U.S. SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

☑ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended <u>September 30, 2021</u>

□ TRANSITION REPORT PURSUANT TO 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to ____

COMMISSION FILE NUMBER: <u>1-10526</u>

UNITED-GUARDIAN, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation or Organization) <u>11-1719724</u> (I.R.S. Employer Identification No.)

230 Marcus Boulevard, Hauppauge, New York 11788 (Address of Principal Executive Offices)

> (631) 273-0900 (Registrant's Telephone Number)

> > N/A

(Former name, former address, and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, \$0.10 par value per share	UG	NASDAQ Global Market

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 \square No \square

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 \square No \square

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See 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	Smaller reporting company	Ø
	Emerging growth company	

If an emerging growth company, indicate by checkmark 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. \Box

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date:

As of November 1, 2021, the Registrant had issued and outstanding 4,594,319 shares of Common Stock, \$.10 par value per share ("Common Stock").

UNITED-GUARDIAN, INC.

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UNITED-GUARDIAN, INC.

Part I. FINANCIAL INFORMATION

ITEM 1. Condensed Financial Statements

STATEMENTS OF INCOME

(UNAUDITED)

	THREE MO SEPTI <u>2021</u>	ONTHS Ember		NINE MO SEPT <u>2021</u>	S ENDED ER 30, <u>2020</u>			
Net Sales	\$ <u>3,179,746</u>	\$	<u>2,336,360</u>	\$	<u>10,268,592</u>	\$	<u>8,613,918</u>	
Costs and expenses:								
Cost of sales	1,320,509		974,763		4,180,912		3,634,528	
Operating expenses	458,582		493,204		1,428,721		1,520,114	
Research and development	130,742		114,836		349,053		331,134	
Total costs and expenses	1,909,833		<u>1,582,803</u>		<u>5,958,686</u>		<u>5,485,776</u>	
Income from operations	<u>1,269,913</u>		753,557		<u>4,309,906</u>		<u>3,128,142</u>	
Other Income:								
Investment income	38,747 38,932			124,147	124,147			
Net (loss) gain on marketable securities	(25,108)		<u>113,248</u>		40,419		143,832	
Total other income	<u> (20,100)</u> <u> 13,639</u>		<u>152,180</u>		164,566		275,150	
			102,100					
Income before provision for income taxes	1,283,552		905,737		4,474,472		3,403,292	
Provision for income taxes	267,046		<u>188,205</u>		932,240		708,842	
Net Income	\$ <u>1,016,506</u>	\$	<u>717,532</u>	\$	<u>3,542,232</u>	\$	<u>2,694,450</u>	
Earnings per common share (Basic and Diluted)	\$ 0.22	\$	0.16	\$	0.77	\$	0.59	
Weighted average shares – basic and diluted	4,594,319		4,594,319		4,594,319		4,594,319	

BALANCE SHEETS

ASSETS

	SEPTEMBER 30, <u>2021</u>	DECEMBER 31, <u>2020</u>
Current assets:	(UNAUDITED)	(AUDITED)
Cash and cash equivalents	\$ 691,921	\$ 591,444
Marketable securities	8,893,454	7,591,381
Accounts receivable, net of allowance for doubtful accounts of \$27,296 at September 30, 2021 and \$14,017 at December 31, 2020	1,930,183	1,387,698
Inventories, net	1,287,234	1,415,773
Prepaid expenses and other current assets	159,361	161,208
Prepaid income taxes		99,107
Total current assets	<u>12,962,153</u>	<u>11,246,611</u>
Net property, plant, and equipment:		
Land	69,000	69,000
Factory equipment and fixtures	4,571,364	4,516,335
Building and improvements	<u>2,853,718</u>	2,848,585
Total property, plant, and equipment	7,494,082	7,433,920
Less: Accumulated depreciation	6,830,549	6,760,255
Total property, plant, and equipment, net	663,533	673,665
TOTAL ASSETS	\$ <u>13,625,686</u>	\$ <u>11,920,276</u>

BALANCE SHEETS

(continued)

LIABILITIES AND STOCKHOLDERS' EQUITY

	SEPTEMBER 30, 2021	DECEMBER 31, 2020
Current liabilities:	(UNAUDITED)	(AUDITED)
Accounts payable	\$ 87,158	\$ 31,800
Accrued expenses and other current liabilities	1,542,760	1,363,457
Income taxes payable	57,614	
Dividends payable	19,685	19,028
Total current liabilities	<u>1,707,217</u>	<u>1,414,285</u>
Deferred income taxes	227,203	<u> 151,684</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock (at \$.10 par value) (10,000,000 shares authorized; 4,594,319 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively)	459,432	459,432
Retained earnings	<u>11,231,834</u>	9,894,875
Total stockholders' equity	<u>11,691,266</u>	<u>10,354,307</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ <u>13,625,686</u>	\$ <u>11,920,276</u>

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2021

	Com <u>Shares</u>	mon stock <u>Amount</u>	Retained <u>Earnings</u>	Total		
Balance, January 1, 2021	4,594,319	\$ 459,432	\$ 9,894,875	\$ 10,354,307		
Net income			1,181,202	1,181,202		
Balance, March 31, 2021	4,594,319	\$ 459,432	\$ 11,076,077	\$ 11,535,509		
Net income			1,344,524	1,344,524		
Dividends declared and paid (\$0.48 per share)			(2,204,616)	(2,204,616)		
Dividends declared, not paid (\$0.48 per share)			(657)	(657)		
Balance, June 30, 2021	4,594,319	\$ 459,432	\$ 10,215,328	\$ 10,674,760		
Net income			1,016,506	1,016,506		
Balance, September 30, 2021	<u>4,594,319</u>	\$ <u>459,432</u>	\$ <u>11,231,834</u>	\$ <u>11,691,266</u>		

THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2020

	Comn <u>Shares</u>	non stock <u>Amount</u>	Retained <u>Earnings</u>	<u>Total</u>		
Balance, January 1, 2020	4,594,319	\$ 459,432	\$ 10,173,466	\$ 10,632,898		
Net income			790,307	790,307		
Balance, March 31, 2020	4,594,319	\$ 459,432	\$ 10,963,773	\$ 11,423,505		
Net income			1,186,611	1,186,611		
Dividends declared and paid (\$0.42 per share)			(1,928,969)	(1,928,969)		
Dividends declared, not paid (\$0.42 per share)			(645)	(645)		
Balance, June 30, 2020	4,594,319	\$ 459,432	\$ 10,220,770	\$ 10,680,202		
Net income			717,532	717,532		
Balance, September 30, 2020	<u>4,594,319</u>	\$ <u>459,432</u>	\$ <u>10,938,302</u>	\$ <u>11,397,734</u>		

STATEMENTS OF CASH FLOWS

(UNAUDITED)

		NTHS E Embef	
	<u>2021</u>		2020
Cash flows from operating activities:	2021		2020
Net income	\$ 3,542,232	\$	2,694,450
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	106,928		121,669
Net gain on marketable securities	(40,419)		(143,832)
Gain on sale of asset	(14,799)		
Allowance for doubtful accounts	13,279		(992)
Deferred income taxes (Increase) decrease in operating assets:	75,519		(155,127)
Accounts receivable	(555,764)		815,808
Inventories	128,539		(327,542)
Prepaid expenses and other current assets	1,847		4,185
Prepaid income taxes	99,107		38,969
Increase (decrease) in operating liabilities:	55 050		(00, 400)
Accounts payable	55,358		(30,460)
Accrued expenses and other current liabilities	179,303		29,233
Income taxes payable	57,614		
Dividends payable			(124,657)
Net cash provided by operating activities	3,648,744		<u>2,921,704</u>
Cash flows from investing activities:			
Acquisition of property, plant and equipment	(81,997)		(25,437)
Proceeds from sale of marketable securities	1,832,829		3,802,205
Purchases of marketable securities	<u>(3,094,483</u>)		<u>(4,932,754</u>)
Net cash used in investing activities	<u>(1,343,651</u>)		<u>(1,155,986</u>)
Cash flows from financing activities:			
Dividends paid	<u>(2,204,616</u>)		<u>(1,928,969</u>)
Net cash used in financing activities	<u>(2,204,616</u>)		<u>(1,928,969</u>)
Net increase (decrease) in cash and cash equivalents	100,477		(163,251)
Cash and cash equivalents at beginning of period	591,444		<u>1,048,311</u>
Cash and cash equivalents at end of period	\$ <u> 691,921</u>	\$	885,060
Supplemental disclosure of cash flow information:			
Taxes paid	\$ 700,000	\$	825,000
Supplemental disclosure of non-cash items:			
Dividends payable	\$ <u> </u>	\$	<u> </u>
Trade-in received from sale of asset	\$ 29,000	\$	

UNITED-GUARDIAN, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(UNAUDITED)

1. Nature of Business

United-Guardian, Inc. (the "Company") is a Delaware corporation that, through its Guardian Laboratories division, conducts research, product development, manufacturing and marketing of cosmetic ingredients, pharmaceuticals, medical products and proprietary specialty industrial products. The Company's research and development department modifies, refines, and expands the uses for existing products for additional uses and markets. It also develops new products using natural and environmentally friendly raw materials, which is important to many of the Company's cosmetic customers.

2. Basis of Presentation

Interim condensed financial statements of the Company are prepared in accordance with United States Generally Accepted Accounting Principles ("US GAAP") for interim financial information, pursuant to the requirements for reporting on Form 10-Q and Regulation S-X. In the opinion of management, all adjustments, including normal recurring accruals, considered necessary for the fair presentation of financial statements for the interim periods have been included. The results of operations for the three and nine months ended September 30, 2021 (also referred to as the "third quarter of 2021" and the "first nine months of 2021", respectively) are not necessarily indicative of results that ultimately may be achieved for any other interim period or for the year ending December 31, 2021. The interim unaudited condensed financial statements and notes thereto should be read in conjunction with the audited financial statements and notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2020.

3. Impact of Coronavirus (COVID-19)

While the coronavirus pandemic ("pandemic") continues to impact the Company's operations, the substantial impact the pandemic had on Company sales in 2020 significantly lessened in the first nine months of 2021. The current impact is coming primarily from supply chain disruptions, which have resulted in increased packaging and shipping costs, and increases in the cost of some raw materials, although it has not significantly affected the ability of the Company to obtain raw materials. It has, however, resulted in some shipping delays due to the shortage of truck drivers. The Company has been able to maintain production throughout the pandemic.

Sales of the Company's non-pharmaceutical medical products ("medical products") had also been negatively impacted by the pandemic in 2020, but those impacts have lessened as well in the first three quarters of 2021. Sales of the Company's pharmaceutical products were not impacted by the pandemic in 2020 or in the first nine months of 2021.

There continues to be some uncertainty in regard to the future impact of the pandemic on the Company's operations or financial results and as a result it is difficult for the Company to provide an accurate estimate or projection as to what the future impact of the pandemic will be on the

Company's future operations or financial results. The Company does not expect the carrying value of its assets or its liquidity to be impaired by the coronavirus pandemic.

4. Use of Estimates

In preparing financial statements in conformity with 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 revenues and expenses during the reporting period. Actual results could differ from those estimates. Such estimated items include the allowance for bad debts, reserve for inventory obsolescence, accrued distribution fees, outdated material returns, possible impairment of marketable securities, and the allocation of overhead.

5. 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 September 30, 2021 and December 31, 2020, approximately \$806,000 and \$653,000 exceeded the FDIC limit.

