

Corporate Divisions GUARDIAN LABORATORIES

Corporate Headquarters 230 MARCUS BLVD. HAUPPAUGE, NY 11788 Mailing Address P.O. BOX 18050 HAUPPAUGE, NY 11788

 TEL:
 (631) 273-0900

 FAX:
 (631) 273-0858

 E-MAIL:
 pgc@u-g.com

# Second Quarter 2013 Report to Stockholders

August 29, 2013

Dear Stockholder:

The second quarter of 2013 was another strong quarter for us, with net income up 12% over last year's second quarter, and earnings per share for the quarter increasing from \$0.26 to \$0.29. As a result, net income for the first half of the year increased by 20% from \$2.4 million (\$0.53 per share) to \$2.9 million (\$0.63 per share). Earnings for the second quarter and the first six months of 2013 both reached new company highs.

On the revenue side we were down slightly for both the second quarter and first half of the year. This was attributable to the lack of sales of Renacidin<sup>®</sup> Irrigation, our largest urological product. Those of you who have been stockholders of ours for the past couple of years will know that Renacidin has been off the market since August 2012 due to manufacturing issues at our supplier's production facility. This production curtailment significantly impacted our sales for the first half of this year. However, despite the lack of Renacidin sales, we were still able to attain record second quarter and six-month earnings. I will provide more details on the status of Renacidin later in this letter.

As a result of our increase in earnings, our balance sheet has continued to strengthen, with working capital increasing from \$11,795,895 as of December 31, 2012 to \$12,359,730 as of June 30, 2013, an increase of \$563,835. Stockholders equity during this period increased from \$12,838,018 to \$13,463,702.

Despite the absence of Renacidin sales we still came close to our 2012 six-month revenue figures. This was the result of increased sales of our personal care products, primarily our Lubrajel<sup>®</sup> line of water-based moisturizing and lubricating gels. Sales of those products to our largest marketing partner, Ashland Specialty Ingredients ("ASI"; formerly International Specialty Products), increased almost 12% compared with last year's second quarter, and almost 13% compared with the first six months of 2012. Overall, sales of personal care products in the second quarter 2013 increased almost 10% compared with the same period last year, and personal care product sales for the first half of 2012 increased 12% over the comparable period last year. In addition, sales of our non-pharmaceutical medical products, such as our radiation-resistant catheter lubricants, increased by about 14% for the quarter and 22% for the first six months of the year.

As far as Renacidin Irrigation is concerned, we are proceeding on two fronts: first, to get the current product back on the market through our current supplier, and second, to obtain FDA approval for us to market the product in a new 30mL plastic vial (versus our current 500mL glass bottle). In terms of getting our current product back on the market, in June our current supplier produced an engineering run, implementing some manufacturing and equipment changes. The data from that run was submitted to the FDA in the beginning of August. We are hoping to hear back from them in the next

few weeks. Our ability to resume production will depend not only on receiving FDA approval, but also on passing the 3-month inspection of the batch that will be conducted by the supplier on September 6<sup>th</sup>. If the product passes we will be able to resume production as soon as we are sure that the FDA is satisfied with our submission, which we currently hope will be in mid-September. If all goes well we hope to have new product to sell by the end of October.

In regard to our efforts to bring to market a new 30mL plastic single-dose unit to replace our current 500mL glass bottle, we have been actively working on this project with Smiths Medical, an Illinoisbased global provider of medical devices. Smiths is part of Smiths Group plc, a London-based global technology company listed on the London Stock Exchange. We expect Smiths to be our supplier for the new dosage size. A few months ago, with Smiths assistance, we contracted with a company to produce a mold for us that will be used to manufacture the new plastic bottle. The mold is due to be completed by the end of the first week of September. The next step will be to produce three small batches of product that will be put up for stability testing. The data from that testing will be used to support our regulatory submission to the FDA, which we hope to file by the end of this year. How quickly the FDA acts on that submission may depend in part on whether we are able to resume production of our current product. We expect to know a lot more about the timing in the next few weeks. If for any reason our current supplier does not resume manufacturing, then we anticipate that the FDA will expedite the review of our new submission. If that were to happen, we might be able to go into production on the new dosage size by the end of the first guarter of 2014 or early in the second guarter. If production does resume we intend to bring in sufficient inventory to last us until our new submission is approved and we can begin production of the new single-dose unit.

