

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 12, 2022

SYNTHETIC BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of
incorporation)

001-12584

(Commission File No.)

13-3808303

(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 September 12, 2022, a poster entitled “A Phase I Study to Evaluate the Safety, Tolerability, and Efficacy of VCN-01 in Combination with Durvalumab (MEDI4736) in Subjects with Recurrent/ Metastatic Squamous Cell Carcinoma of the Head and Neck (R/M HNSCC)” was presented at the European Society for Medical Oncology (ESMO) Congress in Paris by Dr. Ricard Mesia, Head of the Medical Oncology Department at Institut Català d’Oncologia (Barcelona, Spain). A copy of the Poster Presentation is filed as Exhibit 99.1.

Key data and conclusions featured in the Poster 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).
 - o The most common treatment-related adverse events (TRAEs) were pyrexia, flu-like symptoms and increases in liver transaminases.
 - o 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 1x10¹³ 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.
 - o Observed an increase in CD8 T cells, a marker of tumor inflammation and an upregulation of PD-L1 in tumors.
 - o 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	Poster entitled “A Phase I Study to Evaluate the Safety, Tolerability, and Efficacy of VCN-01 in Combination with Durvalumab (MEDI4736) in Subjects with Recurrent/ Metastatic Squamous Cell Carcinoma of the Head and Neck (R/M HNSCC)”
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 12, 2022

SYNTHETIC BIOLOGICS, INC.

By: /s/ Steven A. Shallcross

Name: Steven A. Shallcross

Title: Chief Executive Officer
and Chief Financial Officer