6. Revenue Recognition

The Company records revenue in accordance with ASC Topic 606 "Revenue from Contracts with Customers." Under this 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 or services. The Company's principal source of revenue is product sales.

The Company's sales, as reported, are subject to a variety of deductions, some of which are estimated. These deductions are recorded in the same period in which the revenue is recognized. Such deductions, primarily related to the sale of the Company's pharmaceutical products, include chargebacks from the United States Department of Veterans Affairs ('VA"), rebates in connection with the Company's current participation in Medicare programs and its past participation in Medicaid programs, distribution fees, discounts, and outdated product returns. These deductions represent estimates of the related obligations and, as such, knowledge and judgment are required when estimating the impact of these revenue deductions on sales for a reporting period.

During 2021 and 2020, the Company participated in various government drug rebate programs related to the sale of Renacidin[®], its most important pharmaceutical product. These programs include the Veterans Affairs Federal Supply Schedule (FSS), and the Medicare Part D Coverage Gap Discount Program (CGDP). These programs require the Company to sell its product at a discounted price. In addition, during 2020, the Company also participated in the Medicaid Drug Rebate Program (MDRP), which required the Company to pay a significant rebate to the various states where Renacidin was provided to Medicaid patients, as well as the Section 340B Drug Pricing Program (340B), which required the Company to sell Renacidin at a deeply discounted price. Due to the overly burdensome nature of the Medicaid rebates, and the deeply discounted pricing associated with the 340B Program, the Company terminated its participation in the MDRP

and the 340B Programs, effective December 31, 2020. The Company's sales, as reported, are net of these rebates, some of which are estimated and are recorded in the same period that the revenue is recognized.

The Company recognizes revenue from sales of its cosmetic ingredients, 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 and the Company's performance obligation is satisfied. 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, which is when the risk of loss and responsibility for the shipment passes to the customer, and the performance obligation of the Company is satisfied. 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 under ASC Topic 606-10-32-8. 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 September 30, 2021 and December 31, 2020, the allowance for doubtful accounts receivable was \$27,296 and \$14,017, respectively. Prompt-pay discounts are offered to some customers; however, due to the uncertainty of the customers taking the discounts, the discounts are recorded when they are taken.

At September 30, 2021, the Company recorded an advance payment from one of its customers in the amount of \$128,636. The related performance obligation associated with this payment had not been satisfied as of the balance sheet date. The deferred revenue related to this payment is included in accrued expenses and other current liabilities.

The Company has distribution fee contracts with certain distributors of its pharmaceutical products that entitles them to distribution and service-related fees. The Company records distribution fees and estimates distribution fees as offsets to revenue.

Disaggregated sales by product class are as follows:

	Three months ended September 30,							nths ended ember 30,		
	<u>2021</u>			<u>2020</u>		<u>2021</u>			<u>2020</u>	
Cosmetic Ingredients	\$ 1,578,650	:	\$	550,177	\$	5,065,022		\$	3,358,956	
Pharmaceutical	1,216,747			1,232,586		3,509,235			3,463,738	
Medical	343,884			517,036		1,580,657			1,683,682	
Industrial products	40,465			36,561		113,678			107,542	
Total Sales	\$ <u>3,179,746</u>	:	\$	<u>2,336,360</u>	\$	<u>10,268,592</u>		\$	<u>8,613,918</u>	

The Company's cosmetic ingredients are marketed worldwide by five marketing partners, of which U.S.-based Ashland Specialty Ingredients ("ASI") purchases the largest volume. Approximately 16% of the Company's total sales in the third quarter of 2021 were to customers located outside of the United States, compared with approximately 22% in the third quarter of 2020. For the nine months ended September 30, 2021, approximately 21% of the Company's total sales were to customers located outside of the United States, compared with approximately 21% of the Company's total sales were to customers located outside of the United States, compared with approximately 20% for the nine months ended September 30, 2020.

Disaggregated sales by geographic region are as follows:

		onths ended ember 30,		nths ended mber 30,		
	2021	2020	2021	2020		
United States*	\$ 2,670,515	\$ 1,819,084	\$ 8,115,145	\$ 6,887,726		
Other countries	509,231	<u>517,276</u>	2,153,447	<u>1,726,192</u>		
Total Sales	\$ <u>3,179,746</u>	\$ <u>2,336,360</u>	\$ <u>10,268,592</u>	\$ <u>8,613,918</u>		

* Since substantially all purchases by ASI are shipped to ASI's warehouses in the U.S., all sales to ASI are reported as U.S. sales for financial reporting purposes, even though a significant quantity of those purchases will be shipped by ASI to foreign customers. ASI has reported to the Company that approximately 76% of its sales of the Company's products in the third quarter of 2021 were to foreign customers compared with 69% for the same period in 2020, with China representing approximately 29% of those foreign sales in the third quarter of 2021, compared with approximately 30% in the third quarter of 2020.

For the nine months ended September 30, 2021 approximately 72% of ASI's sales of the Company's products were to customers in other countries, with China accounting for approximately 35% of ASI's sales of the Company's products, as compared with approximately 69% of ASI's sales going to customers in other countries for the nine months ended September 30, 2020, with China accounting for approximately 33% of ASI's sales of the Company's products during that period.

7. Marketable Securities

Marketable securities include investments in fixed income and equity mutual funds, and U.S. Government securities with maturities greater than 3 months, all of which are reported at their fair values.

