

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 19, 2023

**United-Guardian, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation)

**001-10526**  
(Commission File Number)

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

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

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

**Not Applicable**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

**Item 8.01. Other Events**

On October 19, 2023, United-Guardian, Inc. (the “Company”) informed the U.S. Food and Drug Administration (the “FDA”) of a potential supply shortage of Renacidin® Irrigation (the “Product”).

By way of background, on September 29, 2023 the Company was informed by Amsino Healthcare (USA), Inc. (“Amsino”), the successor in interest to Smiths Medical, one of its material suppliers, that Amsino was temporarily ceasing the manufacture and supply of the Product as its facility underwent required maintenance and addresses several observations made by the FDA. At the time, Amsino informed the Company that the delays would extend until early December.

On October 10, 2023, several weeks after the initial correspondence, Amsino informed the Company that it was extending the production shutdown and revised the timeline that it initially provided. As a result, Amsino currently anticipates that two outstanding purchase orders of the Product originally scheduled for December 5, 2023 and January 9, 2024 will now take place on or about February 2, 2024 and February 9, 2024, respectively.

Given the latest information, the Company has determined it will likely exceed its current supply levels of the Product prior to the delivery dates provided by Amsino in its revised timeline. In connection with the Company’s mandatory notice to the FDA regarding the shortage of the Product, the Company is taking every measure reasonably available to mitigate the impact caused by these delays.

**SIGNATURES**

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

UNITED-GUARDIAN, INC.

By: /s/ Donna Vigilante

Name: Donna Vigilante

Title: President

Date: October 25, 2023