and Exchange Commission.

Business

ULURU Inc. (hereinafter “we”, “our”, “us”, “ULURU”, or the “Company”) is a Nevada corporation. We are a diversified specialty pharmaceutical company committed to developing and commercializing a broad range of innovative wound care and mucoadhesive film products based on our patented Nanoflex® and OraDisc™ technologies, with the goal of improving outcomes for patients, health care professionals, and health care payers.

Our strategy is twofold:

- Establish a market leadership position in wound management by developing and commercializing a customer focused portfolio of innovative wound care products based on our Nanoflex® technology to treat the various phases of wound healing; and
- Develop our oral-mucoadhesive film technology (OraDisc™) and generate revenues through multiple licensing agreements.

Utilizing our technologies, three of our products have been approved for marketing in various global markets. In addition, numerous additional products are under development utilizing our patented Nanoflex® and OraDisc™ technologies.

Altrazeal® Transforming Powder Dressing, based on our Nanoflex® technology, has the potential to change the way health care providers approach their treatment of wounds. Launched in September 2008, the product is indicated for both exuding acute wounds such as partial thickness burns, donor sites, non-healing surgical wounds, and trauma and for chronic wounds such as venous leg ulcers, diabetic foot ulcers, and pressure ulcers.

Aphthasol®, our Amlexanox 5% paste product, is the first drug approved by the FDA for the treatment of canker sores.

OraDisc™ A was developed as an improved drug delivery system for amlexanox, the same active ingredient used in Aphthasol® paste for the treatment of canker sores. We anticipate that higher amlexanox concentrations will be achieved at the disease site, increasing the effectiveness of the product.

Recent Developments

Operating Lease

In March 2015, we executed a Second Amendment to Lease Agreement (the “Second Amendment”) with our current landlord that renewed and extended our lease for a period of 36 months. The Second Amendment will require a minimum monthly lease obligation of \$9,436, which is inclusive of monthly operating expenses, until March 31, 2018.

LIQUIDITY AND CAPITAL RESOURCES

We have funded our operations primarily through the public and private sales of convertible notes and common stock. Product sales, royalty payments, contract research, licensing fees and milestone payments from our corporate alliances have also provided, and are expected in the future to provide, funding for operations. Our principal source of liquidity is cash and cash equivalents. As of December 31, 2014, our cash and cash equivalents were approximately \$550,000 which is an increase of approximately \$545,000 as compared to our cash and cash equivalents at December 31, 2013 of approximately \$5,000. Our working capital (current assets less current liabilities) was approximately \$(53,000) at December 31, 2014 as compared to our working capital at December 31, 2013 of approximately \$(1,783,000).

Consolidated Cash Flow Data

| <u>Net Cash Provided by (Used in)</u> | Year Ended December 31, | |
|--|--------------------------------|--------------------|
| | <u>2014</u> | <u>2013</u> |
| Operating activities | \$ (1,057,000) | \$ (1,734,000) |
| Investing activities | (31,000) | (34,000) |
| Financing activities | 1,633,000 | 1,752,000 |
| Net increase (decrease) in cash and cash equivalents | <u>\$ 545,000</u> | <u>\$ (16,000)</u> |

Operating Activities

For the year ended December 31, 2014, net cash used in operating activities was approximately \$1,057,000. The principal components of net cash used for the year ended December 31, 2014 were, in approximate numbers, our net loss of \$1,939,000, a decrease of \$198,000 in accounts payable due to timing of vendor payments, a decrease of \$59,000 in deferred revenues due to amortization of revenues, a decrease of \$43,000 in accrued liabilities related to compensation, a decrease of \$13,000 in accrued interest, an increase of \$617,000 in accounts receivable related to higher international product sales, and an increase of \$14,000 in prepaid expense. Our net loss for the year ended December 31, 2014 included substantial non-cash charges of approximately \$978,000 in the form of share-based compensation, amortization of patents, depreciation, amortization of debt discount, amortization of deferred financings costs, interest due on convertible notes settled with common stock, common stock and warrants issued for services, and the loss on early extinguishment of a convertible note. The aforementioned net cash used for the year ended December 31, 2014 was partially offset by, in approximate numbers, a decrease of \$778,000 in notes receivable due to our offset in January 2014 of all outstanding Investor Notes issued by Inter-Mountain, and a decrease of \$70,000 in inventory primarily related to finished goods.

For the year ended December 31, 2013, net cash used in operating activities was approximately \$1,734,000. The principal components of net cash used for the year ended December 31, 2013 were, in approximate numbers, our net loss of \$3,081,000, a decrease in accounts payable of \$606,000 due to timing of vendor payments, an increase in accounts receivable of \$73,000, a decrease in accrued liabilities of \$57,000, a decrease in accrued interest of \$28,000 due to annual interest payments on our convertible notes, and the cancellation of a warrant issued for services of \$49,000. Our net loss for the year ended December 31, 2013 included substantial non-cash charges of approximately \$1,357,000 in the form of share-based compensation, amortization of patents, depreciation, amortization of debt discount, amortization of deferred financing costs, common stock issued for wages and services, and interest due on convertible notes settled with common stock. The aforementioned net cash used for the year ended December 31, 2013 was partially offset by, in approximate numbers, a decrease in notes receivable of \$524,000 due to remittance of Investor Notes by Inter-Mountain, a decrease in inventory of \$132,000 due to product sales and the write-off of obsolete inventory, a net increase in deferred revenues of \$76,000 due primarily to the receipt of a licensing milestone, and a decrease in prepaid expenses of \$71,000 due to amortization of expenses.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2014 was approximately \$31,000 and relates to the purchase of equipment for the manufacture of Altrazeal® and equipment for our computer systems.

Net cash used in investing activities for the year ended December 31, 2013 was approximately \$34,000 and is comprised of our purchase of manufacturing equipment for approximately \$39,000 which was partially offset by the proceeds from the sale of equipment for approximately \$5,000.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2014 was approximately \$1,633,000 and was comprised of, in approximate numbers, the final funding of \$500,000 from the sale of common stock and warrants pursuant to the January 2013 Offering, the final funding of \$110,000 from the sale of common stock and warrants pursuant to the March 2013 Offering, the funding of \$1,800,000 from the exercise of warrants to purchase 3,000,000 shares of common stock pursuant to the Implementation Agreement with Michael Sacks and The Punch Trust, and the repayment of \$777,000 of principle due on the convertible promissory note with Inter-Mountain attributable to the deduction and offset in January 2014 of the outstanding Investor Notes against the outstanding principle due on the convertible promissory note with Inter-Mountain.

Net cash provided by financing activities for the year ended December 31, 2013 was approximately \$1,752,000 and was comprised of, in approximate numbers, net proceeds of \$1,496,000 from the sale of common stock and warrants pursuant to the January 2013 Offering, net proceeds of \$328,000 from the sale of common stock and warrants pursuant to the March 2013 Offering, \$2,000 from the net proceeds of our redemption of Series A preferred stock, and \$8,000 from a decrease in the actual offering costs associated with the sale of preferred stock that occurred in 2011. These increases due to financing activities were partially offset by the repayment of approximately \$82,000 of principle due on the convertible note with Inter-Mountain.

Liquidity

As of December 31, 2014, we had cash and cash equivalents of approximately \$550,000. We expect to use our cash, cash equivalents, and investments on working capital, general corporate purposes, property and equipment, and the payment of contractual obligations. Our long-term liquidity will depend to a great extent on our ability to fully commercialize our Altrazeal® and OraDisc™ technologies; therefore we are continuing to look both domestically and internationally for opportunities that will enable us to expand our business. At this time, we cannot accurately predict the effect of certain developments on the rate of sales growth, if any, during 2015 and beyond, such as the speed and degree of market acceptance, patent protection and exclusivity of our products, the impact of competition, the effectiveness of our sales and marketing efforts, and the outcome of our current efforts to develop, receive approval for, and successfully launch our near-term product candidates.

As of December 31, 2014, our working capital (current assets less current liabilities) was approximately \$(53,000). Our liquidity as of December 31, 2014 will not be sufficient to fund operations beyond the first quarter of 2015. In order to continue to advance our business plan and outstanding obligations, we need to raise additional capital. We need capital in the immediate-term to fund our current operations. In addition, in light of our stage of development and limited sales, we may need additional capital in the foreseeable future in order to expand our business and fund our operations. We expect to seek funding through through public and/or private offerings of debt and equity securities. We may also seek capital from other sources, including contribution by others to joint ventures, or collaborative arrangements or licensing for the development, testing, manufacturing and marketing of products under development.

Historically, we have been able to raise capital as needed to fund our operations at a base level, but we

have generally not raised capital sufficient to fund unexpected occurrences, to cover projected expenses over the long term or to fund extensive research, marketing and development. We are currently in discussions with various parties about potential financings, and management believes that we can raise capital as necessary for our near term needs; however, no party has signed any binding commitment to provided capital. As a result, there is a risk that we will not be able to obtain capital as needed in the near term. In addition, we will need to continue to seek capital from the market over the long term. To the extent we raise capital, it generally will be on terms that are dilutive to shareholders and may require the issuance of warrants or similar incentives, the agreement to restrictive covenants and/or the pledge of our assets as securities for debt financings.

Our future capital requirements and adequacy of available funds will depend on many factors including:

- our ability to successfully commercialize our wound management products and the market acceptance of these products;
- our ability to establish and maintain collaborative arrangements with corporate partners for the development and commercialization of certain product opportunities;
- continued scientific progress in our development programs;
- our ability to collect outstanding receivables;
- the costs involved in filing, prosecuting and enforcing patent claims;
- competing technological developments;
- the trading volume and price of our capital stock;
- the actions of parties whose consents, waivers or prompt responses are required for approval of a financing (such as parties with rights of first refusal or consent rights);
- our general financial situation, including the amount of our indebtedness; and
- the cost of manufacturing and production scale-up.

Contractual Obligations

The following table summarizes our outstanding contractual cash obligations as of December 31, 2014, which consists of a lease agreement for office and laboratory space in Addison, Texas and a lease agreement for office equipment. These obligations and commitments assume non-termination of agreements and represent expected payments based on current operating forecasts, which are subject to change:

| Contractual Obligations | Payments Due By Period | | | | |
|------------------------------------|-------------------------------|-----------------------------|----------------------|----------------------|--------------------------|
| | Total | Less Than 1 Year | 1-2 Years | 3-5 Years | After 5 Years |
| Operating leases | \$ 388,571 | \$ 120,033 | \$ 239,680 | \$ 28,858 | \$ --- |
| Total contractual cash obligations | \$ 388,571 | \$ 120,033 | \$ 239,680 | \$ 28,858 | \$ --- |

Capital Expenditures

For the years ended December 31, 2014 and 2013, our expenditures for property, equipment, and leasehold improvements were, in approximate numbers, \$31,000 and \$39,000, respectively. Such expenditures in 2014 relate primarily to the purchase of equipment for the manufacture of Altrazeal® and computer equipment for our administrative office. At this time, we believe that our capital expenditures for 2015 will be approximately \$60,000 and consist of equipment related to the manufacture of our products.

Off-Balance Sheet Arrangements

As of December 31, 2014, we did not have any off balance sheet arrangements.

Impact of Inflation

We have experienced only moderate price increases over the last three fiscal years under our agreements with third-party manufacturers as a result of raw material and labor price increases. However, there can be no assurance that possible future inflation would not impact our operations.

Concentrations of Credit Risk

Concentration of credit risk with respect to financial instruments, consisting primarily of cash and cash equivalents, potentially expose us to concentrations of credit risk due to the use of a limited number of banking institutions and due to maintaining cash balances in banks, which, at times, may exceed the limits of amounts insured by the Federal Deposit Insurance Corporation. During 2014 and 2013, we utilized Bank of America, N.A. and Bank of America Investment Services, Inc. as our banking institutions. At December 31, 2014 and December 31, 2013 our cash and cash equivalents totaled approximately \$550,000 and \$5,000, respectively. We also invest cash in excess of immediate requirements in money market accounts, certificates of deposit, corporate commercial paper with high quality ratings, and U.S. government securities. These investments are not held for trading or other speculative purposes. We are exposed to credit risk in the event of default by these institutions.

Concentration of credit risk with respect to trade accounts receivable are customers with balances that exceed 5% of total consolidated trade accounts receivable at December 31, 2014 and at December 31, 2013. As of December 31, 2014, three customers, each being one of our international distributors, exceeded the 5% threshold, with 71%, 19%, and 9%, respectively. Two customers, each being one of our international distributors, exceeded the 5% threshold at December 31, 2013, with 86% and 11%, respectively. To reduce risk, we routinely assess the financial strength of our most significant customers and monitor the amounts owed to us, taking appropriate action when necessary. As a result, we believe that accounts receivable credit risk exposure is limited. We maintain an allowance for doubtful accounts, but historically have not experienced any significant losses related to an individual customer or group of customers.

Concentrations of Foreign Currency Risk

Currently, a portion of our revenues and all of our expenses are denominated in U.S. dollars. We are experiencing an increase in revenues in international territories denominated in a foreign currency. Certain of our licensing and distribution agreements in international territories are denominated in Euros. Currently, we do not employ forward contracts or other financial instruments to mitigate foreign currency risk. As our international operations continue to grow, we may engage in hedging activities to hedge our exposure to foreign currency risk.

RESULTS OF OPERATIONS

Fluctuations in Operating Results

Our results of operations have fluctuated significantly from period to period in the past and are likely to continue to do so in the future. We anticipate that our quarterly and annual results of operations will be affected for the foreseeable future by several factors, including the timing and amount of payments received pursuant to our current and future collaborations, the timing of shipments to our international marketing partners, and the progress and timing of expenditures related to our development and commercialization efforts. Due to these fluctuations, we believe that the period-to-period comparisons of our operating results may not be a good indication of our future performance.

Comparison of the year ended December 31, 2014 and 2013

Total Revenues

Revenues totaled approximately \$864,000 for the year ended December 31, 2014, as compared to revenues of approximately \$371,000 for the year ended December 31, 2013, and were comprised of, in approximate numbers, licensing fees of \$59,000 from Altrazeal® and OraDisc™ licensing agreements, royalties of \$63,000 from the sale of Altrazeal® by our international distributors, and product sales of approximately \$742,000 for Altrazeal®.

The year ended December 31, 2014 revenues represent an overall increase of approximately \$493,000 versus the comparative year ended December 31, 2013 revenues. The increase in revenues is primarily attributable to, in approximate numbers, an increase of \$450,000 in Altrazeal® product sales by our international distributors, an increase of \$33,000 in royalties related to Altrazeal® from our international distributors, and an increase of \$10,000 in Altrazeal® licensing.

Costs and Expenses

Cost of Goods Sold

Cost of goods sold totaled approximately \$512,000 for the year ended December 31, 2014 and was comprised of, in approximate numbers, \$493,000 from the sale of our Altrazeal® products and \$19,000 from the write-off of obsolete inventory.

Cost of goods sold totaled approximately \$222,000 for the year ended December 31, 2013 and was comprised of, in approximate numbers, \$162,000 from the sale of our Altrazeal® products and \$60,000 from the write-off of obsolete finished goods and raw materials.

Research and Development

Research and development expenses totaled approximately \$771,000 for the year ended December 31, 2014, including \$36,000 in share-based compensation, as compared to approximately \$788,000 for the year ended December 31, 2013, which included \$17,000 in share-based compensation.

The decrease of approximately \$17,000 in research and development expenses was primarily due to, in approximate numbers, a decrease of \$77,000 in direct research costs primarily related to Altrazeal®, a decrease of \$67,000 in regulatory costs, and a decrease of \$12,000 in miscellaneous operating costs. These expense decreases were partially offset by an increase of \$119,000 in scientific compensation related to share-based compensation and a higher head count, and an increase of \$20,000 in clinical study costs related to Altrazeal®.

The direct research and development expenses for the years ended December 31, 2014 and 2013 were, in approximate numbers, as follows:

| Technology | Year Ended December 31, | |
|---------------------------------|------------------------------------|-------------------|
| | 2014 | 2013 |
| Wound care & Nanoflex® | \$ 246,000 | \$ 321,000 |
| OraDisc™ | 15,000 | 18,000 |
| Aphthasol® & other technologies | 3,000 | 2,000 |
| Total | \$ 264,000 | \$ 341,000 |

Selling, General and Administrative

Selling, general and administrative expenses totaled approximately \$1,774,000 for the year ended December 31, 2014, including \$113,000 in share-based compensation, as compared to approximately \$1,288,000 for the year ended December 31, 2013, which included \$65,000 in share-based compensation.

The increase of approximately \$486,000 in selling, general and administrative expenses was primarily due to, in approximate numbers, an increase of \$328,000 in legal expenses related to a licensing agreement dispute and a warrant exercise dispute, an increase of \$93,000 in sales and marketing expenses, an increase of \$44,000 in director fees related to share-based compensation, an increase of \$24,000 in legal fees related to our patents, an increase of \$18,000 in investor relations consulting primarily related to share-based compensation, an increase of \$14,000 in accounting fees primarily related to updating internal controls, an increase of \$12,000 in compensation costs related to share-based compensation, an increase of \$11,000 in insurance costs, and an increase of \$9,000 in occupancy costs. These expense increases were partially offset by, in approximate numbers, a decrease of \$50,000 in accruals related to estimated merger costs from 2008, a decrease of \$10,000 in consulting related to product licensing, a decrease of \$4,000 in consulting costs related to XBRL reporting, and a decrease of \$3,000 in property tax expense.

