

UNITED GUARDIAN INC  
Form 10-K  
March 21, 2019

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, 2018

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 11-1719724  
(State or other jurisdiction (I.R.S. Employer  
of incorporation or organization) Identification No.)

230 Marcus Blvd., Hauppauge, NY 11788  
(Address of principal executive offices) (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 every Interactive Data file required to be submitted 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 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, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company  
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Edgar Filing: UNITED GUARDIAN INC - Form 10-K

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 29, 2018, 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 \$ 61,483,641. (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, 2019, 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 2019 annual meeting of stockholders ("2019 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

UNITED-GUARDIAN, INC.

This Annual Report on Form 10-K ("Annual Report") 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", "Registrant", or "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 67% of the Company's sales in 2018, and RENACIDIN® IRRIGATION SOLUTION ("RENACIDIN"), a pharmaceutical product that accounted for approximately 27% of the Company's sales in 2018. All references in this Annual Report to "sales" or "Sales" shall mean Gross Sales.

UNITED-GUARDIAN, INC.

(b) **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. ASI manufactures and markets globally an extensive line of personal care and pharmaceutical additives and various other specialty products. The Company's personal care products are sold directly to those marketing partners, which in turn resell those products to their customers for use in the formulation of one or more of the customers' personal care and cosmetic products. The Company's non-pharmaceutical medical products (referred to hereinafter as "medical products") and its specialty industrial products are sold directly by the Company to marketers of finished products or to the contract manufacturers utilized by those marketers. The Company's pharmaceutical products are marketed primarily through its dedicated RENACIDIN web site and by online promotion, 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 with comparable regulatory agencies in some foreign countries.

**PRODUCTS**

As stated above, 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 2018 was LUBRAJEL OIL, followed by LUBRAJEL PF (also sold under the trade name “Norgel”). Some other formulations of LUBRAJEL that are sold for cosmetic use (all using the LUBRAJEL name), in descending order of sales, are CG, MS, DV, and NP. In addition, many of these products are available in equivalent 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 and DV Free), indicating that those formulations are free of parabens.



UNITED-GUARDIAN, INC.

**LUBRAJEL PF** is different from the other products in the LUBRAJEL line in that it is a completely preservative-free form of LUBRAJEL. Tests have shown that this product self-preserved, and that it aids in the preservation of other cosmetic ingredients with which it is formulated. 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. Purchases of this product by the company's largest marketing partner, ASI, for distribution in China, increased significantly in 2018 compared with 2017.

**LUBRAJEL NATURAL** was the first product in a 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. Ecocert, one of the global organizations authorized to certify natural and organic products, has certified that LUBRAJEL NATURAL complies with the Cosmetic Organic and Natural Standard (“COSMOS”), indicating that the product is suitable for use in natural and organic cosmetic products. This product is now being actively marketed, but sales in 2018 decreased slightly from 2017.

**LUBRASIL™** is a special formulation of LUBRAJEL in which silicone oil is incorporated into a LUBRAJEL base by microemulsification, thereby maintaining much of the clarity of regular LUBRAJEL. The product has a silky feel, and is water resistant while at the same time providing moisturization. The current LUBRASIL formulation is known as LUBRASIL II SB, which contains substantially higher levels of silicone than the original LUBRASIL formulation.

**LUBRAJEL MARINE™**: This is the second product that the Company developed for its new line of products that use only “natural” ingredients. It was formulated using naturally-derived polysaccharides, with some of the ingredients sourced from marine vegetation. This product was developed jointly with ASI, and for that reason is being marketed globally on an exclusive basis by ASI. Like the original LUBRAJEL NATURAL, this product has received COSMOS certification for use in natural and organic cosmetic products. This product is being actively marketed by ASI, and the Company has begun to receive orders for it as companies begin to bring their formulations to market. The Company is hopeful that it will see steady growth in sales of this product during the coming years.

Total sales of the Company's personal care products increased by \$661,260 (approximately 10%) for the year ended December 31, 2018 when compared with 2017, primarily due to the increase in sales of LUBRAJEL PF to ASI for distribution in China and sales of LUBRASIL II SB to ASI for sale to a new customer in Vietnam that started purchasing the product in 2018. LUBRAJEL personal care products represented 52% of the Company's sales in 2018.



UNITED-GUARDIAN, INC.

Each of the following products accounted for less than 2% of the Company's sales in 2018, 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. There is also a paraben-free version of this product known as LUBRAJEL II XD Free. Sales of Lubrajel II XD and Lubrajel II XD Free increased by 69.9% in 2018 primarily due to ASI sales to new customers.

**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.

**LUBRASLIDE™** and a related product, B-122™, are powdered lubricants used in the manufacture of cosmetics such as pressed powders, eyeliners, and rouges. The products act as binders, increasing water-repellency and drop strength and lowering the coefficient of friction in the products in which they are used. There are also some industrial applications for these products.

**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 primary customers for the product.

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 manufacturers of some lower-cost competitors to LUBRAJEL that have negatively impacted the sales of the Company's personal care ingredients. In particular, the Company has experienced significant pricing pressure from competitive products being marketed in China by some Asian manufacturers. These lower-cost competitive products are likely to continue to negatively impact the Company's profit margins on some of its products in certain geographic areas.

The Company believes that there is still potential to expand the sales of its LUBRAJEL line of products through new product development, modifications to make some of its current products more competitive, 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 copies of its products, but that it will still be necessary to be more competitive with its product pricing in certain geographic areas in order to maintain and grow its market share.

## **MEDICAL**

**LUBRAJEL RR** and **RC** are both water-based gels used primarily as lubricants for urinary catheters. They 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 as a lower-cost alternative to the LUBRAJEL RR for those customers who are in more cost-sensitive markets. Sales of LUBRAJEL RR were down by approximately 10% in 2018 compared with 2017 due to one of the customers for that product replacing LUBRAJEL RR with a different LUBRAJEL. Sales of LUBRAJEL RC were down by 21% for the year due to changes in the purchasing pattern of the primary customer for this product. The combined sales of both products accounted for approximately 9% of the Company's sales in 2018.

UNITED-GUARDIAN, INC.

**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 increased by approximately 6% in 2018 compared with 2017, which the Company believes was the result of fluctuations in the buying patterns of customers for this product. Sales of this product represented approximately 5% of the Company's sales in 2018.

**LUBRAJEL LC, LUBRAJEL FA, and LUBRAJEL BA** are LUBRAJEL formulations that were developed for use in oral care applications. Combined sales for these products increased by \$39,263 (approximately 41%) compared with 2017 due primarily to sales to a new customer for LUBRAJEL BA. The combined sales of LUBRAJEL LC, LUBRAJEL FA and LUBRAJEL BA accounted for approximately \$135,000 (approximately 1%) of Company sales in both 2018 and 2017.

**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 in limited use, as a replacement for silicone oils in pre-lubricated condoms. The Company has only one customer for this product, and sales of this product did not contribute significantly to the Company's overall sales.

Sales of all of the medical grades of LUBRAJEL decreased by approximately 6% in 2018 compared with 2017 and accounted for approximately 15% of the Company's sales in 2018 compared with approximately 18% in 2017. The Company believes that the decrease was due primarily to fluctuations in the purchasing patterns of its customers. The medical products also became a smaller percentage of total Company sales due to increased sales of the Company's personal care and pharmaceutical products relative to the medical products.

## **PHARMACEUTICAL**

**RENACIDIN®** is a prescription drug product that is used primarily to prevent and to dissolve calcifications in urethral catheters and in the urinary bladder. It is currently marketed in a plastic 30 mL single-dose bottle. Sales of RENACIDIN increased by approximately 15% in 2018 compared with 2017 and represented approximately 27% of total Company sales.

**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 2018, sales increased by approximately 3% and

represented approximately 4% of the Company's sales. The Company believes that the increase was due to normal year-to-year fluctuations rather than any significant trend in sales.

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

UNITED-GUARDIAN, INC.

## **INDUSTRIAL**

**DESELEX™** 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. Sales of this product increased by \$3,214 (approximately 4%) from \$71,767 in 2017 to \$74,981 in 2018.

