

UNITED GUARDIAN INC
Form 10-K
March 25, 2011

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, 2010

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)

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

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

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

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

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

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

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☒
(Do not check if a smaller reporting company.)

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

As of June 30, 2010, 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 \$28,995,436. (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, 2011, the Registrant had issued and outstanding 4,596,439 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 from the Registrant's definitive proxy statement for the 2011 annual meeting of stockholders ("2011 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 no later than 120 days after Registrant's fiscal year end.

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

PART I

Item 1. Business.

(a) Introduction

United-Guardian, Inc. ("United", the "Registrant", or the "Company") is a Delaware corporation that, through its Guardian Laboratories Division ("Guardian"), manufactures and markets cosmetic ingredients, personal care products, pharmaceuticals, medical and health care products, and specialty industrial products. It also conducts research and development, primarily related to the development of new and unique cosmetic and personal care 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 United to Delaware.

The Company conducts research, product development, manufacturing and marketing of cosmetic ingredients, personal and health care products, pharmaceuticals, and specialty industrial products. The research and development 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.

The Company has a broad range of products, some of which are currently marketed, some of which are marketable but are not currently marketed by the Company, and some of which are still in the developmental 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 78% of

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the Company's sales in 2010, and its RENACIDIN® IRRIGATION ("RENACIDIN"), a pharmaceutical product that accounted for approximately 17% of the Company's sales in 2010. The Company actively seeks other companies as potential marketers for its products, particularly for those products that are not yet being actively marketed by the Company or by the Company's marketing partners.

(b) Narrative Description of Business

The Company manufactures and markets cosmetic ingredients, personal care products, pharmaceuticals, medical and health care products, 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 endeavors to develop products that fill a need in the marketplace, have unique properties, and use proprietary technology that it protects with patents whenever possible. 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 international cosmetic and personal care products companies. The Company sells product outright to its marketing partners, FOB the Company's plant in Hauppauge, New York, and those marketing partners in turn resell those products to their customers, who are typically the end-users of the 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: pharmaceuticals, personal care products (including cosmetic ingredients), medical products, and industrial products. Each product category is marketed differently.

The Company's pharmaceutical products are marketed by direct advertising, mailings, and trade exhibitions, and are sold to end-users primarily through major drug wholesalers, which purchase the Company's products outright for resale to their customers. The Company's pharmaceutical products are returnable only at the discretion of the Company unless (a) they are found to be defective, or (b) they are outdated but within one year after their expiration date, which is in accordance with standard pharmaceutical industry practice. The Company also sells a small quantity of pharmaceutical products directly to hospitals and pharmacies. The non-pharmaceutical medical products and the specialty industrial products are sold directly by the Company to the end-users.

The Company's products are sold under trademarks or trade names owned by the Company. The marks for the most important products, LUBRAJEL® and RENACIDIN®, as well as some other Company trademarks, are registered as trademarks with the United States Patent and Trademark Office.

PRODUCTS

The Company operates in one business segment and serves several end markets:

PERSONAL CARE

LUBRAJEL is an extensive line of water-based moisturizing and lubricating gel formulations that are used as ingredients in personal care and medical products. In the personal care industry, they are used primarily as moisturizers and bases for other cosmetic ingredients, and can be found as an ingredient in skin creams, moisturizers, makeup, and body lotions. For medical products, their primary use is as a lubricant. The largest selling product in the LUBRAJEL line in 2010 was LUBRAJEL CG, the original form of LUBRAJEL, followed in sales by LUBRAJEL Oil. Some of the other varieties of LUBRAJEL sold for

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cosmetic use (all using the LUBRAJEL name) are MS, DV, TW, NP, WA, PF and LUBRAJEL II XD. In addition, many of the above products are available in comparable formulations that do not use parabens as the preservative and use a different preservative instead, which is preferred by some customers. Those equivalent products are differentiated by adding the word 'Free' after the name (for example, LUBRAJEL MS Free), indicating that it does not contain parabens.

LUBRAJEL PF is a completely preservative-free form of LUBRAJEL currently being marketed primarily by Societe D'Etudes Dermatologiques ("Sederma"), a subsidiary of Croda International Plc ("Croda"), under Sederma's tradename "Norgel". Sederma is the Company's marketing partner and distributor in France and, along with its parent company, Croda, is a major supplier of cosmetic ingredients in Europe. The product is distributed by some of the Company's other marketing partners under the LUBRAJEL "PF" tradename. Tests conducted by Sederma indicated that the product self-preserved, and aids in the preservation of other cosmetic ingredients with which it is formulated.