Amortization of Intangible Assets

Amortization expense of intangible assets totaled approximately \$475,000 for the year ended December 31, 2014 as compared to approximately \$475,000 for the year ended December 31, 2013. The expense for each period consists of amortization associated with our acquired patents. There were no purchases of patents during the years ended December 31, 2014 and 2013.

Depreciation

Depreciation expense totaled approximately \$237,000 for the year ended December 31, 2014 as compared to approximately \$245,000 for the year ended December 31, 2013. The decrease of approximately \$8,000 is attributable to certain equipment being fully depreciated.

Interest and Miscellaneous Income

Interest and miscellaneous income totaled approximately \$5,000 for the year ended December 31, 2014 as compared to approximately \$70,000 for the year ended December 31, 2013. The decrease of approximately \$65,000 in interest income is attributable to the offset in January 2014 of the outstanding Inter-Mountain notes receivable.

Interest Expense

Interest expense totaled approximately \$51,000 for the year ended December 31, 2014 as compared to approximately \$507,000 for the year ended December 31, 2013. Interest expense is comprised of financing costs for our insurance policies, interest costs related to regulatory fees, and interest costs and amortization of debt discount and financing costs related to our convertible debt. The decrease of approximately \$456,000 is primarily attributable to the deduction and offset in January 2014 of the outstanding notes receivable against the outstanding principle due on the convertible promissory note with Inter-Mountain and the final payoff of the convertible promissory note with Inter-Mountain in March 2014, the final payoff of the June 2011 convertible promissory note in June 2014, and the final payoff of the July 2011 convertible note in July 2014.

Foreign Currency Transaction (Loss)

Foreign currency transaction loss totaled approximately \$54,000 for the year ended December 31, 2014 as compared to nil for the year ended December 31, 2013. The increase of approximately \$54,000 is related to a decrease in the Euro exchange rate experienced during 2014 and the pricing of Altrazeal® to our international distributors being denominated in Euros.

Loss on Early Extinguishment of Convertible Note

Loss on early extinguishment of convertible note totaled approximately \$135,000 for the year ended December 31, 2014 as compared to nil for the year ended December 31, 2013, with such loss in 2014 occurring as a result of our election to exercise our rights under the June 2012 Note and to offset amounts we owed to Inter-Mountain against amounts it owed to us under the Investor Notes.

Proceeds from Litigation Settlement

Proceeds from litigation settlement totaled approximately \$1,200,000 for the year ended December 31, 2014 as compared to nil for the year ended December 31, 2013. Refer to Item 3 – Legal Proceedings.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Management's Discussion and Analysis of Financial Condition and Results of Operations set forth herein are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for financial information. The preparation of our financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, we evaluate these estimates and judgments. We base our estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We set forth below those material accounting policies that we believe are the most critical to an investor's understanding of our financial results and condition and which require complex management judgment.

Revenue Recognition

We recognize revenue in accordance with generally accepted accounting principles as outlined in the ASC Topic 605, *Revenue Recognition* ("ASC Topic 605"), which requires that four basic criteria be met before revenue can be recognized: (i) persuasive evidence of an arrangement exists; (ii) the price is fixed or determinable; (iii) collectability is reasonably assured; and (iv) product delivery has occurred or services have been rendered. We recognize revenue as products are shipped based on FOB shipping point terms when title passes to customers. We negotiate credit terms on a customer-by-customer basis and products are shipped at an agreed upon price. All product returns must be pre-approved.

We also generate revenue from license agreements and research collaborations and recognize this revenue when earned. In accordance with ASC Topic 605-25, *Revenue Recognition - Multiple Element Arrangements*, for deliverables which contain multiple deliverables, we separate the deliverables into separate accounting units if they meet the following criteria: i) the delivered items have a stand-alone value to the customer; ii) the fair value of any undelivered items can be reliably determined; and iii) if the arrangement includes a general right of return, delivery of the undelivered items is probable and substantially controlled by the seller. Deliverables that do not meet these criteria are combined with one or more other deliverables into one accounting unit. Revenue from each accounting unit is recognized based on the applicable accounting literature, primarily ASC Topic 605.

We analyze the rate of historical returns when evaluating the adequacy of the allowance for sales returns. At December 31, 2014 and 2013, this reserve was nil as we have not experienced historically any product returns. If the historical data we use to calculate these estimates does not properly reflect future returns, revenue could be overstated.

Allowance for Doubtful Accounts

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. This allowance is regularly evaluated by us for adequacy by taking into consideration factors such as past experience, credit quality of the customer base, age of the receivable balances, both individually and in the aggregate, and current economic conditions that may affect a customer's ability to pay. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required. Actual write-off of receivables may differ from estimates due to changes in customer and economic circumstances.

Inventory

We state our inventory at the lower of cost (first-in, first-out method) or market. The estimated value of excess, obsolete and slow-moving inventory as well as inventory with a carrying value in excess of its net realizable value is established by us on a quarterly basis through review of inventory on hand and assessment of future demand, anticipated release of new products into the market, historical experience and product expiration. Our stated value of inventory could be materially different if demand for our products decreased because of competitive conditions or market acceptance, or if products become obsolete because of advancements in the industry.

Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services which have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements.

In accruing service fees, we estimate the time period over which services will be provided and the level of effort in each period. If the actual timing of the provision of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify costs that have begun to be incurred or we underestimate or overestimate the level of services performed or the costs of such services, our actual expenses could differ from such estimates. The date, on which some services commence, the level of services performed on or before a given date and the cost of such services are often subjective determinations. We make judgments based upon facts and circumstances known to us in accordance with GAAP.

Share based Compensation – Employee Share based Awards

We primarily grant qualified stock options for a fixed number of shares to employees with an exercise price equal to the market value of the shares at the date of grant. Under the fair value recognition provisions of ASC Topic 718, *Stock Compensation* (“ASC Topic 718”), and ASC Topic 505, *Equity* (“ASC Topic 505”), share based compensation cost is based on the value of the portion of share based awards that is ultimately expected to vest during the period.

We selected the Black-Scholes option pricing model as the most appropriate method for determining the estimated fair value for share based awards. The Black-Scholes model requires the use of assumptions which determine the fair value of the share based awards. Determining the fair value of share based awards at the grant date requires judgment, including estimating the expected term of stock options, the expected volatility of our stock, and expected dividends. In accordance with ASC Topic 718 and ASC Topic 505, we are required to estimate forfeitures at the grant date and recognize compensation costs for only those awards that are expected to vest. Judgment is required in estimating the amount of share based awards that are expected to be forfeited.

If factors change and we employ different assumptions in the application of ASC Topic 718 and ASC Topic 505 in future periods, the compensation expense that we record may differ significantly from what we have recorded in the current period. Therefore, we believe it is important for investors to be aware of the high degree of subjectivity involved when using option pricing models to estimate share-based compensation under ASC Topic 718 and ASC Topic 505. There is risk that our estimates of the fair values of our share-based compensation awards on the grant dates may differ from the actual values realized upon the exercise, expiration, early termination or forfeiture of those share-based payments in the future. Certain share-based payments, such as employee stock options, may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our financial statements. Alternatively, value may be realized from these instruments that is significantly in excess of the fair values originally estimated on the grant date and reported in our financial statements. Although the fair value of employee share-based awards is determined in accordance with ASC Topic 718 and ASC Topic 505 using an option pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction.

Share based Compensation – Non-Employee Share based Awards

We occasionally grant stock option awards to our consultants and directors. Such grants are accounted for pursuant to ASC Topic 505 and, accordingly, we recognize compensation expense equal to the fair value of such awards and amortize such expense over the performance period. We estimate the fair value of each award using the Black-Scholes model. The unvested equity instruments are revalued on each subsequent reporting date until performance is complete, with an adjustment recognized for any changes in their fair value. We amortize expense related to non-employee stock options in accordance with ASC Topic 718.

Income Taxes

The carrying value of our net deferred tax assets assumes that we will be able to generate sufficient taxable income in the United States based on estimates and assumptions. We record a valuation allowance to reduce the carrying value of our net deferred tax asset to the amount that is more likely than not to be realized. In the event we were to determine that we would be able to realize our deferred tax assets in the future, an adjustment to the deferred tax asset would increase net income in the period such determination is made. On a quarterly basis, we evaluate the realizability of our deferred tax assets and assess the requirement for a valuation allowance.

Asset Valuations and Review for Potential Impairment

We review our fixed assets and intangible assets at least annually or whenever events or changes in circumstances indicate that its carrying amount may not be recoverable. This review requires that we make assumptions regarding the value of these assets and the changes in circumstances that would affect the carrying value of these assets. If such analysis indicates that a possible impairment may exist, we are then required to estimate the fair value of the asset and, as deemed appropriate, expense all or a portion of the asset. The determination of fair value includes numerous uncertainties, such as the impact of competition on future value. We believe that we have made reasonable estimates and judgments in determining whether our long-term assets have been impaired; however, if there is a material change in the assumptions used in our determination of fair value or if there is a material change in economic conditions or circumstances influencing fair value, we could be required to recognize certain impairment charges in the future.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

This item is not applicable to smaller reporting companies.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this Item is included in our Financial Statements and Supplementary Data listed in Item 15 of Part IV of this annual report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Based on their evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of December 31, 2014, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to the Company's management, as appropriate, to allow timely decisions regarding required disclosure, and are operating in an effective manner.

Changes in Internal Controls Over Financial Reporting

During the fiscal quarter ended December 31, 2014, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting; however, see disclosure under “Management’s Annual Report on Internal Control Over Financial Reporting” with respect to certain changes made after December 31, 2014.

Management’s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2014. In making this assessment, our management used the criteria set forth in the *Internal Control-Integrated Framework (2013 Framework)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”). Based on this assessment, management believes that as of December 31, 2014 our internal control over financial reporting was not effective as of December 31, 2014. In connection with the preparation of our consolidated financial statements included in this Report, we determined, as previously reported, that the financial statements included in our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2014, June 30, 2014 and September 30, 2014 included an error. As a result, we reevaluated our internal controls over financial reporting effective as of December 31, 2014 and identified a material weakness in the effectiveness of our internal control over financial reporting with respect to our accounting for the early extinguishment of, and final conversion of, a convertible promissory note. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company’s annual or interim financial statements will not be prevented or detected on a timely basis.

After identifying this material weakness, we implemented in the first quarter of 2015 new procedures, including enhanced documentation, analysis and review of non-routine accounting matters. We have retrained those working in corporate finance, as to the importance of appropriate communication and review of non-routine accounting matters so that any such changes can be properly assessed under generally accepted accounting principles.

As of the date of our filing of this Report, management believes our remediation efforts are effective with respect to our internal control over financial reporting and that the previous material weakness in our internal control over financial reporting has been remediated. Notwithstanding the beliefs of managers, we will continue to assess the effectiveness of our remediation efforts in connection with our evaluations of internal control over financial reporting. There remains a risk that the processes and procedures on which we currently rely will fail to be sufficiently effective, which could result in an error in our disclosure in the future. Moreover, because of the inherent limitations in all control systems, no evaluation of controls—even where we conclude the controls are operating effectively—can provide absolute assurance that all control issues have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and breakdowns can occur because of simple error or mistake.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit smaller reporting companies to provide only management's report in this annual report.

ITEM 9B. OTHER INFORMATION

None.

Part III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item is incorporated herein by reference from our definitive proxy statement, to be filed pursuant to Regulation 14A, related to our 2015 Annual Meeting of Stockholders (our "2015 Proxy Statement").

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated herein by reference from our 2015 Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item is incorporated herein by reference from our 2015 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this Item is incorporated herein by reference from our 2015 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated herein by reference from our 2015 Proxy Statement.

Part IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

1. Financial Statements

| | |
|--|----|
| Report of Independent Registered Public Accounting Firm | 51 |
| Consolidated Balance Sheets as of December 31, 2014 and 2013 | 52 |
| Consolidated Statements of Operations for the years ended December 31, 2014 and 2013 | 53 |
| Consolidated Statements of Stockholders' Equity for the years ended December 31, 2014 and 2013 | 54 |
| Consolidated Statements of Cash Flows for the years ended December 31, 2014 and 2013 | 55 |
| Notes to Consolidated Financial Statements | 56 |

2. Financial Statement Schedules

All other schedules are omitted because they are not applicable or because the required information is shown in the consolidated financial statements or the notes thereto.

3. List of Exhibits

The exhibits which are filed with this report or which are incorporated herein by reference are set forth in the Exhibit Index hereto.

In reviewing the agreements included as exhibits to this annual report on Form 10-K, please remember they are included to provide you with information regarding their terms and are not intended to provide any other factual or disclosure information about the Company or the other parties to the agreements. The agreements contain representations and warranties by each of the parties to the applicable agreement. These representations and warranties have been made solely for the benefit of the other parties to the applicable agreement and:

- should not in all instances be treated as categorical statements of fact, but rather as a way of allocating the risk to one of the parties if those statements prove to be inaccurate;
- have been qualified by disclosures that were made to the other party in connection with the negotiation of the applicable agreement, which disclosures are not necessarily reflected in the agreement;
- may apply standards of materiality in a way that is different from what may be viewed as material to you or other investors; and
- were made only as of the date of the applicable agreement or such other date or dates as may be specified in the agreement and are subject to more recent developments. Accordingly, these representations and warranties may not describe the actual state of affairs as of the date they were made or at any other time.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ULURU Inc.

Date: March 31, 2015

By /s/ Kerry P. Gray
Kerry P. Gray
Chief Executive Officer
Principal Executive Officer

Date: March 31, 2015

By /s/ Terrance K. Wallberg
Terrance K. Wallberg
Chief Financial Officer
Principal Accounting Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Date: March 31, 2015