**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 \$3,067 (approximately 4%) from \$72,807 in 2017 to \$69,740 in 2018.

## **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 OIL NATURAL:** This will be the third product in the “Natural” line of Lubrajel products. Like LUBRAJEL MARINE, this product is based on naturally derived polysaccharides. It is being developed to provide lubricating properties and viscosity similar to the Company’s regular LUBRAJEL OIL, but utilizing only natural ingredients. The polymer network in this product is based solely on vegetable feedstock. The Company is working with ASI to fine tune this formula and is awaiting the results of some testing ASI is doing to make sure that the Company has the best possible formulation to take to market. Like the Company’s other “Natural” products, this product has been certified by Ecocert to comply with the COSMOS standards for use in natural and organic cosmetic products. The Company is working closely with its marketing partners to determine the primary benefits of this product, and hopes to obtain feedback soon so that it can begin marketing this product by the third quarter of 2019.



UNITED-GUARDIAN, INC.

**Lubrajel Terra™:** This is intended to be the fourth product in the LUBRAJEL “Natural” line. It is based on polysaccharides from plant-based materials. The preliminary formula has been sent to ASI for feedback and testing. The Company plans to submit this product to Ecocert for certification under COSMOS standards for use in natural and organic cosmetic products. This will enable the Company to have a broad range of “Natural” products to offer its customers. The Company continues to believe that there is a growing demand for natural products, especially in personal care products, and expects to add additional products to this line in the future if these initial products are successful.

**LUBRAJEL OIL PF:** This product was developed as a result of the high demand for the Company’s very popular LUBRAJEL OIL. The benefit of this product would be to enable formulators to use their own preservative systems without having to account for preservatives that the Company already incorporated. This approach has been very successful with the Company’s LUBRAJEL PF, and the Company is hopeful that a preservative-free LUBRAJEL OIL will also be successful. The Company has been fine-tuning this formula to replicate the characteristics of its existing LUBRAJEL OIL, and is awaiting feedback from the Company’s marketing partners. The Company hopes to launch this product sometime in 2019.

**OIL/WAX HYDRATION:** This product concept was developed at a meeting between United-Guardian and ASI at the end of 2018. The concept for this product is an anhydrous textured gel that can be added to the oil phase of a cosmetic formula. Like many of the Company’s other “natural” products this product would be formulated to comply with the COSMOS standard for natural products. This product is in the early stages of development and the Company hopes to have prototype formulas later this year.

**LUBRAJEL 24:** This is another product concept that came out of a development meeting between the Company and ASI. The idea is to produce a product with 24-hour hydration. While the Company’s current water-based moisturizing products provide excellent hydration, the goal is to build upon this to produce a product with superior hydration that will last a full 24 hours. This product is in the early stages of development and the Company hopes to have prototype formulas later this year.

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 2018 were \$399,517 as compared with \$646,079 in 2017. The Company expects its research and development expenses in 2019 to be comparable to those of 2018. 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.

7

UNITED-GUARDIAN, INC.

## **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 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. All of the patents that had previously been issued to the Company have expired. 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<sup>®</sup>, RENACIDIN<sup>®</sup>, and CLORPACTIN<sup>®</sup>.

## **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 its predecessor company, International Specialty Products ("ISP"), for the marketing of the Company's cosmetic ingredients in North, Central, and South America. Since that time this initial agreement has been modified and expanded multiple times (see "Marketing Agreements" below). ASI also has a non-exclusive right to sell certain of the Company's other industrial and medical products. It was also granted the exclusive right to market globally an oral care product, LUBRAJEL BA, which was specifically developed for ASI in 2012 but which, to date, has not had significant sales, and LUBRAJEL MARINE, the second product in the Company's LUBRAJEL NATURAL line of products. The current agreement with ASI automatically renewed on January 1, 2018 and will automatically renew again on January 1, 2020 unless either party chooses to terminate, which can be done by giving 60 days' notice prior to the then expiration date.

Revenue from domestic sales of all Company products accounted for approximately 83% of the Company's total sales revenue in 2018, compared with 81% in 2017. Sales to the Company's largest marketing partner, ASI, accounted for approximately 42% of total Company sales in 2018 and 40% in 2017. Although a significant percentage of ASI's purchases from the Company are ultimately sold to foreign customers, all sales to ASI are included in domestic sales revenue because all shipments to ASI are delivered to ASI's warehouses in the U.S.

The Company's pharmaceutical products are marketed only in the United States and are sold primarily through full-line drug wholesalers and accounted for approximately 31% of Company sales in 2018, and approximately 30% in 2017. Domestic sales of the Company's medical (non-pharmaceutical) products accounted for approximately 8% of Company sales in 2018 and 10% in 2017. Although all shipments of medical products to U.S. locations are considered "Domestic Sales", a certain percentage of those shipments are subsequently shipped by some customers to foreign manufacturing facilities which then produce finished products that are marketed globally.

Domestic sales of the Company's specialty industrial products accounted for approximately 1% of Company sales in both 2018 and 2017. The medical and industrial products are sold directly to customers or their contract manufacturers, who incorporate these products into their finished products.

UNITED-GUARDIAN, INC.

## **FOREIGN SALES**

In 2018 and 2017 approximately 17% and 19%, respectively, of the Company's sales revenue was from foreign sources and was derived from (a) sales of its personal care products to the Company's foreign marketing partners, which accounted for approximately 10% of Company sales in 2018 and 11% in 2017, and (b) sales of some of the Company's medical products directly to certain customers in foreign countries, which accounted for approximately 7% of Company sales in 2018 and 8% in 2017.

Because all shipments to the Company's largest marketing partner, ASI, are delivered to ASI's warehouses in the U.S., all sales to ASI are included in "Domestic Sales", even though a significant percentage of ASI's sales of the Company's products are to customers in foreign countries. Based on sales information provided to the Company by ASI, in 2018 approximately 75% of ASI's sales were to customers in foreign countries, compared with 72% in 2017. ASI's largest foreign market in both 2018 and 2017 was China, which accounted for approximately 55% of ASI's sales of Company products in 2018 and 2017.

Since the Company 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 adjust its prices in order to 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. The Company is also closely monitoring the current trade negotiations with China and other foreign markets, and when necessary will set aside reserves to account for any possible import duties that appear likely to be imposed.

## **SALES AND MARKETING**

The Company markets its products through marketing partners and distributors, promotion on the Company's web sites, and by internet advertising. 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 formulation of one or more of their products. 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 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**

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.

UNITED-GUARDIAN, INC.

The marketing agreement with ASI was entered into in 1994 with ISP, the predecessor company of ASI. That agreement set forth provisions under which ISP/ASI 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. In 1996, the parties entered into another agreement, extending ASI's distribution rights to the United States, Canada, Mexico, and Central and South America. In July 2000, December 2002, December 2005, May 2010, November 2012, and November 2013 the parties entered into additional agreements that modified, extended, and consolidated the 1994 and 1996 agreements, and provided for automatic two-year renewals of ASI's marketing rights unless either party terminated the arrangement upon 60 days' notice. The agreement automatically renewed on January 1, 2012, 2014, 2016, and 2018 for additional two-year terms. The current contract ends on December 31, 2019.

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, 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 six major raw material vendors that together accounted for approximately 80% of the raw material purchases by the Company in 2018 and 88% in 2017.

## **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 all 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.



UNITED-GUARDIAN, INC.

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 companies and with suppliers of specialty chemicals used in personal care and healthcare applications. The pharmaceutical, health care, and cosmetic industries are all highly competitive, and the Company experienced a high level of competition for its cosmetic ingredients during 2018. During 2018 the U.S. dollar strengthened against many foreign currencies, which made the Company's products less competitive in those markets. The Company believes that there will continue to be increased competition in coming years, especially from Asian competitors, 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. 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 9001:2015 REGISTRATION**

On July 23, 2018 the Company was certified by Underwriters Laboratories, Inc. to be in compliance with the latest ISO standard, ISO 9001:2015, indicating that the Company's documented procedures and overall operations had attained the high level of quality needed to comply with this current ISO certification level. From October 2009 to July 2018 the Company had been registered under the ISO 9001:2008 standard; from December 2003 to October 2009 the Company had been registered under the ISO 9001:2000 standard; and between November 1998 and December 2003 the Company had been registered under the ISO 9002 standard. The Company has been in continuous compliance with ISO standards since November 1998.

