UNITED GUARDIAN INC
Form 8-K
November 18, 2013

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): November 12, 2013

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

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

230 Marcus Boulevard, Hauppauge, New York	11788
(Address of Principal Executive Offices)	(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 1.01 Entry into a Material Definitive Agreement.

On November 12, 2013 the Registrant entered into a written manufacturing and supply agreement with Smiths Medical ASD, Inc. ("Smiths"), retroactive to November 1, 2013, pursuant to which Smiths would supply Registrant with a new single-dose form of one of the Registrant's pharmaceutical products, Renacidin® Irrigation. The agreement provides for the Registrant and Smiths to work together to develop the new product and provide sufficient data for the Registrant to file a supplement to its currently approved New Drug Application for Renacidin with the U.S. Food and Drug Administration. The approval would allow the Registrant to market Renacidin in a new single dose sterile 30mL vial that would be manufactured using blow-fill-seal packaging technology. Smith's obligations under the agreement are contingent upon the Registrant obtaining FDA approval to market the new product by March 31, 2015. The Registrant expects to file the application in the first half of 2014.

Item 9.01 – Financial Statements and Exhibits

(d) Exhibits. The following exhibits are filed with this report:

Exhibit Number	Description
10.1	Manufacturing and Supply Agreement between the Registrant and Smiths Medical ASD, Inc. signed November 12, 2013 and effective as of November 1, 2013.

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

November 18, 2013