

UNITED GUARDIAN INC  
Form 10-K  
March 24, 2016

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

**FORM 10-K**

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2015

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 number 1-10526

**UNITED-GUARDIAN, INC.**

(Exact name of Registrant as specified in its charter)

Edgar Filing: UNITED GUARDIAN INC - Form 10-K

Delaware  
(State or other jurisdiction  
of incorporation or organization)

11-1719724  
(I.R.S. Employer  
Identification No.)

230 Marcus Blvd., Hauppauge, NY  
(Address of principal executive offices)

11788  
(Zip Code)

Registrant's telephone number, including area code: (631) 273-0900

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, \$.10 par value	The NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act:

None

Cover Page 1 of 2

Edgar Filing: UNITED GUARDIAN INC - Form 10-K

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 (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 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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 the definitions 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   
(Do not check if a smaller reporting company)

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

As of June 30, 2015, the last business day of the Registrant's most recently completed second fiscal quarter, the aggregate market value of the Registrant's common stock held by non-affiliates (based on the closing sales price of

such shares on The NASDAQ Global Market ("NASDAQ") on such date) was approximately \$51,361,676. (For the purpose of this report it has been assumed that all officers and directors of the Registrant, as well as all stockholders holding 10% or more of Registrant's stock, are affiliates of the Registrant).

As of March 1, 2016, the Registrant had issued and outstanding 4,594,319 shares of Common Stock, \$.10 par value per share ("Common Stock").

DOCUMENTS INCORPORATED BY REFERENCE:

Certain information required by Part III (portions of Item 10, as well as Items 11, 12, and 13) is incorporated by reference to the Registrant's definitive proxy statement for the 2016 annual meeting of stockholders ("2016 Proxy Statement"), which, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is to be filed with the Securities and Exchange Commission (the "SEC") no later than 120 days after Registrant's fiscal year end.

Cover Page 2 of 2

This Annual Report on Form 10-K contains both historical and "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, which provides a safe harbor for forward-looking statements by the Registrant about its expectations or beliefs concerning future events, such as financial performance, business prospects, and similar matters. The Registrant desires to take advantage of such "safe harbor" provisions and is including this statement for that express purpose. Words such as "anticipates", "believes", "expects", "intends", "future", and similar expressions identify forward-looking statements. Any such "forward-looking" statements in this report reflect the Registrant's views as of the date of filing of this report with the United States Securities and Exchange Commission (the "SEC") with respect to future events and financial performance, and are subject to a variety of factors that could cause the Registrant's actual results or performance to differ materially from historical results or from the anticipated results or performance expressed or implied by such forward-looking statements. Because of such factors, there can be no assurance that the actual results or developments anticipated by the Registrant will be realized or, even if substantially realized, that they will have the anticipated results. The risks and uncertainties that may affect the Registrant's business include, but are not limited to: economic conditions, governmental regulations, technological advances, pricing and competition, acceptance by the marketplace of new products, retention of key personnel, the sufficiency of financial resources to sustain and expand the Registrant's operations, and other factors described in this report and in prior filings with the SEC. Readers should not place undue reliance on such forward-looking statements, which speak only as of the date hereof, and should be aware that except as may be otherwise legally required of the Registrant, the Registrant undertakes no obligation to publicly revise any such forward-looking statements to reflect events or circumstances that may arise after the date hereof.

## **PART I**

### **Item 1. Business.**

#### **(a) Introduction**

United-Guardian, Inc. ("United", the "Registrant", or the "Company") is a Delaware corporation that, through its Guardian Laboratories Division ("Guardian"), manufactures and markets cosmetic ingredients, personal care products, pharmaceuticals, medical lubricants, health care products, and specialty industrial products. It also conducts research and product development, primarily related to the development of new and unique cosmetic and personal care products. The Company's research and development department also modifies, refines, and expands the uses for existing products, with the goal of further developing the market for the Company's products.

United's predecessor, United International Research, Inc. ("UIR"), was founded and incorporated in New York in 1942 by Dr. Alfred R. Globus, United's Chairman and Director of Research until his death on April 9, 2009. On February 10, 1982, a merger took place between UIR and Guardian Chemical Corp. ("GCC"), an affiliate of UIR, whereby GCC was merged into UIR and the name was changed to United-Guardian, Inc., a New York corporation. On September 14, 1987, United-Guardian, Inc. (New York) was merged with and into a newly-formed Delaware corporation by the same name, United-Guardian, Inc., for the purpose of changing the domicile of the Company to Delaware.

The Company has a broad range of products, some of which are currently marketed and some of which are still in the research and development stage. Of the products being actively marketed, the two largest product lines are the LUBRAJEL® line of cosmetic ingredients and medical lubricants, which accounted for approximately 85% of the Company's sales in 2015, and RENACIDIN® IRRIGATION ("RENACIDIN"), a pharmaceutical product that accounted for approximately 10% of the Company's sales in 2015.

(b) **Narrative Description of Business**

The Company manufactures and markets cosmetic ingredients, personal and health care products, medical lubricants, pharmaceuticals, and specialty industrial products. It also conducts research and development, primarily related to the development of new and unique cosmetic and personal care products. The Company focuses on the development of products that fill unmet market needs, have unique properties, and use proprietary technology that it sometimes protects with patents. Many of the Company's products are marketed through collaborative agreements with larger companies. The personal care products manufactured by the Company, including the cosmetic ingredients, are marketed to end users through the Company's worldwide network of marketing partners and distributors, and are currently used by many of the major manufacturers of cosmetic and personal care products. The Company sells product outright to its marketing partners, Ex Works (EXW) the Company's plant in Hauppauge, New York. Those marketing partners in turn resell those products to their customers, who are typically the manufacturers and marketers of cosmetic and personal care products, and who in turn utilize the Company's products in their finished products. The products are not sold on a consignment basis, so unless a product is determined to be defective it is not returnable except at the discretion of the Company.

The Company operates in one business segment. The Company's products are separated into four distinct product categories: personal care products (including cosmetic ingredients), pharmaceuticals, medical products, and industrial products. Each product category is marketed differently.

The Company's personal care products, including cosmetic ingredients, are marketed globally by six marketing partners, of which Ashland Specialty Ingredients ("ASI"), a business segment of Ashland, Inc., is the largest. The products are sold directly to those marketing partners, which in turn resell those products to its customers for use in the manufacture or compounding of the customers' personal care and cosmetic products. The Company's non-pharmaceutical medical products (referred to hereinafter as "medical products") and the specialty industrial products are sold directly by the Company to the end users or to contract manufacturers utilized by the end users. The Company's pharmaceutical products are marketed by direct advertising, mailings, and trade exhibitions, and are sold to hospitals and pharmacies primarily through full-line drug wholesalers, which purchase the Company's products outright for resale to their customers. The Company also sells a small quantity of pharmaceutical products directly to hospitals and pharmacies. The Company's products are sold under trademarks or trade names owned by the Company, some of which are registered with the United States Patent and Trademark Office as well as comparable regulatory agencies in some foreign countries.

**PRODUCTS**

The Company operates in one business segment, and its product lines are separated into four distinct product categories:

**PERSONAL CARE**

**LUBRAJEL®** is an extensive line of water-based moisturizing and lubricating gel formulations that are used as ingredients in personal care (primarily cosmetic/skincare) products. In the personal care industry, they are used primarily as moisturizers and as bases for other cosmetic ingredients, and can be found as an ingredient in skin creams, moisturizers, makeup, and body lotions. The largest product by sales in the LUBRAJEL personal care line in 2015 was LUBRAJEL OIL, followed by LUBRAJEL CG. Some of the other varieties of LUBRAJEL sold for cosmetic use (all using the LUBRAJEL name), in descending order of sales, are PF (including Norgel (see LUBRAJEL PF below)), MS, DV, and NP. In addition, many of these products are available in comparable formulations that do not contain parabens as the preservative, and instead use a different preservative system that is preferred by some customers. Those equivalent products are differentiated by adding the word “Free” after the name (for example, LUBRAJEL MS Free, DV Free, etc.), indicating that those formulations do not contain parabens.



**LUBRAJEL PF** is different from the other products in the LUBRAJEL line in that it is a completely preservative-free form of LUBRAJEL. It is marketed under the LUBRAJEL PF tradename in all geographic markets other than France, where it is marketed under the tradename “Norgel” by Societe D'Etudes Dermatologiques (“Sederma”), a subsidiary of Croda International Plc (“Croda”). Sederma is the Company's exclusive marketing partner and distributor of the Company’s cosmetic ingredients in France and, along with its parent company, Croda, is a major supplier of specialty cosmetic ingredients to the personal care products industry. Tests have shown that this product self-preserves, and that it aids in the preservation of other cosmetic ingredients with which it is formulated.

**LUBRAJEL NATURAL** is the first product in a new line of LUBRAJEL products for cosmetic use that are produced using only ingredients that are considered “natural”. This product, as well as the additional “natural” products under development (see “Development Activities” below) are based on natural polysaccharides, which contribute moisturization, emulsion stabilization, and emolliency to personal care products, particularly creams and lotions. LUBRAJEL NATURAL has been certified as natural by Ecocert, a leading industry certification organization for natural and organic products. This product is now being actively marketed, and there were some initial small sales in 2015.

Each of the following products accounted for less than 4% of the Company’s sales in 2015, listed in descending order of sales:

**LUBRAJEL II XD** is a version of LUBRAJEL that was developed to be a direct replacement for one of the competitive products to LUBRAJEL. In 2015 sales increased by over 100% over 2014, from \$120,084 to \$322,451.

**KLENSOFT™** is a surfactant (a surface active agent, such as a soap or detergent) that can be used in shampoos, shower gels, makeup removers, and other cosmetic formulations. KLENSOFT sales have been highly variable due to the ordering patterns of the customers for the product. In 2015 sales of KLENSOFT decreased 54% compared with 2014, declining from \$237,248 to \$109,726. The Company expects the variability in sales of this product to continue.

**LUBRASIL™** is a special form of LUBRAJEL in which silicone oil is incorporated into a LUBRAJEL base by micro-emulsification, thereby maintaining clarity similar to the other LUBRAJEL products. The product has a silky feel, and is water resistant while moisturizing the skin.

**LUBRASLIDE™** and a related product, B-122™, are powdered lubricants used in the manufacture of cosmetics such as pressed powders, eyeliners, and rouges. They are used as binders for these products, increasing water-repellency and drop strength and lowering the coefficient of friction.

**ORCHID COMPLEX™** is an oil-soluble base for skin creams, lotions, cleansers, and other cosmetics. It is an extract of fresh orchids modified by stabilizers and preservatives, and is characterized by its excellent lubricity, spreadability, light feel, and emolliency. Because of its alcohol solubility, it may also be used in fragrance products such as perfumes and toiletries. Its emolliency makes it an excellent additive to shampoos, bath products and facial cleansers. It is also a superior emollient for sunscreens, vitamin creams, toners and skin serums.

**UNITWIX II™** is a cosmetic additive used as a thickener for oils and oil-based liquids. It is a proprietary, unpatented product that the Company developed in 2011 as a direct replacement for the Company's original UNITWIX, which is no longer being manufactured due to the raw material cost issues. The new formula is less expensive to manufacture, and therefore can be marketed at a lower price.