**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 U.S. Food & Drug Administration ("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. Although the Company does not currently market any medical devices, if it were to do so a 510(k) pre-market notification to the FDA would be required 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. While the Company does not have any current plans to develop any new pharmaceutical products, any new drug product would require clinical evaluation under an Investigational New Drug Application, and the subsequent submission to the FDA of a New Drug Application.

UNITED-GUARDIAN, INC.

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 2018 and 2017 the Company incurred approximately \$43,000 and \$37,000, 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 29 employees, 4 of whom serve in an executive capacity, 17 in research, quality control and manufacturing, 5 in maintenance and construction, and 3 in office and administrative support services. Of the total number of employees, 23 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.

12

UNITED-GUARDIAN, INC.

**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.

**Holder of Record**

As of March 1, 2019, there were 450 holders of record of Common Stock.

**Cash Dividends**

On May 16, 2018, the Company's Board of Directors declared a semi-annual cash dividend of \$0.50 per share, which was paid on June 13, 2018 to all stockholders of record as of May 30, 2018. On November 28, 2018, the Company's Board of Directors declared a semi-annual cash dividend of \$0.55 per share which was paid on December 17, 2018 to all stockholders of record as of December 10, 2018.

On May 17, 2017, the Company's Board of Directors declared a semi-annual cash dividend of \$0.42 per share, which was paid on June 12, 2017 to all stockholders of record as of May 30, 2017. On November 29, 2017, the Company's Board of Directors declared a semi-annual cash dividend of \$0.50 per share, and an additional special dividend of \$0.50 per share, for a total dividend of \$1.00 per share, which was paid on December 18, 2017 to all stockholders of record as of December 11, 2017.

**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 Generally Accepted Accounting Principles in the United States of America ("US GAAP"). 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 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.

UNITED-GUARDIAN, INC.

### **Marketable Securities**

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 and realized gains and losses included in net income. Realized gains or losses on mutual funds are determined using the average cost method. 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 records 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 2018 and 2017 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 from sales of its personal care, medical, and industrial products at the time the products are shipped, as long as a valid purchase order has been received and future collection of the sale amount is reasonably assured. These products are shipped "Ex-Works" from the Company's facility in Hauppauge, NY, and it is at this time that risk of loss, control, and responsibility for the shipment passes to the customer. Sales of these products are deemed final, and there is no obligation on the part of the Company to repurchase or allow the return of these goods unless they are defective.

The Company's pharmaceutical products are shipped via common carrier upon receipt of a valid purchase order, with, in most cases, the Company paying the shipping costs. Sales of pharmaceutical products are final, and revenue is recognized at the time of shipment. Pharmaceutical products are returnable only at the discretion of the Company unless (a) they are found to be defective; (b) the product is damaged in shipping; or (c) the product is outdated (but not more than one year after their expiration date, which is a return policy which conforms to standard pharmaceutical industry practice). The Company estimates an allowance for outdated material returns based on prior year historical returns of its pharmaceutical products.

The Company does not make sales on consignment, and the collection of the proceeds of the sale of any of the Company's products is not contingent upon the customer being able to sell the goods to a third party.

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



UNITED-GUARDIAN, INC.

The timing between recognition of revenue for product sales and the receipt of payment is not significant. The Company's standard credit terms, which vary depending on the customer, range between 30 and 60 days. The Company uses its judgment on a case-by-case basis to determine its ability to collect outstanding receivables and provides allowances for any receivables for which collection has become doubtful. Prompt-pay discounts are offered to some customers; however, due to the uncertainty of the customers actually taking the discounts, the discounts are recorded when they are taken.

Gross revenues are subject to a variety of deductions, which generally are estimated and recorded in the same period that the revenues are recognized. Such variable consideration includes chargebacks from the United States Department of Veterans Affairs ("VA"), rebates, distribution fees, and sales returns. These deductions represent estimates of the related obligations and, as such, knowledge and judgment is required when estimating the impact of these revenue deductions on gross sales for a reporting period.

The Company has distribution fee contracts with certain distributors of the Company's pharmaceutical products that entitles those distributors to receive payment for distribution-related fees. The Company estimates and records distribution fees due to these customers in sales returns and allowances.

### **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, 2018 compared with the year ended December 31, 2017:

#### **Sales**

Sales increased from \$13,434,460 in 2017 to \$14,458,055 in 2018, an increase of \$1,023,595 (approximately 8%). The overall increase was due primarily to increases in sales of the Company's personal care products to its primary distributor, ASI, as well as an increase in sales of the Company's pharmaceutical products, primarily RENACIDIN. Those increases were partially offset by decreases in sales of the Company's medical (non-pharmaceutical) products.

UNITED-GUARDIAN, INC.

The net increase in sales was the result of the following specific changes in sales in the different product categories:

(a) **Personal care products:**

Sales of the Company's personal care products, including cosmetic ingredients, increased from \$6,868,227 in 2017 to \$7,529,487 in 2018, an increase of \$661,260 (approximately 10%). The increase was attributable primarily to an increase in sales of the Company's LUBRAJEL products to ASI, the Company's largest marketing partner. Sales to ASI increased by \$717,429 (approximately 13%) from \$5,350,392 in 2017 to \$6,067,821 in 2018. Aggregate sales to the Company's other marketing partners decreased by \$44,522 (approximately 3%) from \$1,464,053 in 2017 to \$1,419,531 in 2018. Sales in the United Kingdom, France and Switzerland increased in the aggregate by \$190,206 (approximately 23%) from \$831,399 in 2017 to \$1,021,605 in 2018, while aggregate sales to the Company's distributors in Italy and South Korea decreased by \$234,728 (approximately 37%) from \$632,654 in 2017 to \$397,926 in 2018. There was a decrease of \$11,646 in sales of personal care products to four other direct customers of the Company.

Although a significant percentage of ASI's purchases from the Company are sold to foreign customers, all sales to ASI are considered U.S. sales for financial reporting purposes, since all shipments to ASI are shipped to ASI's warehouses in the U.S. A certain percentage of those products are subsequently shipped by ASI to its foreign customers. Based on sales information provided to the Company by ASI, in 2018 approximately 75% of ASI's sales were to customers in foreign countries, compared with 72% in 2017. ASI's largest foreign market in both 2018 and 2017 was China, which accounted for approximately 55% of ASI's sales in both 2018 and 2017. The increase in sales to ASI was primarily the result of an increase in ASI's sales of one of the Company's LUBRAJEL products in China and Vietnam.

Sales of the Company's products in Europe decreased slightly in 2018 compared with 2017. There continues to be more competition in the European marketplace than there had been in previous years due to Asian competitors selling imitations of the Company's products at much lower prices. The strengthening of the U.S. dollar relative to the Euro also contributed to the increasingly competitive situation in Europe. To offset this competitive disadvantage the Company from time to time offers additional volume discounts and more aggressive pricing in order to maintain and increase sales and bring in new customers. While this may result in lower margins on certain sales, the Company believes that the additional volumes that will be generated by this policy will more than offset the lower profit margins on those sales.

(b) **Pharmaceuticals:**

Sales of the Company's two pharmaceutical products, RENACIDIN and CLORPACTIN, together increased by \$529,461 (approximately 13%), from \$3,987,076 in 2017 to \$4,516,537 in 2018, with RENACIDIN accounting for most of the increase. Sales of RENACIDIN increased by \$513,783 (approximately 15%) from \$3,424,896 in 2017 to

\$3,938,679 in 2018, and accounted for approximately 27% of the Company's sales in 2018, as compared with 25% in 2017. The increase was due to higher sales of the Company's 30mL single dose form of the product, which was introduced in April 2016 and has gradually been increasing in sales. The single-dose unit was engineered to be more patient friendly by being able 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 Company's previous 500mL glass bottle. The Company believes that this more user-friendly package is responsible for the increase in demand for the product. The Company has launched a web site dedicated to RENACIDIN, and beginning in the second half of 2018 began advertising the product on the internet. The Company is continuing to work with an internet marketing consultant to increase both patient and physician awareness of the product.