The disaggregated net gains and losses on the marketable securities recognized in the income statements for the three and nine months ended September 30, 2021 and 2020, respectively, are as follows:

	Three months ended September 30,				Nine months ende September 30,		
	<u>2021</u>		<u>2020</u>		<u>2021</u>		<u>2020</u>
Net (losses) gains recognized during the period on marketable securities	\$ (25,108)	\$	113,248	\$	40,419	\$	143,832
Less: Net gains recognized during the period on marketable securities sold during the period			25,062		<u>112,180</u>		29,918
Unrealized (losses) gains recognized during the reporting period on marketable securities still held at the reporting date	\$ <u>(25,108</u>)	\$	<u>88,186</u>	\$	<u>(71,761</u>)	\$	<u>113,914</u>

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 marketable equity securities, which are considered available for sale 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:

September 30, 2021 (Unaudited)

Equity Securities	<u>Cost</u>	Fair Value	Unrealized <u>Gain</u>
Fixed income mutual funds Equity and other mutual funds Total equity securities	\$ 8,050,443 <u>610,542</u> <u>8,660,985</u>	\$ 8,172,762 <u>720,692</u> <u>8,893,454</u>	\$ 122,319 <u>110,150</u> <u>232,469</u>
Total marketable securities	\$ <u>8,660,985</u>	\$ <u>8,893,454</u>	\$ <u>232,469</u>

December 31, 2020 (Audited)

Equity Securities	<u>Cost</u>	Fair Value	Ľ	<u>Gain</u>
Fixed income mutual funds Equity and other mutual funds Total equity securities	\$ 6,703,107 <u>584,044</u> 7,287,151	\$ 6,907,270 <u>684,111</u> 7,591,381	\$	204,163 <u>100,067</u> 304,230
Total marketable securities	\$ <u>7,287,151</u>	\$ <u>7,591,381</u>	\$	<u>304,230</u>

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 a specific identification basis.

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Proceeds from the sale and redemption of marketable securities amounted to \$1,832,829 for the nine months ended September 30, 2021, which included realized gains of \$112,180. Proceeds from the sale and redemption of marketable securities amounted to \$3,802,205 for the nine months ended September 30, 2020, which included realized gains of \$29,918.

8. Inventories

	September 30, <u>2021</u>	December 31, <u>2020</u>		
	(UNAUDITED)	(AUDITED)		
Inventories consist of the following:				
Raw materials	\$ 434,178	\$ 415,415		
Work in process	75,716	59,258		
Finished products	777,340	941,100		
Total inventories	\$ <u>1,287,234</u>	\$ <u>1,415,773</u>		

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. Finished product inventories at September 30, 2021 and December 31, 2020 are stated net of a reserve of \$35,000 for slow moving and obsolete inventory. At September 30, 2021 and December 31, 2020, the Company had allowances of \$311,311 and \$302,713 respectively, for possible outdated material returns, which is included in accrued expenses.

As of the date of this report, the Covid-19 pandemic has not materially impacted the valuation of the Company's finished products, work in process, or raw material inventories, but increases in the cost of some raw materials may impact future inventory valuations.

9. Income Taxes

The Company's tax provision is based on its estimated annual effective tax rate. The Company continues to fully recognize its tax benefits, and as of September 30, 2021 and December 31, 2020, the Company did not have any unrecognized tax benefits. The Company's provision for income taxes for the three and nine months ended September 30 comprises the following:

	Three months ended September 30,		Nine months ended September 30,		er 30,	
Provision for federal income taxes - current	\$ <u>2021</u> 340,981	\$	<u>2020</u> 81,323	\$ <u>2021</u> 856,621	\$	<u>2020</u> 863,819
Provision for state income taxes - current				100		150
(Benefit from) provision for federal income taxes – deferred	<u>(73,935</u>)		<u>106,882</u>	75,519		<u>(155,127</u>)
Total provision for income taxes	\$ <u>267,046</u>	\$	<u>188,205</u>	\$ <u>932,240</u>	\$	708,842

10. Defined Contribution Plan

The Company sponsors a 401(k) defined contribution plan ("DC Plan") that provides for a dollarfor-dollar employer matching contribution of the first 4% of each employee's pay that is deferred by the employee. Employees become fully vested in employer matching contributions after one year of employment.

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. 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. The Company accrued \$87,000 in contributions to the DC Plan for the nine months ended September 30, 2021, and \$108,750 for the nine months ended September 30, 2020. For the first three quarters of 2021 and 2020, the Company did not make any discretionary contributions to the DC Plan.

11. Related-Party Transactions

During the three months ended September 30, 2021, there were no payments made to related parties. For the nine months ended September 30, 2021, the Company made payments of \$9,500, to the accounting firm PKF O'Connor Davies ("PKF") for accounting and tax services. For the three and nine months ended September 30, 2020, the Company made payments of \$9,500 for accounting and tax services to Bonamassa, Maietta and Cartelli, LLP "Bonamassa"). Lawrence Maietta, a partner at PKF O'Connor Davies, and previously a partner at Bonamassa before its combination with PKF, is a director of the Company.

12. Other Information

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

Accrued Expenses	September 30, <u>2021</u> (Unaudited)			December 31, <u>2020</u> (Audited)		
Bonuses	\$	237,000	\$	210,000		
Distribution fees		362,315		325,792		
Payroll and related expenses		225,328		245,521		
Reserve for outdated material		311,311		302,713		
Company 401(k) contribution		87,000				
Deferred revenue		128,636				
Audit fee		57,875		50,500		
Annual report expenses		46,462		63,432		
Sales rebates		51,428		149,346		
Other		35,405		16,153		
Total Accrued Expenses	\$	<u>1,542,760</u>	\$	<u>1,363,457</u>		

13. Recent Accounting Pronouncements

On January 1, 2021, the Company adopted Accounting Standards Update (ASU) 2019-12, "Simplifying the Accounting for Income Taxes." This standard modified ASU 740 and simplifies the accounting for income taxes. The Company has determined that these modifications did not have an 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. In November 2019, the FASB amended the effective date of implementation of this standard for smaller reporting companies. The new effective date is for fiscal years beginning after December 15, 2022. The Company is currently evaluating if this pronouncement will have a potential impact on its financial statements.