The Company believes that its ability to maintain and/or increase sales of its cosmetic and other personal care products will depend on (a) the ability and determination of its marketing partners, especially its largest marketing partner, ASI, to continue to aggressively promote the Company's products, particularly to new customers, and to find new marketing opportunities; (b) the Company's success in developing additional new products, including new varieties of LUBRAJEL, as well as new applications for existing products; and (c) the ability of the Company to find ways to compete with lower-cost imitations of its LUBRAJEL products that have become significant competitors to the Company's products in the past couple of years, and which negatively impacted the Company's sales of these products in 2015. In particular, the Company has experienced significant pricing pressure from LUBRAJEL imitations being manufactured in China. The new lower-priced competitors are likely to adversely affect the Company's ability to continue marketing certain of its existing LUBRAJEL products at profit margins comparable to what they have been in the past.

The Company believes that there is still potential to expand the sales of its LUBRAJEL line of products through product modifications, additional claim substantiation, and geographic expansion. The Company believes that its strong brand identity and reputation for supplying quality products will be advantageous in its efforts to compete with the growing number of lower-cost imitations of its products, but that it will still be necessary to be more competitive with its product pricing in order to maintain and grow its market share.

## **MEDICAL**

**LUBRAJEL RR** and **RC** are both gels used primarily as lubricants for urinary catheters. Both are special grades of LUBRAJEL that can withstand sterilization by gamma radiation, which is one of the methods of terminally sterilizing medical and hospital products. LUBRAJEL RR was the original radiation-resistant LUBRAJEL product. LUBRAJEL RC was developed specifically for one customer that packages the product in unit doses as a catheter lubricant for many manufacturers. Combined sales of these two products in 2015 decreased by 16.1% compared with 2014, with LUBRAJEL RR accounting for the largest portion of that decrease. The combined sales of both products accounted for approximately 10.0% of the Company's sales in 2015. Sales of both of these products are subject to year-to-year variations based on the ordering patterns of the customers for these two products.

**LUBRAJEL LC** was developed for a specific customer who required a product suitable for oral use, to be used in a line of mouth moisturizers that it markets. Sales increased by approximately 29.0% in 2015 compared with 2014.

**LUBRAJEL MG** is the original form of LUBRAJEL, developed as a medical lubricant in the 1970s. It is used by many medical device manufacturers for lubricating urinary catheters, pre-lubricated enema tips, and other medical devices. Sales decreased by 5.9% in 2015 compared with 2014, which the Company believes was the result of fluctuations in the buying patterns of customers for this product. Sales of this product represented 4.3% and 4.8% of the Company's sales in 2015 and 2014, respectively.

**LUBRAJEL FLUID** is a very low viscosity form of LUBRAJEL that was developed to provide superior lubrication in water-soluble products. It was specifically developed, and is currently being used, as a replacement for silicone oils in pre-lubricated condoms. The Company has only one customer for this product, and while sales in 2015 increased compared with 2014, these sales did not contribute significantly to the Company's overall sales.

**LUBRAJEL BA** is a Lubrajel formulation that was specifically developed for ASI for an oral care use. ASI is actively promoting this product. Sales of this product are not yet a significant contributor to the Company's revenue, and it is too early to project whether or not it will become a significant product for the Company.

**LUBRAJEL TF** is a medical lubricant specifically developed for a global medical products company. Initial sales of this product began at the end of 2012. Although the Company is still hopeful that sales of this product will increase, sales of this product to date have been lower than expected due to the customer's uncertain marketing plans for this product.

Sales of all of the medical grades of LUBRAJEL decreased by 11.7% in 2015 compared with 2014. Sales of these products accounted for 15.7% of the Company's sales in 2015 compared with approximately 18.5% in 2014. The Company believes that the decrease was primarily due to fluctuations in the purchasing patterns of its customers.

## **PHARMACEUTICAL**

**RENACIDIN®** is a prescription drug product that is used primarily to prevent and to dissolve calcifications in urethral catheters and the urinary bladder. Since 1991 it has been marketed as a ready-to-use sterile solution in 500mL glass bottles. It currently has regulatory approval only in the United States. The product had been manufactured for the Company under a long-term contract with a major U.S. drug company. That supplier experienced two production curtailments in the past five years, which resulted in a decline in RENACIDIN sales. As a result of those curtailments, the Company lost sales opportunities due to inventory shortages. In order to compensate the Company for its lost sales the Company and its supplier entered into a settlement agreement whereby the supplier reimbursed the Company for the profit it lost during the curtailment periods. The final reimbursement payment under that settlement agreement, in the amount of \$24,402, was received by the Company in the first quarter of 2014.

The Company's contract with its RENACIDIN supplier expired in the first quarter of 2015. In 2013, in anticipation of that contract expiration, the Company began working with a new supplier to produce RENACIDIN in a smaller, more user-friendly container. The new product is a sterile, single dose, 30 mL plastic bottle that was engineered to dispense the product directly into an indwelling catheter, eliminating the need to use a separate syringe to extract a small amount of product from the current 500mL bottle. The change to a new supplier and new packaging required a new submission to, and approval by, the United States Food and Drug Administration ("FDA"). The Company submitted its application to the FDA in August 2014 in the form of a supplement to its previous New Drug Application ("NDA") for RENACIDIN, and received final approval to market the new product in December 2015. Prior to the expiration of its previous supply agreement for the 500mL bottles the Company had purchased sufficient inventory to last until it received FDA approval for the new product. The Company expects to begin selling the new single-dose 30mL bottles in April 2016, around the same time that it expects to sell off its remaining inventory of 500mL glass bottles. The Company is optimistic that this new, more user-friendly bottle will enable the Company to increase its sales of RENACIDIN over the next few years, and intends to actively market the new product beginning in April 2016.

**CLORPACTIN® WCS-90** is an antimicrobial product used primarily in urology to treat infections in the urinary bladder. It is also used in surgery for treating a wide range of localized infections in the peritoneum (the lining of the abdominal cavity), as well as the eye, ear, nose and throat, and sinuses. The product is a powder that is mixed with water by the end user and used as a solution. It is also a powerful disinfectant, fungicide, and deodorizer. Sales of CLORPACTIN have been very consistent from year-to-year. In 2015 sales increased by 2.2% and represented approximately 4.0% of the Company's sales.

The Company's pharmaceutical products are returnable only at the discretion of the Company unless (a) they are found to be defective, or (b) they are outdated (but not more than one year after their expiration date, a return policy that conforms to standard pharmaceutical industry practice).

## **INDUSTRIAL**

**DESELEX™ Liquid** is a sequestering and chelating agent that is used primarily as a replacement for phosphates in the manufacture of detergents. It also has some use in personal care products as a chelating agent in shampoos and body washes.

**THOROCLENS** is a chlorine-based cleanser manufactured and packaged by the Company for a small company in New England that resells the product to its customers. Sales of this product decreased by 9.8% in 2015.

## **DEVELOPMENT ACTIVITIES**

In coordination with, and with input from, its marketing partners, the Company's research and development department has developed products that can be used in many different industries, including the personal care (including cosmetic), pharmaceutical, medical, health care, and specialty chemical industries. These products are in various stages of development, some currently marketable and some in the very early stages of development requiring a substantial amount of development work to bring them to market. Research is also being done on new uses for currently marketed products.

Prior to initiating research and development work on a product, market research is done to determine the marketability of the product, including the potential market size and the most effective method of marketing the product. After that, the research and development department will determine whether the product can be successfully developed, including (a) laboratory refinements and adjustments to suit the intended uses of the product; (b) stability studies to determine the effective shelf life of the product and suitable storage and transportation conditions; and (c) laboratory efficacy tests to determine the effectiveness of the product under different conditions. If development proves feasible, the Company will then determine whether production and sales costs make it feasible to bring the product to market.

If the initial development work is successful, and the estimated costs of further development are acceptable to the Company, further development work to bring the product to market will continue, including scaling up from laboratory production batches to pilot batches to full-scale production batches. In the case of drug products or medical devices, significant additional work would have to be done, including studies to determine safety and effectiveness, preparation of an Investigational New Drug (IND) Application, and finally the filing of an NDA. Due to the size of the Company and the costs involved in bringing new drugs or medical devices to market, the Company does not

currently have plans to develop any new drugs or medical devices, and intends to focus its research and development efforts on the development of new and innovative products for the personal care and medical (non-drug) markets.

While there can be no assurance that any particular project will result in a new marketable product or a commercially successful product, the Company believes that a number of its development projects, including those discussed below, may have commercial potential if the Company's development efforts are successful.

The Company's major research focus is on the development of new and unique ingredients for cosmetic and other personal care products. The following are some of the projects that the Company is either working on or intends to work on in the near future:



**LUBRAJEL NATURAL MARINE and LUBRAJEL OIL NATURAL:** These will be the next two products in the LUBRAJEL “Natural” line, produced using only ingredients that are considered “natural”. Like the original LUBRAJEL NATURAL they are based on natural polysaccharides. The LUBRAJEL NATURAL MARINE uses some components derived from marine vegetation. The LUBRAJEL OIL NATURAL will be a new natural form of the Company’s original LUBRAJEL OIL, with similar lubricating properties but based on all-natural components. The polymer network in this product is based solely on vegetable feedstock. Like the original LUBRAJEL NATURAL, both of these products have been certified as natural by Ecocert. The formulations for both products are still being finalized. The Company hopes to begin marketing both products by the end of 2016. The Company believes that there is a growing demand, especially in personal care products, for natural products, and expects to add additional products to this line in the future if these initial products are successful.

**Lubrajel Terra:** This is intended to be the fourth product in the LUBRAJEL “Natural” line. It will be based on polysaccharides from soil-grown raw materials. This product is in a very early stage of development. If the research proves to be promising our goal would be to have samples to our marketing partners by the end of 2016.

**GLYCERYL GLYCOLATE:** This material is intended to function as an anti-aging skincare ingredient. The Company has finalized the product formulation and is in the process of developing recommended applications as well as instructions for potential customers as to how it can be used in finished formulations.

**Guardian Ester C24P:** This new product is designed to be an alternative to silicone fluid in creams and lotions. Very preliminary samples have been sent to our distributors for an initial evaluation to determine whether there is sufficient interest to proceed further.

**Amla Complex:** This product consists of an extract of the Amla fruit (Indian Gooseberry), which is believed to have certain health benefits, including improved skin health and healthier hair. It is high in antioxidant content, such as vitamin C. This product is in the R&D phase and samples are not yet available for evaluation.

It should be emphasized that some of the projects listed above are in the very early stages of research and development, and there can be no guarantee that any particular development project will result in a marketable product or in significant sales if it is marketed.

The Company’s research and development expenses in 2015 were \$648,211, as compared with \$730,412 in 2014. It expects its research and development expenses in 2016 to be comparable to those of 2015. Any additional increase in development and/or production costs will depend on whether capital investments are required in order to continue development work on, or to manufacture, any of the new products under development.

The Company requires all employees and consultants who may receive confidential and proprietary information to agree in writing to keep such information confidential.

## **TRADEMARKS AND PATENTS**

The Company strongly believes in protecting its intellectual property and intends, whenever reasonably possible and economically practical, to obtain patents in connection with its product development program. The Company currently holds two United States patents and several trademarks relating to its products. In recent years the Company has relied more on trade secrets and proprietary formulations and manufacturing methods to protect its intellectual property rather than patents, since under current patent law the filing of a patent now provides detailed proprietary information that can be copied by companies in other countries where enforcement would be difficult and expensive, such as in China. The Company believes that in many cases it is better to protect its intellectual property in other ways that do not require the disclosure of proprietary information. Many patents that had previously been issued to the Company have expired. There can be no assurance that any patents held by the Company will be valid or otherwise of value to the Company, or that any patent applied for will be granted. The Company will continue to file patent applications in situations where it believes that relying on trade secrets would be insufficient protection.

The various trademarks and trade names owned or used by the Company in its business are of varying importance to the Company. The most significant trademarks are LUBRAJEL® and RENACIDIN®.