UNITED-GUARDIAN, INC.

The increase in sales of the Company's pharmaceutical products was partially offset by an increase of \$222,399 (approximately 48%) in allowances for distribution fees, outdated material returns, and rebates paid to the VA and the U. S. Department of Defense. This increase was primarily due to the higher sales of RENACIDIN.

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

Sales of the Company's medical products decreased by \$185,626 (approximately 8%) from \$2,424,439 in 2017 to \$2,238,813 in 2018. The decrease was primarily the result of a \$166,724 (approximately 21%) decrease in sales of LUBRAJEL RC, and a \$73,654 (approximately 10%) decrease in sales of LUBRAJEL RR, which was partially offset by increases in sales of some of the Company's other medical products. The large percentage decrease in sales of LUBRAJEL RC and RR was primarily due to lower sales to two customers, both of which have purchasing patterns which can vary widely from year to year.

(d) **Industrial and other products:**

Sales of the Company's industrial products, as well as other miscellaneous products, increased by \$18,500 (approximately 12%) from \$154,718 in 2017 to \$173,218 in 2018. The increase is primarily due to the increase in sales of one of the Company's industrial products by \$5,185 (approximately 94%) in 2018 compared to 2017 combined with revenue derived from a research and development project conducted during 2018 for a new customer.

**Gross Profit on Net Sales**

Gross profit was approximately 59% in 2018 and 2017.

**Operating Expenses**

Operating expenses increased by \$337,586 (approximately 19%) in 2018 compared with 2017, increasing from \$1,785,160 in 2017 to \$2,122,746 in 2018. The increase was mainly attributable to increases in computer services, consulting expenses, payroll and payroll related expenses.

**Research and Development Expenses**

Research and development expenses amounted to \$646,079 and \$399,517 in 2017 and 2018, respectively. The decrease of \$246,562 was primarily related to a decrease in payroll and payroll related expenses resulting from the retirement of two of the Company's highly-paid R&D chemists. The Company is currently working more closely than it has in the past with ASI's R&D department to jointly develop and test new products, and as a result the Company has been able to continue its strong R&D efforts with a smaller in-house staff.

### **Investment Income**

Investment income decreased by \$49,882 (approximately 18%) from \$281,868 in 2017 to \$231,986 in 2018. The decrease was due to a decrease in investment income from both stock and bond mutual funds.

UNITED-GUARDIAN, INC.

### **Net (Loss) Gain on Marketable Securities**

In 2018, in accordance with ASU 2016-01, which requires all unrealized gains and losses on marketable securities to be recognized in net income, the Company recognized an unrealized loss of \$337,342, which was netted with a realized gain of \$4,204 for a net loss on marketable securities of \$333,138. In 2017 the Company had a realized gain of \$33,297 on the income statement, and an unrealized gain on marketable securities, net of taxes, of \$255,796 in accumulated other comprehensive income in stockholders' equity.

### **Provision for Income Taxes**

The provision for income taxes decreased by \$592,966 (approximately 35%) from \$1,706,489 in 2017 to \$1,113,523 in 2018. This decrease was mainly due to a decrease in the federal statutory corporate income tax rate from 34% in 2017 to 21% in 2018. The Company's effective income tax rate was approximately 30% in 2017 and approximately 20% in 2018, and is lower than the federal statutory rate primarily due to the additional tax deduction for domestic production activities in 2017, and the utilization of research and development tax credits in both 2017 and 2018.

### **Liquidity and Capital Resources**

Working capital decreased from \$10,428,139 at December 31, 2017 to \$10,320,949 at December 31, 2018, a decrease of \$107,190 (approximately 1%). The current ratio increased from 8.3 to 1 at December 31, 2017 to 8.6 to 1 at December 31, 2018. The decrease in working capital and the increase in the current ratio were mainly due to a decrease in accounts receivable and a decrease in income taxes payable.

Accounts receivable (net of allowance for doubtful accounts) as of December 31, 2018 decreased by \$232,848 (approximately 12%) from \$1,905,415 in 2017 to \$1,672,567 in 2018. The receivables turnover, or Days Sales Outstanding, for 2018 was 47 days, compared with 49 days in 2017. The decrease was mainly the result of increased collection efforts and implementing electronic payments from some larger customers. The Company has bad debt reserves of \$16,895 and \$21,220 for 2018 and 2017, respectively, and believes that the net balance of its accounts receivable is fully collectible as of December 31, 2018.

The Company generated cash from operations of \$4,950,412 in 2018 compared with \$3,992,287 in 2017. The increase in 2018 was primarily due to an increase in net income and a decrease in accounts receivable and an increase in deferred income taxes.

Net cash used in investing activities was \$308,759 for the year ended December 31, 2018 compared with net cash provided by investing activities of \$2,815,382 for the year ended December 31, 2017. This decrease in net cash was mainly due to an increase in purchases of marketable securities in 2018 compared with 2017.

Cash used in financing activities was \$4,816,239 and \$6,507,249 during the years ended December 31, 2018 and 2017, respectively. The decrease was due to the payment of lower dividends in 2018 compared with 2017.

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.



UNITED-GUARDIAN, INC.

**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, which note is incorporated herein by reference.

**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, 2018. 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.

UNITED-GUARDIAN, INC.

(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, 2018.

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 2018 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 2019 Proxy Statement.

20

UNITED-GUARDIAN, INC.

### **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 2019 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 2019 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 2019 Proxy Statement.

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

### **Audit Fees**

The aggregate fees that have been, or are expected to be, billed by Raich Ende Malter & Co. LLP ("Raich"), the Company's principal accountants since March 29, 2018, for the quarterly reviews of the Company's financial statements for the first, second and third quarters of 2018 and the audit of the Company's financial statements for the 2018 fiscal year were \$68,000.

**Audit-Related Fees**

During 2018 and 2017 there were no fees paid to Raich in connection with the Company's compliance with Section 404 of the Sarbanes-Oxley Act of 2002.

No other fees were billed by Raich 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.

UNITED-GUARDIAN, INC.

**Tax Fees**

There were no fees billed by Raich 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 Raich in 2018 or 2017.

**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 President and the 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.

(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.



UNITED-GUARDIAN, INC.

**Item 16. Form 10-K Summary.**

None.

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 20, 2019      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: <u>/s/ Kenneth H. Globus</u> Kenneth H. Globus	President, General Counsel, Chairman of the Board of Directors (Principal Executive Officer)	March 20, 2019
By: <u>/s/ Robert S. Rubinger</u> Robert S. Rubinger	Executive Vice President, Secretary, Director	March 20, 2019
By: <u>/s/ Andrea J. Young</u>	Controller, Treasurer (Principal Financial	March 20, 2019

Edgar Filing: UNITED GUARDIAN INC - Form 10-K

Andrea J. Young      Officer and Principal Accounting Officer)

By: /s/ Lawrence F. Maietta      Director      March 20, 2019  
Lawrence F. Maietta

By: /s/ Arthur M. Dresner      Director; Audit Committee member      March 20, 2019  
Arthur M. Dresner

By: /s/ Andrew A. Boccone      Director; Audit Committee member      March 20, 2019  
Andrew A. Boccone

By: /s/ S. Ari Papoulias      Director; Audit Committee member      March 20, 2019  
S. Ari Papoulias

UNITED-GUARDIAN, INC.

EXHIBIT INDEX

<u>Exhibit #</u>	<u>Description</u>
2 P	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) P	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) P	By-laws of the Company. Incorporated by reference to Exhibit 4.2 to the 1987 8-K.
4(a) P	Specimen Certificate for shares of Common Stock of the Company. Incorporated by reference to Exhibit 4(a) to the 1988 10-K.
10(a) P	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)	<u>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.</u>
10(c)	<u>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.</u>
10(d)	<u>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.</u>
10(e)	<u>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.</u>
10(f)	<u>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.</u>

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
----------------------------------	----------	-----

24

UNITED-GUARDIAN, INC.

