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): September 5, 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 7.01. Regulation FD Disclosure.

On September 5, 2022, Synthetic Biologics, Inc. (the "Company") issued a press release announcing a presentation of initial data from a Phase 1 investigator-sponsored study evaluating VCN-01 in combination with durvalumab for patients with recurrent/metastatic squamous cell carcinoma of the head and neck (R/M HNSCC). Data will be featured in a poster presentation at the European Society for Medical Oncology (ESMO) Congress, being held both virtually and in Paris from September 9-13, 2022.

The information in this Item 7.01 and in the press release furnished as Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended and shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

The press release furnished as Exhibit 99.1 to this Current Report on Form 8-K includes "safe harbor" language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained therein are "forward-looking" rather than historical.

Item 8.01. Other Events.

On September 5, 2022, the Company issued a press release announcing a presentation of initial data from a Phase 1 investigator-sponsored study evaluating VCN-01 in combination with durvalumab for patients with recurrent/metastatic squamous cell carcinoma of the head and neck (R/M HNSCC). Data will be featured in a poster presentation at the European Society for Medical Oncology (ESMO) Congress, being held both virtually and in Paris from September 9-13, 2022.

Key data and conclusions featured in the ESMO presentation include:

- **Safety**: Treatment with VCN-01 had an acceptable safety profile when administered with durvalumab in the sequential regimen (single dose of VCN-01 administered 14 days prior to the first dose of durvalumab; n=14).
    - The most common treatment-related adverse events (TRAEs) were pyrexia, flu-like symptoms and increases in liver transaminases.
    - TRAEs were dose-dependent, reversible and consistent with TRAEs previously described for other adenovirus-based products.
- **Pharmacokinetics (PK) and pharmacodynamics (PD)**: Based on toxicology and PK/PD analysis the recommended Phase 2 dose is $1x10^{13}$ viral particles (vp)/patient.
- **Biological activity**: Sustained blood levels of VCN-01 viral genomes and increased serum hyaluronidase levels were maintained for over six weeks.
    - Observed an increase in CD8 T cells, a marker of tumor inflammation and an upregulation of PD-L1 in tumors.
    - Analysis of serial tumor biopsies revealed differential gene expression profiles and downregulation

of matrix-related pathways after VCN-01 administration.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by Synthetic Biologics, Inc., dated September 5, 2022
104	Cover Page Interactive Data File (embedded within the XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Current Report on Form 8-K to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: September 6, 2022

SYNTHETIC BIOLOGICS, INC.

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