Set forth below is a table listing certain information with respect to all unexpired U.S. patents held by the Company.

PATENT NAME	PATENT #	FILING DATE	ISSUE DATE	EXPIRATION DATE
Delivery system for oil-soluble actives in cosmetic and personal care products	6,117,419	9 /1996	9 /2000	12 /2016
Microemulsion of silicone in a water-based gel that forms a clear, transparent, highly stable moisturizer and lubricant for cosmetic and medical use	6,348,199	1 /1994	2 /2002	2 /2019

### **DOMESTIC SALES**

In the United States the Company's cosmetic ingredient products are marketed and distributed exclusively by ASI in accordance with a marketing agreement entered into in 1996 with International Specialty Products (“ISP”), the predecessor company of ASI. That agreement was amended and expanded in July 2000, December 2002, December 2005, May 2010, November 2012, and November 2013. ASI also has certain non-exclusive rights to sell some of the Company's other industrial and medical products. It was also granted the exclusive right to market an oral care product, LUBRAJEL BA, which was specifically developed for ASI in 2012. The Company received its first order for that product in February 2014.

The Company's domestic sales of pharmaceutical products are handled primarily through full-line drug wholesalers, and accounted for approximately 13.3% of the Company's sales in 2015, and 12.5% in 2014. The Company's other products, such as its medical and specialty industrial products, are sold directly to customers or their contract manufacturers, who incorporate these products into their finished products.

### **FOREIGN SALES**

In 2015, approximately 53% of the Company's products were sold by its marketing partners to customers in foreign countries, compared with approximately 65% in 2014. These foreign sales consisted primarily of sales of its cosmetic ingredients to customers in Canada, Europe and Asia. In Asia the growth in sales in the first three quarters of 2015 came almost exclusively from sales into China.

The Company currently has six distributors for its personal care products outside the United States, with ASI being the largest. The Company has a written marketing agreement only with ASI; all other marketing arrangements are subject to cancellation at any time by either the Company or the distributor. The marketing agreement with ASI gives it exclusive foreign marketing rights with the exception of the following territories, where the Company's other marketing partners have exclusive marketing rights: the United Kingdom (by The Azelis Group); France (by Sederma SAS, a subsidiary of Croda International Plc.); Italy (by Luigi & Felice Castelli S.R.L.); Switzerland (by Azelis Cosmetics GmbH.); and South Korea (by C&M International). The Company also has significant sales of one of its medical lubricants to the manufacturing plant in India of a multi-national medical products customer.

Since the Company's sells its products in U.S. Dollars, the Company's selling prices are not affected by fluctuations in foreign currency exchange rates except to the extent that a stronger dollar compared with foreign currencies can make the Company's products less competitive in foreign markets, sometimes requiring the Company to reduce its prices in order be more competitive. In recent years sales have been negatively impacted by the strength of the U.S. Dollar relative to other currencies, particularly the Euro, which has resulted in some of the Company's products being more price sensitive than they had been in the past. It has also enabled some of the Company's competitors to take some market share from the Company in those markets.

## **MARKETING**

The Company markets its products through marketing partners and distributors, advertising in medical and trade journals, mailings to physicians and to the trade, and exhibitions at medical meetings. The pharmaceutical products are sold in the United States primarily to drug wholesalers, which in turn distribute and resell those products to drug stores, hospitals, physicians, long-term care facilities, the U.S. Department of Veterans Affairs, and other government agencies. The cosmetic ingredients and other personal care products are sold outright (not on consignment) to the Company's marketing partners, which in turn market and resell the products to cosmetic and other personal care manufacturers for use in the manufacture or compounding of their products. The medical and specialty industrial products are sold by the Company directly to the end users. The industrial products are older products that have limited marketability but are still being sold to some long-time customers. They are not actively marketed, but are available for sale to any new customers.

## **MARKETING AGREEMENTS**

In 1994, the Company entered into a marketing agreement with ISP, the predecessor of ASI, whereby it would market and distribute the Company's personal care products, as well as some medical and specialty industrial products, in certain parts of Europe, Asia, Australia, and Africa. ISP manufactured and marketed globally (and continues to do so as ASI) an extensive line of personal care and pharmaceutical additives and various other industrial products. In 1996, the parties entered into another agreement, extending ISP's distribution rights to the United States, Canada, Mexico, and Central and South America. In July 2000, the parties entered into an Exclusive Marketing Agreement (the "2000 Agreement"), which modified, extended, and consolidated the 1994 and 1996 agreements. In December 2002, December 2005, May 2010, November 2012, and November 2013 the parties entered into letter agreements that further modified and extended the 2000 Agreement. The May 2010 agreement also provided for automatic two-year renewals after December 31, 2011 unless either party terminated the arrangement upon 60 days' notice. Since at no time has either party provided notice to the other with respect to termination of the contract, the agreement automatically renewed on January 1, 2012, 2014, and 2016 for additional two-year terms. The current contract ends on December 31, 2017.

The Company believes that in the event ASI were to cease marketing the Company's products alternative arrangements could be made with one of the other global marketers of personal care products to continue to supply products to customers currently using the Company's products, without any significant interruption of sales.

The Company has other marketing arrangements with marketing partners in the U.K., France, Switzerland, South Korea, and Italy (see "Foreign Sales" above), but all of these other arrangements are operating under either verbal agreements or expired written agreements, and are subject to termination at any time by either party.

## **RAW MATERIALS**

The principal raw materials used by the Company consist of common industrial organic and inorganic chemicals. Most of these materials are available in ample supply from numerous sources. The Company has five major raw material vendors that together accounted for approximately 89% of the raw material purchases by the Company in 2015, and 84% in 2014. The names of the suppliers and the specific raw materials are considered by the Company to be confidential and proprietary.

## **INVENTORIES, RETURNS, and ALLOWANCES**

The Company's business requires that it maintain moderate inventories of certain of its finished goods. Historically, sufficient inventory levels, returns and allowances have not been a significant factor in the Company's business.

## **BACKLOG**

The Company currently does not have any significant backlog of orders.

## **SEASONALITY**

Due to the nature of the Company's business and the types of products it markets it is not subject to any significant seasonal fluctuations in sales.

## **CUSTOMERS**

The Company's personal care/cosmetic ingredients are marketed and sold globally by six marketing partners. Those marketing partners in turn market and distribute those products to their customers. Although the Company depends on those marketing partners for the marketing and distribution of its personal care products, it is confident that if any of its marketing partners were to decide not to sell the Company's products, or if the Company chose to replace one or more of those marketing partners, it would be able to put in place new marketing agreements to service its customers in any of the geographic areas affected. If necessary, the Company would also be able to sell directly to the end users

of its products until such time as a new marketing partner is put in place.

The Company's pharmaceutical products are sold to, and distributed by, full-line drug wholesalers throughout the United States. Its medical and specialty industrial products are sold directly by the Company to the end users of those products or, in some cases, to contract manufacturers used by some of those end users.

## **COMPETITION**

The Company has some products or processes that are either proprietary or have some unique characteristics, and its LUBRAJEL line of products is well known globally and has an excellent reputation for quality. The Company believes that these characteristics will be advantageous to the Company in its continuing efforts to compete effectively with other pharmaceutical, personal care, specialty chemical, or health care companies. The pharmaceutical, health care, and cosmetic industries are all highly competitive, and the Company experienced higher levels of competition for its cosmetic ingredients during 2015, not only because of additional competition in the marketplace, but also because of the strengthened U.S. dollar causing the Company's products to be less competitive than they had been in the past when the dollar was not as strong. The Company anticipates that this increased competition will continue in the coming years, and is working with ASI, its primary marketing partner, to address the issue and determine how the Company can make its products more competitive in the marketplace in light of the changed circumstances. The Company is aware that there are other domestic and foreign companies that are engaged in the same or similar areas of research as those in which the Company is engaged, some of which have substantially greater financial, research, manpower, marketing and distribution resources than the Company. In addition, there are many large, integrated and established pharmaceutical, specialty chemical, personal care and health care companies that have greater capacity than the Company to develop and to commercialize types of products upon which the Company's research and development programs are based. The Company intends to focus its research efforts on the development of new and innovative products for which there is not the same competitive situation as there is for some of the Company's older products, and is optimistic that the development of unique products, such as its focus on the development of products made exclusively with natural ingredients, will enable it to continue to compete in a market in which competition has become more of a factor than it had been in the past.



### **ISO 9001:2008 REGISTRATION**

In October 2009 the Company was certified by Underwriters Laboratories, Inc. to be in compliance with the current ISO 9001:2008 standard, indicating that the Company's documented procedures and overall operations had attained the high level of quality needed to comply with this ISO certification level. Prior to that, since December 2003 the Company had been registered under the previous ISO 9001:2000 standard, also by Underwriters Laboratories, Inc. The Company had first earned ISO registration in November 1998, when it earned ISO 9002 registration, and has been in continuous compliance with each of these standards from the time of its approval under each standard.

### **GOVERNMENT REGULATION**

Regulation by governmental authorities in the United States and other countries is a significant factor in the manufacturing and marketing of many of the Company's products. The Company and many of the Company's products are subject to certain government regulations. Products that may be developed and sold by the Company in the United States may require approval from federal regulatory agencies, such as the FDA, as well as state regulatory agencies. Products that may be developed and sold by the Company outside the United States may require approval from foreign regulatory agencies. Any medical device products developed by the Company will be subject to FDA regulation, and will usually require a 510(k) pre-market notification to the FDA to demonstrate that the device is at least as safe and effective as a legally marketed device. The Company would then need to receive clearance from the FDA prior to marketing the device. Most new pharmaceutical products will require clinical evaluation under an IND Application prior to submission of an NDA for approval of a new drug product.

The Company is required to comply with all pertinent current Good Manufacturing Practices of the FDA for medical devices and drugs. Accordingly, the regulations to which the Company and certain of its products may be subject, and any changes with respect thereto, may materially affect the Company's ability to produce and market new products developed by the Company.

The Company's present and future activities are, and will likely continue to be, subject to varying degrees of additional regulation under the Occupational Safety and Health Act, Environmental Protection Act, import, export and customs regulations, and other present and possible future foreign, federal, state and local regulations.

Portions of the Company's operating expenses are directly attributable to complying with federal, state, and local environmental statutes and regulations. In 2015 and 2014 the Company incurred \$38,000 and \$42,000, respectively, in federal, state, and local environmental law compliance expenses. There was no material financial or other impact on the Company as a result of compliance with environmental laws.



## **EMPLOYEES**

The Company presently has 34 employees, 4 of whom serve in an executive capacity, 18 in research, quality control and manufacturing, 6 in maintenance and construction, and 6 in office and administrative support services. Of the total number of employees, 29 work full time.

### **Item 1A. Risk Factors.**

The information to be reported under this item is not required of smaller reporting companies.

### **Item 1B. Unresolved Staff Comments.**

The information to be reported under this item is not required of smaller reporting companies.

### **Item 2. Properties.**

The Company maintains its principal office and factory, and conducts its research, at a 50,000 square foot facility on a 2.7-acre parcel at 230 Marcus Boulevard, Hauppauge, New York 11788, which the Company owns. Of the 50,000 square feet, approximately 30,000 square feet is manufacturing space, 15,000 square feet is warehouse space, and 5,000 square feet is office and laboratory space. The Company has fully developed the 2.7 acres, and fully utilizes the building occupying the land. The Company believes that the aforementioned property is adequate for its immediately foreseeable needs. The property is presently unencumbered and, in the Company's opinion, is adequately insured.