14. Concentrations of Credit Risk

<u>Customer concentration</u> - 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 and its overall credit worthiness 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 credit risk from accounts receivable is low.

For the three months ended September 30, 2021, one of the Company's marketing partners, and three of its distributors, together accounted for 86% of the Company's sales and 79% of its

outstanding accounts receivable at September 30, 2021. During the three months ended September 30, 2020, the same marketing partner and three distributors together were responsible for 79% of the Company's sales and 70% of its outstanding accounts receivable at September 30, 2020.

For the nine months ended September 30, 2021, one of the Company's marketing partners, and three of its distributors, together accounted for 79% of the Company's sales and 79% of its outstanding accounts receivable at September 30, 2021. During the nine months ended September 30, 2020, the same marketing partner and three distributors together were responsible for 79% of the Company's sales and 70% of its outstanding accounts receivable at September 30, 2020.

15. Earnings Per Share

Basic earnings per share is computed by dividing net income available to common shareholders by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings per share is computed by dividing income available to common shareholders by the weighted-average number of shares of common stock outstanding during the period increased to include the number of additional shares of common stock that would have been outstanding if the potentially dilutive securities had been issued.

Per share basic and diluted earnings were \$0.22 and \$0.16 for the three months ended September 30, 2021 and 2020, respectively, and \$0.77 and \$0.59 for the nine months ended September 30, 2021 and 2020, respectively.

17. Subsequent Events

The Company has evaluated all subsequent events from the date of the financial statements through the date of this report. As detailed in Note 3 above, the Covid-19 pandemic is an ongoing event, and as such, the Company is not able to project or quantify the impact of this event on the Company's future operations and financial results.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

FORWARD-LOOKING STATEMENTS

Statements made in this Form 10-Q which are not purely historical are forward-looking statements with respect to the goals, plans, objectives, intentions, expectations, financial condition, results of operations, future performance and business of the Company. Forward-looking statements may be identified by the use of such words as "believes", "may", "will", "should", "intends", "plans", "estimates", "anticipates", or other similar expressions.

Forward-looking statements involve inherent risks and uncertainties, and important factors (many of which are beyond the Company's control) could cause actual results to differ materially from those set forth in the forward-looking statements. In addition to those specific risks and uncertainties set forth in the Company's reports currently on file with the SEC, some other factors that may affect the future results of operations of the Company are: the development of products that may be superior to those of the Company; changes in the quality or composition of the

Company's products; lack of market acceptance of the Company's products; the Company's ability to develop new products; general economic or industry conditions; changes in intellectual property rights; changes in interest rates; new legislation or regulatory requirements; conditions of the securities markets; the Company's ability to raise capital; changes in accounting principles, policies or guidelines; financial or political instability; acts of war or terrorism; and other economic, competitive, governmental, regulatory and technical factors that may affect the Company's operations, products, services and prices. Accordingly, results achieved may differ materially from those anticipated as a result of such forward-looking statements, and those statements speak only as of the date they are made. The Company does not undertake, and specifically disclaims, any obligation to update any forward-looking statements to reflect events or circumstances occurring after the date of such statements.

OVERVIEW

The Company is a Delaware corporation that, through its Guardian Laboratories division, conducts research, product development, manufacturing, and marketing of cosmetic ingredients, personal and health care products, pharmaceuticals, non-pharmaceutical medical products, and proprietary specialty industrial products. All the products that the Company markets, with the exception of Renacidin, are produced at its facility in Hauppauge, New York. Renacidin, a urological product, is manufactured for the Company by an outside contract manufacturer.

The Company's most important product line is its Lubrajel[®] line of water-based moisturizing and lubricating gels, which are used primarily as ingredients in cosmetic products but are also used in medical products, primarily catheter lubricants. These products are marketed worldwide for cosmetic uses by five marketing partners, each handling a different geographic area, with the largest being U.S.-based ASI. The Company's research and development department is actively working on the development of new products to expand the Company's line of cosmetic ingredients. Many of the Company's products use proprietary manufacturing processes, and the company relies primarily on trade secret protection to protect its intellectual property.

Renacidin and the Company's other pharmaceutical product, Clorpactin[®], which is also used primarily in urology, are distributed through full-line drug wholesalers and marketed only in the United States. Those wholesalers in turn sell the products to pharmacies, hospitals, nursing homes, and other long-term care facilities, and to government agencies, primarily the VA. The Company promotes Renacidin through internet advertising as well as a dedicated website. Clorpactin and some of the Company's other products are marketed through information provided on the Company's corporate website.

The Company's non-pharmaceutical medical products, such as its catheter lubricants, as well as its specialty industrial products, are sold directly to end-users, or to contract manufacturers utilized by those end-users. They are also available for marketing on a non-exclusive basis by the Company's marketing partners.

While the Company does have competition in the marketplace for some of its products, particularly its cosmetic ingredients, some of its pharmaceutical and medical products have some unique characteristics, and do not have direct competitors. However, these products may have indirect competition from other products that are not marketed as direct competitors to the Company's products but may have functionality or properties that are similar to the Company's products.

The Company recognizes revenue when all of the following requirements are satisfied: (a) persuasive evidence of a sales arrangement exists; (b) products are shipped, which is when the performance obligation is satisfied and title and risk of loss pass to the customers; and (c) collections are reasonably assured. An allowance for returns, based on historical experience, is taken as a reduction of sales within the same period the revenue is recognized.