Each of the following products accounted for less than 2% of the Company's sales in 2010:

LUBRASIL™ is a special form of LUBRAJEL in which silicone oil is incorporated into a LUBRAJEL base by microemulsification, thereby maintaining clarity similar to the other LUBRAJEL products. The product has a silky feel, and is water resistant while moisturizing the skin. The newest products in the LUBRASIL line are the LUBRASIL II products, which currently consist of LUBRASIL II DM and LUBRASIL II SB. Both products contain substantially higher levels of silicone than the original LUBRASIL products, and are intended to be additions to the line, not replacements for the original LUBRASIL.

LUBRAJEL II XD is a version of LUBRAJEL that was developed to be a direct replacement for one of the competitive products to LUBRAJEL.

KLENSOFT™ is a surfactant (a surface active agent, such as a soap or detergent, that can reduce the surface tension of a liquid and thus allow it to foam or penetrate solids or act as a wetting agent) that can be used in shampoos, shower gels, makeup removers, and other cosmetic formulations. Klensoft sales have been inconsistent due to the buying patterns of the main customer for the product. As a result, in 2010 sales of Klensoft increased significantly over 2009, but are expected to decline again in 2011.

UNITWIX® is a cosmetic additive used as a thickener for oils and oil-based liquids. It is a proprietary, unpatented product. The Company is presently working on a new formula for Unitwix that will lower the cost and make it more competitive in the marketplace. However, until it is evaluated by customers the Company cannot be sure that the new formula will be acceptable to existing customers for this product.

CONFETTI™ DERMAL DELIVERY FLAKES is a product line introduced in 2000 that incorporates various functional oil-soluble ingredients into colorful flakes that can be added to, and suspended in, various water-based products. The product color and ingredients can be customized to meet the needs of individual customers. Sales of this product have declined over the years, and there is currently only one customer for this product. That customer did not purchase any product in 2010 but is expected to purchase again in 2011.

ORCHID COMPLEX™ is a successor product to the Company's previous Oil of Orchids product, and is a base for skin creams, lotions, cleansers, and other cosmetics. It is an extract of fresh orchids, modified by extractants, 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. It is sold in two forms, water-soluble and oil-soluble.

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

AQUATHIK™ is a powder that is used as a gelling agent for aqueous solutions or emulsions with a pH below 7.

HYDRAJEL™ PL is a personal lubricant originally developed specifically for the feminine personal care market.

The Company believes that its ability to increase sales of its LUBRAJEL products for cosmetic and other personal care uses will depend on (a) the ability of its marketing partners, especially International Specialty Products Inc. ("ISP"), its largest marketing partner, to continue to aggressively promote the Company's products, particularly to new customers, and (b) the Company's success in developing new forms of LUBRAJEL that will enable the product to be used in new applications. The Company is continuing to develop new varieties of LUBRAJEL to extend the line even further, and is working with its marketing partners to find new marketing opportunities.

The Company believes that there is still significant potential to expand the sales of its LUBRAJEL line of products through product modifications, additional claim substantiation, and geographic expansion, especially in such developing markets as mainland China, India, and Eastern Europe.

Any future increases in sales of the LUBRAJEL line of products may be negatively impacted by sales of competitive products, especially new products being produced in China. However the Company believes that, because of the proprietary nature of the LUBRAJEL formulations, the strong brand name identity, the cost to the end-user of reformulation, the Company's long history of supplying quality products, the extensive line of LUBRAJEL formulations, and the Company's continuing product development programs, it will continue to be able to compete effectively in the marketplace and expand the market for its LUBRAJEL product line. See "Competition" below.