### **Item 3. Legal Proceedings.**

None.

### **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 Information**

The Common Stock of the Company has traded on the NASDAQ Global Market since March 16, 2009, under the symbol "UG". From December 1, 2008 through March 13, 2009, following the merger of the American Stock Exchange with the New York Stock Exchange, the Company's Common Stock was traded on the NYSE Amex Stock Exchange under the same symbol. Prior to December 1, 2008 its stock traded on the American Stock Exchange under the same symbol.

The following table sets forth the high and low closing sale prices of the shares of Common Stock, as reported by NASDAQ, for the period January 1, 2014 to December 31, 2015. The quotations represent prices between dealers and do not include retail markup, markdown or commission:

<u>Quarters</u>		Year Ended		Year Ended	
		December 31,		December 31,	
		2015		2014	
		High	Low	High	Low
First	(1/1 - 3/31)	\$22.13	\$18.20	\$29.25	\$26.95
Second	(4/1 - 6/30)	22.81	18.08	34.43	26.66
Third	(7/1 - 9/30)	20.00	18.00	30.60	20.99
Fourth	(10/1 - 12/31)	20.89	18.01	22.89	19.00

### **Holders of Record**

As of March 1, 2016, there were 832 holders of record of Common Stock.

### **Cash Dividends**

On May 13, 2015, the Company's Board of Directors declared a semi-annual cash dividend of \$0.50 per share, which was paid on June 15, 2015 to all stockholders of record as of June 1, 2015. On November 18, 2015, the Company's Board of Directors declared a semi-annual cash dividend of \$0.50 per share, which was paid on December 15, 2015 to all stockholders of record as of December 1, 2015.

On May 14, 2014, the Company's Board of Directors declared a semi-annual cash dividend of \$0.48 per share, which was paid on June 13, 2014 to all stockholders of record as of May 30, 2014. On November 20, 2014, the Company's Board of Directors declared a semi-annual cash dividend of \$0.32 per share, which was paid on December 22, 2014 to all stockholders of record as of December 8, 2014.

### **Item 6. Selected Financial Data.**

The information to be reported under this item is not required of smaller reporting companies.

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

**Critical Accounting Policies**

The Company's financial statements have been prepared in accordance with U.S. generally accepted accounting principles. Preparation of financial statements requires the Company to make estimates and assumptions affecting the reported amounts of assets, liabilities, revenues, and expenses and the disclosure of contingent assets and liabilities. The Company uses its historical experience and other relevant factors when developing its estimates and assumptions, which are continually evaluated. Note A, Nature of Business and Summary of Significant Accounting Policies, of the Notes to Financial Statements, included in Item 8, Financial Statements and Supplementary Data, of this Annual Report on Form 10-K includes a discussion of the Company's significant accounting policies. The following accounting policies are those that the Company considers critical to an understanding of the financial statements because their application places the most significant demands on the Company's judgment. The Company's financial results might have been different if other assumptions had been used or other conditions had prevailed.

### **Marketable Securities**

The Company classifies its marketable securities as available-for-sale at the time of purchase and re-evaluates such designation as of each balance sheet date. The Company's marketable securities include investments in equity and fixed income mutual funds, and government securities. The Company's marketable securities are reported at fair value with the related unrealized gains and losses included in accumulated other comprehensive income (loss), a component of stockholders' equity. Realized gains or losses on mutual funds are determined using the average cost method, while realized gains or losses on government securities and bonds are determined using the specific-identification method. Realized gains or losses on the Company's marketable securities are insignificant for the years ended December 31, 2015 and 2014. The Company evaluates its investments periodically for possible other-than-temporary impairment by reviewing factors such as the length of time and extent to which fair value had been below cost basis, the financial condition of the issuer and the Company's ability and intent to hold the investment for a period of time which may be sufficient for anticipated recovery of market value. The Company would record an impairment charge to the extent that the cost of the available-for-sale securities exceeds the estimated fair value of the securities and the decline in value is determined to be other-than-temporary. During 2015 and 2014 the Company did not record an impairment charge regarding its investment in marketable securities because management believes, based on its evaluation of the circumstances, that the decline in fair value below the cost of certain of the Company's marketable securities is temporary.

### **Revenue Recognition**

The Company recognizes revenue when products are shipped, title and risk of loss pass to customers, persuasive evidence of a sales arrangement exists, and collections are reasonably assured. Any allowances for returns are taken as a reduction in sales within the same period the revenue is recognized. Such allowances are based on historical experience as well as other factors that, in the Company's judgment, could reasonably be expected to cause sales returns or doubtful accounts to differ from historical experience.

### **Accounts Receivable Allowance**

The Company performs ongoing credit evaluations of the Company's customers and adjusts credit limits, as determined by a review of current credit information. The Company continuously monitors collection and payments from customers and maintains an allowance for doubtful accounts based upon historical experience, the Company's anticipation of uncollectible accounts receivable and any specific customer collection issues that have been identified. While the Company's credit losses have historically been low and within expectations, the Company may not continue to experience the same credit loss rates that have historically been attained. The receivables are highly concentrated in a relatively small number of customers. Therefore, a significant change in the liquidity, financial position, or willingness to pay timely, or at all, of any one of the Company's significant customers would have a significant impact

on the Company's results of operations and cash flows.

**Inventory Valuation Allowance**

In conjunction with the Company's ongoing analysis of inventory valuation, management constantly monitors projected demand on a product-by-product basis. Based on these projections, management evaluates the levels of write-downs required for inventory on hand and inventory on order from contract manufacturers. Although the Company believes that it has been reasonably successful in identifying write-downs in a timely manner, sudden changes in buying patterns from customers, either due to a shift in product interest and/or a complete pull back from their expected order levels, may result in the recognition of larger-than-anticipated write-downs.



## **Results of Operations**

Year ended December 31, 2015 compared with the year ended December 31, 2014:

### **Net Sales**

Net sales in 2015 increased by \$556,565 (4.1%) compared with 2014. The net increase was the result of the following changes in sales in the different product categories:

(a) **Personal care products:**

Sales of the Company's personal care products, including cosmetic ingredients, increased by \$501,089 (5.3%) for the year ended December 31, 2015 when compared with 2014. The increase was attributable primarily to an increase in sales to ASI, the Company's largest marketing partner, of one of the Company's LUBRAJEL products for export to China. Sales to ASI in 2015 increased by \$416,122 (5.2%) compared with 2014. Sales to three of the Company's marketing partners in Europe, decreased by \$206,244 (19.9%) in 2015 compared with 2014, while sales to the Company's distributor in Korea increased by \$258,840 (64.0%) in 2015 compared with 2014. The increase in sales of the Company's personal care products was augmented by a decrease of \$189,980 in sales discounts as compared with 2014.

The increase in sales to ASI for export to China took place primarily in the first three quarters of 2015. As a result of both a regulatory issue in China unrelated to the Company's product but affecting the products in which the Company's product was being used, as well as an overstock situation in China resulting from ASI having brought into China more material than it needed for order fulfillment, there were no significant sales to ASI of product intended for China in the fourth quarter of 2015. Based on information provided to the Company by ASI, it is expected that sales of the Company's product into China is not expected to resume again until the third quarter of 2016, which will significantly impact the Company's sales to ASI in the first half of 2016.

Sales to the Company's other marketing partners in Europe declined as a result of the continuing economic problems in Europe, as well as the strong U.S. dollar relative to the Euro, which made the Company's products less competitive in Europe. There has also been more competition in the European marketplace than there had been in previous years due to other companies selling imitations of the Company's product at much lower prices, particularly a large Korean company that is manufacturing imitations of the Company's products in China. This has resulted in a loss of some customers to these competitive products.

From time to time the Company offers discounts to maintain and increase sales and bring in new customers. The additional competition coming from products manufactured in China has resulted in the Company offering deeper discounts than it has in the past, and it is likely that the Company's margins on some of its products will be lower in the future due to this increased competition.

During 2015 the Company had offered a discounted price to a significant customer of ASI in Canada for one of its LUBRAJEL products in exchange for a commitment to purchase a specific amount of product during the year. Since that customer did not attain the level of purchases on which that rebate was conditioned, ASI is obligated to return to the Company the rebate that was given to that customer, in the amount of \$88,360.

(b)

**Pharmaceuticals:**

Sales of the Company's two pharmaceutical products, RENACIDIN and CLORPACTIN, together increased by \$177,592 (10.5%) for the year ended December 31, 2015 compared with 2014, with RENACIDIN accounting for most of the increase. RENACIDIN accounted for 9.6% of the Company's sales in 2015, and 8.8% of sales in 2014. RENACIDIN had been off the market from late 2010 to May 2011, and then again from August 2012 until the end of October 2013, due to production and regulatory problems experienced by the Company's then sole supplier. RENACIDIN sales are still significantly lower than they were prior to those production curtailments, and the Company is continuing its efforts to try to recover some of the customers it lost as a result of those production curtailments and the consequent inventory shortage.

In 2013 the Company began working with a new exclusive supplier to produce RENACIDIN in a smaller, more user-friendly container. The new product is a sterile, single dose, 30 mL plastic bottle that was engineered to dispense the product directly into an indwelling catheter, eliminating the need to use a separate syringe to extract a small amount of product from the current 500mL bottle. The change to a new supplier and new packaging required a new submission to, and approval by, the United States Food and Drug Administration ("FDA"). The Company submitted its application to the FDA in August 2014 in the form of a supplement to its previous New Drug Application ("NDA") for RENACIDIN, and received final approval to market the new product in December 2015. Prior to the expiration of its previous supply agreement for the 500mL bottles the Company had purchased sufficient inventory to last until it received FDA approval for the new product. The Company expects to begin selling the new single-dose 30mL bottles in April 2016, around the same time that it will be selling off its remaining inventory of 500mL glass bottles. The Company is optimistic that this new, more user-friendly package will enable it to increase its sales of RENACIDIN over the next few years. The Company intends to actively market the new product beginning in April 2016.

The increase in sales of the Company's pharmaceutical products was partially offset by an increase of \$26,656 in allowances for distribution fees, product returns, chargebacks paid to the U.S. Department of Veterans Affairs, and rebates paid for Medicaid- and Medicare-related sales.

(c)

**Medical (non-pharmaceutical) products:**

Sales of the Company's medical products decreased by \$290,315 (11.6%) in 2015 compared with 2014. The decrease is believed to be due to the timing of orders from certain customers.

(d)

**Industrial and other products:**

Sales of the Company's industrial products, as well as other miscellaneous products, increased by \$4,875 (2.9%) in 2015 when compared with 2014.

**Cost of Sales**

Cost of sales as a percentage of net sales in 2015 decreased to 37.1% from 39.5% in the prior year. The decrease was the result of (a) an increase in sales of the Company's products in 2015 compared to 2014, which resulted in greater production efficiency due to the increased production volume, and (b) increases in the sales of some of the Company's higher margin products.

**Operating Expenses**

Operating expenses decreased by \$48,295 (2.5%) in 2015 compared with the prior year. The decrease was mainly attributed to decreases in insurance, payroll, and payroll-related expenses.

16

### **Research and Development Expenses**

Research and development expenses amounted to \$648,211 and \$730,412 for 2015 and 2014 respectively. The decrease of \$82,201 (11.3%) was primarily related to a decrease in payroll and payroll-related expenses.

### **Other Income (Expense)**

Other income (net) increased by \$67,831 (25.7%) for the year ended December 31, 2015 when compared with 2014. The increase was mainly due to an increase in investment income from both stock and bond mutual funds, as well as realized gains from the sales of some of the Company's mutual funds. The increase was partially offset by the cessation of the RENACIDIN damage settlement payments. In 2014 the Company received its last payment of \$24,402 from that settlement.

