

UNITED GUARDIAN INC
Form 8-K
December 09, 2010
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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): December 8, 2010

UNITED-GUARDIAN, INC.
(Exact name of Registrant as Specified in Charter)

| | | |
|---|-------------------------------------|--|
| DELAWARE (State or Other Jurisdiction of Incorporation) | 1-10526 (Commission File Number) | 11-1719724 (IRS Employer Identification No.) |
|---|-------------------------------------|--|

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

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

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))

Item 8.01 OTHER EVENTS

One of the Company's pharmaceutical products, Renacidin Irrigation, has been made for the Company for many years by an outside contractor. As a result of regulatory issues at the contractor's manufacturing facility it was necessary for them to shut down production of Renacidin, as well as other products, at that facility and gradually resume production of each product as they comply with the regulatory concerns cited by the Food and Drug Administration ("FDA").

It was originally estimated that production of Renacidin would resume in December, 2010. Had that happened the Company would have had sufficient inventory on hand to fill orders until production resumed. In mid-November, 2010 the Company was informed by the contractor that resumption of production of Renacidin was going to be delayed until January at the earliest, and recommended that while that resumption was pending the Company also seek approval from the FDA to begin manufacturing the product at one of the contractor's other manufacturing sites.

Until December 8, 2010 the Company had been hopeful that it would be able to begin production in the new facility before its supply of product was depleted, but during a conference call with the contractor on December 8th the Company was informed by the contractor that it believes that FDA guidelines require that a prior approval supplement be filed with, and approved by, the FDA before production can be resumed.

As a result of this new information the Company now believes that its supply of product will most likely be depleted before it receives FDA approval to begin production in the new facility. The Company is unable at this time to accurately predict how long it will be without product, since that will depend on whether it can expedite the FDA review process. The product accounts for approximately 18% of the Company's revenues, averaging approximately \$210,000 per month in sales. The Company is estimating, based on the information being provided to it by its contractor, that it could be without revenue from this product for 2-9 months, depending on how quickly it can obtain FDA approval and how soon thereafter the contractor can resume production and deliveries. The Company does not expect to recover business lost during this product shortage, but has informed its supplier that it will hold it responsible for any business lost and expenses incurred as a result of this production curtailment.

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/ Kenneth H. Globus
Name: Kenneth H. Globus
Title: President

December 9, 2010