/s/ Jeffrey B. Davis
Jeffrey B. Davis, Director

Date: March 31, 2015

/s/ Kerry P. Gray
Kerry P. Gray, Director

Date: March 31, 2015

/s/ Helmut Kerschbaumer
Helmut Kerschbaumer, Director

Date: March 31, 2015

/s/ Klaus Kuehne
Klaus Kuehne, Director

INDEX TO EXHIBITS

| <u>Exhibit Number</u> | <u>Description of Document</u> |
|-----------------------|--|
| 2.1 | Agreement and Plan of Merger and Reorganization dated October 12, 2005 by and among the Registrant, ULURU Acquisition Corp., and ULURU Delaware Inc. (1) |
| 2.2.1 | Asset Sale Agreement dated October 12, 2005 by and between ULURU Delaware Inc. and Access Pharmaceuticals, Inc. (3) |
| 2.2.2 | Amendment to Asset Sale Agreement dated December 8, 2006 by and between ULURU Delaware Inc. and Access Pharmaceuticals, Inc. (4) |
| 3.1 | Restated Articles of Incorporation dated November 5, 2007. (6) |
| 3.2 | Amended and Restated Bylaws dated December 5, 2008. (7) |
| 3.3 | Certificate of Designations of Series A Preferred Stock. (17) |
| 4.1 | Common Stock Purchase Warrants dated November 16, 2009 by and between ULURU Inc. and the purchasers' party thereto. (11) |
| 4.2 | Common Stock Purchase Warrants dated January 3, 2011 by and between ULURU Inc. and the purchasers' party thereto. (15) |
| 4.3 | Common Stock Purchase Warrant dated June 13, 2011 by and between ULURU Inc. and Kerry P. Gray. (16) |
| 4.4 | Common Stock Purchase Warrant dated July 28, 2011 by and between ULURU Inc. and Kerry P. Gray. (17) |
| 4.5 | Common Stock Purchase Warrant #4 dated June 27, 2012 by and between ULURU Inc. and Inter-Mountain Capital Corp. (20) |
| 4.6 | Common Stock Purchase Warrant dated December 21, 2012 by and between ULURU Inc. and IPMD GmbH (22) |
| 4.7 | Common Stock Purchase Warrant dated March 14, 2013 by and between ULURU Inc. and Kerry P. Gray. (23) |
| 4.8 | Common Stock Purchase Warrant dated March 14, 2013 by and between ULURU Inc. and Terrance K. Wallberg. (23) |
| 4.9 | Common Stock Purchase Warrant dated March 6, 2014 by and between ULURU Inc. and San Diego Torrey Hills Capital, Inc. (28) |
| 10.1 | Patent Assignment Agreement dated October 12, 2005 by and between ULURU Delaware Inc. and Access Pharmaceuticals, Inc. (3) |
| 10.2 | License Agreement dated October 12, 2005 by and between ULURU Delaware Inc. and Access Pharmaceuticals, Inc. (3) |
| 10.3.1 | Lease Agreement dated January 31, 2006 by and between ULURU Delaware Inc. and Addison Park Ltd. (3) |
| 10.3.2 | Amendment to Lease Agreement dated February 22, 2013 by and ULURU Delaware Inc. and Addison Park Ltd. (27) |
| 10.3.3 | * Second Amendment to Lease Agreement dated March 17, 2015 by and ULURU Delaware Inc. and Addison Park Ltd. (**) |
| 10.4 | License Agreement dated August 14, 1998 by and between ULURU Delaware Inc. and Strakan Ltd. (3) |
| 10.5 | * ULURU Inc. 2006 Equity Incentive Plan. (2) |
| 10.5.1 | * First Amendment to the ULURU Inc. 2006 Equity Incentive Plan dated May 8, 2007. (5) |
| 10.5.2 | * Second Amendment to the ULURU Inc. 2006 Equity Incentive Plan dated December 17, 2009. (12) |
| 10.5.3 | * Third Amendment to the ULURU Inc. 2006 Equity Incentive Plan dated June 10, 2010. (13) |
| 10.5.4 | * Fourth Amendment to the ULURU Inc. 2006 Equity Incentive Plan dated June 14, 2012. (19) |
| 10.5.5 | * Fifth Amendment to the ULURU Inc. 2006 Equity Incentive Plan dated June 13, 2013. (25) |
| 10.5.6 | * Sixth Amendment to the ULURU Inc. 2006 Equity Incentive Plan dated June 5, 2014. (29) |
| 10.6 | License and Supply Agreement dated November 17, 2008 by and between ULURU Inc. and Meda AB. (8) |
| 10.7 | * Indemnification Agreement dated July 10, 2009 by and between ULURU Inc. and Kerry P. Gray (9) |
| 10.8 | * Indemnification Agreement dated July 10, 2009 by and between ULURU Inc. and Jeffrey B. Davis (9) |
| 10.9 | * Indemnification Agreement dated July 13, 2009 by and between ULURU Inc. and Terrance K. Wallberg. (10) |
| 10.10 | Acquisition and Licensing Agreement dated June 25, 2010 by and between ULURU Inc., Strakan International Limited and Zindaclin Limited. (14) |
| 10.11.1 | Shareholders' Agreement dated January 11, 2012 by and between ULURU Inc. and Melmed Holding AG. (18) |
| 10.11.2 | Amendment to Shareholders' Agreement dated February 1, 2014 by and between ULURU Inc. and Melmed Holding AG. (27) |
| 10.12.1 | License and Supply Agreement dated January 11, 2012 by and between ULURU Inc. and Melmed Holding AG. (18) |
| 10.12.2 | Amendment No. 1 to License and Supply Agreement dated December 21, 2012 by and between ULURU Inc. and Melmed Holding AG. (24) |
| 10.12.3 | Amendment No. 2 to License and Supply Agreement dated December 21, 2012 by and between ULURU Inc. and Melmed Holding AG. (27) |
| 10.12.4 | Amendment No. 3 to License and Supply Agreement dated February 2, 2014 by and between ULURU Inc. and Melmed Holding AG. (27) |
| 10.13 | Binding Term Sheet dated September 20, 2012 by and between ULURU Inc. and Regenertec Invest GmbH. (21) |
| 10.14 | Shareholders' Agreement dated October 19, 2012 by and between ULURU Inc. and ORADISC GmbH. (24) |
| 10.15 | License and Supply Agreement dated October 19, 2012 by and between ULURU Inc. and ORADISC GmbH. (24) |
| 10.16 | Securities Purchase Agreement dated December 21, 2012 by and between ULURU Inc. and IPMD GmbH. (22) |
| 10.17 | Securities Purchase Agreement dated March 14, 2013 by and between ULURU Inc. and the purchasers' party thereto. (23) |
| 10.18.1 | Exclusive License and Supply Agreement dated September 30, 2013 by and between ULURU Inc. and Altrazeal AG. (26) |
| 10.18.2 | Amendment No. 1 to Exclusive License and Supply Agreement dated February 1, 2014 by and between ULURU Inc. and Altrazeal AG. (27) |
| 10.19 | Registration Rights Agreement dated January 31, 2014 by and between ULURU Inc. and the investors' party thereto. (27) |
| 10.20 | Shareholders' Agreement dated February 1, 2014 by and between ULURU Inc. and Altrazeal AG. (27) |

- 21.1 ** Subsidiaries of ULURU Inc.
- 23.1 ** Consent of Lane Gorman Trubitt, PLLC, Independent Registered Public Accounting Firm.
- 31.1 ** Certification Pursuant to Rule 13a-14 and 15d-14 under the Securities Exchange Act of 1934, as Amended.
- 31.2 ** Certification Pursuant to Rule 13a-14 and 15d-14 under the Securities Exchange Act of 1934, as Amended.
- 32.1 ** Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 ** Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101 *** The following financial statements are from ULURU Inc.'s Annual Report on Form 10-K for the year ended December 31, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets; (ii) Consolidated Statements of Operations; (iii) Consolidated Statements of Cash Flows; and (iv) Notes to Consolidated Financial Statements.

-
- (1) Incorporated by reference to the Company's Current Report on Form 8-K filed on October 18, 2005.
 - (2) Incorporated by reference to the Company's Definitive Schedule 14C filed on March 1, 2006.
 - (3) Incorporated by reference to the Company's Form 8-K filed on March 31, 2006.
 - (4) Incorporated by reference to the Company's Form SB-2 Registration Statement filed on December 15, 2006.
 - (5) Incorporated by reference to the Company's Form S-8 Registration Statement filed on May 30, 2007.
 - (6) Incorporated by reference to the Company's Form 8-K filed on November 6, 2007.
 - (7) Incorporated by reference to the Company's Form 8-K filed on December 11, 2008.
 - (8) Incorporated by reference to the Company's Form 10-K filed on March 30, 2009.
 - (9) Incorporated by reference to the Company's Form 8-K filed on July 10, 2009.
 - (10) Incorporated by reference to the Company's Form 8-K filed on July 14, 2009.
 - (11) Incorporated by reference to the Company's Form 8-K filed on November 12, 2009.
 - (12) Incorporated by reference to the Company's Form S-8 Registration Statement filed on January 28, 2010.
 - (13) Incorporated by reference to the Company's Form S-8 Registration Statement filed on July 16, 2010.
 - (14) Incorporated by reference to the Company's Form 10-Q filed on August 16, 2010.
 - (15) Incorporated by reference to the Company's Form 8-K filed on January 4, 2011.
 - (16) Incorporated by reference to the Company's Form 8-K filed on June 14, 2011.
 - (17) Incorporated by reference to the Company's Form 8-K filed on August 1, 2011.
 - (18) Incorporated by reference to the Company's Form 10-K filed on March 30, 2012.
 - (19) Incorporated by reference to the Company's Form S-8 Registration Statement filed on June 28, 2012.
 - (20) Incorporated by reference to the Company's Form 8-K filed on July 3, 2012.
 - (21) Incorporated by reference to the Company's Form 10-Q filed on November 14, 2012.
 - (22) Incorporated by reference to the Company's Form 8-K filed on December 27, 2012.
 - (23) Incorporated by reference to the Company's Form 8-K filed on March 15, 2013.
 - (24) Incorporated by reference to the Company's Form 10-K filed on March 29, 2013.
 - (25) Incorporated by reference to the Company's Form S-8 Registration Statement filed on June 28, 2013.
 - (26) Incorporated by reference to the Company's Form 10-Q filed on November 14, 2013.
 - (27) Incorporated by reference to the Company's Form 10-K filed on March 31, 2014.
 - (28) Incorporated by reference to the Company's Form 10-Q filed on May 15, 2014.
 - (29) Incorporated by reference to the Company's Form S-8 Registration Statement filed on June 16, 2014.

* Management contract or compensation plan arrangements.

** Filed herewith.

*** Pursuant to Rule 406T of Regulation S-T, the XBRL-related information in Exhibit 101 to this Annual Report on Form 10-K is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, and otherwise is not subject to liability under these sections.

INDEX TO FINANCIAL STATEMENTS

| | <u>Page</u> |
|--|-------------|
| Financial Statements | |
| Report of Independent Registered Public Accounting Firm | F – 1 |
| Consolidated Balance Sheets as of December 31, 2014 and 2013 | F – 2 |
| Consolidated Statements of Operations for the years ended December 31, 2014 and 2013 | F – 3 |
| Consolidated Statements of Stockholders' Equity for the years ended December 31, 2014 and 2013 | F – 4 |
| Consolidated Statements of Cash Flows for the years ended December 31, 2014 and 2013 | F – 5 |
| Notes to Consolidated Financial Statements | F – 6 |

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
ULURU Inc.
Addison, Texas

We have audited the accompanying consolidated balance sheets of ULURU Inc. (a Nevada corporation) (the "Company") as of December 31, 2014 and 2013, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2014. ULURU Inc's management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of ULURU Inc. as of December 31, 2014 and 2013, and the consolidated results of its operations and its cash flows for each of the years in the two -year period ended December 31, 2014 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations, negative cash flows from operating activities and is dependent upon raising additional funds from strategic transactions, sales of equity, and/or issuance of debt. The Company's ability to consummate such transactions is uncertain. As a result, there is substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments to reflect the outcome of this uncertainty.

/s/ Lane Gorman Trubitt, PLLC
Lane Gorman Trubitt, PLLC
Dallas, TX

March 31, 2015

ULURU Inc.
CONSOLIDATED BALANCE SHEETS

| ASSETS | December 31, | |
|--|--------------|--------------|
| | 2014 | 2013 |
| Current Assets | | |
| Cash and cash equivalents | \$ 550,458 | \$ 5,119 |
| Accounts receivable, net | 3,879 | 10,771 |
| Accounts receivable – related party, net | 798,147 | 174,307 |
| Notes receivable and accrued interest, current portion | --- | 777,710 |
| Inventory | 325,657 | 395,605 |
| Prepaid expenses and deferred charges | 137,858 | 123,812 |
| Total Current Assets | 1,815,999 | 1,487,324 |
| Property, Equipment and Leasehold Improvements, net | 432,110 | 638,614 |
| Other Assets | | |
| Intangible assets, net | 3,195,689 | 3,670,837 |
| Investment in unconsolidated subsidiary | --- | --- |
| Deferred financing costs, net | --- | 86,770 |
| Deposits | 18,069 | 18,069 |
| Total Other Assets | 3,213,758 | 3,775,676 |
| TOTAL ASSETS | \$ 5,461,867 | \$ 5,901,614 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities | | |
| Accounts payable | \$ 1,536,612 | \$ 1,734,725 |
| Accrued liabilities | 273,201 | 315,963 |
| Accrued interest | --- | 13,360 |
| Convertible notes payable, net of unamortized debt discount, current portion | --- | 1,147,057 |
| Deferred revenue, current portion | 58,959 | 58,959 |
| Total Current Liabilities | 1,868,772 | 3,270,064 |
| Long Term Liabilities | | |
| Convertible notes payable, net of unamortized debt discount and current portion | --- | --- |
| Deferred revenue, net of current portion | 839,174 | 898,133 |
| Total Long Term Liabilities | 839,174 | 898,133 |
| TOTAL LIABILITIES | 2,707,946 | 4,168,197 |
| COMMITMENTS AND CONTINGENCIES | --- | --- |
| STOCKHOLDERS' EQUITY | | |
| Preferred Stock – \$0.001 par value; 20,000 shares authorized; Series A Preferred Stock, 1,000 shares designated; no shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively | --- | --- |
| Common Stock – \$ 0.001 par value; 200,000,000 shares authorized; 24,458,018 and 18,871,420 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively | 24,458 | 18,872 |
| Additional paid-in capital | 56,289,882 | 53,336,127 |
| Accumulated (deficit) | (53,560,419) | (51,621,582) |

| | | |
|---|---------------------|---------------------|
| TOTAL STOCKHOLDERS' EQUITY | <u>2,753,921</u> | <u>1,733,417</u> |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | <u>\$ 5,461,867</u> | <u>\$ 5,901,614</u> |

The accompanying notes are an integral part of these consolidated financial statements.

ULURU Inc.
CONSOLIDATED STATEMENTS OF OPERATIONS

| | Years Ended December 31, | |
|--|---------------------------------|-----------------------|
| | 2014 | 2013 |
| Revenues | | |
| License fees | \$ 58,959 | \$ 48,688 |
| Royalty income | 62,966 | 30,016 |
| Product sales, net | 741,932 | 291,864 |
| Total Revenues | <u>863,857</u> | <u>370,568</u> |
| Costs and Expenses | | |
| Cost of goods sold | 511,943 | 222,122 |
| Research and development | 770,542 | 788,242 |
| Selling, general and administrative | 1,773,540 | 1,288,050 |
| Amortization of intangible assets | 475,148 | 475,148 |
| Depreciation | 237,388 | 244,704 |
| Total Costs and Expenses | <u>3,768,561</u> | <u>3,018,266</u> |
| Operating (Loss) | <u>(2,904,704)</u> | <u>(2,647,698)</u> |
| Other Income (Expense) | | |
| Interest and miscellaneous income | 5,386 | 69,686 |
| Interest expense | (50,574) | (506,529) |
| Equity in earnings (loss) of unconsolidated subsidiary | --- | --- |
| Foreign currency transaction (loss) | (53,867) | --- |
| Loss on early extinguishment of convertible note | (135,078) | --- |
| Proceeds from litigation settlement | 1,200,000 | --- |
| Gain on sale of equipment | --- | 3,627 |
| (Loss) Before Income Taxes | <u>(1,938,837)</u> | <u>(3,080,914)</u> |
| Income taxes | --- | --- |
| Net (Loss) | <u>\$ (1,938,837)</u> | <u>\$ (3,080,914)</u> |
| Less preferred stock dividends | --- | (30,236) |
| Net (Loss) Allocable to Common Stockholders | <u>\$ (1,938,837)</u> | <u>\$ (3,111,150)</u> |
| | | |
| Basic and diluted net (loss) per common share | <u>\$ (0.08)</u> | <u>\$ (0.21)</u> |
| | | |
| Weighted average number of common shares outstanding | <u>23,639,427</u> | <u>14,772,578</u> |

The accompanying notes are an integral part of these consolidated financial statements.

ULURU Inc.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Years Ended December 31, 2014 and 2013

| | Preferred Stock | | Common Stock | | Additional Paid-in Capital | Promissory Notes Receivable and Accrued Interest | Accumulat ed (Deficit) | Stockholde rs' Equity |
|--|------------------|--------|------------------|-----------|----------------------------------|--|------------------------------|-----------------------------|
| | Shares Issued | Amount | Shares Issued | Amount | | | | |
| Balance as of December 31, 2012 | 65 | \$--- | 10,074,448 | \$ 10,075 | \$ 51,336,931 | \$ (985,287) | \$(48,510,432) | \$ 1,851,287 |
| Issuance of common stock and warrants in a private placement, net of offering costs of \$4,379 | --- | --- | 3,750,000 | 3,750 | 1,491,871 | --- | --- | 1,495,621 |
| Issuance of common stock and warrants in a private placement, net of offering costs of \$2,175 | --- | --- | 825,000 | 825 | 327,000 | --- | --- | 327,825 |
| Issuance of common stock for principle and interest due on convertible note | --- | --- | 3,072,648 | 3,073 | 915,257 | --- | --- | 918,330 |
| Issuance of common stock for services and wages | --- | --- | 423,750 | 424 | 177,826 | --- | --- | 178,250 |
| Issuance of common stock – 725,274 shares for cashless exercise of warrants to purchase 1,571,428 shares | --- | --- | 725,274 | 725 | (725) | --- | --- | --- |
| Issuance of common stock – vesting of restricted stock | --- | --- | 300 | --- | --- | --- | --- | --- |
| Redemption of Series A preferred stock | (65) | --- | --- | --- | (992,430) | 994,294 | --- | 1,864 |
| Offering costs adjustment – Series A preferred stock sale in 2011 | --- | --- | --- | --- | 8,000 | --- | --- | 8,000 |
| Cancellation of warrants issued for services | --- | --- | --- | --- | (48,776) | --- | --- | (48,776) |
| Accrued interest on promissory notes for issuance of common stock | --- | --- | --- | --- | 9,007 | (9,007) | --- | --- |
| Accrued dividends on Series A preferred stock | --- | --- | --- | --- | 30,236 | --- | (30,236) | --- |
| Share-based compensation of employees | --- | --- | --- | --- | 15,648 | --- | --- | 15,648 |
| Share-based compensation of non-employees | --- | --- | --- | --- | 66,282 | --- | --- | 66,282 |
| Net (loss) | --- | --- | --- | --- | --- | --- | (3,080,914) | (3,080,914) |
| Balance as of December 31, 2013 | --- | \$--- | 18,871,420 | \$ 18,872 | \$ 53,336,127 | \$ --- | \$(51,621,582) | \$ 1,733,417 |
| Issuance of common stock and warrants in a private placement | --- | --- | 1,250,000 | 1,250 | 498,750 | --- | --- | 500,000 |
| Issuance of common stock and warrants in a private placement | --- | --- | 275,000 | 275 | 109,725 | --- | --- | 110,000 |
| Issuance of common stock for principle and interest due | --- | --- | 911,690 | 912 | 318,180 | --- | --- | 319,092 |

on convertible note

| | | | | | | | | |
|--|-----|-------|-------------------|------------------|----------------------|---------------|-----------------------|---------------------|
| Loss on conversion of convertible note settled with common stock | --- | --- | --- | --- | (234,042) | --- | --- | (234,042) |
| Issuance of common stock for principle due on convertible notes | --- | --- | 232,408 | 232 | 264,768 | --- | --- | 265,000 |
| Issuance of common stock for services | --- | --- | 67,500 | 67 | 64,283 | --- | --- | 64,350 |
| Cancellation of common stock issued for services | --- | --- | (150,000) | (150) | (86,850) | --- | --- | (87,000) |
| Issuance of common stock for exercise of warrant | --- | --- | 3,000,000 | 3,000 | 1,797,000 | --- | --- | 1,800,000 |
| Warrants issued for services | --- | --- | --- | --- | 72,771 | --- | --- | 72,771 |
| Share-based compensation of employees | --- | --- | --- | --- | 27,667 | --- | --- | 27,667 |
| Share-based compensation of non-employees | --- | --- | --- | --- | 121,503 | --- | --- | 121,503 |
| Net (loss) | --- | --- | --- | --- | --- | --- | (1,938,837) | (1,938,837) |
| Balance as of December 31, 2014 | --- | \$--- | <u>24,458,018</u> | <u>\$ 24,458</u> | <u>\$ 56,289,882</u> | <u>\$ ---</u> | <u>\$(53,560,419)</u> | <u>\$ 2,753,921</u> |

The accompanying notes are an integral part of these consolidated financial statements.