### **Provision for Income Taxes**

The provision for income taxes increased by \$313,928 (18.4%) in 2015 compared with 2014. This increase was mainly due to an increase in income from operations. The Company's effective income tax rate was approximately 30% in both 2015 and 2014, and is lower than the federal statutory rate of 34% primarily due to the additional tax deduction for domestic production activities as well as the utilization of research and development tax credits.

### **Liquidity and Capital Resources**

Working capital decreased from \$13,688,101 at December 31, 2014 to \$13,529,593 at December 31, 2015, a decrease of \$158,508 (1.2%). The current ratio decreased from 15.0 to 1 at December 31, 2014 to 14.7 to 1 at December 31, 2015. The decreases in working capital and the current ratio were mainly due to a decrease in accounts receivable.

Accounts receivable (net of allowance for doubtful accounts) as of December 31, 2015 decreased by \$658,506 compared with 2014. The receivables turnover, or Days Sales Outstanding (DSO), for 2015 was 33 days, compared with 46 days in 2014. The decrease was mainly the result of lower accounts receivables in 2015 with higher sales for the year. The Company has bad debt reserves of \$8,654 and \$29,894 for 2015 and 2014, respectively, and believes that the net balance of its accounts receivable is fully collectable as of December 31, 2015.

The Company does not maintain a line of credit with a financial institution because the Company has no foreseeable need for a line of credit, and therefore management believes that the cost of maintaining a line of credit is not justified, especially considering the strong financial condition of the Company.

The Company generated cash from operations of \$5,199,972 in 2015 compared with \$4,480,752 in 2014. The increase in 2015 was primarily due to an increase in net income and a decrease in accounts receivable.

Net cash used in investing activities was \$1,674,250 for the year ended December 31, 2015, compared with \$414,480 for the year ended December 31, 2014. This increase was mainly due to an increase in purchases of marketable securities in 2015 compared with 2014.

Cash used in financing activities was \$4,468,616 and \$3,677,151 during the years ended December 31, 2015 and 2014, respectively. The increase was mainly due to higher dividends being paid out in 2015 than were paid in 2014.

The Company believes that its working capital is sufficient to support its operating requirements for the next fiscal year. The Company's long-term liquidity position will be dependent upon its ability to generate sufficient cash flow from profitable operations. The Company has no material commitments for future capital expenditures.

### **Off Balance-Sheet Arrangements**

The Company has no off balance-sheet transactions that have, or are reasonably likely to have, a current or future effect on the Company's financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

### **Contractual Obligations and Commitments**

The information to be reported under this item is not required of smaller reporting companies.

### **New Accounting Pronouncements**

See Note "A" to the financial statements regarding new accounting pronouncements.

### **Item 7A. Quantitative and Qualitative Disclosures about Market Risk.**

The information to be reported under this item is not required of smaller reporting companies.

### **Item 8. Financial Statements and Supplementary Data.**

Annexed hereto starting on page F-1.

### **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

None.

**Item 9A. Controls and Procedures.**

(a) **Evaluation of Disclosure Controls and Procedures**

The Company's management, with the participation of the Company's Principal Executive Officer and Principal Financial Officer, has evaluated the design, operation, and effectiveness of the Company's disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act as of December 31, 2015. On the basis of that evaluation, management concluded that the Company's disclosure controls and procedures are designed to be, and are, effective at providing reasonable assurance that the information required to be disclosed in reports filed or submitted pursuant to the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to management, including its Principal Executive Officer and Principal Financial Officer as appropriate, to allow timely decisions regarding required disclosure.

18



(b) **Management's Report on Internal Control over Financial Reporting**

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). The Company's internal control system is designed to provide reasonable assurance to management and to the Company's Board of Directors regarding the preparation and fair presentation of published financial statements. Under the supervision and with the participation of management, including the Company's Principal Executive Officer and Principal Financial Officer, management conducted an evaluation of the effectiveness of the Company's internal control over financial reporting based on the framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO 2013). Based on management's evaluation under the framework in Internal Control—Integrated Framework, management concluded that the Company's internal control over financial reporting was effective as of December 31, 2015.

This Annual Report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Since the Company is a non-accelerated filer, management's report is not subject to attestation by the Company's registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002. As a result, this Annual Report contains only management's report on internal controls.

(c) **Changes in Internal Control over Financial Reporting**

There were no changes in the Company's internal control over financial reporting that occurred in the fourth quarter of 2015 that materially affected, or would be reasonably likely to materially affect, the Company's internal control over financial reporting.

(d) **Limitations of the Effectiveness of Internal Controls**

The effectiveness of the Company's system of disclosure controls and procedures and internal control over financial reporting is subject to certain limitations, including the exercise of judgment in designing, implementing and evaluating the control system, the assumptions used in identifying the likelihood of future events, and the inability to eliminate fraud and misconduct completely. As a result, there can be no assurance that the Company's disclosure controls and procedures and internal control over financial reporting will detect all errors or fraud. However, the Company's control systems have been designed to provide reasonable assurance of achieving their objectives, and the Company's Principal Executive Officer and Principal Financial Officer have concluded that the Company's disclosure controls and procedures and internal control over financial reporting are effective at the reasonable assurance level.

**Item 9B. Other Information.**

None.

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance.**

The information required by this item is incorporated by reference to the section entitled “Directors and Executive Officers” to be contained in the Company’s 2016 Proxy Statement.

19

### **Code of Ethics**

The Company has adopted a Code of Business Conduct and Ethics that applies to all officers, directors, and employees serving in any capacity to the Company, including the Chief Executive Officer and/or President, Chief Financial Officer, and Principal Accounting Officer. A copy of the Company's Code of Business Conduct and Ethics is available on the Company's web site at <http://www.u-g.com/corporate>. The Company intends to satisfy the disclosure requirement under Item 5.05 of Form 8-K relating to amendments to or waivers from any provision of its Code of Business Conduct and Ethics applicable to the Chief Executive Officer, Chief Financial Officer and Principal Accounting Officer by posting this information on the Company's web site.

### **Item 11. Executive Compensation.**

The information required by this item is incorporated herein by reference to the section entitled "Compensation of Directors and Executive Officers" to be contained in the Company's 2016 Proxy Statement.

### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The information required by this item is incorporated by reference to the section entitled "Voting Securities and Principal Stockholders" to be contained in the Company's 2016 Proxy Statement.

### **Item 13. Certain Relationships and Related Transactions, and Director Independence.**

The information required by this item is incorporated by reference to the section entitled "Directors and Executive Officers" to be contained in the Company's 2016 Proxy Statement.

### **Item 14. Principal Accounting Fees and Services.**

### **Audit Fees**

The aggregate fees that have been, or are expected to be, billed by Baker Tilly Virchow Krause, LLP (“Baker Tilly”), the Company’s principal accountants, to the Company for the quarterly reviews and year-end audit of the Company's financial statements for 2015 and 2014, were approximately \$83,000 for each of those fiscal years (\$7,000 for each of the first three fiscal quarters and \$61,000 for the year-end audit). In addition, Baker Tilly was reimbursed up to \$1,000 for out-of-pocket expenses each fiscal year.

**Audit-Related Fees**

During 2015 and 2014 there were no fees paid to Baker Tilly in connection with the Company's compliance with Section 404 of the Sarbanes-Oxley Act of 2002.

No other fees were billed by Baker Tilly for the last two fiscal years that were reasonably related to the performance of the audit or review of the Company's financial statements and not reported under "Audit Fees" above.

**Tax Fees**

There were no fees billed by Baker Tilly during the last two fiscal years for professional services rendered for tax compliance, tax advice, or tax planning. Accordingly, none of such services were approved pursuant to pre-approval procedures or permitted waivers thereof.

**All Other Fees**

There were no other non-audit-related fees billed to the Company by Baker Tilly in 2015 or 2014.

**Pre-Approval Policies and Procedures**

Engagement of accounting services by the Company is not made pursuant to any pre-approval policies and procedures. Rather, the Company believes that its accounting firm is independent because all of its engagements by the Company are approved by the Company's Audit Committee prior to any such engagement.

The Audit Committee of the Company's Board of Directors meets periodically to review and approve the scope of the services to be provided to the Company by its Independent Registered Public Accounting Firm, as well as to review and discuss any issues that may arise during an engagement. The Audit Committee is responsible for the prior approval of every engagement of the Company's Independent Registered Public Accounting Firm to perform audit and permissible non-audit services for the Company, such as quarterly financial reviews, tax matters, and consultation on new accounting and disclosure standards.

Before the auditors are engaged to provide those services, the Chief Financial Officer and Controller will make a recommendation to the Audit Committee regarding each of the services to be performed, including the fees to be charged for such services. At the request of the Audit Committee, the Independent Registered Public Accounting Firm and/or management shall periodically report to the Audit Committee regarding the extent of services being provided by the Independent Registered Public Accounting Firm, and the fees for the services performed to date.

**Item 15. Exhibits, Financial Statement Schedules.**

(a) Documents filed as part of this report.

(i) Financial Statements - see Item 8. Financial Statements and Supplementary Data.

(ii) Financial Statement Schedules – None.

(Financial statement schedules have been omitted either because they are not applicable, not required, or the information required to be set forth therein is included in the financial statements or notes thereto.)

(iii) Report of Independent Registered Public Accounting Firm.

(iv) Notes to Financial Statements.

(b) Exhibits

The exhibits listed on the accompanying Exhibit Index are filed as part of this Annual Report.

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.

UNITED-GUARDIAN,  
INC.

By: /s/ Kenneth H. Globus  
Kenneth H. Globus

Date: March 23, 2016 President and Director

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.

Signature	Title	Date
By: /s/ Kenneth H. Globus Kenneth H. Globus	President, General Counsel, Chairman of the Board of Directors (Principal Executive Officer)	March 23, 2016
By: /s/ Robert S. Rubinger Robert S. Rubinger	Executive Vice President, Secretary, Chief Financial Officer, Director (Principal Financial Officer and Principal Accounting Officer)	March 23, 2016
By: /s/ Lawrence F. Maietta Lawrence F. Maietta	Director	March 23, 2016
By: /s/ Arthur M. Dresner Arthur M. Dresner	Director	March 23, 2016
By: /s/ Andrew A. Boccone Andrew A. Boccone	Director	March 23, 2016





EXHIBIT INDEX

Exhibit #    Description

- 2                    Certificate of Merger of United-Guardian, Inc. (New York) with and into United-Guardian, Inc. (Delaware) as filed with the Secretary of State of the State of Delaware on September 10, 1987. Incorporated by reference to Exhibit 3(b) of the Registrant's Annual Report on Form 10-K for the fiscal year ended February 29, 1988 (the "1988 10-K").
- 3    (a)                Certificate of Incorporation of the Company as filed April 22, 1987. Incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, dated September 21, 1987 (the "1987 8-K").
- 3    (b)                By-laws of the Company. Incorporated by reference to Exhibit 4.2 to the 1987 8-K.
- 4    (a)                Specimen Certificate for shares of Common Stock of the Company. Incorporated by reference to Exhibit 4(a) to the 1988 10-K.
- 10   (a)                Qualified Retirement Income Plan for Employees of the Company, as restated April 1, 1976. Incorporated by reference to Exhibit 11(c) of the Registrant's Registration Statement on Form S-1 (Registration No. 2-63114) declared effective February 9, 1979.
- 10   (b)                Exclusive Distributor Agreement between the Company and ISP Technologies Inc., dated July 5, 2000. Incorporated by reference to Exhibit 10(d) of the Registrant's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2000.
- 10   (c)                Letter Amendment between the Company and ISP Technologies Inc. dated December 16, 2002 amending the Exclusive Distributor Agreement between the Registrant and ISP Technologies Inc. dated July 5, 2000. Incorporated by reference to Exhibit 10(d) to the Registrant's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002.
- 10   (d)                Letter Amendment between the Company and ISP Technologies Inc. dated December 20, 2005 amending the Exclusive Distributor Agreement between the Registrant and ISP Technologies Inc. dated July 5, 2000 and amended on December 31, 2002. Incorporated by reference to Exhibit 10(d) of the Registrant's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2005.
- 10   (e)                Letter Amendment between the Company and ISP Technologies Inc. dated May 5, 2010 amending the Exclusive Distributor Agreement

between the Company and ISP Technologies Inc. dated July 5, 2000 and amended on December 16, 2002 and December 20, 2005. Incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2010.