- 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 Andrea J. Young, Principal 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 Andrea J. Young, Principal Financial Officer of the Company, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

P: Indicates a paper filing

UNITED-GUARDIAN, INC.

INDEX TO FINANCIAL STATEMENTS

(For the years ended

December 31, 2018 and 2017)

	<u>Page</u>
<u>Report of Independent Registered Public Accounting Firm</u>	<u>F-2</u>
<u>Financial Statements</u>	
<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>Statements 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-21</u>

F-1

UNITED-GUARDIAN, INC.

## **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of United-Guardian, Inc.

Hauppauge, New York

### **Opinion on the Financial Statements**

We have audited the accompanying balance sheets of United-Guardian, Inc. (the Company) as of December 31, 2018 and 2017, and the related statements of income, comprehensive income, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2018, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

### **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ RAICH ENDE MALTER & CO. LLP

We have served as the Company's auditor since 2016.

Melville, New York

March 20, 2019

F-2



UNITED-GUARDIAN, INC.

**STATEMENTS OF INCOME**

	Years ended December 31,	
	2018	2017
Sales:		
Gross sales	\$14,458,055	\$13,434,460
Sales allowances and returns	(688,654 )	(466,255 )
Net sales	13,769,401	12,968,205
Costs and expenses:		
Cost of sales	5,667,295	5,301,352
Operating expenses	2,122,746	1,785,160
Research and development	399,517	646,079
Total costs and expenses	8,189,558	7,732,591
Income from operations	5,579,843	5,235,614
Other (expense) income:		
Investment income	231,986	281,868
Net (loss) gain on marketable securities	(333,138 )	33,297
Loss on trade-in of equipment	(12,837 )	—
Total other (expense) income	(113,989 )	315,165
Income before provision for income taxes	5,465,854	5,550,779
Provision for income taxes	1,113,523	1,706,489
Net income	\$4,352,331	\$3,844,290
Earnings per common share (basic and diluted)	\$0.95	\$0.84
Weighted average shares (basic and diluted)	4,594,319	4,594,319

**STATEMENTS OF COMPREHENSIVE INCOME**

	Years ended December 31,	
	2018	2017
Net income	\$4,352,331	\$3,844,290
Other comprehensive income:		
Unrealized gain on marketable securities	—	323,793

Income tax expense related to other comprehensive income	—	(67,997 )
Total other comprehensive income, net of tax	—	255,796
<b>Total comprehensive income</b>	\$4,352,331	\$4,100,086

See Notes to Financial Statements

F-3

UNITED-GUARDIAN, INC.

**BALANCE SHEETS****ASSETS**

	December 31,	
	2018	2017
Current assets:		
Cash and cash equivalents	\$550,135	\$724,721
Marketable securities	7,622,196	7,721,568
Accounts receivable, net of allowance for doubtful accounts of \$16,895 in 2018 and \$21,220 in 2017	1,672,567	1,905,415
Inventories(net)	1,482,151	1,340,523
Prepaid expenses and other current assets	159,364	157,964
Prepaid income taxes	200,687	331
 Total current assets	 11,687,100	 11,850,522
Property, plant, and equipment:		
Land	69,000	69,000
Factory equipment and fixtures	4,406,174	4,363,978
Building and improvements	2,801,582	2,793,402
Total property, plant and equipment	7,276,756	7,226,380
 Less accumulated depreciation	 6,448,831	 6,283,493
Total property, plant, and equipment, net	827,925	942,887
 Other assets (net)	 29,647	 59,471
<b>TOTAL ASSETS</b>	<b>\$12,544,672</b>	<b>\$12,852,880</b>

See Notes to Financial Statements

UNITED-GUARDIAN, INC.

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

	December 31,	
	2018	2017
Current liabilities:		
Accounts payable	\$ 186,797	\$ 354,285
Accrued expenses	1,040,635	881,327
Income taxes payable	—	55,848
Dividends payable	138,719	130,923
Total current liabilities	1,366,151	1,422,383
Deferred income taxes (net)	253,583	33,855
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$.10 par value; 10,000,000 shares authorized; 4,594,319 shares issued and outstanding at December 31, 2018 and 2017, respectively	459,432	459,432
Accumulated other comprehensive income	—	466,025
Retained earnings	10,465,506	10,471,185
Total stockholders' equity	10,924,938	11,396,642
<b>TOTAL LIABILITIES AND STOCKHOLDERS EQUITY</b>	<b>\$ 12,544,672</b>	<b>\$ 12,852,880</b>

See Notes to Financial Statements

F-5

UNITED-GUARDIAN, INC.

**STATEMENTS OF STOCKHOLDERS' EQUITY**

Years ended December 31, 2018 and 2017

	Common stock		Accumulated other comprehensive income	Retained earnings	Total
	Shares	Amount			
Balance, January 1, 2017	4,594,319	\$ 459,432	\$ 175,634	\$ 13,185,423	\$ 13,820,489
Change in unrealized gains on marketable securities, net of deferred income tax of \$67,997	—	—	255,796	—	255,796
Reclassification of tax effect from accumulated other comprehensive income due to federal tax rate change	—	—	34,595	(34,595 )	—
Net income	—	—	—	3,844,290	3,844,290
Dividends declared, not paid	—	—	—	(16,684 )	(16,684 )
Dividends declared and paid	—	—	—	(6,507,249 )	(6,507,249 )
Balance, December 31, 2017	4,594,319	459,432	466,025	10,471,185	11,396,642
Reclassification of accumulated unrealized gains on marketable securities in accordance with ASU 2016-01(See Note B)	—	—	(466,025 )	466,025	—
Net income	—	—	—	4,352,331	4,352,331
Dividends declared, not paid	—	—	—	(7,796 )	(7,796 )
Dividends declared and paid	—	—	—	(4,816,239 )	(4,816,239 )
Balance, December 31, 2018	4,594,319	\$ 459,432	\$ —	\$ 10,465,506	\$ 10,924,938

See Notes to Financial Statements

F-6

UNITED-GUARDIAN, INC.

**STATEMENTS OF CASH FLOWS**

	Years ended December 31,	
	2018	2017
Cash flows from operating activities:		
Net income	\$4,352,331	\$3,844,290
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	191,942	200,677
Unrealized loss on marketable securities	337,342	-----
Realized gain on sales of marketable securities	(4,204 )	(33,297 )
Loss on trade-in of equipment	12,837	----
Bad debt (recovery) expense	(4,325 )	4,277
Decrease (increase) in operating assets:		
Accounts receivable	237,173	(311,695 )
Inventories	(141,628 )	(84,710 )
Prepaid expenses and other current assets	(1,400 )	(37,644 )
Prepaid income taxes	(200,356 )	82,401
Other assets	15,000	----
(Decrease) increase in operating liabilities:		
Accounts payable	(167,488 )	271,464
Income taxes payable	(55,848 )	55,848
Accrued expenses	159,308	32,999
Dividends payable	—	(563 )
Deferred income taxes	219,728	(31,760 )
Net cash provided by operating activities	4,950,412	3,992,287
Cash flows from investing activities:		
Acquisitions of property, plant and equipment	(74,993 )	(38,149 )
Purchases of marketable securities	(8,256,570)	(1,922,513)
Proceeds from sales of marketable securities	8,022,804	4,776,044
Net cash (used in) provided by investing activities	(308,759 )	2,815,382
Cash flows from financing activities:		
Dividends paid	(4,816,239)	(6,507,249)
Net cash used in financing activities	(4,816,239)	(6,507,249)
Net (decrease) increase in cash and cash equivalents	(174,586 )	300,420
Cash and cash equivalents, beginning of year	724,721	424,301
Cash and cash equivalents, end of year	\$550,135	\$724,721
Non-cash investing activities:		

Edgar Filing: UNITED GUARDIAN INC - Form 10-K

Cost of equipment traded in (net)	39,837	—
Supplemental disclosure of cash flow information		
Taxes paid	1,150,000	1,600,000
Supplemental disclosure of non-cash dividends payable	\$7,796	\$16,684

See Notes to Financial Statements

F-7



UNITED-GUARDIAN, INC.