ULURU Inc.
CONSOLIDATED STATEMENTS OF CASH FLOWS

| | Years Ended December 31, | |
|--|---------------------------------|----------------|
| | 2014 | 2013 |
| OPERATING ACTIVITIES : | | |
| Net (loss) | \$ (1,938,837) | \$ (3,080,914) |
| Adjustments to reconcile net (loss) to net cash used in operating activities: | | |
| Amortization of intangible assets | 475,148 | 475,148 |
| Depreciation | 237,388 | 244,704 |
| Share-based compensation for stock and options issued to employees | 27,667 | 15,648 |
| Share-based compensation for options issued to non-employees | 121,503 | 66,282 |
| Equity in earnings (loss) of unconsolidated subsidiary | --- | --- |
| Amortization of debt discount on convertible notes | (78,078) | 178,548 |
| Amortization of deferred financing costs | 7,309 | 74,000 |
| Warrants issued (cancelled) for services | 72,771 | (48,776) |
| Common stock issued (cancelled) for services | (22,650) | 158,250 |
| Common stock issued for wages | --- | 20,000 |
| Common stock issued for interest due on convertible note | 2,063 | 127,343 |
| Loss on early extinguishment of convertible note | 135,078 | --- |
| Gain on sale of equipment | --- | (3,627) |
| Change in operating assets and liabilities: | | |
| Accounts receivable | (616,948) | (73,180) |
| Other receivable | --- | --- |
| Inventory | 69,949 | 132,038 |
| Prepaid expenses and deferred charges | (14,046) | 70,636 |
| Notes receivable and accrued interest | 777,710 | 524,510 |
| Accounts payable | (198,113) | (606,057) |
| Accrued liabilities | (42,762) | (57,002) |
| Accrued interest | (13,360) | (27,781) |
| Deferred revenue | (58,959) | 76,312 |
| Total | 881,670 | 1,346,996 |
| Net Cash Used in Operating Activities | (1,057,167) | (1,733,918) |
| INVESTING ACTIVITIES : | | |
| Purchase of property and equipment | (30,884) | (39,093) |
| Proceeds from sale of equipment | --- | 4,937 |
| Net Cash Used in Investing Activities | (30,884) | (34,156) |
| FINANCING ACTIVITIES : | | |
| Proceeds from sale of common stock and warrants, net | 610,000 | 1,823,446 |
| Proceeds from exercise of warrant | 1,800,000 | --- |
| Proceeds from redemption of preferred stock, net | --- | 1,864 |
| Repayment of principle due on convertible note | (776,610) | (81,666) |
| Offering cost adjustment – preferred stock sale in 2011 | --- | 8,000 |
| Net Cash Provided by Financing Activities | 1,633,390 | 1,751,644 |
| Net Increase (Decrease) in Cash | 545,339 | (16,430) |
| Cash, beginning of period | 5,119 | 21,549 |
| Cash, end of period | \$ 550,458 | \$ 5,119 |
| SUPPLEMENTAL CASH FLOW DISCLOSURE: | | |
| Cash paid for interest | \$ 30,775 | \$ 35,467 |

| | | |
|---|-------------------|-------------------|
| Non-cash investing and financing activities: | | |
| Issuance of common stock for promissory note | \$ --- | \$ --- |
| Issuance of common stock for principle due on convertible notes | <u>\$ 582,029</u> | <u>\$ 790,987</u> |

The accompanying notes are an integral part of these consolidated financial statements.

ULURU Inc.

**NOTES TO
CONSOLIDATED FINANCIAL STATEMENTS**

NOTE 1. COMPANY OVERVIEW AND BASIS OF PRESENTATION

Company Overview

ULURU Inc. (hereinafter “we”, “our”, “us”, “ULURU”, or the “Company”) is a Nevada corporation. We are a diversified specialty pharmaceutical company committed to developing and commercializing a broad range of innovative wound care and mucoadhesive film products based on our patented Nanoflex® and OraDisc™ technologies, with the goal of improving outcomes for patients, health care professionals, and health care payers.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United State of America (“U.S. GAAP”) and include the accounts of ULURU Inc., a Nevada corporation, and its wholly-owned subsidiary, ULURU Delaware Inc., a Delaware corporation. Both companies have a December 31 fiscal year end.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, as well as disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting periods. Actual results may differ from those estimates and assumptions. These differences are usually minor and are included in our consolidated financial statements as soon as they are known. Our estimates, judgments, and assumptions are continually evaluated based on available information and experience. Because of the use of estimates inherent in the financial reporting process, actual results could differ from those estimates.

All intercompany transactions and balances have been eliminated in consolidation.

Liquidity and Going Concern

The Company is unable to assert that its liquidity will be sufficient to fund operations beyond the first quarter of 2015, and as a result, there is substantial doubt about our ability to continue as a going concern beyond the first quarter of 2015. These consolidated financial statements have been prepared with the assumption that we will continue as a going concern and will be able to realize its assets and discharge its liabilities in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the inability of the Company to continue as a going concern. We may not be able to raise sufficient capital on acceptable terms, or at all, to continue operations and may not be able to execute any strategic transaction.

Our liquidity, and our ability to raise additional capital or complete any strategic transaction, depends on a number of factors, including, but not limited to, the following:

- the market price of our stock and the availability and cost of additional equity capital from existing and potential new investors;
- general economic and industry conditions affecting the availability and cost of capital;
- our financial condition, including its revenues, the amount of its indebtedness and its ability to control costs associated with its operations;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the terms and conditions of our existing collaborative and licensing agreements.

The sale of additional equity or convertible debt securities will likely result in substantial additional dilution to our stockholders. If we raise additional funds through the incurrence of indebtedness, the obligations related to such indebtedness would be senior to rights of holders of our capital stock and could contain covenants that would restrict our operations. We also cannot predict what consideration might be available, if any, to us or our stockholders, in connection with any strategic transaction. Should strategic alternatives or additional capital not be available to us in the near term, or not be available on acceptable terms, we may be unable to realize value from its assets and discharge its liabilities in the normal course of business which may, among other alternatives, cause us to further delay, substantially reduce or discontinue operational activities to conserve its cash resources.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The following is a summary of significant accounting policies used in the preparation of these consolidated financial statements:

Cash and Cash Equivalents

Cash and cash equivalents include highly liquid investments with original maturities of three months or less. The carrying value of these cash equivalents approximates fair value.

We invest cash in excess of immediate requirements in money market accounts, certificates of deposit, corporate commercial paper with high quality ratings, and U.S. government securities taking into consideration the need for liquidity and capital preservation. These investments are not held for trading or other speculative purposes.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are recorded at the invoiced amount and do not bear interest. We estimate the collectability of our accounts receivable. In order to assess the collectability of these receivables, we monitor the current creditworthiness of each customer and analyze the balances aged beyond the customer's credit terms. These evaluations may indicate a situation in which a certain customer cannot meet its financial obligations due to deterioration of its financial viability, credit ratings or bankruptcy. The allowance requirements are based on current facts and are reevaluated and adjusted as additional information is received. Accounts receivable are subject to an allowance for collection when it is probable that the balance will not be collected. As of December 31, 2014 and 2013, the allowance for doubtful accounts was \$887 and \$907, respectively. For the years ended December 31, 2014 and 2013, the accounts written off as uncollectible or previously written off and recovered were \$779 and \$(1,126), respectively.

Notes Receivable

Notes receivable are stated at unpaid principle balance. Interest on notes receivable is recognized over the term of the note and is calculated by the simple interest method on principle amounts outstanding. We estimate the collectability of our notes receivable. This estimate is based on similar evaluation criteria as used in estimating the collectability of our trade accounts receivable. Notes receivable are subject to an allowance for collection when it is probable that the balance, or a portion thereof, will not be collected. As of December 31, 2014 and 2013, the allowance for collection for our notes receivable was nil.

Inventory

Inventories are stated at the lower of cost or market value. Raw material inventory cost is determined on the first-in, first-out method. Costs of finished goods are determined by an actual cost method. We regularly review inventories on hand and write down the carrying value of our inventories for excess and potentially obsolete inventories based on historical usage and estimated future usage. In assessing the ultimate realization of our inventories, we are required to make judgments as to future demand requirements. As actual future demand or market conditions may vary from those projected by us, adjustment to inventories may be required.

Prepaid Expenses and Deferred Charges

From time to time fees are payable to the United States Food and Drug Administration ("FDA") in connection with new drug applications submitted by us and annual prescription drug user fees ("PDUFA"). Such fees are being amortized ratably over the FDA's prescribed fiscal period of twelve months ending September 30th. As of December 31, 2014 and 2013, the amount of prepaid PDUFA fees was nil. Additionally, we amortize our insurance costs ratably over the term of each policy. Typically, our insurance policies are subject to renewal in July and October of each year.

Property, Equipment and Leasehold Improvements

Property, equipment, and leasehold improvements are recorded at cost. Depreciation is provided over the estimated useful lives of the related assets using the straight-line method. Estimated useful lives for property, equipment, and leasehold improvements categories are as follows:

| | |
|--|------------|
| Laboratory and manufacturing equipment | 7 years |
| Computers, office equipment, and furniture | 5 years |
| Computer software | 3 years |
| Leasehold improvements | Lease term |

Intangible Assets

We expense internal patent and application costs as incurred because, even though we believe the patents and underlying processes have continuing value, the amount of future benefits to be derived from them are uncertain. Purchased patents are capitalized and amortized over the life of the patent.

Impairment of Assets

In accordance with the provisions of Accounting Standards Codification (“ASC”) Topic 350-30, *Intangibles Other than Goodwill*, our policy is to evaluate whether there has been a permanent impairment in the value of long-lived assets and certain identifiable intangibles when certain events have taken place that indicate the remaining unamortized balance may not be recoverable, or at least annually to determine the current value of the intangible asset. When factors indicate that the intangible assets should be evaluated for possible impairment, we use an estimate of undiscounted cash flows. Considerable management judgment is necessary to estimate the undiscounted cash flows. Accordingly, actual results could vary significantly from management’s estimates.

Deferred Financing Costs

We defer financing costs associated with the issuance of our convertible notes payable and amortize those costs over the period of the convertible notes using the effective interest method. In 2012, we incurred \$200,000 of financing costs related to our convertible note payable with Inter-Mountain Capital Corp. During 2014 and 2013, we recorded amortization of approximately \$7,000 and \$74,000, respectively, of deferred financing costs. Other assets at December 31, 2014 and 2013 included net deferred financing costs of approximately of nil and \$87,000, respectively.

Accrual for Clinical Study Costs

We record accruals for estimated clinical study costs. Clinical study costs represent costs incurred by clinical research organizations, or CROs, and clinical sites. These costs are recorded as a component of research and development expenses. We analyze the progress of the clinical trials, including levels of patient enrollment and/or patient visits, invoices received and contracted costs when evaluating the adequacy of the accrued liabilities. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual costs incurred may or may not match the estimated costs for a given accounting period. As of December 31, 2014 and 2013, the accrual for estimated clinical study costs was nil.

Shipping and Handling Costs

Shipping and handling costs incurred for product shipments are included in cost of goods sold.

Income Taxes

We use the liability method of accounting for income taxes pursuant to ASC Topic 740, *Income Taxes*. Under this method, deferred income taxes are recorded to reflect the tax consequences in future periods of temporary differences between the tax basis of assets and liabilities and their financial statement amounts at year-end.

Revenue Recognition and Deferred Revenue

License Fees

We recognize revenue from license payments not tied to achieving a specific performance milestone ratably during the period over which we are obligated to perform services. The period over which we are obligated to perform services is estimated based on available facts and circumstances. Determination of any alteration of the performance period normally indicated by the terms of such agreements involves judgment on management's part. License revenues with no specific performance criteria are recognized when received from our foreign licensee and their various foreign sub-licensees as there is no control by us over the various foreign sub-licensees and no performance criteria to which we are subject.

We recognize revenue from performance payments ratably, when such performance is substantially in our control and when we believe that completion of such performance is reasonably probable, over the period during which we estimate that we will complete such performance obligations. In circumstances where the arrangement includes a refund provision, we defer revenue recognition until the refund condition is no longer applicable unless, in our judgment, the refund circumstances are within our operating control and are unlikely to occur.

Substantive at-risk milestone payments, which are based on achieving a specific performance milestone when performance of such milestone is contingent on performance by others or for which achievement cannot be reasonably estimated or assured, are recognized as revenue when the milestone is achieved and the related payment is due, provided that there is no substantial future service obligation associated with the milestone.

Royalty Income

We receive royalty revenues under license agreements with a number of third parties that sell products based on technology we have developed or to which we have rights. The license agreements provide for the payment of royalties to us based on sales of the licensed products. We record these revenues based on estimates of the sales that occurred during the relevant period. The relevant period estimates of sales are based on interim data provided by licensees and analysis of historical royalties we have been paid (adjusted for any changes in facts and circumstances, as appropriate).

We maintain regular communication with our licensees in order to gauge the reasonableness of our estimates. Differences between actual royalty revenues and estimated royalty revenues are reconciled and adjusted for in the period in which they become known, typically the following quarter. Historically, adjustments have not been material based on actual amounts paid by licensees. As it relates to royalty income, there are no future performance obligations on our part under these license agreements. To the extent we do not have sufficient ability to accurately estimate revenue; we record it on a cash basis.

Product Sales

We recognize revenue and related costs from the sale of our products at the time the products are shipped to the customer. Provisions for returns, rebates, and discounts are established in the same period the related product sales are recorded.

We review the supply levels of our products sold to major wholesalers in the U.S., primarily by reviewing reports supplied by our major wholesalers and available volume information for our products, or alternative approaches. When we believe wholesaler purchasing patterns have caused an unusual increase or decrease in the sales of a major product compared with underlying demand, we disclose this in our product sales discussion if we believe the amount is material to the product sales trend; however, we are not always able to accurately quantify the amount of stocking or destocking. Wholesaler stocking and destocking activity historically has not caused any material changes in the rate of actual product returns.

We establish sales return accruals for anticipated product returns. We record the return amounts as a deduction to arrive at our net product sales. Consistent with Revenue Recognition accounting guidance, we estimate a reserve when the sales occur for future product returns related to those sales. This estimate is primarily based on historical return rates as well as specifically identified anticipated returns due to known business conditions and product expiry dates. Actual product returns have been nil over the past two years.

We establish sales rebate and discount accruals in the same period as the related sales. The rebate and discount amounts are recorded as a deduction to arrive at our net product sales. We base these accruals primarily upon our historical rebate and discount payments made to our customer segment groups and the provisions of current rebate and discount contracts.

Foreign currency transaction gain (loss)

Our functional currency and our reporting currency is the U.S. dollar and foreign currency transactions are primarily undertaken in Euros. Monetary assets and liabilities are translated using the foreign currency exchange rate prevailing at the balance sheet date. Revenues, non-monetary assets and liabilities denominated in foreign currencies are translated at rates of foreign currency exchange in effect at the date of the transaction. Expenses are translated at average foreign currency exchange rates for the period. Gains and losses arising on translation or settlement of foreign currency denominated transactions or balances are included in the determination of net income.

Research and Development Expenses

Pursuant to ASC Topic 730, *Research and Development*, our research and development costs are expensed as incurred. Research and development expenses include, but are not limited to, salaries and benefits, laboratory supplies, facilities expenses, preclinical development cost, clinical trial and related clinical manufacturing expenses, contract services, consulting fees and other outside expenses. The cost of materials and equipment or facilities that are acquired for research and development activities and that have alternative future uses are capitalized when acquired. There were no such capitalized materials, equipment or facilities for the years ended December 31, 2014 and 2013.

Basic and Diluted Net Loss Per Common Share

In accordance with ASC Topic 260, *Earnings per Share*, basic earnings (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period. Diluted earnings (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period increased to include potential dilutive common shares. The effect of outstanding stock options, restricted vesting common stock and warrants, when dilutive, is reflected in diluted earnings (loss) per common share by application of the treasury stock method. We have excluded all outstanding stock options, restricted vesting common stock and warrants from the calculation of diluted net loss per common share because all such securities are antidilutive for all periods presented.

Concentrations of Credit Risk

Concentration of credit risk with respect to financial instruments, consisting primarily of cash and cash equivalents, that potentially expose us to concentrations of credit risk due to the use of a limited number of banking institutions and due to maintaining cash balances in banks, which, at times, may exceed the limits of amounts insured by the Federal Deposit Insurance Corporation. During 2014 and 2013, we utilized Bank of America, N.A. as our banking institution. At December 31, 2014 and December 31, 2013 our cash and cash equivalents totaled \$550,458 and \$5,119, respectively. We also invest cash in excess of immediate requirements in money market accounts, certificates of deposit, corporate commercial paper with high quality ratings, and U.S. government securities. These investments are not held for trading or other speculative purposes. We are exposed to credit risk in the event of default by these high quality corporations.

