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): July 8, 2022

SYNTHETIC BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Nevada	**001-12584**	**13-3808303**
(State or other jurisdiction of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

9605 Medical Center Drive, Suite 270
Rockville, Maryland 20850
(Address of principal executive offices and zip code)

(301) 417-4364
Registrant's telephone number, including area code

N/A
(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 (see General Instruction A.2. below):

¨ 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, par value $0.001 per share	SYN	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in in Rule 405 of the Securities Act of 1933 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2 of this chapter).

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. ¨

Item 8.01. Other Events.

On July 8, 2022, Synthetic Biologics, Inc. (the “Company”) was notified of the clearance of the safety evaluation period by the first patient that had been dosed in the investigator sponsored Phase 1 clinical trial evaluating VCN-01 (NCT05057715), an intravenous oncolytic adenovirus, in combination with mesothelin-directed lentiviral transduced human chimeric antigen receptor modified T cells (huCART-meso) for patients with pancreatic and serious epithelial ovarian cancers. VCN-01 was developed by Synthetic Biologics’ wholly-owned subsidiary VCN Biosciences, SL.

The Phase 1, open-label, non-randomized trial, which is the first clinical trial of VCN-01 being conducted in the US, is designed to evaluate the safety and feasibility of intravenously administered VCN-01 in combination with mesothelin-directed lentiviral transduced huCART-meso cells in a 3+3 dose design for patients with pancreatic or serous epithelial ovarian cancers. VCN-01 will be administered at a single dose of 3.3x1012 vp (cohort 1) or 1 x 1013 vp (cohort 2) followed by a single dose of 5x107 huCART-meso cells on Day 14. The trial may also evaluate the safety of a different sequence of administration for these two investigational products at the same dose levels used in cohort 1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document)

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 hereunto duly authorized.

Dated: July 14, 2022

SYNTHETIC BIOLOGICS, INC.

By: /s/ Steven A. Shallcross
Name: Steven A. Shallcross
Title: Chief Executive Officer and Chief Financial Officer