10 (f) Manufacturing and Supply Agreement between the Company and Smiths Medical ASD, Inc. signed November 12, 2013 and effective as of November 1, 2013. Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K dated and filed November 18, 2013.

21 Subsidiaries of the Company:

<u>Name</u>	<u>Jurisdiction of Name Under Which Incorporation</u>	<u>it does Business</u>
-------------	---	-------------------------

Dieselite Corporation (Inactive)	Delaware	N/A
----------------------------------	----------	-----

31.1 Certification of Kenneth H. Globus, President and Principal Executive Officer of the Company, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2 Certification of Robert S. Rubinger, Chief Financial Officer of the Company, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32 Certifications of Kenneth H. Globus, President and Principal Executive Officer of the Company, and Robert S. Rubinger, Chief Financial Officer of the Company, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

23

INDEX TO FINANCIAL STATEMENTS

(For the years ended  
December 31, 2015 and 2014)

	<u>Page</u>
<u>Report of Independent Registered Public Accounting Firm</u>	<u>F-2</u>
Financial Statements	
<u>Statements of Income</u>	<u>F-3</u>
<u>Statements of Comprehensive Income</u>	<u>F-3</u>
<u>Balance Sheets</u>	<u>F-4 - F-5</u>
<u>Statement of Stockholders' Equity</u>	<u>F-6</u>
<u>Statements of Cash Flows</u>	<u>F-7</u>
<u>Notes to Financial Statements</u>	<u>F-8 - F-19</u>

F-1

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Stockholders

United-Guardian, Inc.

Hauppauge, New York

We have audited the accompanying balance sheets of United-Guardian, Inc. (the "Company") as of December 31, 2015 and 2014, and the related statements of income, comprehensive income, stockholders' equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these 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 audit 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 audits 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 also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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 financial statements referred to above present fairly, in all material respects, the financial position of United-Guardian, Inc. as of December 31, 2015 and 2014, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Baker Tilly Virchow Krause, LLP

Melville, New York

March 23, 2016

F-2

**STATEMENTS OF INCOME**

	Years ended December 31,	
	2015	2014
Net sales	\$14,006,244	\$13,449,679
Costs and expenses:		
Cost of sales	5,202,158	5,317,707
Operating expenses	1,862,290	1,910,585
Research and development	648,211	730,412
Total costs and expenses	7,712,659	7,958,704
Income from operations	6,293,585	5,490,975
Other income:		
Investment income	332,705	239,592
Loss from sale of asset	(879 )	---
Income from damage settlement	---	24,403
Total other income	331,826	263,995
<b>Income from operations before income taxes</b>	<b>6,625,411</b>	<b>5,754,970</b>
Provision for income taxes	2,018,482	1,704,554
Net income	\$4,606,929	\$4,050,416
Earnings per common share (basic and diluted)	\$1.00	\$.88
Weighted average shares (basic and diluted)	4,594,319	4,596,439

**STATEMENTS OF COMPREHENSIVE INCOME**

	Years ended December	
	31,	
	2015	2014
Net income	\$4,606,929	\$4,050,416
Other comprehensive income (loss):		
Unrealized (loss) gain on marketable securities	(284,103 )	191,533
Income tax benefit (expense)	96,595	(63,787 )
Other comprehensive (loss) income, net of tax	(187,508 )	127,746

Comprehensive income	\$4,419,421	\$4,178,162
----------------------	-------------	-------------

See Notes to Financial Statements

F-3

**BALANCE SHEETS****ASSETS**

	December 31,	
	2015	2014
Current assets:		
Cash and cash equivalents	\$1,080,489	\$2,023,383
Marketable securities	10,719,470	9,389,501
Accounts receivable, net of allowance for doubtful accounts of \$8,654 in 2015 and \$29,894 in 2014		
	934,754	1,593,260
Inventories (net)	1,293,642	1,237,154
Prepaid expenses and other current assets	160,533	165,691
Prepaid income taxes	95,767	30,643
Deferred income taxes	233,305	223,439
Total current assets	14,517,960	14,663,071
Property, plant, and equipment:		
Land	69,000	69,000
Factory equipment and fixtures	4,175,940	4,138,875
Building and improvements	2,776,602	2,773,002
Total property, plant and equipment	7,021,542	6,980,877
Less accumulated depreciation	5,925,429	5,772,974
Net property, plant, and equipment	1,096,113	1,207,903
Other assets:	74,118	68,042
Total assets	\$15,688,191	\$15,939,016

See Notes to Financial Statements

F-4



**BALANCE SHEETS****LIABILITIES AND STOCKHOLDERS' EQUITY**

	December 31,	
	2015	2014
Current liabilities:		
Accounts payable	\$96,815	\$141,111
Accrued expenses	785,623	833,859
Dividends payable	105,929	---
Total current liabilities	988,367	974,970
Deferred income taxes	118,010	227,108
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$.10 par value; 10,000,000 shares authorized; 4,594,319 and 4,596,439 shares issued and outstanding at December 31, 2015 and 2014, respectively	459,432	459,644
Accumulated other comprehensive income	72,361	259,869
Retained earnings	14,017,637	14,017,425
Total stockholders' equity	14,581,814	14,736,938
Total liabilities and stockholders' equity	\$15,688,191	\$15,939,016

See Notes to Financial Statements

F-5

**STATEMENT OF STOCKHOLDERS' EQUITY**

Years ended December 31, 2015 and 2014

	Common stock		Accumulated other comprehensive income	Retained earnings	Total
	Shares	Amount			
Balance, January 1, 2014	4,596,439	\$ 459,644	\$ 132,123	\$ 13,644,160	\$ 14,235,927
Change in unrealized gains on marketable securities, net of deferred income tax expense of \$63,787			127,746		127,746
Net income				4,050,416	4,050,416
Dividends declared and paid				(3,677,151 )	(3,677,151 )
Balance, December 31, 2014	4,596,439	459,644	259,869	14,017,425	14,736,938
Change in unrealized gains on marketable securities, net of deferred income tax benefit of \$96,595			(187,508 )		(187,508 )
Net income				4,606,929	4,606,929
Shares surrendered	(2,120 )	(212 )		212	---
Reimbursement of overpaid prior year dividends				21,894	21,894
Dividends declared, not paid				(6,975 )	(6,975 )
Dividends declared and paid				(4,589,464 )	(4,589,464 )
Balance, December 31, 2015	4,594,319	\$ 459,432	\$ 72,361	\$ 14,050,021	\$ 14,581,814

See Notes to Financial Statements

**STATEMENTS OF CASH FLOWS**

	Years ended December 31,	
	2015	2014
Cash flows from operating activities:		
Net income	\$4,606,929	\$4,050,416
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	173,484	181,188
Realized (gain) loss on sales of marketable securities	(2,395 )	25,127
Realized loss on sale of asset	879	---
(Decrease) increase in allowance for bad debts	(21,240 )	12,325
Deferred income taxes	(22,369 )	(254 )
Increase (decrease) in cash resulting from changes in operating assets and liabilities:		
Accounts receivable	679,746	185,162
Receivable from damage settlement	---	48,805
Inventories	(56,488 )	373,593
Prepaid expenses and other current and non-current assets	(918 )	(94,585 )
Prepaid income taxes	(65,124 )	(30,643 )
Accounts payable	(44,296 )	(244,588 )
Accrued expenses and taxes payable	(48,236 )	(25,794 )
Net cash provided by operating activities	5,199,972	4,480,752
Cash flows from investing activities:		
Acquisitions of plant and equipment	(62,573 )	(54,590 )
Purchases of marketable securities	(5,556,065 )	(3,437,478 )
Proceeds from sales of marketable securities	3,944,388	3,077,588
Net cash used in investing activities	(1,674,250 )	(414,480 )
Cash flows from financing activities:		
Dividends received on unconverted shares	120,848	---
Dividends paid	(4,589,464 )	(3,677,151 )
Net cash used in financing activities	(4,468,616 )	(3,677,151 )
Net (decrease) increase in cash and cash equivalents	(942,894 )	389,121
Cash and cash equivalents, beginning of year	2,023,383	1,634,262
Cash and cash equivalents, end of year	\$1,080,489	\$2,023,383

See Notes to Financial Statements

## NOTES TO FINANCIAL STATEMENTS

### NOTE A - NATURE OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### Nature of Business

United-Guardian, Inc. (the "Company") is a Delaware corporation that, through its Guardian Laboratories Division, manufactures and markets cosmetic ingredients, personal care products, pharmaceuticals, medical lubricants, health care products, and specialty industrial products. It also conducts research and product development, primarily related to the development of new and unique cosmetic and personal care products. The Company's research and development department also modifies, refines, and expands the uses for existing products, with the goal of further developing the market for the Company's products. Two major product lines, LUBRAJEL<sup>®</sup> and RENACIDIN<sup>®</sup> IRRIGATION ("RENACIDIN") together accounted for 94.9% and 94.6% of revenue for the years ended December 31, 2015 and December 31, 2014, respectively. LUBRAJEL accounted for 85.3% and 85.9% of revenue for the years ended December 31, 2015 and December 31, 2014, respectively, and RENACIDIN accounted for 9.6% and 8.8% of revenue for the years ended December 31, 2015 and December 31, 2014, respectively.

#### Accounts Receivable and Reserves

The carrying amount of accounts receivable is reduced by a valuation allowance that reflects our best estimate of the amounts that will not be collected. The reserve for accounts receivable comprises the allowance for doubtful accounts and sales returns. In addition to reviewing delinquent accounts receivable, we consider many factors in estimating our reserve, including historical data, experience, customer types and credit worthiness, and economic trends. From time to time, we adjust our assumptions for anticipated changes in any of these or other factors expected to affect collectability.

#### Revenue Recognition

The Company recognizes revenue when products are shipped, title and risk of loss pass to customers, persuasive evidence of a sales arrangement exists, and collections are reasonably assured. All products are shipped Ex Works ("EXW") Hauppauge, New York, the location of the Company's plant. Both title and risk of loss are deemed by both the Company and its customers to have passed to the customers at the time the goods leave the Company's plant. Shipments are only made after confirmation that a valid purchase order has been received and that the future collection of the sale amount is reasonably assured. All sales of the Company's products are deemed final, and there is

no obligation on the part of the Company to repurchase or allow the return of the goods unless they are defective. The Company does not make sales on consignment, and the collection of the proceeds of the sale is not contingent upon the customer being able to sell the goods to a third party.

Any allowance for returns is taken as a reduction of sales within the same period the revenue is recognized. Such allowances are based on historical experience. The Company has not experienced significant fluctuations between estimated allowances and actual activity.