Concentration of credit risk with respect to trade accounts receivable are customers with balances that exceed 5% of total consolidated trade accounts receivable at December 31, 2014 and at December 31, 2013. As of December 31, 2014, three customers, each being one of our international distributors, exceeded the 5% threshold, with 71%, 19%, and 9%, respectively. Two customers, each being one of our international distributors, exceeded the 5% threshold at December 31, 2013, with 86% and 11%, respectively. To reduce risk, we routinely assess the financial strength of our most significant customers and monitor the amounts owed to us, taking appropriate action when necessary. As a result, we believe that accounts receivable credit risk exposure is limited. We maintain an allowance for doubtful accounts, but historically have not experienced any significant losses related to an individual customer or group of customers.

Concentrations of Foreign Currency Risk

A portion of our revenues and all of our expenses are denominated in U.S. dollars. We are experiencing an increase in revenues in international territories denominated in a foreign currency. Certain of our licensing and distribution agreements in international territories are denominated in Euros. Currently, we do not employ forward contracts or other financial instruments to mitigate foreign currency risk. As our international operations continues to grow, we may engage in hedging activities to hedge our exposure to foreign currency risk.

Fair Value of Financial Instruments

In accordance with portions of ASC Topic 820, *Fair Value Measurements*, certain assets and liabilities of the Company are required to be recorded at fair value. Fair value is determined based on the exchange price that would be received for an asset or paid to transfer a liability in an orderly transaction between market participants.

Our financial instruments, including cash, cash equivalents, accounts receivable, and accounts payable are carried at cost, which approximates their fair value because of the short-term maturity of these instruments. We believe that the carrying value of our other receivable, notes receivable and accrued interest, and convertible note payable balances approximates fair value based on a valuation methodology using the income approach and a discounted cash flow model.

Derivatives

We occasionally issue financial instruments that contain an embedded instrument. At inception, we assess whether the economic characteristics of the embedded derivative instrument are clearly and closely related to the economic characteristics of the financial instrument (host contract), whether the financial instrument that embodies both the embedded derivative instrument and the host contract is currently measured at fair value with changes in fair value reported in earnings, and whether a separate instrument with the same terms as the embedded instrument would meet the definition of a derivative instrument.

If the embedded derivative instrument is determined not to be clearly and closely related to the host contract, is not currently measured at fair value with changes in fair value reported in earnings, and the embedded derivative instrument would qualify as a derivative instrument, the embedded derivative instrument is recorded apart from the host contract and carried at fair value with changes recorded in current-period earnings.

We determined that all embedded items associated with financial instruments during 2014 and 2013 which qualify for derivative treatment, were properly separated from their host. As of December 31, 2014 and 2013, we did not have any derivative instruments.

NOTE 3. THE EFFECT OF RECENTLY ISSUED ACCOUNTING STANDARDS

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, “*Revenue from Contracts with Customers*,” which supersedes the revenue recognition requirements of Accounting Standards Codification (“ASC”) Topic 605, “Revenue Recognition” and most industry-specific guidance on revenue recognition throughout the ASC. The new standard is principles-based and provides a five step model to determine when and how revenue is recognized. The core principle of the new standard is that revenue should be recognized when a company transfers promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The new standard also requires disclosure of qualitative and quantitative information surrounding the amount, nature, timing and uncertainty of revenues and cash flows arising from contracts with customers. The new standard will be effective for us in the first quarter of the year ending December 31, 2017 and can be applied either retrospectively to all periods presented or as a cumulative-effect adjustment as of the date of adoption. Early adoption is not permitted. We are currently evaluating the impact of adoption of ASU 2014-09 on our consolidated financial statements.

In August 2014, FASB issued ASU No. 2014-15, “*Presentation of Financial Statements – Going Concern*”. ASU No 2014-15 provides guidance regarding management’s responsibility to evaluate whether there exists substantial doubt about an organization’s ability to continue as a going concern and to provide related footnote disclosures in certain circumstances. ASU No. 2014-15 is effective for annual reporting periods beginning after December 15, 2016, and interim periods thereafter. We do not believe ASU No. 2015-15 will have a material effect on our financial position and results of operations.

There are no other new accounting pronouncements adopted or enacted during the year ended December 31, 2014 that had, or are expected to have, a material impact on our financial statements.

NOTE 4. SEGMENT INFORMATION

We operate in one business segment: the research, development, and commercialization of pharmaceutical products. Our corporate headquarters in the United States collects proceeds from product sales, licensing fees, royalties, and sponsored research revenues from our arrangements with external customers and licensees. Our entire business is managed by a single management team, which reports to the Chief Executive Officer.

Our revenues are currently derived primarily from seven licensees for international activities and our domestic sales activities for Altrazeal®.

Revenues per geographic area, along with relative percentages of total revenues, for the year ended December 31, are summarized as follows:

| Revenues | 2014 | % | 2013 | % |
|-----------------|-------------------|-------------|-------------------|-------------|
| Domestic | \$ 37,465 | 4% | \$ 65,546 | 18% |
| International | 826,392 | 96% | 305,022 | 82% |
| Total | <u>\$ 863,857</u> | <u>100%</u> | <u>\$ 370,568</u> | <u>100%</u> |

A significant portion of our revenues are derived from a few major customers. Customers with greater than 10% of total revenues, along with their relative percentage of total revenues, for the year ended December 31 are represented on the following table:

| Customers | Product | 2014 | 2013 |
|------------------|----------------|-------------|-------------|
| Customer A | Altrazeal® | 80% | 8% |
| Customer B | Altrazeal® | 11% | 67% |
| Total | | <u>91%</u> | <u>75%</u> |

NOTE 5. NOTES RECEIVABLE

On June 27, 2012, we entered into a Securities Purchase Agreement related to our issuance of a \$2,210,000 Secured Convertible Note (the “June 2012 Note”), with Inter-Mountain Capital Corp., a Delaware corporation (“Inter-Mountain”). As part of the June 2012 Note transaction, we received \$1,500,000 in the form of six promissory notes in favor of the Company, each in the principal amount of \$250,000 (the “Investor Notes”) and each of which became due as the outstanding balance under the June 2012 Note was reduced to certain levels. On October 5, 2012, we and Inter-Mountain entered into a First Amendment to Buyer Trust Deed Note #1 (the “Trust Deed Note Amendment”) for the purpose of revising certain terms and conditions contained in the Buyer Trust Deed Note #1, to include receiving payments of \$100,000, \$100,000, and \$50,000 on October 5, 2012, November 30, 2012, and December 31, 2012, respectively, and any interest thereon. As of December 31, 2013, we had \$777,710 in notes receivable which was comprised of \$687,500 for three Investor Notes and \$90,210 for accrued interest thereon.

On January 22, 2014, we provided notice to Inter-Mountain of our election to exercise our rights under the June 2012 Note and to offset amounts we owed to Inter-Mountain against amounts it owed to us under the three Investor Notes of \$687,500 and accrued interest thereon of \$94,456. As a result of the deduction and offset, the amounts owed to us under the June 2012 Note was reduced to zero.

NOTE 6. INVENTORY

As of December 31, 2014 and 2013, our inventory was comprised of Altrazeal® finished goods, manufacturing costs incurred in the production of Altrazeal®, and raw materials. Inventories are stated at the lower of cost (first in, first out method) or market. We regularly review inventories on hand and write down the carrying value of our inventories for excess and potentially obsolete inventories based on historical usage and estimated future usage. In assessing the ultimate realization of our inventories, we are required to make judgments as to future demand requirements. As actual future demand or market conditions may vary from those projected by us, adjustment to inventories may be required. For the years ended December 31, 2014 and 2013, we wrote off approximately \$19,000 and \$60,000, respectively, in obsolete inventories.

The components of inventory, at the different stages of production, consisted of the following at December 31:

| <u>Inventory</u> | <u>2014</u> | <u>2013</u> |
|-------------------------|--------------------|--------------------|
| Raw materials | \$ 41,648 | \$ 10,148 |
| Work-in-progress | 271,571 | 299,464 |
| Finished goods | 12,438 | 85,993 |
| Total | <u>\$ 325,657</u> | <u>\$ 395,605</u> |

NOTE 7. PROPERTY, EQUIPMENT AND LEASEHOLD IMPROVEMENTS

Property, equipment and leasehold improvements, net, consisted of the following at December 31:

| <u>Property, equipment and leasehold improvements</u> | <u>2014</u> | <u>2013</u> |
|--|--------------------|--------------------|
| Laboratory equipment | \$ 424,888 | \$ 424,888 |
| Manufacturing equipment | 1,599,894 | 1,581,728 |
| Computers, office equipment, and furniture | 153,078 | 140,360 |
| Computer software | 4,108 | 4,108 |
| Leasehold improvements | 95,841 | 95,841 |
| | <u>2,277,809</u> | <u>2,246,925</u> |
| Less: accumulated depreciation and amortization | <u>(1,845,699)</u> | <u>(1,608,311)</u> |
| Property, equipment and leasehold improvements, net | <u>\$ 432,110</u> | <u>\$ 638,614</u> |

Depreciation expense on property, equipment, and leasehold improvements was \$237,388 and \$244,704 for the years ended December 31, 2014 and 2013, respectively.

NOTE 8. INTANGIBLE ASSETS

Intangible assets are comprised of patents acquired in October 2005. Intangible assets, net consisted of the following at December 31:

| Intangible assets | 2014 | 2013 |
|--|---------------------|---------------------|
| Patent - Amlexanox (Aphthasol®) | \$ 2,090,000 | \$ 2,090,000 |
| Patent - Amlexanox (OraDisc™ A) | 6,873,080 | 6,873,080 |
| Patent - OraDisc™ | 73,000 | 73,000 |
| Patent - Hydrogel nanoparticle aggregate | 589,858 | 589,858 |
| | <u>9,625,938</u> | <u>9,625,938</u> |
| Less: accumulated amortization | (6,430,249) | (5,955,101) |
| Intangible assets, net | <u>\$ 3,195,689</u> | <u>\$ 3,670,837</u> |

We performed an evaluation of our intangible assets for purposes of determining possible impairment as of December 31, 2014. Based upon recent market conditions and comparable market transactions for similar intangible assets, we determined that an income approach using a discounted cash flow model was an appropriate valuation methodology to determine each intangible asset's fair value. The income approach converts future amounts to a single present value amount (discounted cash flow model). Our discounted cash flow models are highly reliant on various assumptions, including estimates of future cash flow (including long-term growth rates), discount rate, and expectations about variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows, all of which we consider level 3 inputs for determination of fair value. We believe we have appropriately reflected our best estimate of the assumptions that market participants would use in determining the fair value of our intangible assets at the measurement date. Upon completion of the evaluation, the fair value of our intangible assets exceeded the recorded remaining book value.

Amortization expense for intangible assets was \$475,148 and \$475,148 for the years ended December 31, 2014 and 2013, respectively. The future aggregate amortization expense for intangible assets, remaining as of December 31, 2014, is as follows:

| Calendar Years | Future Amortization Expense |
|-----------------------|--|
| 2015 | \$ 475,148 |
| 2016 | 476,450 |
| 2017 | 475,148 |
| 2018 | 475,148 |
| 2019 | 475,148 |
| 2020 & Beyond | 818,647 |
| Total | <u>\$ 3,195,689</u> |

NOTE 9. INVESTMENT IN UNCONSOLIDATED SUBSIDIARY

We use the equity method of accounting for investments in other companies that are not controlled by us and in which our interest is generally between 20% and 50% of the voting shares or we have significant influence over the entity, or both.

Altrazeal Trading Ltd.

On January 11, 2012, we executed a shareholders' agreement for the establishment of Altrazeal Trading Ltd., a single purpose entity to be used for the exclusive marketing of Altrazeal® throughout the European Union, Australia, New Zealand, North Africa, and the Middle East. As a result of this transaction, we received a non-dilutable 25% ownership interest in Altrazeal Trading Ltd. On February 1, 2014, Altrazeal Trading Ltd. transferred all of their rights and obligations under the existing shareholders' agreement to Altrazeal Trading GmbH.

Audited financial statements of Altrazeal Trading Ltd. for the years ended December 31, 2014 and 2013 have not been released to us and, therefore, we have not included the effect of the financial activities of Altrazeal Trading Ltd. in our financial statements for each reporting period. We believe that our share of the cumulative losses of Altrazeal Trading Ltd. for the years ended December 31, 2014, 2013, and 2012 would exceed the carrying value of our investment, therefore the equity method of accounting would be suspended for such reporting periods and no additional losses would be charged to operations.

Based upon audited financial statements received in May 2014, our unrecorded share of Altrazeal Trading Ltd. losses for the year ended December 31, 2012 totaled \$129,207.

Summarized financial information for our investment in Altrazeal Trading Ltd. assuming 100% ownership is as follows:

| <u>Altrazeal Trading Ltd.</u> | <u>December 31, 2012</u> |
|-------------------------------|--------------------------|
| Balance sheet | |
| Total assets | \$ 136,661 |
| Total liabilities | \$ 660,006 |
| Total stockholders' (deficit) | \$ (523,345) |
| Statement of operations | |
| Revenues | \$ 61,028 |
| Net (loss) | \$ (516,829) |

Altrazeal Trading GmbH

On February 1, 2014, Altrazeal Trading Ltd. transferred all of their rights and obligations under the existing shareholders' agreement to Altrazeal Trading GmbH. As a result of this transfer, we received a non-dilutable 25% ownership interest in Altrazeal Trading GmbH.

Audited financial statements of Altrazeal Trading GmbH for the years ended December 31, 2014 and 2013 have not been released to us and, therefore, we have not included the effect of the financial activities of Altrazeal Trading GmbH. in our financial statements for each reporting period. We believe that our share of the cumulative losses of Altrazeal Trading GmbH for the years ended December 31, 2014 and 2013 would exceed the carrying value of our investment, therefore the equity method of accounting would be suspended for such reporting periods and no additional losses would be charged to operations.

Based upon the unaudited financial statements for the year ended December 31, 2013, our unrecorded share of Altrazeal Trading GmbH cumulative losses as of December 31, 2013 totaled \$213,370.

Summarized financial information for our investment in Altrazeal Trading GmbH assuming 100% ownership is as follows:

| <u>Altrazeal Trading GmbH</u> | <u>December 31, 2013</u> <u>(Unaudited)</u> |
|--------------------------------------|--|
| Balance sheet | |
| Total assets | \$ 757,784 |
| Total liabilities | \$ 1,563,046 |
| Total stockholders' (deficit) | \$ (805,262) |
| Statement of operations | |
| Revenues | \$ --- |
| Net (loss) | \$ (798,009) |

ORADISC GmbH

On October 19, 2012, we executed a shareholders' agreement for the establishment of ORADISC GmbH, a single purpose entity to be used for the exclusive development and marketing of OraDisc™ erodible film technology products. We received a non-dilutable 25% ownership interest in ORADISC GmbH.

Audited financial statements of ORADISC GmbH for the years ended December 31, 2014 and 2013 have not been released to us and, therefore, we have not included the effect of the financial activities of ORADISC GmbH in our financial statements for each reporting period. We believe that our share of the cumulative losses of ORADISC GmbH for the years ended December 31, 2014 and 2013 would exceed the carrying value of our investment, therefore the equity method of accounting would be suspended for such reporting periods and no additional losses would be charged to operations.

Based upon the unaudited financial statements for the year ended December 31, 2013, our unrecorded share of ORADISC GmbH cumulative losses as of December 31, 2013 totaled \$11,430.

Summarized financial information for our investment in ORADISC GmbH assuming 100% ownership is as follows:

| <u>ORADISC GmbH</u> | <u>December 31, 2013</u> <u>(Unaudited)</u> |
|----------------------------|--|
| Balance sheet | |
| Total assets | \$ 305,069 |
| Total liabilities | \$ 302,572 |
| Total stockholders' equity | \$ 2,497 |
| Statement of operations | |
| Revenues | \$ --- |
| Net (loss) | \$ (34,671) |

Altrazeal AG

On February 1, 2014, we executed a shareholders' agreement with Altrazeal AG, a single purpose entity for the marketing of Altrazeal® in several territories, including Africa (markets not already licensed), Latin America, Georgia, Turkmenistan, Ukraine, the Commonwealth of Independent States, Jordan, Syria, Asia and the Pacific (excluding China, Hong Kong, Macau, Taiwan, South Korea, Japan, Australia, and New Zealand). As a result of this transaction, we received a non-dilutable 25% ownership interest in Altrazeal AG.

Audited or unaudited financial statements of Altrazeal AG for the year ended December 31, 2014 have not been released to us and, therefore, we have not included the effect of the financial activities of Altrazeal AG in our financial statements for such reporting period. We believe that our share of the cumulative losses of Altrazeal AG for the year ended December 31, 2014 would exceed the carrying value of our investment, therefore the equity method of accounting would be suspended for such reporting periods and no additional losses would be charged to operations.