Over the years the Company has been issued many patents and trademarks, and it still maintains several registered trademarks, the two most important of which are "Lubrajel" and "Renacidin." However, regarding the protection of the Company's proprietary formulations and manufacturing technology, the Company currently relies primarily on trade secret protection rather than patent protection due to the current disclosure requirements needed to obtain patents, the limited protection they afford, and the difficulty and expense of enforcing them globally. However, the Company may, from time to time, seek patent protection when it believes it would be in the Company's best interest to do so. All of the Company's previously issued patents have expired; however, the Company does not believe that the expiration of those patents has had, or will have, any material impact on its sales, since in recent years protection for the Company's most important products has been based on trade secrets and proprietary manufacturing methods rather than patent protection.

As discussed in Note 3 above, while the coronavirus pandemic ("pandemic") continues to impact the Company's operations, the substantial impact the pandemic had on Company sales in 2020 significantly lessened in the first nine months of 2021. While the Company believes that sales of its cosmetic ingredients are still being negatively impacted, the sales situation has improved substantially, and the current impact is coming more from increased shipping costs and some higher raw material costs, which could have some impact on the Company's profit margins in upcoming quarters. It has also been more difficult to ship the Company's products due to a shortage of truck drivers, which has meant some delays in having orders picked up, even though the Company's products are available to ship. The shortage of truck drivers is expected to continue into 2022, and the Company is doing what it can to minimize the impact on customers by making customers aware of some longer lead times due to the trucking issues.

Sales of the Company's non-pharmaceutical medical products (referred to herein as "medical products") had also been negatively impacted by the pandemic in 2020, but those impacts have lessened as well in the first three quarters of 2021. There continues to be some impact on shipping schedules, with the shipping of some customers' orders being delayed due to the shortage of truck drivers.

Sales of the Company's pharmaceutical products were not impacted by the pandemic in 2020 or in the first nine months of 2021. However, the Company is beginning to see a small decrease in gross pharmaceutical sales due the termination of its participation in the Medicaid Drug Rebate Program. Please refer to the pharmaceutical sales section of the MD&A for further discussion.

The pandemic has not significantly affected the ability of the Company to obtain raw materials, but it has made some of those materials more expensive, which could impact the Company's gross profit margins in the future. The Company has been able to maintain production throughout the pandemic.

There continues to be uncertainty in regard to the future impact of the pandemic on the Company's operations or financial results. While the impact on the Company's' sales lessened considerably in 2021, the Company is still unable to provide an accurate estimate or projection as to what the

future impact of the pandemic will be on the Company's future operations or financial results. The Company does not expect the carrying value of its assets or its liquidity to be impaired by the coronavirus pandemic.

CRITICAL ACCOUNTING POLICIES

As disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, the discussion and analysis of the Company's financial condition and results of operations are based on its financial statements, which have been prepared in conformity with US GAAP. The preparation of those financial statements required the Company to make estimates and assumptions that affect the carrying value of assets, liabilities, revenues and expenses reported in those financial statements. Those estimates and assumptions can be subjective and complex, and consequently actual results could differ from those estimates and assumptions. The Company's most critical accounting policies relate to revenue recognition, concentration of credit risk, investments, inventory, and income taxes. Since December 31, 2020, there have been no significant changes to the assumptions and estimates related to those critical accounting policies.

The following discussion and analysis covers material changes in the financial condition of the Company since the year ended December 31, 2020, and a comparison of the results of operations for the third quarter of 2021 and 2020 and the first nine months of 2021 and 2020. This discussion and analysis should be read in conjunction with "Management's Discussion and Analysis or Plan of Operation" included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020. All references in this quarterly report to "sales" or "Sales" shall mean "net sales" unless specifically identified as "gross sales".

The Company recognizes revenue from sales of its cosmetic ingredients, medical products, and industrial products when all of the following requirements are satisfied: (a) a valid purchase order has been received; (b) products are shipped, which is when the performance obligation is satisfied and title and risk of loss pass to the customers; and (c) 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 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. The Company assumes responsibility for the shipment arriving at its intended destination. 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 gross sales of its pharmaceutical products.

RESULTS OF OPERATIONS

<u>Sales</u>

Sales for the third quarter of 2021 increased by \$843,386 (36%) when compared with the same period in 2020. Sales for the first nine months of 2021 increased by \$1,654,674 (19%) as

compared with the corresponding period in 2020. The increase in sales for both the third quarter of 2021 and the first nine months of 2021 were attributable to changes in sales of the following product lines:

Cosmetic ingredients:

a) Third quarter sales: For the third quarter of 2021, the Company's sales of cosmetic ingredients increased by \$1,028,473 (187%) when compared with the third quarter of 2020. The increase in third quarter sales was due primarily to an increase of \$983,466 (308%) in sales of the Company's personal care products to ASI. Based on information provided to the Company by ASI, the Company's marketing partner in China, the increase was due primarily to the continued increase in shipments of the Company's products to China by ASI.

Third quarter sales to the Company's four other marketing partners, as well as to four small direct cosmetic ingredient customers, had a net increase of \$45,007 (20%) compared with the third quarter of 2020. Sales to the Company's marketing partners in the United Kingdom, Switzerland, and Italy increased by a total of \$117,448 (112%), while sales to the Company's marketing partner in France and four of the Company's small direct cosmetic customers decreased by \$72,440 (58%).

b) Nine-month sales: For the first nine months of 2021, the Company's sales of cosmetic ingredients increased by \$1,706,066 (51%) when compared with the same period in 2020. This increase was due primarily to an increase of \$1,486,664 (58%) in shipments of the Company's extensive line of cosmetic ingredients to ASI. The primary reason for the increase in sales to ASI during the first nine months of 2021 was the same as for the increase in sales in the third quarter, which was due to the continued increase in shipments of the Company's products to China by ASI.

Cosmetic ingredient sales for the first nine months of the year to the Company's four other marketing partners, as well as to the four direct cosmetic customers, increased by a net of \$219,402 (28%) compared with the same period in 2020. Nine-month sales to the Company's marketing partners in the UK, France, Switzerland and Italy increased by \$240,985 (32%), while sales to the four direct cosmetic customers, decreased by \$21,583 (52%).