MEDICAL

LUBRAJEL RR and RC are water-based gels used primarily as lubricants for catheters. Both are special grades of LUBRAJEL that can withstand sterilization by gamma radiation, which is one of the methods of terminally sterilizing medical and hospital products. On April 11, 1995, the Company was granted a U.S. patent for these unique forms of LUBRAJEL that expires in December 2013. LUBRAJEL RR was the original radiation-resistant LUBRAJEL product. LUBRAJEL RC was developed specifically for one customer that packages the product in unit doses as a catheter lubricant for many manufacturers. Combined sales of these two products were 11% of the Company's sales in 2010. Sales of these two products decreased by 3% compared with sales of these two products in 2009. The decrease was primarily the result of the purchasing pattern of one customer for LUBRAJEL RC.

LUBRAJEL MG is the original form of LUBRAJEL developed for medical use, and is used by many medical device manufacturers for lubricating urinary catheters, prelubricated enema tips, and other medical devices. Sales increased by 10% in 2010 due to what the Company believes are fluctuations in the buying patterns of customers for this product. Sales of this product represented 3% of the Company's sales in 2010.

LUBRAJEL LC was developed for a specific customer who required a product suitable for oral use in a line of mouth moisturizers that it markets. Sales of this product decreased by 13% in 2010 compared with sales in 2009. This was a result of that customer having filled its distribution channels following the

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acquisition of the product line that includes this product by a major multinational pharmaceutical company in 2009. Sales of this product represented 4% of the Company's sales in 2010.

LUBRAJEL FLUID is a very low viscosity form of LUBRAJEL that was developed to provide superior lubrication in water-soluble products. It was specifically developed, and is currently being used, as a replacement for silicone oils in pre-lubricated condoms.

Sales of all of the medical grades of LUBRAJEL decreased by 3% and accounted for approximately 19% of the Company's sales in 2010 compared with 20% in 2009. Company believes that this was the result of fluctuations in the purchasing patterns of the customers and not the result of a long-term decrease in demand.

PHARMACEUTICAL

RENACIDIN is a prescription drug product that is used primarily to prevent and to dissolve calcifications in urethral catheters and the urinary bladder. It is marketed as a ready-to-use sterile solution. It is also approved for use in dissolving certain types of kidney stones. It currently has regulatory approval only in the United States. Historically, RENACIDIN has accounted for 16-18% of the Company's annual revenues. This product has been manufactured for the Company under a long-term contract with a major U.S. drug company that experienced regulatory problems unrelated to the production of RENACIDIN, which resulted in a temporary suspension of RENACIDIN production in August 2010. As a result, the Company's regular inventory of this product was on allocation to the Company's customers beginning at the end of November, 2010, resulting in approximately a 60% reduction in sales each month until the Company ran out of product completely in the beginning of February 2011. At the beginning of March 2011 the Company obtained permission from the FDA to market a validation batch that had been produced in 2009, and the Company began allocating this batch to customers in mid-March 2011. It may run out of product again sometime in May 2011, depending on when production resumes.

The Company has been working closely with its supplier to resume production as quickly as possible. At the present time the Company is projecting that production will resume in April, in which case normal shipments will resume in May. The Company estimates that if this schedule holds, it will have lost approximately \$550,000 in gross sales as a result of this shortage, of which approximately \$150,000 in gross sales would have impacted the Company's 2010 sales, and the balance will impact the Company's revenue in 2011. The Company has formally notified the supplier that it believes it is in breach of its supply agreement and that the Company intends to hold it responsible for any business lost and expenses incurred as a result of this temporary curtailment of production and deliveries.

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 abdominal cavity, the eye, ear, nose and throat, and the 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.

INDUSTRIAL

DESELEX™ Liquid is a sequestering and chelating agent that is a replacement for phosphates in the manufacture of detergents.

POLYCOMPLEX M and Q are complexing agents capable of producing clear solutions of specific water-insoluble materials.

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DEVELOPMENT ACTIVITIES

The Company's research and development department has developed a large number of products that can be used in many different industries, including the pharmaceutical, medical, personal care (including cosmetic), 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 the product cost makes 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 some or all of the following: (a) clinical studies needed to determine safety and effectiveness of drug or medical device products; (b) preparatory work for the filing of Investigational New Drug Applications or New Drug Applications; and (c) scaling up from laboratory production batches to pilot batches to full-scale production batches.

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:

EMOLIEN: A water-based emollient and moisturizer. It is intended to be a cost-effective emollient to increase lubricity and moisturization for creams, lotions and gels, as well as other potential uses.