During 2015 the Company had offered a discounted price to a significant customer of ASI in Canada for one of its LUBRAJEL products in exchange for a commitment to purchase a specific amount of product during the year. Since that customer did not attain the level of purchases required for that rebate, ASI is obligated to return to the Company the rebate that was given to that customer, in the amount of \$88,360.

### **Cash and Cash Equivalents**

For financial statement purposes, the Company considers as cash equivalents all highly liquid investments with an original maturity of three months or less at inception. The Company deposits cash and cash equivalents with high credit quality financial institutions and believes that any amounts in excess of insurance limitations to be at minimal risk. Cash and cash equivalents held in these accounts are currently insured by the Federal Deposit Insurance Corporation up to a maximum of \$250,000.

### **Dividends**

On May 13, 2015, the Company's Board of Directors declared a semi-annual cash dividend of \$0.50 per share, which was paid on June 15, 2015 to all stockholders of record as of June 1, 2015. On November 18, 2015, the Company's Board of Directors declared a semi-annual cash dividend of \$0.50 per share, which was paid on December 15, 2015 to all stockholders of record as of December 1, 2015. In 2015 the Company declared a total of \$4,596,439 in dividends, of which \$4,589,464 was paid. The balance of \$6,975 is payable to stockholders who could not be located at the time the dividend was paid, and is being held by the Company for possible future payment.

On May 14, 2014, the Company's Board of Directors declared a semi-annual cash dividend of \$0.48 per share, which was paid on June 13, 2014 to all stockholders of record as of May 30, 2014. On November 20, 2014, the Company's Board of Directors declared a semi-annual cash dividend of \$0.32 per share, which was paid on December 22, 2014 to all stockholders of record as of December 8, 2014. Total dividends declared and paid in 2014 were \$3,677,151.

### **Supplemental Disclosures of Non-cash Investing and Financing Activities**

Cash payments for income taxes were \$2,125,000 and \$1,867,089 for the years ended December 31, 2015 and 2014, respectively.

The Company has a number of unconverted shares of one of its previous corporate entities, Guardian Chemical Corporation ("Guardian"), that would convert to approximately 11,106 shares of United-Guardian, Inc. common stock if all of the remaining holders of those Guardian shares converted their Guardian stock to United-Guardian stock. Since the early 1990's, the Company has been paying accumulated dividends directly to those shareholders as those shares were converted, while at the same time its transfer agent was holding duplicate funds to cover those same payments (as well as future payments for Guardian shares that had not yet been converted). In September 2015 it was agreed that those duplicate funds would be returned to the Company, and the Company recorded a receivable from the

transfer agent in the amount of \$120,848. Of that amount, \$21,894 was added to retained earnings to account for the amount that had been previously exchanged and paid, and the balance of \$98,954 will continue to be accounted for as a potential liability in the event that one or more of the holders of that Guardian stock can be located and request conversion of their Guardian shares, in which case the accumulated dividends will be paid to them and the liability reduced accordingly. Payment of the amount owed to the Company by its transfer agent was received in October 2015. The Company is presently researching its options in regard to the distribution of the funds it is continuing to hold, in the event the remaining holders of Guardian stock cannot be located. The Company will continue to accumulate a dividend payable on the above shares as dividends are paid. The Company accrued an additional \$6,975 dividend payable on the dividend paid December 15, 2015.

### **Marketable Securities**

Marketable securities include investments in equity and fixed income mutual funds, and government securities, all of which have a high degree of liquidity, are classified as "Available for Sale" securities, and are reported at their fair values. Unrealized gains and losses on "Available for Sale" securities are reported as accumulated other comprehensive income (loss) in stockholders' equity, net of the related tax effects. Investment income is recognized when earned. Realized gains and losses on sales of investments and declines in value judged to be other than temporary, if any, are reported in other income with cost being determined on a specific identification basis. Fair values are based on quoted market prices. The Company evaluates its investments periodically for possible impairment and reviews factors such as the length of time and extent to which fair value has been below cost basis and the Company's ability and intent to hold the investment for a period of time which may be sufficient for anticipated recovery in market value.

**Inventories**

Inventories are valued at the lower of cost or current market value. Cost is determined using the average cost method, which approximates cost determined by the first-in, first-out (“FIFO”) method. Inventory costs include material, labor and factory overhead.

**Property, Plant and Equipment**

Property, plant and equipment are carried at cost, less accumulated depreciation. Major replacements and betterments are capitalized, while routine maintenance and repairs are expensed as incurred. Assets are depreciated under both accelerated and straight-line methods. Depreciation charged to income as a result of using accelerated methods was not materially different than that which would result from using the straight-line method for all periods presented. Certain factory equipment and fixtures are constructed by the Company using purchased materials and in-house labor. Such assets are capitalized and depreciated on a basis consistent with the Company's purchased fixed assets.

Estimated useful lives are as follows:

Factory equipment and fixtures (in years)	5-7
Building (in years)	40
Building improvements (in years)	Lesser of useful life or 20 years

**Impairment of Long-Lived Assets**

Long-lived assets and certain identifiable intangibles are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. No impairments were necessary at December 31, 2015 and 2014.

**Other Assets**



Other assets at December 31, 2015 consisted of \$74,118 expended in connection with the development of a new dosage form and manufacturing process for RENACIDIN. The Company will determine the appropriate amortization rate for these assets at such time as they are put into service.

F-10

### **Fair Value of Financial Instruments**

Management of the Company believes that the fair value of financial instruments, consisting of cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximates their carrying value due to their short payment terms and liquid nature.

### **Concentration of Credit Risk**

Accounts receivable potentially exposes the Company to concentrations of credit risk. The Company monitors the amount of credit it allows each of its customers, using the customer's prior payment history to determine how much credit to allow or whether any credit should be given at all. It is the Company's policy to discontinue shipments to any customer that is substantially past due on its payments. The Company sometimes requires payment in advance from customers whose payment record is questionable. As a result of its monitoring of the outstanding credit allowed for each customer, as well as the fact that the majority of the Company's sales are to customers whose satisfactory credit and payment record has been established over a long period of time, the Company believes that its accounts receivable credit risk has been reduced.

For the year ended December 31, 2015, two of the Company's distributors and marketing partners accounted for 65.9% of the Company's revenues during the year, and 19.7% of its outstanding accounts receivable at year end. For the year ended December 31, 2014, two of the Company's distributors and marketing partners, one the same as in 2015, accounted for a total of 64.7% of the Company's revenues during the year, and 56.3% of its outstanding accounts receivable at year end.

### **Vendor Concentration**

The principal raw materials used by the Company consist of common industrial organic and inorganic chemicals. Most of these materials are available in ample supply from numerous sources. The Company has five major raw material vendors that collectively accounted for approximately 89% and 84% of the raw material purchases by the Company in 2015 and 2014, respectively.

### **Income Taxes**

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to the temporary differences between the financial statement carrying amounts of assets and liabilities and their respective tax bases and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that includes the enactment date. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Uncertain tax positions are accounted for utilizing a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. As of December 31, 2015 and 2014, the Company did not have any unrecognized income tax benefits. It is the Company's policy to recognize interest and penalties related to taxes as interest expense as incurred. During the years ended December 31, 2015 and 2014 the Company did not record any interest or penalties. The Company's tax returns are subject to examination by the United States Internal Revenue Service and by the State of New York for years 2012 through 2015. In March 2014 the New York State Department of Taxation and Finance ("DTF") commenced a routine examination of the Company's income tax returns for years 2010 through 2012. The DTF has completed its examination and has accepted the tax returns as filed.

### **Research and Development**

Research and development expenses are expenditures incurred in connection with in-house research on new and existing products. It includes payroll and payroll related expenses, outside laboratory expenditures, lab supplies, and equipment depreciation.

### **Shipping and Handling Expenses**

Shipping and handling costs are classified in operating expenses in the accompanying statements of income. Shipping and handling costs were approximately \$94,000 and \$86,000 for the years ended December 31, 2015 and 2014, respectively.

### **Advertising Expenses**

Advertising expenses are expensed as incurred. During 2015 and 2014 the Company incurred approximately \$18,000 and \$20,000, respectively, in advertising expenses.

### **Stock-Based Compensation**

In 2004, the Company approved a stock option plan ("2004 Stock Option Plan") authorizing the granting of stock options to Company employees and Directors. No options were ever issued under this plan, and it expired in March 2014.

### **Earnings Per Share Information**

Basic earnings per share are computed by dividing net income by the weighted average number of common shares outstanding during the year. Diluted earnings per share include the dilutive effect of outstanding stock options.

### **Use of Estimates**

In preparing financial statements in conformity with U.S. generally accepted accounting principles, management is required to 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 revenues and expenses during the reporting period. Actual results could differ from those estimates. Such estimated items include the allowance for bad debts, possible impairment of marketable securities, reserve for inventory obsolescence, and the allocation of overhead.

### **New Accounting Standards**

On February 25, 2016, the Financial Accounting Standards Board (FASB) issued ASU 2016-2, "Leases" (Topic 842), which is intended to improve financial reporting for lease transactions. This ASU will require organizations that lease assets, such as real estate and manufacturing equipment, to recognize on assets and liabilities on their balance sheet for the rights to use those assets for the lease term and obligations to make lease payments created by those leases that have terms of greater than 12 months. The recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as finance or operating lease. This ASU will also require disclosures to help investors and other financial statement users better understand the amount and timing of cash flows arising from leases. These disclosures will include qualitative and quantitative requirements, providing additional information about the amounts recorded in the financial statements. This ASU will be effective for public entities beginning the first quarter 2019. We do not believe that this ASU will have a material impact on our financial statements.

In November 2015, the FASB issued ASU 2015-17, "Income Taxes, Balance Sheet Classifications of Deferred Taxes." This amendment simplifies the presentation of deferred taxes by requiring that all deferred tax liabilities and assets now be recorded as noncurrent. This amendment is effective for interim and annual reporting periods beginning after December 15, 2016 with early adoption permissible. The Company will adopt this amendment in January of 2017. This amendment has no material impact on the Company's results of operation.

In August 2015, the FASB issued ASU 2015-14, "Revenue from Contracts with Customers." This amendment defers the effective date of implementation to after December 15, 2017.

In July 2015, the FASB issued ASU 2015-11, "Inventory. Simplifying the Measurement of Inventory." This amendment only applies to entities that use the first-in, first-out (FIFO) or average cost methods of valuing inventory. Entities should now measure inventory at the lower of cost and net realizable value. This amendment aligns measurement of inventory in GAAP with the International Financial Reporting Standards (IFRS). This amendment is effective for annual periods beginning after December 15, 2016 with early adoption permitted. The Company will adopt this amendment in January 2017 and is also evaluating the potential impact on the Company's results of operations.

In April 2015, the FASB issued ASU 2015-05, "Intangibles-Goodwill and other Internal Use Software: Customer's Accounting for Fees paid in Cloud Computing Arrangement." This standard gives clarification as to whether or not a cloud computing arrangement includes the sale or license of software and how to properly account for it. If the arrangement includes a software license, then account for the agreement as an acquisition of software licenses. If not, then account for the arrangement as a service contract. The amendment is effective for annual periods beginning after December 15, 2015 and interim periods in annual periods beginning after December 15, 2016. Early adoption is permitted. The Company will adopt the amendment in January 2016. This amendment is not expected to have a material impact on the Company's results of operations.

In May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers." This standard applies to any entity that uses the guidance of GAAP for entering into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets unless those contracts are within the scope of other standards. It requires that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration the entity expects to receive for the exchange of goods or services. This amendment is effective for interim and annual reporting periods beginning after December 15, 2016. The Company is still evaluating the potential impact on the Company's results of operations.