## 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 SOLUTION ("RENACIDIN") together accounted for approximately 94% of the Company's sales for the years ended December 31, 2018 and December 31, 2017. LUBRAJEL accounted for approximately 67% and 69% of the Company's sales for the years ended December 31, 2018 and December 31, 2017, respectively, and RENACIDIN accounted for approximately 27% and 25% of the Company's sales for the years ended December 31, 2018 and December 31, 2017, respectively.

#### Use of Estimates

In preparing financial statements in conformity with a Generally Accepted Accounting Principles in the United States of America ("US GAAP"), 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 revenue and expenses during the reporting period. Actual results could differ from those estimates. Such estimated items include the allowance for bad debts, accrued distribution fees, outdated material returns, possible impairment of marketable securities and the allocation of overhead to inventory.

#### Accounts Receivable and Reserves

The carrying amount of accounts receivable is reduced by a valuation allowance that reflects the Company's 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, the Company considers many factors in estimating this reserve, including historical data, experience, customer types and credit worthiness,

and economic trends. From time to time, the Company adjusts its assumptions for anticipated changes in any of these or other factors expected to affect collectability.

### **Revenue Recognition**

Effective January 1, 2018, the Company adopted ASC Topic 606, “Revenue from Contracts with Customers”, using the modified retrospective method. Results for the year ended December 31, 2018 are presented under Topic 606, while prior period amounts have not been adjusted and continue to be reported in accordance with our historic accounting under Topic 605. There was no material impact on the Company’s financial statements as a result of the Company’s adoption of this new revenue standard, and there was no adjustment to beginning retained earnings on January 1, 2018. The Company continues to recognize revenue at the time its products are shipped.

F-8

UNITED-GUARDIAN, INC.

Under the new guidance, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration expected to be received in exchange for those goods and services. The Company's principal source of revenue is product sales.

The Company's gross revenues are subject to a variety of deductions, which generally are estimated and recorded in the same period that the revenues are recognized. Such variable consideration includes chargebacks from the United States Department of Veterans Affairs ("VA"), rebates, distribution fees, and sales returns. These deductions represent estimates of the related obligations and, as such, knowledge and judgment is required when estimating the impact of these revenue deductions on gross sales for a reporting period.

The Company recognizes revenue from sales of its personal care, medical, and industrial products when those products are shipped, as long as a valid purchase order has been received and future collection of the sale amount is reasonably assured. These products are shipped "Ex Works" from the Company's facility in Hauppauge, NY, and it is at this time that risk of loss and responsibility for the shipment passes to the customer. Sales of these products are deemed final, and there is no obligation on the part of the Company to repurchase or allow the return of those goods unless they are defective.

The Company's pharmaceutical products are shipped via common carrier upon receipt of a valid purchase order, with, in most cases, the Company paying the shipping costs. Sales of pharmaceutical products are final, and revenue is recognized at the time of shipment. Pharmaceutical products are returnable only at the discretion of the Company unless (a) they are found to be defective; (b) the product is damaged in shipping; or (c) the product is outdated (but not more than one year after their expiration date, which is a return policy which conforms to standard pharmaceutical industry practice). The Company estimates an allowance for outdated material returns based on prior year historical returns of their pharmaceutical products.

The Company does not make sales on consignment, and the collection of the proceeds of the sale of any of the Company's products is not contingent upon the customer being able to sell the goods to a third party.

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

The timing between recognition of revenue for product sales and the receipt of payment is not significant. The Company's standard credit terms, which vary depending on the customer, range between 30 and 60 days. The Company uses its judgment on a case-by-case basis to determine its ability to collect outstanding receivables and

provides allowances for any receivables for which collection has become doubtful. As of December 31, 2018 and 2017, the allowance for doubtful accounts receivable amounted to \$16,895 and \$21,220, respectively. Prompt-pay discounts are offered to some customers however, due to the uncertainty of the customers actually taking the discounts, the discounts are recorded when they are taken.

The Company has distribution fee contracts with certain customers in connection with the sales of its products that entitle them to distribution-related fees. The Company estimates and records distribution fees due to these customers in sales returns and allowances.

F-9

## UNITED-GUARDIAN, INC.

Disaggregated net sales by product class is as follows:

	Year ended December 31,	
	2018	2017
Personal care	\$7,529,487	\$6,868,227
Pharmaceutical	4,516,537	3,987,076
Medical	2,238,813	2,424,439
Industrial and other	173,218	154,718
	14,458,055	13,434,460
Less: Allowances and returns	(688,654 )	(466,255 )
Net Sales	\$13,769,401	\$12,968,205

The Company's personal care products are marketed worldwide by six marketing partners, of which United States ("U.S.")-based Ashland Specialty Ingredients ("ASI") purchases the largest volume. Because all ASI's purchases are shipped to ASI's warehouses in the U.S., all sales to ASI are considered domestic sales, even though a certain percentage of the products shipped to ASI will be sold by ASI to customers outside the U.S. (see below). In 2018 and 2017 approximately 17% and 19%, respectively, of the Company's products were sold to end users located outside the U.S., either directly by the Company or by the Company's five other marketing partners.

Disaggregated gross sales by geographic region is as follows:

	Year ended December 31,	
	2018	2017
United States*	\$11,937,499	\$10,900,284
Other countries	2,520,556	2,534,176
Gross Sales	\$14,458,055	\$13,434,460

\* Although a significant percentage of ASI's purchases from the Company are sold to foreign customers, all sales to ASI are considered U.S. (domestic) sales for financial reporting purposes, since all shipments to ASI are shipped to ASI's warehouses in the U.S. A certain percentage of those products are subsequently shipped by ASI to its foreign customers. Based on sales information provided to the Company by ASI, in 2018 approximately 75% of ASI's sales were to customers in foreign countries, with a significant amount going to China. In addition, there are four customers for the Company's medical products that take delivery of their purchases in the U.S. but may be subsequently shipped to manufacturing facilities outside the U.S. Since the Company makes those shipments to U.S. locations, sales to those customers are also considered domestic sales.

**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 the time of purchase. 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 (“FDIC”) up to a maximum of \$250,000. At December 31, 2018, approximately \$313,000 exceeded the FDIC limit.

F-10

UNITED-GUARDIAN, INC.

### **Dividends**

On May 16, 2018, the Company's Board of Directors declared a semi-annual cash dividend of \$0.50 per share, which was paid on June 13, 2018 to all stockholders of record as of May 30, 2018. On November 28, 2018, the Company's Board of Directors declared a semi-annual cash dividend of \$0.55 per share which was paid on December 17, 2018, to all stockholders of record as of December 10, 2018. In 2018 the Company declared a total of \$4,824,035 in dividends, of which \$4,816,239 was paid. The balance of \$7,796 is payable to stockholders who could not be located at the time the dividend was paid and is being held by the Company for future payment.

On May 17, 2017, the Company's Board of Directors declared a semi-annual cash dividend of \$0.42 per share, which was paid on June 12, 2017 to all stockholders of record as of May 30, 2017. On November 29, 2017, the Company's Board of Directors declared a semi-annual cash dividend of \$0.50 per share and an additional special dividend of \$0.50 per share, for a total dividend of \$1.00 per share, which was paid on December 18, 2017, to all stockholders of record as of December 11, 2017. In 2017 the Company declared a total of \$6,523,933 in dividends, of which \$6,507,249 was paid. The balance of \$16,684 is payable to stockholders who could not be located at the time the dividend was paid and is being held by the Company for future payment.

### **Reclassification**

Certain items in the 2017 financial statements have been reclassified to conform to the 2018 period presentation. See Note B.

### **Marketable Securities**

Marketable securities include investments in equity and fixed income mutual funds and government securities and are reported at fair value with the related unrealized and realized gains and losses included in net income in accordance with ASU 2016-01. Realized gains or losses on mutual funds are determined using the average cost method. 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 2018 and 2017 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.

**Inventories**

Inventories are valued at the lower of cost and net realizable 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.

F-11



UNITED-GUARDIAN, INC.

**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 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	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, 2018 and 2017.