NOTE 10. ACCRUED LIABILITIES

Accrued liabilities consisted of the following at December 31:

| Accrued Liabilities | 2014 | 2013 |
|-------------------------------|-------------------|-------------------|
| Accrued taxes – payroll | \$ 106,299 | \$ 106,299 |
| Accrued compensation/benefits | 96,795 | 148,683 |
| Accrued insurance payable | 69,815 | 60,113 |
| Product rebates/returns | 13 | 32 |
| Other | 279 | 836 |
| Total accrued liabilities | <u>\$ 273,201</u> | <u>\$ 315,963</u> |

NOTE 11. CONVERTIBLE DEBT

Convertible Note – June 2012

On June 27, 2012, we entered into a Securities Purchase Agreement (the “Purchase Agreement”), related to our issuance of the June 2012 Note, with Inter-Mountain. The purchase price for the June 2012 Note was paid \$500,000 at closing in cash and \$1,500,000 in the form of six Investor Notes in favor of the Company, each in the principal amount of \$250,000 at an interest rate of 8.0% per annum, and each of which became due as the outstanding balance under the June 2012 Note was reduced to certain levels. The purchase price of the June 2012 Note also reflected a \$200,000 original issue discount and \$10,000 in attorney's fees. The Purchase Agreement also includes representations and warranties, restrictive covenants, and indemnification provisions standard for similar transactions.

The June 2012 Note bore interest at the rate of 8.0% per annum, with monthly installment payments of \$83,333 commencing on the date that was the earlier of (i) thirty calendar days after the effective date of a registration statement registering the re-sale of the shares issuable upon conversion under the June 2012 Note or (ii) December 24, 2012, but in no event sooner than September 25, 2012. At our option, subject to certain volume, price, and other conditions, the monthly installment payments on the June 2012 Note may have been paid in whole, or in part, in cash or in our Common Stock. If the monthly installment was paid in Common Stock, such shares being issued would be based on a price that is 80% of the average of the three lowest volume weighted average prices of the shares of Common Stock during the preceding twenty trading days. The percentage declines to 70% if the average of the three lowest volume weighted average prices of the shares of Common Stock during the preceding twenty trading days was less than \$0.05.

At the option of Inter-Mountain, the outstanding principal balance of the June 2012 Note may be converted into shares of our Common Stock at a conversion price of \$0.35 per share, subject to certain pricing adjustments and ownership limitations. The initial tranche was \$710,000 and the six subsequent tranches were each \$250,000, plus interest. At our option, the outstanding principal balance of the June 2012 Note, or a portion thereof, may have been prepaid in cash at 120% of the amount elected to be prepaid. The June 2012 Note was secured by a Security Agreement pursuant to which we granted to Inter-Mountain a first-priority security interest in the assets held by the Company.

Events of default under the June 2012 Note include failure to make required payments or to deliver shares upon conversion, the entry of a \$100,000 judgment not stayed within 30 days, breach of representations or covenants under the transaction documents, various events associated with insolvency or failure to pay debts, delisting of our Common Stock, a restatement of financial statements, and a default under certain other agreements. In the event of default, the interest rate under the June 2012 Note increases to 18% and the June 2012 Note becomes callable at a premium. In addition, the holder had all remedies under law and equity, including foreclosing on our assets under a Security Agreement with Inter-Mountain.

As part of the convertible debt financing, Inter-Mountain also received a total of seven warrants (the "Warrants") to purchase, if they all vested, an aggregate of 3,142,857 shares of Common Stock, which number of shares could increase based upon the terms and conditions of the Warrants. The Warrants had an exercise price of \$0.35 per share, subject to certain pricing adjustments, and were exercisable, subject to vesting provisions and ownership limitations, until June 27, 2017. Warrants for 785,714, 392,857, 392,857, and 392,857 shares of Common Stock vested on June 27, 2012, December 31, 2012, February 26, 2013, and July 15, 2013, respectively. Each of the three remaining Warrants has terminated, as described below. As of December 31, 2014, we have issued 725,274 shares of Common Stock to Inter-Mountain for the cashless exercise of three warrants that vested prior to February 26, 2013 to purchase 1,571,428 shares of Common Stock. Such issuance of shares of Common Stock following the cashless exercise of three warrants by Inter-Mountain during 2013 was based upon an agreement in December 2013 with Inter-Mountain modifying the formula in the Warrants for determining the number of shares to be issued upon a cashless exercise. As of December 31, 2014, there is one warrant that remains vested but unexercised for 392,857 shares of Common Stock. Inter-Mountain delivered a notice of a cashless exercise with respect to this warrant on or about May 1, 2014 purporting to exercise it with respect to the delivery of 782,284 shares of Common Stock. We believe that, as a result of the December 2013 agreement, the warrant is exercisable, on a cashless basis, with respect to only 261,516 shares of Common Stock as of May 1, 2014 and, as a result, have not honored such warrant exercise.

As part of the convertible debt financing, we entered into a Registration Rights Agreement whereby we agreed to prepare and file with the SEC a registration statement for the number of shares referred to therein no later than July 27, 2012 and to cause such registration statement to be declared effective no later than ninety days after such filing with the SEC and to keep such registration statement effective for a period of no less than one hundred and eighty days. The Registration Rights Agreement also grants Inter-Mountain piggy-back registration rights with respect to future offerings by the Company. In accordance with our obligations under the Registration Rights Agreement, we filed with the SEC a registration statement that was declared effective on July 31, 2012, which registration statement expired by rule on April 30, 2013.

On October 5, 2012, we and Inter-Mountain entered into a First Amendment to Buyer Trust Deed Note #1 for the purpose of revising certain terms and conditions contained in the Buyer Trust Deed Note #1, to include an updated schedule for the timing of certain payment obligations by Inter-Mountain contained therein.

On January 22, 2014, we provided notice to Inter-Mountain of our election to exercise our rights under the June 2012 Note and to offset amounts we owed to Inter-Mountain against amounts it owed to us under the Investor Notes. Our notice provided that such deduction and offset occurred on January 22, 2014, that we will not incur the 120% prepayment premium with respect to amounts paid under the June 2012 Note as a result of the deduction and offset, that no warrants will become exercisable as a result of the offset,

and that any warrants unvested as of January 22, 2014 shall immediately and automatically terminate. As a result of the deduction and offset, the outstanding amount owed under the June 2012 Note was reduced to approximately \$317,000 as of January 22, 2014.

On February 27, 2014 and on March 3, 2014, we received conversion notices from Inter-Mountain whereby we issued an aggregate of 435,502 shares of Common Stock for the final payment of approximately \$152,000 due under the June 2012 Note.

Convertible Note – July 2011

On July 28, 2011, we completed a convertible debt financing for \$125,000 with Mr. Kerry P. Gray, the Company's Chairman, President, and Chief Executive Officer (the "July 2011 Note"). The July 2011 Note bore interest at the rate of 10.0% per annum, with annual payments of interest commencing on July 1, 2012. The full amount of principal and any unpaid interest was due on July 28, 2014. The outstanding principal balance of the July 2011 Note may be converted into shares of the Company's Common Stock at a conversion price of \$1.08 per share or 115,741 shares of Common Stock. The July 2011 Note was collateralized by the grant of a security interest in the inventory, accounts receivables and capital equipment held by the Company. The securities issuable on conversion have not been registered under the Securities Act of 1933 and may not be sold absent registration or an applicable exemption from the registration requirements. As part of the convertible debt financing, Mr. Gray also received a warrant to purchase up to 34,722 shares of the Company's Common Stock. The warrant has an exercise price of \$1.08 per share and is exercisable at any time until July 28, 2016.

On July 3, 2012, the Company and Mr. Gray entered into a Modification Agreement for the purpose of deferring the annual payment of interest due on July 1, 2012 of \$11,542 until such time as Mr. Gray provides written notice to us with such notice being no less than 15 days prior to the relevant payment date. Moreover, the parties agreed that no Event of Default under the July 2011 Note had occurred as a result of any failure by us to make the annual payment of interest due on July 1, 2012. Commencing on July 1, 2012, interest at the rate of 12.0% per annum accrued on the deferred interest payment of \$11,542 until the relevant payment date. On September 5, 2013, we remitted to Mr. Gray the annual interest due on July 1, 2012 of \$11,542 and accrued interest thereon of \$1,643.

On July 1, 2013, the Company and Mr. Gray entered into a Modification Agreement for the purpose of deferring the annual payment of interest due on July 1, 2013 of \$12,501 until such time as Mr. Gray provides written notice to us with such notice being no less than 15 days prior to the relevant payment date. Moreover, the parties agreed that no Event of Default under the July 2011 Note had occurred as a result of any failure by us to make the annual payment of interest due on July 1, 2013. Commencing on July 1, 2013, interest at the rate of 12.0% per annum accrued on the deferred interest payment of \$12,501 until the relevant payment date. On October 28, 2013, we remitted to Mr. Gray the annual interest due on July 1, 2013 of \$12,501 and accrued interest thereon of \$492.

On July 28, 2014, we issued 115,741 shares of Common Stock to Mr. Gray for the conversion and final payment of \$125,000 due under the July 2011 Note and remitted to Mr. Gray the annual interest due on July 28, 2014 of \$13,457.

Convertible Note – June 2011

On June 13, 2011, we completed a \$140,000 convertible debt financing with Mr. Gray (the "June 2011 Note"). The June 2011 Note bore interest at the rate of 10% per annum, with annual payments of interest commencing on July 1, 2012. The full amount of principal and any unpaid interest was due on June 13, 2014. The outstanding principal balance of the June 2011 Note may be converted into shares of the Company's Common Stock at a conversion price of \$1.20 per share or 116,667 shares of Common Stock. The June 2011 Note was collateralized by the grant of a security interest in the inventory, accounts receivables, and capital equipment held by the Company. The securities issuable on conversion have not been registered under the Securities Act of 1933 and may not be sold absent registration or an applicable exemption from the registration requirements. As part of the convertible debt financing, Mr. Gray also received a warrant to purchase up to 35,000 shares of the Company's Common Stock. The warrant has an exercise price of \$1.20 per share and is exercisable at any time until June 13, 2016.

On July 3, 2012, the Company and Mr. Gray entered into a Modification Agreement for the purpose of deferring the annual payment of interest due on July 1, 2012 of \$14,653 until such time as Mr. Gray provides written notice to us with such notice being no less than 15 days prior to the relevant payment date. Moreover, the parties agreed that no Event of Default under the June 2011 Note had occurred as a result of any failure by us to make the annual payment of interest due on July 1, 2012. Commencing on July 1, 2012, interest at the rate of 12.0% per annum accrued on the deferred interest payment of \$14,653 until the relevant payment date. On September 5, 2013, we remitted to Mr. Gray the annual interest due on July 1, 2012 of \$14,653 and accrued interest thereon of \$2,080.

On July 1, 2013, the Company and Mr. Gray entered into a Modification Agreement for the purpose of deferring the annual payment of interest due on July 1, 2013 of \$14,001 until such time as Mr. Gray provides written notice to us with such notice being no less than 15 days prior to the relevant payment date. Moreover, the parties agreed that no Event of Default under the June 2011 Note had occurred as a result of any failure by us to make the annual payment of interest due on July 1, 2013. Commencing on July 1, 2013, interest at the rate of 12.0% per annum accrued on the deferred interest payment of \$14,001 until the relevant payment date. On October 28, 2013, we remitted to Mr. Gray the annual interest due on July 1, 2013 of \$14,001 and accrued interest thereon of \$553.

On June 13, 2014, we issued 116,667 shares of Common Stock to Mr. Gray for the conversion and final payment of \$140,000 due under the June 2011 Note and remitted to Mr. Gray the annual interest due on June 13, 2014 of \$13,346.

We account for convertible debt using specific guidelines in accordance with U.S. GAAP. We allocated the value of the proceeds received to the convertible instrument and to the warrant on a relative fair value basis. We calculated the fair value of the warrant issued with the convertible instrument using the Black-Scholes valuation method, using the same assumptions used for valuing employee stock options, except the contractual life of the warrant was used. Using the effective interest method, the allocated fair value was recorded as a debt discount and is being amortized over the expected term of the convertible debt to interest expense.

On the date of issuance of the June 2011 Note, the July 2011 Note, and the June 2012 Note, no portion of the proceeds were attributable to a beneficial conversion feature since the conversion price of the June 2011 Note, the July 2011 Note, and the June 2012 Note exceeded the market price of the Company's Common Stock.

The amount of interest cost recognized from our convertible notes payable was \$20,853 and \$157,027 for years ended December 31, 2014 and 2013, respectively.

The amount of debt discount amortized from our convertible notes payable was \$(78,078) and \$178,548 for years ended December 31, 2014 and 2013, respectively.

NOTE 12. EQUITY TRANSACTIONS

Common Stock Transactions

March 2013 Offering

On March 14, 2013, we entered into a Securities Purchase Agreement (the “March SPA”) with Kerry P. Gray, the Company’s Chairman, President, and Chief Executive Officer and Terrance K. Wallberg, the Company’s Vice President and Chief Financial Officer (collectively, the “Investors”) relating to an equity investment of \$440,000 by the Investors for 1,100,000 shares of our Common Stock (the “March Shares”) and warrants to purchase up to 660,000 shares of our Common Stock (the “March Warrants”) (the “March 2013 Offering”). Under the March SPA, the purchase and sale of the March Shares and March Warrants took place at four closings over twelve months, with \$88,000 being funded at the initial closing under the March SPA, \$110,000 being funded on the four-month anniversary of the initial closing, \$132,000 being funded on the eight-month anniversary of the initial closing, and \$110,000 being funded on the one-year anniversary of the initial closing. The March Warrants have a fixed exercise price of \$0.60 per share, become exercisable in tranches on each of the four funding dates, and expire on the five-year anniversary of the initial closing. On March 14, 2013, we closed the March 2013 Offering and received the initial funding tranche of \$88,000 for the purchase of 220,000 shares of our Common Stock. We received subsequent funding tranches of \$110,000, \$132,000, and \$110,000 for the purchase of 275,000, 330,000, and 275,000 shares of our Common Stock on July 15, 2013, November 14, 2013, and March 14, 2014, respectively.

January 2013 Offering

On December 21, 2012, we entered into a Securities Purchase Agreement (the “SPA”) with IPMD GmbH (“IPMD”) relating to an equity investment of \$2,000,000 by IPMD for 5,000,000 shares of our Common Stock (the “Shares”) and warrants to purchase up to 3,000,000 shares of our Common Stock (the “Warrants”) (the “January 2013 Offering”). Under the SPA, the purchase and sale of the Shares and Warrants took place at four closings over twelve months, with \$400,000 being funded at the initial closing under the SPA, \$500,000 being funded on the four-month anniversary of the initial closing, \$600,000 being funded on the eight-month anniversary of the initial closing, and \$500,000 being funded on the one-year anniversary of the initial closing. The Warrants have a fixed exercise price of \$0.60 per share, become exercisable in tranches on each of the four funding dates, and expire on the one-year anniversary of the initial closing. On January 3, 2013, we closed the January 2013 Offering and received the initial funding tranche of \$400,000 for the purchase of 1,000,000 shares of our Common Stock. We received subsequent funding tranches of \$500,000, \$300,000, \$300,000, and \$500,000 for the purchase of 1,250,000, 750,000, 750,000, and 1,250,000 shares of our Common Stock on May 7, 2013, September 6, 2013, October 24, 2013, and January 6, 2014 respectively.

In the SPA, we also agree to appoint up to two directors nominated by IPMD to serve on our Board of Directors. On January 17, 2013, the Board of Directors of the Company appointed Helmut Kerschbaumer and Klaus Kuehne to each serve as a director of the Company. Messrs. Kerschbaumer and Kuehne are the designees of IPMD to serve on the Company’s Board of Directors pursuant to covenants in the SPA with IPMD.

In the SPA, we also agreed that we would not issue equity securities or rights to acquire equity securities without the unanimous approval of our Board of Directors and granted IPMD a right of first offer with respect to certain offerings or issuances of securities.

On January 3, 2014, the Warrants vested with respect to 3,000,000 shares of our Common Stock and were exercised by IPMD on that date pursuant to a Notice of Exercise, accepted by the Company, that provided for the issuance of 750,000 shares of Common Stock on each of 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.

On January 31, 2014, IPMD entered into an Assignment Agreement (the “Assignment Agreement”) with The Punch Trust (“TPT”) and Michael I. Sacks (“Sacks”) pursuant to which IPMD assigned to TPT and Sacks its rights and interests to purchase up to 3,000,000 shares of our Common Stock as detailed in the Warrants and the Notice of Exercise. Neither TPT nor Sacks paid any monetary consideration to IPMD in connection with the assignments under the Assignment Agreement.

Concurrent with the assignment under the Assignment Agreement described above, ULURU, TPT, Sacks, and IPMD entered into an Implementation Agreement (the “Implementation Agreement”) pursuant to which we consented and agreed to the assignment of the Warrants to TPT and Sacks. We also agreed to issue and facilitate the delivery of the shares of Common Stock under the Warrants to TPT and Sacks upon their payment of the corresponding purchase price due under the Warrants. Under the terms of the Warrants, Sacks made payments of \$450,000 on each of January 31, 2014 and February 28, 2014 and \$150,000 on each of March 31, 2014 and April 30, 2014. The Company issued 750,000 shares of Common Stock to Sacks on each of January 31, 2014 and February 28, 2014 and 250,000 shares of Common Stock on each of March 31, 2014 and April 30, 2014. Under the terms of the Warrants, TPT made payments of \$300,000 on each of March 31, 2014 and April 30, 2014 and the Company issued 500,000 shares of Common Stock to TPT on each date, respectively.

On January 31, 2014, we also entered into a Registration Rights Agreement with TPT and Sacks whereby we agreed to prepare and file with the SEC a registration statement for the number of shares referred to therein within sixty days after request and to use commercially reasonable efforts to cause such registration statement to be declared effective with the SEC and to keep such registration statement effective for a period of eighty days and, if necessary, such eighty day period being extended for up to sixty additional days.