ESSENTIAL ELEMENTS: A new product for skin and hair care applications. The specifics cannot be disclosed until patentability issues are investigated further, but the product would be used to maintain and improve healthy cellular metabolism.

NATURAL POLYMER BLEND: A line of polymers from natural sources (sourced from vegetables and micro-organisms), suitable as a thickener and emulsion stabilizer.

LUBRAJEL UT: A new form of LUBRAJEL, formulated with a new ingredient, that may have health care uses, primarily in the urological field. The Company is in the process of sampling this product to potential customers, and has filed a patent application with the U.S. Patent & Trademark Office.

UNITWIX: The Company has recently completed the development of an alternative formulation of its Unitwix product, which is a cosmetic additive used as a thickener for oils and oil-based liquids. The new formulation is less expensive, which will enable the Company to market it at a substantially lower price than

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the current formulation, while also increasing the Company's profit margin. The new formulation is now being sampled to the Company's customers.

It should be understood that many of the research and development projects listed above are in their early stages of development, and there can be no assurance that marketable products will result from these efforts.

The Company expects its research and development costs for 2011 to be comparable to those of 2010, which were \$596,000. Any additional increase in development and/or production costs will depend on whether capital investments are required in order to continue development work on, or to manufacture, any of the new products under development.

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

TRADEMARKS and PATENTS

The Company strongly believes in protecting its intellectual property and intends, whenever reasonably possible and economically practical, to obtain patents in connection with its product development program. The Company currently holds a number of United States patents and trademarks relating to its products, and regularly has patent and trademark applications pending with respect to a number of its research and development products. Some patents previously issued to the Company on certain products have expired. There can be no assurance that any patents held by the Company will be valid or otherwise of value to the Company, or that any patent applied for will be granted. However, the Company believes that its proprietary manufacturing techniques and procedures with respect to certain products offer it some protection from duplication by competitors regardless of the patent status of the products.

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 products for which the Company has registered trademarks are LUBRAJEL® and RENACIDIN®.

Set forth below is a table listing certain information with respect to all unexpired U.S. patents held by the Company. The Company also has one or more patents pending.

PATENT NAME	PATENT #	FILING DATE	ISSUE DATE	EXPIRATION DATE
Radiation-resistant lubricating gel	5,405,622	12/1993	4/1995	12/2013
Delivery system for oil-soluble actives in cosmetic and personal care products	6,117,419	9/1996	9/2000	12/2016
Microemulsion of silicone in a water-based gel that forms a clear, transparent, highly stable moisturizer and lubricant for cosmetic and medical use	6,348,199	1/1994	2/2002	2/2019

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The following Company patents expired over the past two fiscal years:

PATENT NAME	Expiration Date
Stable, active chlorine-containing antimicrobial compositions ("Cloroline")	July 2009
Stabilized beta carotene	June 2010

The expiration of these patents will not have any impact on the Company's revenues, since there were no sales of products utilizing these patents in 2009 or 2010.

DOMESTIC SALES

In the United States, the Company's cosmetic ingredient products are marketed and distributed exclusively by ISP in accordance with a marketing agreement entered into in 1996 and subsequently amended and expanded in 2000, 2002, 2005 and 2010 (see "Marketing Agreements" below). ISP also has certain non-exclusive rights to sell some of the Company's other industrial and medical products. See "Marketing Agreements" below.

The Company's domestic sales of pharmaceutical products are handled primarily through the major full-line drug wholesalers and accounted for approximately 20% of the Company's sales in 2010 and 21% in 2009. The Company's other products, such as its medical (non-pharmaceutical) and specialty industrial products, are sold directly to manufacturers who incorporate these products in their finished products.

FOREIGN SALES

In 2010, approximately 55% of the Company's sales were to customers in foreign countries, primarily sales of its cosmetic ingredients to customers in Europe and Asia, compared with 50% in 2009. The Company currently has six distributors for its personal care products outside the United States, with ISP being the largest. The Company has a written marketing agreement only with ISP; all other marketing arrangements are subject to cancellation at any time by either the Company or the distributor. The marketing agreement with ISP gives it exclusive foreign marketing rights with the exception of the following areas: the United Kingdom (handled 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 direct sales to a company in Ireland, Harmac Medical Products Ltd., for one of the Company's LUBRAJEL products for a medical use.