**Other Assets (net)**

Other assets at December 31, 2018 and 2017 primarily represents an amount expended in connection with the development of the new single-dose form of RENACIDIN. The Company began amortizing these costs in the first quarter of 2016. At December 31, 2018 and 2017 accumulated amortization for such assets amounted to \$44,472 and \$29,648, respectively.

Future amortization expense is as follows:

For the Years Ending December 31,	Amortization Expense
2019	\$ 14,824
2020	14,823
Total:	\$ 29,647

### **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.

F-12

UNITED-GUARDIAN, INC.

### **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, 2018, two of the Company's distributors and marketing partners accounted for approximately 59% of the Company's sales during the year, and approximately 47% of its outstanding accounts receivable at December 31, 2018. For the year ended December 31, 2017, the same two distributors and marketing partners accounted for a total of approximately 55% of the Company's sales during the year, and 58% of its outstanding accounts receivable at December 31, 2017.

### **Vendor Concentration**

Most of the principal raw materials used by the Company consist of common industrial organic and inorganic chemicals and are available in ample supply from numerous sources. However, there are some raw materials used by the Company that are not readily available or require long lead times. The Company has six major raw material vendors that collectively accounted for approximately 80% and 88% of the raw material purchases by the Company in 2018 and 2017, 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 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, 2018 and 2017, 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, 2018 and 2017 the Company did not record any tax-related 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 2015 through 2017.

On August 3, 2018 the IRS issued IRS Rev. Proc 2018-40, which permits small business taxpayers to obtain automatic IRS consent to implement the small taxpayer provisions under the Tax Cuts and Jobs Act of 2017 ("TCJA") effective for tax years beginning after December 31, 2017. For the year ended December 31, 2018 the Company elected to change its method of tax accounting from an accrual method to the cash method.

F-13

UNITED-GUARDIAN, INC.

### **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 \$81,000 and \$77,000 for the years ended December 31, 2018 and 2017, respectively.

### **Advertising Expenses**

Advertising expenses are expensed as incurred. For the years ended December 31, 2018 and 2017, the Company incurred approximately \$13,000 and \$4,000, respectively, in advertising expense.

### **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 would include the dilutive effect of outstanding stock options, if any.

### **New Accounting Standards**

In February 2018, the Financial Accounting Standards Board (“FASB”) issued ASU 2018-02, “Income Statement-Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income.” This guidance gives businesses the option of reclassifying to retained earnings the so-called “stranded tax effects” left in accumulated other comprehensive income due to the reduction in the corporate income tax

rate resulting from the 2017 Tax Cuts and Jobs Act. This amendment is effective for all organizations for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early adoption is allowed. The Company adopted this amendment in the fourth quarter of 2017. As a result, a reclassification of \$34,595 was made to retained earnings at December 31, 2017 to reflect the effect of the reduction in the federal corporate tax rate as it relates to the unrealized gains on marketable securities that were recorded in other comprehensive income.

In August 2018, the FASB issued ASU 2018-13, “Fair Value Measurement” (Topic 820), Changes to the Disclosure Requirements for Fair Value Measurement”. This amendment’s objective is to improve the effectiveness of disclosures about recurring or nonrecurring fair value measurements. This amendment is effective for fiscal years beginning after December 15, 2019. The Company is evaluating the potential impact this standard may have on the financial statements.

In January 2016, the FASB issued ASU 2016-01 “Recognition and Measurement of Financial Assets and Financial Liabilities”. This amendment requires companies to measure equity investments at fair value with changes in fair value recognized in net income. The Company adopted this standard effective January 1, 2018. In accordance with the implementation of the standard, the Company recognized a cumulative effect adjustment related to unrealized gains on marketable securities, to reduce accumulated other comprehensive income and increase retained earnings on January 1, 2018 by \$466,025.

UNITED-GUARDIAN, INC.

In February 2016, the FASB issued ASU 2016-02, “Leases”, 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 both assets and liabilities on their balance sheet for the rights to use those assets for the lease term and obligations to make the 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 a 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 adopted by the Company in the first quarter of 2019, and will not have a material impact on its financial statements.

In June 2016, the FASB issued ASU-2016-13 “Financial Instruments – Credit Losses”. This guidance affects organizations that hold financial assets and net investments in leases that are not accounted for at fair value with changes in fair value reported in net income. The guidance requires organizations to measure all expected credit losses for financial instruments at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. It is effective for fiscal years beginning after December 15, 2019. The Company is evaluating the potential impact on the Company’s financial statements.

## **NOTE B - MARKETABLE SECURITIES**

Marketable securities include investments in fixed income and equity mutual funds and government securities, which are reported at their fair values. Effective January 1, 2018, the Company adopted Accounting Standards Update (“ASU”) 2016-01, “Recognition and Measurement of Financial Assets and Financial Liabilities”. This amendment requires companies to measure equity investments at fair value with the changes in fair value recognized in net income.

In accordance with the implementation of the standard, the Company recognized a cumulative-effect adjustment, related to unrealized gains on marketable equity securities, to reduce accumulated other comprehensive income and increase retained earnings on January 1, 2018 by \$466,025.

In conformity with ASC 205-10 “Presentation of Financial Statements”, as it relates to the comparability of financial statements, because ASU 2016-01 was not implemented retroactively, in order for the amounts presented in the 2018 financial statements to be comparable to the same period in 2017, the following table illustrates the impact the implementation of the standard would have had on the year ended December 31, 2017:

### **Statements of Income**

Year ended

December 31, 2017

	As Reported	Adjustments	Balance With ASU 2016-01 Adoption
Unrealized gain on marketable securities	\$—	\$ 323,793	\$323,793
Income before provision for income taxes	5,550,779	323,793	5,874,572
Provision for income taxes	1,706,489	110,090	1,816,579
Net income	3,844,290	213,703	4,057,993
Earnings per common share (basic and diluted)	\$0.84	\$ 0.04	\$0.88

F-15



UNITED-GUARDIAN, INC.

In addition, the disaggregated net gains and losses on the marketable securities recognized in the income statement for the year ended December 31, 2018 are as follows:

	Year ended December 31, 2018
Net losses recognized during the year on marketable securities	\$333,138 )
Less: Net gains recognized during the year on marketable securities sold during the period	(4,204 )
Unrealized losses recognized during the reporting year on marketable securities still held at the reporting date	\$(337,342)

The fair values of the Company's marketable securities are determined in accordance with US 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 at the measurement date. 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 US 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 Company's 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. The following tables summarize the Company's investments:

**December 31, 2018**

	Cost	Fair value	Unrealized gain
U.S. Treasury Bills (Maturities less than 1 year)	\$3,742,681	\$3,742,681	\$—
Fixed income mutual funds	2,408,799	2,409,213	414
Equity and other mutual funds	1,218,153	1,470,302	252,149
Total marketable securities	\$7,369,633	\$7,622,196	\$252,563

**December 31, 2017**

Fixed income mutual funds	\$6,003,131	\$6,113,099	\$109,968
Equity and other mutual funds	1,128,532	1,608,469	479,937
Total marketable securities	\$7,131,663	\$7,721,568	\$589,905

Investment income is recognized when earned and consists principally of interest income from fixed income mutual funds and U.S. Treasury Bills and dividend income from equity and other mutual funds. Realized gains and losses on sales of investments are determined on an average cost basis.

Proceeds from the sale and redemption of marketable securities amounted to \$8,022,804 for the year ended December 31, 2018, which included realized gains of \$4,204. Proceeds from the sale and redemption of marketable securities for the year ended December 31, 2017 amounted to \$4,776,044, which included realized gains of \$33,297.

UNITED-GUARDIAN, INC.

**NOTE C – INVENTORIES**

Inventories consist of the following:

	December 31,	
	2018	2017
Raw materials	\$467,842	\$363,739
Work in process	30,057	39,004
Finished products	984,252	937,780
Total Inventories	\$1,482,151	\$1,340,523

Inventories are valued at the lower of cost and net realizable value. Cost is determined using the average cost method, which approximates cost determined by the first-in, first-out method. Finished product inventories at December 31, 2018 and December 31, 2017 are net of a reserve of \$20,000 for slow-moving or obsolete inventory. At December 31, 2018 and 2017 the Company had an allowance of \$160,533 and \$127,768, respectively, for possible outdated material returns, which is included in accrued expenses.