NOTE 13. STOCKHOLDERS’ EQUITY

Common Stock

As of December 31, 2014, we had 24,458,018 shares of common stock issued and outstanding. We issued 5,586,598 shares of Common Stock for the year ended December 31, 2014 comprised of 3,000,000 shares of Common Stock issued for the exercise of warrants held by Sacks and TPT, 1,250,000 shares of Common Stock issued to IPMD pursuant to the January 2013 Offering, 275,000 shares of Common Stock issued to Messrs. Gray and Wallberg pursuant to the March 2013 Offering, 911,690 shares of Common Stock issued for installment payments and note conversion on the June 2012 Note with Inter-Mountain, 116,667 shares of Common Stock issued for the conversion and final payment of the June 2011 Note held by Mr. Gray, 115,741 shares of Common Stock issued for the conversion and final payment of the July 2011 Note held by Mr. Gray, and the net cancellation of 82,500 shares of Common Stock related to consulting services provided to the Company.

Preferred Stock

As of December 31, 2014, we had no shares of Series A Preferred Stock (the “Series A Shares”). For the year ended December 31, 2014, we did not issue any new Series A Shares.

On August 15, 2013, we provided notice to Ironridge Global III, LLC (“Ironridge”) for the redemption of all of the outstanding Series A Shares, a total of 65 Series A Shares. An affiliate of Ironridge, the issuer of promissory notes held by us, due 7.5 years from the issue date, in the principal amount of \$969,000 (the “Notes”), agreed to accept the cancellation of the Notes held by us as full and final payment for the redemption amounts of the Series A Shares.

Warrants

The following table summarizes the warrants outstanding and the number of shares of common stock subject to exercise as of December 31, 2014 and the changes therein during the two years then ended:

| | Number of Shares of Common Stock Subject to Exercise | Weighted – Average Exercise Price |
|-------------------------------------|---|--|
| Balance as of December 31, 2012 | 2,041,165 | \$ 0.98 |
| Warrants issued | 4,445,714 | 0.56 |
| Warrants exercised (1) | (1,571,428) | 0.35 |
| Warrants cancelled | (250,000) | 0.35 |
| Balance as of December 31, 2013 | 4,665,451 | \$ 0.82 |
| Warrants issued | 80,000 | 1.20 |
| Warrants exercised | (3,000,000) | 0.60 |
| Warrants cancelled | (69,050) | 3.22 |
| Balance as of December 31, 2014 (1) | 1,676,401 | \$ 1.14 |

- (1) As part of the June 2012 Note, Inter-Mountain received a total of seven warrants to purchase, if they all had vested, an aggregate of 3,142,857 shares of Common Stock, which number of shares could increase based upon the terms and conditions of the warrants. The warrants have an exercise price of \$0.35 per share, subject to certain pricing adjustments, and are exercisable, subject to vesting provisions and ownership limitations, until June 27, 2017. Warrants for 785,714, 392,857, 392,857, and 392,857 shares of Common Stock vested on June 27, 2012, December 31, 2012, February 26, 2013, and July 15, 2013, respectively, and three warrants totaling 1,571,428 shares of Common Stock were exercised in 2013. Such issuance of shares of Common Stock following the cashless exercise of three warrants by Inter-Mountain during 2013 was based upon an agreement in December 2013 with Inter-Mountain modifying the formula in the Warrants for determining the number of shares to be issued upon a cashless exercise. On January 22, 2014, we elected to offset and deduct the three remaining Investor Notes from the principle amount due to Inter-Mountain under the June 2012 Note and as a result of the offset and deduction the three remaining warrants terminated. For the purposes of this Table, only such vested shares of Common Stock from one unexercised warrant (392,857 shares) have been included, based upon an exercise price of \$0.35 per share of Common Stock.

For the year ended December 31, 2014, we issued warrants to purchase up to an aggregate of 80,000 shares of our common stock which consisted of a warrant to Torrey Hills Capital, Inc., at an exercise price of \$1.20 per share, for consulting services.

Of the warrant shares subject to exercise as of December 31, 2014, expiration of the right to exercise is as follows:

| <u>Date of Expiration</u> | <u>Number of Warrant Shares of Common Stock Subject to Expiration</u> |
|----------------------------------|--|
| May 15, 2015 | 357,155 |
| June 13, 2016 | 35,000 |
| July 16, 2016 | 116,667 |
| July 28, 2016 | 34,722 |
| June 27, 2017 | 392,857 |
| March 14, 2018 | 660,000 |
| January 15, 2019 | 80,000 |
| Total | 1,676,401 |

NOTE 14. EARNINGS PER SHARE

Basic and Diluted Net Loss Per Share

In accordance with FASB Accounting Standards Codification (“ASC”) Topic 260, *Earnings per Share*, basic earnings (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period. Diluted earnings (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period, increased to include potential dilutive common shares. The effect of outstanding stock options, restricted vesting common stock, convertible debt, convertible preferred stock, and warrants, when dilutive, is reflected in diluted earnings (loss) per common share by application of the treasury stock method. We have excluded all outstanding stock options, restricted vesting common stock, convertible debt, convertible preferred stock, and warrants from the calculation of diluted net loss per common share because all such securities are antidilutive for all periods presented.

Shares used in calculating basic and diluted net loss per common share exclude these potential common shares as of December 31:

| | <u>December 31, 2014</u> | <u>December 31, 2013</u> |
|--|--------------------------|--------------------------|
| Warrants to purchase Common Stock | 1,676,401 | 4,665,451 |
| Stock options to purchase common stock | 1,699,907 | 1,014,907 |
| Unvested restricted common stock | --- | --- |
| Common stock issuable upon the assumed conversion of our convertible note payable from June 2012 (1) | --- | 3,124,680 |
| Common stock issuable upon the assumed conversion of our convertible note payable from June 2011 (2) | --- | 127,712 |
| Common stock issuable upon the assumed conversion of our convertible note payable from July 2011 (2) | --- | 125,603 |
| Total | <u>3,376,308</u> | <u>9,058,353</u> |

- (1) The outstanding principal balance and the accrued and unpaid interest of the June 2012 Note may have been converted, at the option of Inter-Mountain, into shares of Common Stock at a conversion price of \$0.35 per share, subject to certain pricing adjustments and ownership limitations. For the purposes of this Table, we have assumed a conversion price of \$0.35 per share and no ownership limitations. On February 27, 2014 and on March 3, 2014, we received conversion notices from Inter-Mountain whereby we issued an aggregate of 435,502 shares of Common Stock for the final payment of approximately \$152,000 due under the June 2012 Note.
- (2) On June 13, 2014, Mr. Gray elected to convert the outstanding principal balance (\$140,000) of the June 2011 Note and we issued 116,667 shares of Common Stock for such conversion. On July 28, 2014, Mr. Gray elected to convert the outstanding principal balance (\$125,000) of the July 2011 Note and we issued 115,741 shares of Common Stock for such conversion.

NOTE 15. SHARE BASED COMPENSATION

The Company's share-based compensation plan, the 2006 Equity Incentive Plan ("Incentive Plan"), is administered by the compensation committee of the Board of Directors, which selects persons to receive awards and determines the number of shares subject to each award and the terms, conditions, performance measures and other provisions of the award.

Our Board of Directors granted the following incentive stock option awards to executives or employees and nonstatutory stock option awards to directors or non-employees for the years ended December 31:

| | <u>2014</u> | <u>2013</u> |
|---------------------------------------|-------------|-------------|
| <u>Incentive Stock Options</u> | | |
| Quantity | 125,000 | 232,500 |
| Weighted average fair value per share | \$ 0.81 | \$ 0.24 |
| Fair value | \$ 101,171 | \$ 56,112 |
| <u>Nonstatutory Stock Options</u> | | |
| Quantity | 560,000 | 735,000 |
| Weighted average fair value per share | \$ 0.81 | \$ 0.24 |
| Fair value | \$ 453,250 | \$ 177,388 |

We account for share-based compensation under ASC Topic 718, *Stock Compensation*, which requires the measurement and recognition of compensation expense in the financial statements for all share-based payment awards made to employees, consultants, and directors is measured based on the estimated fair value of the award on the grant date. We use the Black-Scholes option-pricing model to estimate the fair value of share-based awards with the following weighted average assumptions for the years ended December 31:

| | <u>2014</u> | <u>2013</u> |
|-----------------------------------|-------------|-------------|
| <u>Incentive Stock Options</u> | | |
| Expected volatility (1) | 107.66% | 103.55% |
| Risk-free interest rate % (2) | 1.75% | 0.81% |
| Expected term (in years) | 5.0 | 5.0 |
| Dividend yield (3) | --- | --- |
| <u>Nonstatutory Stock Options</u> | | |
| Expected volatility (1) | 107.66% | 103.55% |
| Risk-free interest rate % (2) | 1.75% | 0.81% |
| Expected term (in years) | 5.0 | 5.0 |
| Dividend yield (3) | --- | --- |

- (1) Expected volatility assumption was based upon a combination of historical stock price volatility measured on a daily basis and an estimate of expected future stock price volatility.
- (2) Risk-free interest rate assumption is based upon U.S. Treasury bond interest rates appropriate for the term of the stock options.
- (3) The Company does not currently intend to pay cash dividends, thus has assumed a 0% dividend yield.

Stock Options (Incentive and Nonstatutory)

The following table summarizes share-based compensation related to stock options for the years ended December 31:

| | 2014 | 2013 |
|--|-------------------|------------------|
| Research and development | \$ 35,861 | \$ 16,863 |
| Selling, general and administrative | 113,309 | 64,076 |
| Total share-based compensation expense | <u>\$ 149,170</u> | <u>\$ 80,939</u> |

At December 31, 2014, the balance of unearned share-based compensation to be expensed in future periods related to unvested stock option awards, as adjusted for expected forfeitures, is approximately \$557,694. The period over which the unearned share-based compensation is expected to be recognized is approximately three years.

The following table summarizes the stock options outstanding and the number of shares of common stock subject to exercise as of December 31, 2014 and the changes therein during the two years then ended:

| | Stock Options | Weighted Average Exercise Price per Share |
|-------------------------------------|----------------------|--|
| Outstanding as of December 31, 2012 | <u>158,409</u> | <u>12.32</u> |
| Granted | 967,500 | 0.33 |
| Forfeited/cancelled | (111,002) | 1.03 |
| Exercised | --- | --- |
| Outstanding as of December 31, 2013 | <u>1,014,907</u> | <u>\$ 2.12</u> |
| Granted | 685,000 | 1.15 |
| Forfeited/cancelled | --- | --- |
| Exercised | --- | --- |
| Outstanding as of December 31, 2014 | <u>1,699,907</u> | <u>\$ 1.73</u> |

The following table presents the stock option grants outstanding and exercisable as of December 31, 2014:

| Options Outstanding | | | Options Exercisable | |
|--------------------------------------|--|---|--|--|
| Stock Options Outstanding | Weighted Average Exercise Price per Share | Weighted Average Remaining Contractual Life in Years | Stock Options Exercisable | Weighted Average Exercise Price per Share |
| 892,500 | \$ 0.33 | 8.2 | 595,000 | \$ 0.33 |
| 685,000 | 1.15 | 7.9 | 15,000 | 1.15 |
| 53,334 | 2.38 | 3.5 | 53,334 | 2.38 |
| 69,073 | 25.12 | 2.6 | 69,073 | 25.12 |
| <u>1,699,907</u> | <u>\$ 1.73</u> | <u>7.7</u> | <u>732,407</u> | <u>\$ 2.83</u> |

Restricted Stock Awards

Restricted stock awards, which typically vest over a period of six months to five years, are issued to certain key employees and are subject to forfeiture until the end of an established restriction period. We utilize the market price on the date of grant as the fair market value of restricted stock awards and expense the fair value on a straight-line basis over the vesting period.

The following table summarizes share-based compensation related to restricted stock awards for the years ended December 31:

| | <u>2014</u> | <u>2013</u> |
|--|---------------|---------------|
| Research and development | \$ --- | \$ 444 |
| Selling, general and administrative | --- | 547 |
| Total share-based compensation expense | <u>\$ ---</u> | <u>\$ 991</u> |

At December 31, 2014, the balance of unearned share-based compensation to be expensed in future periods related to restricted stock awards, as adjusted for expected forfeitures, is nil.

The following table summarizes the non-vested restricted stock awards outstanding and the number of shares of common stock subject to potential issue as of December 31, 2014 and the changes therein during the two years then ended:

| | Restricted Stock | Weighted Average Grant Date Fair Value |
|-------------------------------------|-----------------------------|---|
| Outstanding as of December 31, 2012 | <u>300</u> | <u>\$ 34.59</u> |
| Granted | --- | --- |
| Forfeited/cancelled | --- | --- |
| Exercised/issued | <u>(300)</u> | <u>34.59</u> |
| Outstanding as of December 31, 2013 | <u>---</u> | <u>\$ ---</u> |
| Granted | --- | --- |
| Forfeited/cancelled | --- | --- |
| Exercised/issued | --- | --- |
| Outstanding as of December 31, 2014 | <u>---</u> | <u>\$ ---</u> |

Summary of Plans

2006 Equity Incentive Plan

In March 2006, our Board adopted and our stockholders approved our Equity Incentive Plan, which initially provided for the issuance of up to 133,333 shares of our Common Stock pursuant to stock option and other equity awards. At the annual meetings of the stockholders held on May 8, 2007, December 17, 2009, June 15, 2010, June 14, 2012, June 13, 2013, and on June 5, 2014, our stockholders approved amendments to the Equity Incentive Plan to increase the total number of shares of Common Stock issuable under the Equity Incentive Plan pursuant to stock options and other equity awards by 266,667 shares, 200,000 shares, 200,000 shares, 400,000 shares, 600,000 shares, and 1,000,000 shares, respectively, to a total of 2,800,000 shares.

In December 2006, we began issuing stock options to employees, consultants, and directors. The stock options issued generally vest over a period of one to four years and have a maximum contractual term of ten years. In January 2007, we began issuing restricted stock awards to our employees. Restricted stock awards generally vest over a period of six months to five years after the date of grant. Prior to vesting, restricted stock awards do not have dividend equivalent rights, do not have voting rights and the shares underlying the restricted stock awards are not considered issued and outstanding. Shares of Common Stock are issued on the date the restricted stock awards vest.

As of December 31, 2014, we had granted options to purchase 2,061,167 shares of Common Stock since the inception of the Equity Incentive Plan, of which 1,699,907 were outstanding at a weighted average exercise price of \$1.73 per share, and we had granted awards for 68,616 shares of restricted stock since the inception of the Equity Incentive Plan, of which none were outstanding. As of December 31, 2014, there were 1,030,647 shares that remained available for future grants under our Equity Incentive Plan.

NOTE 16. EMPLOYMENT BENEFIT PLAN

We maintain a defined contribution or 401(k) Plan for our qualified employees. Participants may contribute a percentage of their compensation on a pre-tax basis, subject to a maximum annual contribution imposed by the Internal Revenue Code. We may make discretionary matching contributions as well as discretionary profit-sharing contributions to the 401(k) Plan. Our contributions to the 401(k) Plan are made in cash and vest immediately. The Company's common stock is not an investment option available to participants in the 401(k) Plan. We contributed \$24,674 and \$20,917 to the 401(k) Plan during the years ended December 31, 2014 and 2013, respectively.

NOTE 17. FAIR VALUE MEASUREMENTS

In accordance with ASC Topic 820, *Fair Value Measurements*, ("ASC Topic 820") certain assets and liabilities of the Company are required to be recorded at fair value. Fair value is determined based on the exchange price that would be received for an asset or paid to transfer a liability in an orderly transaction between market participants. The guidance in ASC Topic 820 also establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimized the use of unobservable inputs by requiring that the most observable inputs be used when available.

Observable inputs are based on market data obtained from independent sources, while unobservable inputs are based on our market assumptions. Unobservable inputs require significant management judgment or estimation. In some cases, the inputs used to measure an asset or liability may fall into different levels of the fair value hierarchy. In those instances, the fair value measurement is required to be classified using the lowest level of input that is significant to the fair value measurement. Such determination requires significant management judgment.

The three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies, is as follows:

- Level 1 — Valuations based on quoted prices (unadjusted) for identical assets or liabilities in active markets.
- Level 2 — Valuations based on observable inputs other than quoted prices in Level 1, such as quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, and other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Valuations based on unobservable inputs reflecting the Company’s own assumptions, consistent with reasonably available assumptions made by other market participants.

Assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurements. We review the fair value hierarchy classification on a quarterly basis. Changes in the observability of valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy.

Our financial instruments, including cash, cash equivalents, accounts receivable, and accounts payable are carried at cost, which approximates their fair value because of the short-term maturity of these instruments. We believe that the carrying value of our notes receivable and accrued interest and convertible note payable balances approximates fair value based on a valuation methodology using the income approach and a discounted cash flow model.

The fair value of our financial instruments consisted of the following at December 31:

| Description | 2014 | 2013 |
|---------------------------------------|-------------|-------------|
| Assets: | | |
| Notes receivable and accrued interest | --- | \$ 777,710 |
| Liabilities: | | |
| Convertible note – June 2011 | --- | \$ 138,220 |
| Convertible note – July 2011 | --- | \$ 120,738 |
| Convertible note – June 2012 | --- | \$ 888,099 |

NOTE 18. INCOME TAXES

There was no current federal tax provision or benefit recorded for any period since inception, nor were there any recorded deferred income tax assets, as such amounts were completely offset by valuation allowances. Deferred tax assets as of December 31, 2014, of \$18,989,376 were reduced to zero, after considering the valuation allowance of \$18,989,376, since there is no assurance of future taxable income. As of December 31, 2014 we have consolidated net operating loss carryforwards (“NOL”) and research credit carryforwards for income tax purposes of approximately \$51,347,180 and \$531,440, respectively.