The Company believes that the increase in sales of the Company's cosmetic ingredients in Europe was, at least in part, the result of global pandemic conditions improving.

Pharmaceuticals:

Because there are fees, rebates and allowances associated with sales of the Company's two pharmaceutical products, Renacidin and Clorpactin, discussion of the Company's pharmaceutical sales includes references to both *gross sales* (before fees, rebates and allowances) and *net sales* (after fees, rebates and allowances). Gross sales of the Company's pharmaceutical products for the three- and nine-month periods ended September 30, 2021 decreased by \$92,405 (6%) and \$178,459 (4%), respectively, compared with the corresponding periods in 2020. These decreases were due primarily to decreases of \$86,751 (6%) and \$232,493 (6%) in gross sales of Renacidin for the three- and nine-month periods, respectively, ended September 30, 2021. The decrease in both

periods was primarily due to the Company having terminated its participation in the Medicaid Drug Rebate Program on December 31, 2020. Gross sales of the Company's other pharmaceutical product, Clorpactin, decreased by \$5,654 (3%) for the three-month period ended September 30, 2021, and increased by \$54,034 (12%) for the nine-month period ended September 30, 2021, compared with the corresponding periods in 2020. The Company believes the changes in sales of Clorpactin were most likely due to normal fluctuations in the sales of that product.

The decrease in gross sales for the three- and nine-month periods ended September 30, 2021 was partially offset by a decrease in pharmaceutical related fees, rebates and allowances of \$76,567 (22%) and \$223,957 (23%), respectively. The decreases in these fees, rebates and allowances were the result of the Company's termination of its participation in the Medicaid Drug Rebate Program at the end of 2020. Due to the overly burdensome nature of the Medicaid rebates that the Company had to pay under this program, the Company determined that it was no longer profitable for the Company to continue to participate. Accordingly, on October 30, 2020 the Company informed the Centers for Medicare & Medicaid Services (CMS) of its intention to terminate its Medicaid Drug Rebate Agreement and its participation in the Medicaid Program, effective December 31, 2020. As the Company had anticipated, the discontinuation of its participation in this program resulted in the loss of some Renacidin sales, but that loss was more than offset by the elimination of the rebate payments, which resulted in an increase in net income from these sales.

As sales of the Company's pharmaceutical products fluctuate there is typically a corresponding direct relationship in the related allowances, such as for distribution fees, VA chargebacks, Medicare rebates, sales rebates and discounts, outdated material returns, and Medicaid rebates. For the three- and nine-month periods ended September 30, 2021, these allowances decreased by \$74,116 (21%) and \$226,932 (24%), respectively, compared with the same periods in 2020. This was primarily the result of the Company's termination of its participation in the Medicaid Program. Although the Company will no longer be incurring Medicaid-related rebate costs, it will continue to incur costs related to other allowances, including Medicare rebates, distribution fees, chargebacks on VA sales, and outdated material returns.

Medical (non-pharmaceutical) products:

Sales of the Company's medical products decreased by \$173,152 (33%) for the third quarter of 2021, and by \$103,025 (6%) for the nine-month period ended September 30, 2021, compared with the same periods in 2020. The decrease in medical product sales for both periods was primarily attributable to the loss of one of the Company's domestic medical product customers in 2020 due to the reformulation of its product, combined with a decrease in orders from two of the Company's larger direct medical product customers located in China and India, which was partially the result of shipping delays. The Company believes that the other decreases were related to the impact of the coronavirus pandemic.

Industrial products:

Sales of the Company's industrial products increased by \$3,904 (11%) and by \$6,136 (6%) for the three and nine months, respectively, ended September 30, 2021, when compared with the corresponding periods in 2020. The increase in sales for both the three- and nine-

month periods was primarily due to an increase in orders from one of the Company's industrial product customers located in the northeastern United States.

Cost of Sales

Cost of sales as a percentage of sales remained the same for both the third quarter of 2021 and 2020, at 42%. For the first nine months of 2021, cost of sales as a percentage of sales decreased from 42% in 2020 to 41% in 2021.

Operating Expenses

Operating expenses, consisting of selling and general and administrative expenses, decreased by \$34,622 (7%) for the third quarter of 2021, and by \$91,393 (6%) for the first nine months of 2021, compared with the same periods in 2020. The decreases in operating expenses for both periods were primarily attributable to a decrease in payroll and payroll related expenses, combined with the recognition of a gain on the sale of an asset during the third quarter of 2021. Operating expenses are expected to remain relatively consistent for the remainder of the year.

Research and Development Expenses

Research and development expenses increased by \$15,906 (14%) for the third quarter of 2021, and by \$17,919 (5%) for the first nine months of 2021 compared with the same periods in 2020. The increases for both periods were mainly due to an increase in payroll and payroll related expenses.

Investment Income

Investment income decreased by \$185 (less than 1%) for the third quarter of 2021 compared with the third quarter of 2020 and decreased by \$7,171 (5%) for the first nine months of 2021 compared with the same period in 2020. The decreases in both periods were due to decreased interest income from U.S. Treasury Bills combined with lower dividend income from stock and bond mutual funds compared to the same periods in 2020.

Net gain on marketable securities

Net gain on marketable securities decreased by \$138,356 (122%) for the third quarter of 2021 compared with the same period in 2020. The reason for the decrease was a combination of 1) a decrease in realized gains on the sales of marketable securities during the third quarter of 2021 compared with the same period in 2020 (the Company did not sell any securities during the equivalent three-month period in 2021) and 2) in the third quarter of 2020, the market began its recovery after the significant market value decline that occurred in the first and second quarters of 2020 due to the pandemic.