**NOTE D – INCOME TAXES**

The provision for (benefit from) income taxes consists of the following:

	Years ended December 31,	
	2018	2017
Current		
Federal	\$893,768	\$1,738,132
State	27	117
Total current provision for income taxes	893,795	1,738,249
Deferred		
Federal	219,728	(31,760 )
State	—	—
Total deferred provision for income taxes	219,728	(31,760 )
Total provision for income taxes	\$1,113,523	\$1,706,489

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):

Edgar Filing: UNITED GUARDIAN INC - Form 10-K

	Years ended December 31,			
	2018		2017	
	(\$)	Tax rate	(\$)	Tax rate
Income taxes at statutory federal income tax rate	\$1,148,000	21.0%	\$1,887,000	34.0 %
Domestic Production Activities tax benefit	—	—	(160,000 )	(2.9 )
Nondeductible expenses	1,000	—	1,000	—
Research & development credits	(20,000 )	(0.3 )	(34,000 )	(0.6 )
Non-taxable dividends	(6,000 )	(0.1 )	(5,000 )	(0.09)
Deferred tax asset reduction for federal tax rate change	—	—	21,000	0.4
Other, net	(9,000 )	(0.2 )	(4,000 )	(0.1 )
Provision for income taxes	\$1,114,000	20.4%	\$1,706,000	30.7 %

F-17

## UNITED-GUARDIAN, INC.

During 2017, the Company realized the tax benefits of the Domestic Production Activities deduction, which amounted to approximately 9% of net income from domestic production. Under the TCJA this deduction was repealed for tax years beginning in 2018.

The TJCA also favorably amended certain tax provisions applicable to eligible small business taxpayers. On August 3, 2018, the IRS issued Rev. Proc. 2018-40 which permits small business taxpayers to obtain automatic IRS consent to implement the small taxpayer provisions under the act, effective for tax years beginning after December 31, 2017. For the year ended December 31, 2018, in accordance with Rev. Proc. 2018-40, the Company elected to change its method of tax accounting from an accrual method to the cash method.

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

	December 31,	
	2018	2017
Deferred tax assets		
Allowance for doubtful accounts	\$3,548	\$4,456
Inventories	4,200	9,104
Accounts payable	39,227	—
Accrued expenses	215,604	157,610
Total deferred tax assets	262,579	171,170
Deferred tax liabilities		
Accounts receivable	(354,787)	—
Prepaid expenses	(38,913 )	—
Depreciation on property, plant and equipment	(69,424 )	(81,145 )
Unrealized gain on marketable securities	(53,038 )	(123,880)
Total deferred tax liabilities	(516,162)	(205,025)
Net deferred tax liability	\$(253,583)	\$(33,855 )

**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 \$90,000

and \$94,000 for the years ended December 31, 2018 and 2017, respectively.

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. For the year ended December 31, 2018 the Company's Board of Directors authorized discretionary contributions in the amount of \$145,000 per year to be allocated among all eligible employees. For the year ended December 31, 2017, the Company's Board of Directors authorized \$175,000 to be allocated among all eligible employees. 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.

F-18

UNITED-GUARDIAN, INC.

**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 provide the marketing functions for these products on behalf of the Company. They in turn receive their compensation for those efforts by re-selling those products at a markup to their customers. This enables the Company to aggressively have its products marketed without the high cost of maintaining its own in-house marketing staff. The Company has written marketing arrangements with only one of its global distributors, ASI, and that contract renews every two years unless cancelled for any reason by either party at least 90 days prior to the expiration of the two-year marketing period in effect at that time. The current marketing period with ASI ends on December 31, 2019. The Company's other marketing partners are not under any contractual obligation to market the Company's personal care products, and the Company has the ability to cancel those marketing arrangements at any time upon reasonable notice. All sales of the Company's personal care products are final other than product later determined to be defective, and the Company does not make any sales on consignment.

No prior regulatory approval is 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. The Company's marketing efforts for these products are currently centered around the corporate web site as well as a separate web site developed specifically for Renacidin. In 2018 the Company began promoting Renacidin through internet advertising. Both of 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.



## UNITED-GUARDIAN, INC.

The following tables present the significant concentrations of the Company's sales. Although a significant percentage of Customer A's purchases from the Company are sold to foreign customers, in table "b" below all sales to Customer A are included in "United States" sales revenue because all shipments to Customer A are delivered to Customer A's warehouses in the U.S.

In addition, there are four customers for the Company's medical products that take delivery of their shipments in the U.S. but potentially ship some of that product to manufacturing facilities outside the U.S. Since the Company makes those shipments to U.S. locations, sales to those customers are also included in the "United States" revenue number in the table below

	(a)		<u>Net Sales</u>
	Years ended December 31,		
	2018	2017	
Personal care	\$7,529,487	\$6,868,227	
Pharmaceutical	4,516,537	3,987,076	
Medical	2,238,813	2,424,439	
Industrial and other	173,218	154,718	
	14,458,055	13,434,460	
Less: Discounts and allowances	(688,654 )	(466,255 )	
Net Sales	\$13,769,401	\$12,968,205	

	(b)		<u>Geographic Information (Gross Sales)</u>
	Years ended December 31,		
	2018	2017	
United States	\$11,937,499	\$10,900,284	
Other countries	2,520,556	2,534,176	
	\$14,458,055	\$13,434,460	

	(c)		<u>Sales to Major Customers</u>
	Years ended December 31,		
	2018	2017	
Customer A	\$6,067,821	\$5,350,392	
Customer B	2,049,190	1,750,167	
All other customers	6,341,044	6,333,901	
	\$14,458,055	\$13,434,460	

F-20

UNITED-GUARDIAN, INC.

**NOTE G – COMPREHENSIVE INCOME**

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

	December 31, 2018	December 31, 2017
Changes in Accumulated Other Comprehensive Income		
Beginning balance - net of tax	\$466,025	\$175,634
Unrealized gain on marketable securities – net of tax	—	255,796
Reclassification of accumulated other comprehensive income to retained earnings in accordance with ASU-2016-01 (See Note B)	(466,025)	—
Reclassification of tax effect on unrealized gain on marketable securities due to federal tax rate change (See Note A)	—	34,595
Ending balance - net of tax	\$—	\$466,025

**NOTE H - ACCRUED EXPENSES**

Accrued expenses at December 31, 2018 and 2017 consist of:

	2018	2017
Bonuses	\$242,000	\$200,000
Distribution fees	315,242	254,863
Payroll and related expenses	159,385	152,903
Annual report expenses	66,618	62,510
Audit fee	43,668	43,268
Reserve for outdated material	160,533	127,768
Sales rebates	15,000	12,000
Computer services	16,593	—
Other	21,596	28,015
Total accrued expenses	\$1,040,635	\$881,327

**NOTE I - SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION AND NON-CASH INVESTING AND FINANCING ACTIVITIES**

Cash payments for income taxes were \$1,150,000 and \$1,600,000 for the years ended December 31, 2018 and 2017, respectively.

As of December 31, 2018 the Company had a number of unconverted shares of one of its previous corporate entities, Guardian Chemical Corporation (“Guardian”), that would convert to approximately 3,509 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. During 2018 the Company’s transfer agent escheated approximately 8,223 shares of Company stock to the appropriate state authorities. This stock was in the name of stockholders who could no longer be located by the Company or its transfer agent. The Company is now only accruing dividends on the remaining 3,509 shares that have not yet been escheated as of December 31, 2018. The Company will continue to accumulate a dividend payable on the above shares as dividends are declared. The Company anticipates paying the dividends that have been accrued on these escheated shares in the first quarter of 2019.

#### **NOTE J - RELATED PARTY TRANSACTIONS**

During each of the years ended December 31, 2018 and 2017 the Company paid to Bonamassa, Maietta, and Cartelli, LLP, \$15,500 and \$18,000, respectively, for accounting and tax services. Lawrence Maietta, a partner in Bonamassa, Maietta, and Cartelli, LLP, is a director of the Company.