The following are the consolidated operating loss carryforwards and research credit carryforwards that will begin expiring as follows:

| <u>Calendar Years</u> | <u>Consolidated Operating Loss Carryforwards</u> | <u>Research Activities Carryforwards</u> |
|-----------------------|--|--|
| 2021 | \$ 34,248 | \$ --- |
| 2023 | 95,666 | --- |
| 2024 | 910,800 | 13,584 |
| 2025 | 1,687,528 | 21,563 |
| 2026 | 11,950,281 | 60,797 |
| 2027 | 3,431,365 | 85,052 |
| 2028 | 8,824,940 | 139,753 |
| 2029 | 6,889,761 | 81,940 |
| 2030 | 5,113,583 | 41,096 |
| 2031 | 3,728,626 | 43,592 |
| 2032 | 3,695,792 | 8,690 |
| 2033 | 3,187,559 | 15,882 |
| 2034 | 1,797,031 | 19,491 |
| Total | <u>\$ 51,347,180</u> | <u>\$ 531,440</u> |

The Tax Reform Act of 1986 contains provisions, which limit the amount of NOL and tax credit carryforwards that companies may utilize in any one year in the event of cumulative changes in ownership over a three-year period in excess of 50%. Since the effective date of the Tax Reform Act of 1986, the Company has completed significant share issuances in 2003 and 2006 which may significantly limit our ability to utilize our NOL and tax credit carryforwards against taxable earnings in future periods. Ownership changes in future periods may place additional limits on our ability to utilize NOLs and tax credit carryforwards.

An analysis of the tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities at December 31, 2014 and 2013 are as follows:

| | <u>2014</u> | <u>2013</u> |
|--|---------------------|---------------------|
| Deferred tax assets: | | |
| Net operating loss carryforwards | \$ 18,279,724 | \$ 17,657,746 |
| Intangible assets | 188,944 | 247,248 |
| Other | 554,404 | 512,286 |
| Total gross deferred tax assets | <u>19,023,072</u> | <u>18,417,280</u> |
| Deferred tax liabilities: | | |
| Property and equipment | <u>33,696</u> | <u>72,347</u> |
| Total gross deferred tax liabilities | <u>33,696</u> | <u>72,347</u> |
| Net total of deferred assets and liabilities | 18,989,376 | 18,344,933 |
| Valuation allowance | <u>(18,989,376)</u> | <u>(18,344,933)</u> |
| Net deferred tax assets | <u>\$ ---</u> | <u>\$ ---</u> |

The valuation allowance increased by \$644,443 and \$1,065,354 in 2014 and 2013, respectively.

The following is a reconciliation of the expected statutory federal income tax rate to our actual income tax rate for the years ended December 31:

| | <u>2014</u> | <u>2013</u> |
|--|----------------|------------------|
| Expected income tax (benefit) at federal statutory tax rate -35% | \$ (681,109) | \$ (1,137,320) |
| Permanent differences | 52,273 | 21,754 |
| Research tax credits | (19,491) | (15,882) |
| Amortization of deferred start up costs | --- | --- |
| Valuation allowance | <u>648,327</u> | <u>1,131,448</u> |
| Income tax expense | <u>\$ ---</u> | <u>\$ ---</u> |

Effective January 1, 2007, we adopted ASC Topic 740, *Accounting for Uncertainty in Income Taxes*. ASC Topic 740 is a comprehensive model for how a company should recognize, measure, present, and disclose in its financial statements uncertain tax positions that we have taken or expects to take on a tax return. If an income tax position exceeds a more likely than not (greater than 50%) probability of success upon tax audit, we will recognize an income tax benefit in its financial statements. Additionally, companies are required to accrue interest and related penalties, if applicable, on all tax exposures consistent with jurisdictional tax laws. We did not have any unrecognized tax benefits and there was no effect on our financial condition or results of operations as a result of implementing ASC Topic 740.

Federal income tax returns for fiscal years 2011 through 2014 remain open and subject to examination by the Internal Revenue Service. We file and remit state income taxes in various states where we have determined it is required to file state income taxes. Our filings with those states remain open for audit for the fiscal years 2011 through 2014.

We do not believe there will be any material changes in our unrecognized tax positions over the next 12 months. Our policy is that we recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. As of the date of adoption of ASC 740, we did not have any accrued interest or penalties associated with any unrecognized tax benefits nor was any interest expense recognized during the period. The liability for unrecognized tax benefits is zero at December 31, 2014 and 2013.

NOTE 19. COMMITMENTS AND CONTINGENCIES

Operating Leases

On January 31, 2006 we entered into a lease agreement for office and laboratory space in Addison, Texas. The lease commenced on April 1, 2006 and originally continued until April 1, 2013. The lease required a minimum monthly lease obligation of \$9,330, which was inclusive of monthly operating expenses, until April 1, 2011 and at such time increased to \$9,776, which was inclusive of monthly operating expenses. On February 22, 2013, we executed an Amendment to Lease Agreement (the "Lease Amendment") that renewed and extended our lease until March 31, 2015. The Lease Amendment required a minimum monthly lease obligation of \$9,193, which was inclusive of monthly operating expenses, until March 31, 2014 and at such time, increased to \$9,379, which was inclusive of monthly operating expenses. On March 17, 2015, we executed a Second Amendment to Lease Agreement (the "Second Amendment") that renewed and extended our lease until March 31, 2018. The Second Amendment requires a minimum monthly lease obligation of \$9,436, which is inclusive of monthly operating expenses.

On December 10, 2010 we entered into a lease agreement for certain office equipment that commenced on February 1, 2011 and continued until February 1, 2015 and required a minimum lease obligation of \$744 per month. On January 16, 2015 we entered into a new lease agreement for certain office equipment. The new lease, which commenced on February 1, 2015 and continues until February 1, 2018, requires a minimum lease obligation of \$551 per month.

The future minimum lease payments under the 2013 office lease and the 2015 equipment lease are as follows as of December 31, 2014:

| <u>Calendar Years</u> | <u>Future Lease Expense</u> |
|-----------------------|-----------------------------|
| 2015 | \$ 120,033 |
| 2016 | 119,840 |
| 2017 | 119,840 |
| 2018 | 28,858 |
| 2019 | --- |
| Total | <u>\$ 388,571</u> |

Rent expense for our operating leases amounted to \$123,716 and \$116,488 for the years ended December 31, 2014 and 2013, respectively.

Indemnification

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. Our exposure under these agreements is unknown because it involves claims that may be made against us in the future, but have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations.

In accordance with our restated articles of incorporation and our amended and restated bylaws, we have indemnification obligations to our officers and directors for certain events or occurrences, subject to certain limits, while they are serving at our request in their respective capacities. There have been no claims to date and we have a director and officer insurance policy that enables us to recover a portion of any amounts paid for future potential claims. We have also entered into contractual indemnification agreements with each of our officers and directors.

Related Party Transactions and Concentration

On January 17, 2013, the Board of Directors of the Company appointed Helmut Kerschbaumer and Klaus Kuehne to each serve as a director of the Company.

Mr. Kerschbaumer currently serves as a director of Altrazeal Trading GmbH, Altrazeal AG, and Melmed Holding AG (collectively, the “Altrazeal Distributors”) and Mr. Kuehne currently serves as a director of Altrazeal AG. In such capacities, Mr. Kerschbaumer may be considered, either singularly or collectively, to have control of, and make investment and business decisions on behalf of the Altrazeal Distributors and Mr. Kuehne may be considered, either singularly or collectively, to have control of, and make investment and business decisions on behalf of Altrazeal AG.

Mr. Kerschbaumer and Mr. Kuehne currently serves as a director of ORADISC GmbH and in such capacity, Mr. Kerschbaumer and Mr. Kuehne may each be considered, either singularly or collectively, to have control of, and make investment and business decisions on behalf of the ORADISC GmbH.

Currently, we are party to License and Supply Agreements with Altrazeal Trading GmbH, Altrazeal AG, and Melmed Holding AG for the marketing and distribution of Altrazeal in various international territories. We are also party to a License and Supply Agreement with ORADISC GmbH for the marketing of all applications of our OraDisc™ erodible film technology for dental applications including benzocaine (OraDisc™ B), re-mineralization dental strips, fluoride dental strips, long-acting breath freshener, amlexanox (OraDisc™ A) in certain territories, anti-psychotics, neurologic products, and actives for the treatment of erectile dysfunction.

For the years ended December 31, 2014 and 2013, the Company recorded revenues, in approximate numbers, of \$802,000 and \$281,000, respectively, with the various Altrazeal Distributors, which represented approximately 93% and 76% of our total revenues.

As of December 31, 2014 and 2013, Altrazeal Distributors had an outstanding net accounts receivable, in approximate numbers, of \$798,000 and \$174,000, respectively, which represented approximately 99% and 94% of our net outstanding accounts receivables.

Related Party Obligations

Since 2011, our named executive officers and certain key executives have temporarily deferred portions of their compensation as part of a plan to conserve the Company’s cash and financial resources.

As of December 31, 2014, the following table summarizes the compensation temporarily deferred and subsequent repayments:

| <u>Name</u> | <u>2014</u> | <u>2013</u> | <u>2012</u> | <u>2011</u> | <u>Total</u> |
|-----------------------|--------------------|--------------------|-------------------|-------------------|-------------------|
| Kerry P. Gray (1) (2) | \$(119,986) | \$ (91,000) | \$ 220,673 | \$ 140,313 | \$ 150,000 |
| Terrance K. Wallberg | (25,000) | (35,769) | \$ 24,230 | \$ 36,539 | --- |
| Key executives | (28,239) | (20,000) | \$ 27,253 | \$ 20,986 | --- |
| Total | <u>\$(173,225)</u> | <u>\$(146,769)</u> | <u>\$ 272,156</u> | <u>\$ 197,838</u> | <u>\$ 150,000</u> |

- (1) During 2014, Mr. Gray temporarily deferred compensation of \$150,000 which consisted of \$62,500 earned as salary compensation for his duties as President of the Company and \$87,500 for his duties as Chairman of the Executive Committee of the Company’s Board of Directors. During 2014, Mr. Gray was also repaid \$269,986 of temporarily deferred compensation, of which \$100,000 was used by Mr. Gray for funding required pursuant to the March 2013 Offering.
- (2) During 2013, Mr. Gray temporarily deferred compensation of \$221,500 which consisted of \$11,500 earned pursuant to a Separation Agreement and \$210,000 for his duties as Chairman of the Executive Committee of the Company’s Board of Directors. During 2013, Mr. Gray was also repaid \$312,500 of temporarily deferred compensation, of which \$300,000 was used by Mr. Gray for funding required pursuant to the March 2013 Offering.

As of December 31, 2014, the Company's obligation for temporarily deferred compensation was \$150,000 of which \$62,500 was included in accrued liabilities and \$87,500 was included in accounts payable, respectively. As of December 31, 2013, the Company's obligation for temporarily deferred compensation was \$323,225 of which \$207,500 was included in accounts payable and \$115,725 was included in accrued liabilities, respectively

Contingent Milestone Obligations

We are subject to paying Access Pharmaceuticals, Inc. ("Access") for certain milestones based on our achievement of certain annual net sales, cumulative net sales, and/or our having reached certain defined technology milestones including licensing agreements and advancing products to clinical development. As of December 31, 2014, the future milestone obligations that we are subject to paying Access, if the milestones related thereto are achieved, total \$4,750,000. Such milestones are based on total annual sales of 20 and 40 million dollars of certain products, annual sales of 20 million dollars of any one certain product, and cumulative sales of such products of 50 and 100 million dollars.

On March 7, 2008, we terminated the license agreement with ProStrakan Ltd. for Amlexanox-related products in the United Kingdom and Ireland. As part of the termination, we agreed to pay ProStrakan Ltd. a royalty of 30% on any future payments received by us from a new licensee in the United Kingdom and Ireland territories, up to a maximum of \$1,400,000. On November 17, 2008, we entered into a licensing agreement for Amlexanox-related product rights to the United Kingdom and Ireland territories with MEDA AB.

NOTE 20. LEGAL PROCEEDINGS

On or about August 22, 2014, Inter-Mountain filed a Complaint against ULURU in a matter now pending in the U.S. Federal Court for the District of Utah, Central Division. The Complaint relates to Inter-Mountain's delivery of a notice of a cashless exercise with respect to its last remaining warrant to purchase Common Stock on or about May 1, 2014 purporting to exercise it with respect to the delivery of 782,284 shares of Common Stock under the non-standard cashless exercise or conversion provisions in the warrant. ULURU declined to honor the exercise on the basis that, as a result of an amendment to the warrant agreed to in December 2013, the warrant was exercisable, on a cashless basis, with respect to only 261,516 shares of Common Stock as of May 1, 2014. Inter-Mountain alleges that ULURU's refusal to honor the exercise constitutes a breach of the warrant, breach of implied covenant of good faith and fair dealing, unjust enrichment, a violation of securities laws and common law fraud and seeks actual damages, consequential damages, treble damages, specific performance, attorneys' fees and costs and other relief. Answers and counterclaims have been filed. A preliminary settlement has been reached and is in the process of being documented. All proceedings have been placed on hold pending documentation of the settlement.

On or about November 6, 2012, Discus Dental, LLC (“Discus”) and Philips Oral Healthcare Inc. (“Philips”) filed a Complaint against ULURU in the United States District Court, Central District of California (the “Action”). Discus, a subsidiary of Philips’ parent company, was party to a license agreement under which ULURU’s predecessor granted it a defined license. The license contractually required that Discus use commercially reasonable efforts to, market and sell Aphthasol® paste, a prescription pharmaceutical. Prior to the filing of the Action, ULURU sent a demand letter contending that Discus did not fulfill its obligations under the license agreement, including the obligation to retain an adequate selling organization and otherwise use commercially reasonable efforts to market and sell Aphthasol® paste. In response to ULURU’s demand letter, the Plaintiffs instituted the Action seeking a declaratory judgment that Discus did not breach the license agreement. On November 20, 2012, the Plaintiffs filed Amended Complaint adding a claim requesting that ULURU be ordered to return certain royalty payments that Discus paid to ULURU after the expiration of the license period. On October 7, 2014, Discus filed a Second Amended Complaint, withdrawing Philips as a plaintiff and adding claims that ULURU breached the license by allegedly making a profit from the manufacture of Aphthasol® paste. ULURU denied liability with regard to Discus’s claims and asserted counterclaims for breach of contract against Discus, seeking compensatory damages and attorneys’ fees. On November 18, 2014, ULURU and Discus agreed to settle, resolve, and dismiss the claims asserted in the Action, with the terms and conditions of the settlement subject to an agreement of confidentiality. The settlement included a release by each party in favor of the other and a settlement payment in favor of ULURU.

NOTE 21. SUBSEQUENT EVENTS

None.

CORPORATE INFORMATION

BOARD OF DIRECTORS

Kerry P. Gray

*Chairman, President & Chief Executive Officer
ULURU Inc.*

Jeffrey B. Davis

*Chief Operating Officer
Abeona Therapeutics Inc.*

Helmut Kerschbaumer

*Chairman
Melmed Holding AG*

Klaus Kuehne

*Director
Altrazeal AG*

Bradley J. Sacks

*Managing Member
Centric Capital Venture LLC*

OFFICERS & SENIOR MANAGEMENT

Kerry P. Gray

*President & Chief Executive Officer
Principal Executive Officer*

Terrance K. Wallberg

*Vice President & Chief Financial Officer
Principal Accounting Officer*

Daniel G. Moro

Vice President of Polymer Drug Delivery

CORPORATE HEADQUARTERS

ULURU Inc.

4452 Beltway Drive
Addison, TX 75001
Phone: (214) 905-5145
Fax: (214) 905-5130

INTERNET WEB SITE - CORPORATE

<http://www.uluruinc.com>

LEGAL COUNSEL

Bryan T. Allen, Esq.
Parr Brown Gee & Loveless
185 South State Street, Suite 800
Salt Lake City, Utah 84111
Phone: (801) 532-7840
Fax: (801) 532-7750

INDEPENDENT AUDITORS

Lane Gorman Trubitt PLLC
2626 Howell Street, Suite 700
Dallas, Texas 75204
Phone: (214) 871-7500
Fax: (214) 871-0011

TRANSFER AGENT

For questions concerning stock certificates, change of address, consolidation of accounts, transfer of ownerships, or other stock account matters, please contact ULURU Inc. transfer agent:

Continental Stock Transfer & Trust Company

17 Battery Place
New York, New York 10004
Phone: (212) 509-4000
Fax: (212) 509-5150
cstmail@continentalstock.com

INVESTOR RELATIONS

To receive an Annual Report and Form 10-K or for additional investor inquiries, please contact:

ULURU Inc.

Investor Relations
4452 Beltway Drive
Addison, TX 75001
Phone: (214) 905-5145
Fax: (214) 905-5130
mneledec@uluruinc.com

ULURU INC.
4452 BELTWAY DRIVE
ADDISON, TEXAS 75001
P: 214.905.5145
F: 214.905.5130
WWW.ULURUINC.COM