MARKETING

The Company markets its products through marketing partners and distributors, advertising in medical and trade journals, mailings to physicians and to the trade, and exhibitions at medical meetings. The pharmaceutical products are sold in the United States primarily to drug wholesalers, which in turn distribute and resell those products to drug stores, hospitals, physicians, long-term care facilities, and the Veteran's Administration and other government agencies. The proprietary cosmetic ingredients and other personal care products are sold outright (not on consignment) to the Company's marketing partners, which in turn market and resell the products to cosmetic and other personal care manufacturers for use in the manufacture or compounding of their products. The medical (non-pharmaceutical) and specialty industrial products are sold by the Company directly to the end-users.

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MARKETING AGREEMENTS

In 1994, the Company entered into a marketing agreement with ISP whereby ISP would market and distribute the Company's personal care products, as well as some medical and specialty industrial products, in certain parts of Europe, Asia, Australia, and Africa. ISP manufactures and markets globally an extensive line of personal care and pharmaceutical additives and various other industrial products. In 1996, the parties entered into another agreement, extending ISP's distribution rights to the United States, Canada, Mexico, and Central and South America. In July 2000, the parties entered into an Exclusive Marketing Agreement (the "2000 Agreement"), which modified, extended, and consolidated the 1994 and 1996 agreements. The 2000 Agreement also gave the Company greater flexibility in appointing other marketing partners in areas where ISP was not active or had not been successful, gave ISP certain additional territories, and granted ISP exclusivity in the territories assigned to it as long as annual minimum purchase requirements were met.

In December 2002, the parties entered into a letter agreement that extended and modified the 2000 Agreement. This was further modified in December 2005 to extend ISP's marketing rights until December 2008, and to provide for automatic extensions until December 2010 if specified minimum annual purchase levels were attained. It also specified guidelines and provisions for future price increases by the Company. Although ISP did not attain the sales levels required for the automatic extension at the end of 2008, the Company was satisfied with the marketing efforts of ISP, and on May 5, 2010 a letter agreement was signed that extended the marketing agreement until December 31, 2011. The new amendment provided for automatic two-year renewals unless either party terminated the arrangement upon 60 days notice. Because the renewal term was now only two years, the 2010 amendment also eliminated the minimum purchase requirements that had been in effect during the previous contract periods.

The Company believes that in the event ISP were to cease marketing the Company's products alternative arrangements could be made 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 five major raw material vendors that together account for approximately 89% of the raw material purchases by the Company. The names of the suppliers and the specific raw materials are considered by the Company to be confidential and proprietary information.

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; however, for 2011 the Company does anticipate that it will be unable to fulfill all of the orders for its RENACIDIN due to supply problems (see Part I, Item 1(b) above).

BACKLOG

The Company currently does not have any significant backlog.

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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

Except for non-pharmaceutical medical products and specialty industrial products that are sold directly by the Company to the end-users, the Company's customers are primarily its marketing partners and distributors. They in turn sell the Company's products to hundreds of end-users. Although the Company has relatively few marketing partners and distributors, it is not dependent on any one of those companies for the sale of its products. The Company is confident that if any of its marketing partners or distributors were to decide not to sell the Company's products, the end-users of its products would still purchase the Company's products, either directly from the Company or from a replacement marketing partner or distributor.

COMPETITION

The Company has many products or processes that are either proprietary or have some unique characteristics, and therefore the Company believes it has been able, and will continue to be able, to compete effectively with other pharmaceutical, personal care, specialty chemical, or health care companies as to products deemed competitive with the those of the Company. The pharmaceutical, health care, and cosmetic industries are all highly competitive, and the Company expects competition to intensify as advances in the field are made and become widely known. 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. However, the Company believes that the expense of testing and evaluating possible substitutes for the Company's products that are already in customers' formulations, as well as the expense to the customer in relabeling its products, is a significant barrier to displacing the Company's products in current customer formulations. These cost factors make it less likely that a customer would choose a competitive product, unless there was a significant cost savings in doing so. The Company believes that manufacturing, regulatory, distribution and marketing expertise will be increasingly important competitive factors in favor of the Company. In this regard, the Company believes that its marketing arrangements with its global marketing partners will be important in the commercialization of many of the products it is currently developing.

ISO 9001:2008 REGISTRATION

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

UNITED-GUARDIAN, INC.

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 a