In August 2014, the FASB issued ASU 2014-15, "Presentation of Financial Statements-Going Concern. Disclosure of Uncertainties about Entity's Ability to Continue as a Going Concern." Currently, GAAP lacks guidance about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern. This amendment now provides guidance by providing a definition of substantial doubt, requires evaluation by management every reporting period for going concern issues, provides principles for considering any

mitigating effects implemented by management, and the disclosures required for the assessment period of one year after issuance of the financial statements. This update becomes effective for interim and annual reporting periods beginning after December 15, 2016 with early application being permitted. The update will be adopted for reporting periods starting January 2015, and is not expected to have a material impact on the Company's results of operations.

**NOTE B - MARKETABLE SECURITIES**

The fair values of the Company's marketable securities are determined in accordance with GAAP, with fair value being defined as the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the Company utilizes the three-tier value hierarchy, as prescribed by GAAP, which prioritizes the inputs used in measuring fair value as follows:

Level 1 - inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 - inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the financial instrument.

Level 3 – inputs to the valuation methodology are unobservable and significant to the fair value measurement.

The following available-for-sale securities, which comprise all of the Company's marketable securities, are re-measured to fair value on a recurring basis and are valued using Level 1 inputs using quoted prices (unadjusted) for identical assets in active markets:

<u>December 31, 2015</u>	Cost	Fair Value	Unrealized Gain/(Loss)
Available for sale:			
Fixed income mutual funds	\$9,968,948	\$9,900,587	\$(68,361)
Equity and other mutual funds	640,884	818,883	177,999
	\$10,609,832	\$10,719,470	\$109,638

December 31, 2014

Available for sale:			
Fixed income mutual funds	\$8,373,674	\$8,575,285	\$201,611
Equity and other mutual funds	622,086	814,216	192,130
Total Investments	\$8,995,760	\$9,389,501	\$393,741



Proceeds from the sale and redemption of marketable securities amounted to \$3,944,388 and \$3,077,588 for the years ended December 31, 2015 and 2014, respectively. Gains of \$2,395 and losses of \$25,127 were realized for the years ended December 31, 2015 and 2014, respectively.

Investment income consisted principally of unrealized and realized gains and losses, interest income from bonds and money market funds, and dividend income from bond funds and mutual funds.

F-14

**NOTE C – INVENTORIES**

Inventories consist of the following:

	December 31,	
	2015	2014
Raw materials and work-in-process	\$379,156	\$395,092
Finished products	914,486	842,062
	\$1,293,642	\$1,237,154

Finished product inventories at December 31, 2015 and 2014 are stated net of a reserve of \$20,000 for slow moving and obsolete items.

**NOTE D – INCOME TAXES**

The provision for income taxes consists of the following:

	Years ended December 31,	
	2015	2014
Current		
Federal	\$2,038,551	\$1,714,387
State	2,300	(9,579 )
	2,040,851	1,704,808
Deferred		
Federal	(22,369 )	(4,003 )
State	---	3,749
	(22,369 )	(254 )
Total provision for income taxes	\$2,018,482	\$1,704,554

The following is a reconciliation of the Company's effective income tax rate to the Federal statutory rate (dollar amounts have been rounded to the nearest thousand):

Years ended December 31,

Edgar Filing: UNITED GUARDIAN INC - Form 10-K

	2015		2014	
	(\$)	Tax rate	(\$)	Tax rate
Income taxes at statutory federal income tax rate of 34%	\$2,253,000	34.0%	\$1,957,000	34.0%
State income taxes, net of Federal benefit	1,000	---	(4,000 )	(0.1 )
Domestic Production Activities tax benefit	(193,000 )	(2.9 )	(168,000 )	(2.9 )
Nondeductible expenses	1,000	---	1,000	---
Prior year over-accrual	---	---	(56,000 )	(1.0 )
R&D credits	(30,000 )	(0.5 )	(25,000 )	(0.4 )
Other, misc.	(14,000 )	(0.2 )	---	---
Actual income tax expense	\$2,018,000	30.4%	\$1,705,000	29.6%

During 2015 and 2014, the Company realized the tax benefits of the Domestic Production Activities deduction, which amounted to approximately 9% of net income from domestic production activities in each year.

The tax effects of temporary differences which comprise the deferred tax assets and liabilities are as follows:

	Years ended December 31,	
	2015	2014
Deferred tax assets		
<u>Current</u>		
Accounts receivable	\$2,942	\$10,164
Inventories	14,421	14,037
Accrued expenses	215,942	199,238
	233,305	223,439
Deferred tax liabilities		
Non-current		
Depreciation	(80,733 )	(93,236 )
Unrealized gain on marketable securities	(37,277 )	(133,872)
	(118,010)	(227,108)
Net deferred tax asset (liability)	\$115,295	\$(3,669 )

## **NOTE E - BENEFIT PLANS**

### **Defined Contribution Plan**

The Company sponsors a 401(k) defined contribution plan ("DC Plan") that provides for a dollar-for-dollar employer matching contribution of the first 4% of each employee's pay. Employees become fully vested in employer matching contributions after one year of employment. Company 401(k) matching contributions were approximately \$102,000 and \$103,000 for each of the years ended December 31, 2015 and 2014, respectively. In 2015 and 2014 employees were able to defer up to \$18,000 and \$17,500 for each year respectively (plus \$6,000 and \$5,500 for employees over the age of 50) of their yearly pay as a pre-tax investment in the 401(k) plan, in accordance with limits set by the IRS. (The 2015 limits are the same for the year 2016, which are \$18,000 (plus an additional \$6,000 for employees over the age of 50)).

The Company also makes discretionary contributions to each employee's account based on a "pay-to-pay" safe-harbor formula that qualifies the 401(k) plan under current IRS regulations. In December 2015 and 2014 the Company's Board of Directors authorized discretionary contributions in the amount of \$175,000 per year, to be allocated among all eligible employees, for the 2015 and 2014 plan years. The 2015 contribution was paid in 2015, and the 2014 contribution was paid in 2014. Employees become vested in the discretionary contributions as follows: 20% after two years of employment, and 20% for each year of employment thereafter until the employee becomes fully vested after six years of employment.

### **Stock Option Plans**

In March 2004 the Board of Directors of the Company approved the adoption of the 2004 Stock Option Plan, which authorized the granting of stock options to both employees and Directors. The plan was ratified by the shareholders on May 19, 2004. No options were ever granted under the plan, and it expired in March 2014.

## **NOTE F - GEOGRAPHIC and OTHER INFORMATION**

The Company manufactures and markets cosmetic ingredients, personal care products, pharmaceuticals, medical lubricants, health care products, and specialty industrial products, through its Guardian Laboratories division. It also conducts research and development, primarily related to the development of new and unique cosmetic and personal care products. The Company's R&D department not only develops new products but also modifies and refines existing products, with the goal of expanding the potential markets for the Company's products. Many of the cosmetic

ingredient products manufactured by Guardian, particularly its LUBRAJEL line of water-based moisturizing and lubricating gels, are currently used by many of the major multinational personal care products companies.

The Company operates in one business segment. The Company's products are separated into four distinct product categories: personal care products (including cosmetic ingredients), pharmaceuticals, medical products, and industrial products. Each product category is marketed differently. The cosmetic ingredient/personal care products are marketed through a global network of marketing partners and distributors. These marketing partners purchase product outright from the Company and market and re-sell those products to the end users. The Company does not make any sales on consignment.

F-16

No prior regulatory approval was needed by the Company to sell any products other than its pharmaceutical products. The end users of its products may or may not need regulatory approvals, depending on the intended claims and uses of those products.

The pharmaceutical products are two urological products that are sold to end users primarily through distribution agreements with the major drug wholesalers. For these products, the Company does the marketing, and the drug wholesalers supply the product to the end users, such as hospitals and pharmacies. These products are drug products that required the Company to obtain regulatory approval before marketing.

The medical products are not pharmaceutical products. They consist primarily of medical lubricants, which are marketed by the Company directly to manufacturers that incorporate them into urologic catheters and other medical devices and products that they sell. These products are distinguished from the pharmaceutical products in that, unlike the pharmaceutical products, the Company is not required to obtain regulatory approval prior to marketing these products. Approvals are the responsibility of the company that markets the medical device. However, the Company is responsible for manufacturing these products in accordance with current Good Manufacturing Practices for medical devices.

The industrial products are also marketed by the Company directly to manufacturers, and generally do not require that the Company obtain regulatory approval. However, the manufacturers of the finished products may have to obtain such regulatory approvals before marketing these products.

The geographic information set forth in table "(b)" below is partially based on sales information provided to the Company by Customer A (shown in table "(c)" below), which exclusively markets the Company's cosmetic ingredients in Canada and China, and also sells some of the Company's products into France on a non-exclusive basis along with Customer B.

(a)	<u>Net Sales</u>	
	Years ended December 31,	
	2015	2014
Personal Care	\$9,922,130	\$9,421,041
Medical	2,203,890	2,494,205
Pharmaceutical	1,864,155	1,686,563
Industrial and other	174,361	169,486
	14,164,536	13,771,295
Less: Discounts and allowances	(158,292 )	(321,616 )

\$14,006,244 \$13,449,679

**(b) Geographic Information**

	Years ended December 31,			
	2015		2014	
	Revenues	Long-Lived Assets	Revenues	Long-Lived Assets
United States	\$6,565,790	\$1,096,113	\$4,723,779	\$1,207,903
China	4,193,631	---	3,500,955	---
Canada	60,117	---	2,436,596	---
Other countries	3,186,706	---	2,788,349	---
	\$14,006,244	\$1,096,113	\$13,449,679	\$1,207,903

(c) **Sales to Major Customers**

	Years ended December 31,	
	2015	2014
Customer A	\$8,463,691	\$7,929,208
All other customers	5,542,553	5,520,471
	\$14,006,244	\$13,449,679

**NOTE G – COMPREHENSIVE INCOME**

Accumulated other comprehensive income comprises unrealized gains and losses on marketable securities net of the related tax effect.

	December 31, 2015	December 31, 2014
Changes in Accumulated Other Comprehensive Income		
Beginning balance - net of tax	\$259,869	\$132,123
Unrealized (loss)/gain on marketable securities before reclassifications - net of tax	(189,903)	152,873
Realized gain/(loss) on sale of securities reclassified from accumulated other comprehensive income	2,395	(25,127)
Ending balance - net of tax	\$72,361	\$259,869

**NOTE H - INCOME FROM DAMAGE SETTLEMENT**

In May 2012 the Company's supplier of RENACIDIN curtailed production due to manufacturing issues. As a result of that curtailment, the Company and its supplier entered into a settlement agreement whereby the supplier reimbursed the company for its lost profits during the curtailment period. The final payment to the Company pursuant to that settlement agreement, in the amount \$24,402, was made in the first quarter of 2014.



**NOTE I - ACCRUED EXPENSES**

Accrued expenses at December 31, 2015 and 2014 consist of:

	2015	2014
Bonuses	\$250,000	\$225,000
Distribution fees	206,977	203,483
Payroll and related expenses	109,451	127,585
Annual report expenses	66,000	61,000
Audit fee	82,000	82,000
Sales rebates	---	96,000
Other	71,195	38,791
	\$785,623	\$833,859

**NOTE J - RELATED PARTY TRANSACTIONS**

During each of the years ended December 31, 2015 and 2014 the Company paid to Bonamassa, Maietta, and Cartelli, LLP, \$13,000, and \$17,000, respectively, for accounting and tax services. Lawrence Maietta, a partner in Bonamassa, Maietta, and Cartelli, LLP, is a director of the Company.