For the first nine months of 2021, the net gain on marketable securities decreased by \$103,413 (72%) compared with the same period in 2020. The primary reason for the decrease was that during the first nine months of 2020 the Company recognized unrealized gains of \$113,914, which represented the upward market adjustment due to improved economic conditions after the significant decline that occurred during the first part of the year due to the pandemic.

Provision for income taxes

The Company's effective income tax rate was approximately 21% for the first nine months of 2021 and 2020. The Company's tax rate is expected to remain at 21% for the current fiscal year.

LIQUIDITY AND CAPITAL RESOURCES

Working capital increased from \$9,832,326 at December 31, 2020 to \$11,254,936 at September 30, 2021, an increase of \$1,422,610. The current ratio decreased from 8.0 to 1 at December 31, 2020 to 7.6 to 1 at September 30, 2021. The increase in working capital was primarily due to an increase in marketable securities and accounts receivable. The decrease in the current ratio was primarily due to decreases in prepaid income taxes and inventory, and an increase in accrued expenses.

The Company believes that its working capital is, and will continue to be, sufficient to support its operating requirements for at least the next twelve months. The Company does not expect to incur any significant capital expenditures for the remainder of 2021.

The Company generated cash from operations of \$3,648,744 and \$2,921,704 for the nine months ended September 30, 2021 and September 30, 2020, respectively. The increase in cash from operations was primarily due to an increase in net income.

Cash used in investing activities for the nine-month period ended September 30, 2021 was \$1,343,651. Cash used in investing activities for the nine-month period ended September 30, 2020 was \$1,155,986. The increase was primarily due to an increase in the purchases of property, plant and equipment, and an increase in fixed income mutual fund purchases.

Cash used in financing activities was \$2,204,616 and \$1,928,969 for the nine months ended September 30, 2021 and September 30, 2020, respectively. The increase was due to an increase in the dividends paid per share from \$0.42 per share in 2020 to \$0.48 per share in 2021.

The Company expects to continue to use its cash to make dividend payments, to purchase marketable securities, and to take advantage of other opportunities that may arise that are in the best interest of the Company and its shareholders.

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.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

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

Item 4. CONTROLS AND PROCEDURES

(a) DISCLOSURE CONTROLS AND PROCEDURES

The Company's management, including its Principal Executive Officer and Chief Financial Officer, has evaluated the design, operation, and effectiveness of the Company's disclosure controls and procedures pursuant to Rule 13a-15 under the Securities Exchange Act of 1934 (the "Exchange Act"). There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon the evaluation performed by the Company's management, including its Principal Executive Officer and Chief Financial Officer, it was determined that, as of the end of the period covered by this guarterly report, the Company's disclosure controls and procedures were effective in providing reasonable assurance that information required to be disclosed in the 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 the Company's management, including its Principal Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding disclosures.

(b) CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

The Company's Principal Executive Officer and Chief Financial Officer have determined that, during the period covered by this quarterly report, there were no changes in the Company's internal control over financial reporting that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting. They have also concluded that there were no significant changes in the Company's internal controls after the date of the evaluation.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

NONE

ITEM 1A. RISK FACTORS

IMPACT OF COVID-19

As a result of the pandemic, global consumer purchases of cosmetic products declined significantly in 2020, which resulted in a significant decline in sales of the Company's cosmetic ingredients in the last three quarters of 2020. Sales of these products were particularly impacted in China, where prior to the pandemic the Company had significant sales. This resulted in an excess inventory situation in China, which severely impacted sales, and which was not resolved until the end of 2020.

The impact of the pandemic on the Company's sales significantly lessened in 2021. Sales of its cosmetic ingredients in the first quarter of 2021 were slightly lower than in the first quarter of 2020 because the pandemic didn't begin to significantly impact sales of the Company's cosmetic ingredients until the latter part of the second quarter of 2020, and that impact continued into the first quarter of 2021.

With the pandemic beginning to abate, sales in the third quarter of 2021 increased significantly compared with the third quarter of 2020. While it is still too soon to predict what the impact of the pandemic will be on future sales, it is likely that there will continue to be some impact on sales of the Company's cosmetic ingredients, but to a lesser degree than in 2020. The current impact of the pandemic is coming primarily from supply chain disruptions, which have resulted in increased packaging and shipping costs, and increases in the cost of some raw materials. Due to the uncertainty surrounding the duration of the pandemic and its impact in the various countries in which the Company does business, it is difficult for the Company to provide an accurate estimate or projection as to what the future impact of the pandemic will be on the Company's future operations or financial results. Although the pandemic had some impact on sales of some of the Company's medical products, it has not impacted sales of its pharmaceutical products.

The Company does not anticipate that the pandemic will affect its ability to obtain raw materials and maintain production, and the Company has multiple sources for many of its raw materials. However, some of the Company's raw materials have experienced price increases, which could impact the manufacturing cost of some of the Company's products in the future. The Company may or may not be able to pass along and recoup these price increases, depending on the product. The Company expects to be able to maintain production levels sufficient to ship orders on a timely basis, but the timely shipping of the Company's products may continue to be impacted by the current shortage of truck drivers.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

NONE

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

NONE

ITEM 4. MINE SAFETY DISCLOSURES

NONE

ITEM 5. OTHER INFORMATION

NONE

ITEM 6. EXHIBITS

31.1*	Certification of Ken 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 Young, Chief Financial Officer of the Company, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32*	Certifications of Principal Executive Officer and Chief Financial Officer of the Company, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document – The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File (Embedded within the inline XBRL document and included in Exhibit 101.1).

* Filed herewith

SIGNATURES

In accordance with the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: November 9, 2021

UNITED-GUARDIAN, INC. (Registrant)

By: <u>/S/ KEN GLOBUS</u> Ken Globus President

By: <u>/S/ ANDREA YOUNG</u> Andrea Young Chief Financial Officer