Although a lot of resources, both time and money, are being devoted to getting Renacidin back on the market, that does not mean that we have ignored our other product lines. Development work is continuing on new products for our personal care products line, and we have two new products in the Lubrajel "Natural" line that are nearing completion and which we expect to send out to our marketing partners by the end of September for evaluation. One of these is an all-natural version of our Lubrajel Oil, which is one of our best selling Lubrajel products. The other is an all-natural water-based gel that is produced using marine-based ingredients. These two products will supplement the first Lubrajel Natural product, which is currently being sampled to potential customers. We are excited about these new products, and hope that their introduction will enable us to continue to expand our personal care products business.

We are also working with ASI to develop some new lower-cost moisturizing gels that might be suitable for marketing in emerging markets, where the cost of using our current line of Lubrajel products is too high for many customers. While being mindful of protecting our current market, we believe that we can develop a product that will not take away market share from our current product lines but could, at the same time, allow us to enter new markets where our current products are not being sold. We are hopeful that the development of such a product or products will help us to further expand the markets for our products.

We are very pleased that we have been able to maintain, and even increase, our earnings despite the loss of Renacidin sales, and are excited about the prospect of getting our current Renacidin product back on the market soon. We are even more excited about the market potential for our new single-dose Renacidin bottle. I hope that by the time our next stockholders letter is due out I will have good news on both fronts.

Sincerely,

UNITED-GUARDIAN, INC.

en Globus

Ken Globus President

### RESULTS FOR THE SECOND QUARTER ENDED JUNE 30, 2013 and JUNE 30, 2012\*

#### **INCOME STATEMENTS**

	THREE MONTHS ENDED JUNE 30,			SIX MONTHS ENDED JUNE 30,	
	<u>2013</u>	<u>2012</u>	<u>2013</u>	<u>2012</u>	
Net sales Costs and expenses Income from operations	\$ 3,628,571 <u>1,999,186</u> 1,629,385	\$ 3,735,100 <u>2,013,373</u> 1,721,727	\$ 7,580,732 <u>3,971,910</u> 3,608,822	\$ 7,623,792 <u>4,156,076</u> 3,467,716	
Other income Income before income taxes	<u>    357,755</u> 1,987,140	<u>41,757</u> 1,763,484	<u>704,767</u> 4,313,589	<u>114,098</u> 3,581,814	
Provision for income taxes Net Income	<u>644,600</u> \$ <u>1,342,540</u>	<u> </u>	<u>1,406,400</u> \$ <u>2,907,189</u>	<u>1,160,100</u> \$ <u>2,421,714</u>	
Earnings per common share (Basic and Diluted)	\$ <u>0.29</u>	\$0.26	\$0.63	\$ <u>0.53</u>	
Weighted average shares - basic and diluted	<u>4,596,439</u>	<u>4,596,439</u>	<u>4,596,439</u>	<u>4,596,439</u>	

## **BALANCE SHEETS**

ASSETS	JUNE 30, <u>2013</u>	DECEMBER 31, <u>2012</u>
		(AUDITED)
Current assets	\$ 13,656,408	\$ 12,623,403
Total property, plant and equipment, net	1,232,688	1,235,863
TOTAL ASSETS	\$ <u>14,889,096</u>	\$ <u>13,859,266</u>

#### LIABILITIES AND STOCKHOLDERS' EQUITY

	JUNE 30, <u>2013</u>	DECEMBER 31, <u>2012</u> (AUDITED)
Current Liabilities	\$ 1,296,678	\$ 827,508
Deferred income taxes	128,716	193,740
Stockholders' equity	<u>13,463,702</u>	<u>12,838,018</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ <u>14,889,096</u>	\$ <u>13,859,266</u>

\* Financial results are unaudited unless indicated otherwise.