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 27, 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 27, 2022, Synthetic Biologics, Inc. (the "Company") issued a press release announcing positive outcome from the Data and Safety Monitoring Committee ("DSMC") review of results from the first Cohort of the Company's Phase 1b/2a randomized, double-blinded, placebo-controlled clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant (HCT) recipients for the prevention of acute graft-versus-host-disease (aGVHD).

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 27, 2022, the Company issued a press release announcing positive outcome from the DSMC review of results from the first Cohort of the Company's Phase 1b/2a randomized, double-blinded, placebo-controlled clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant (HCT) recipients for the prevention of acute graft-versus-host-disease (aGVHD).

Key data and conclusions disclosed in the press release include:

Cohort 1 enrolled 19 patients who received at least 1 dose of study drug (SYN-004 or Placebo randomized 2:1). Sixteen patients received at least one dose of intravenous (IV) meropenem and 12 of these patients completed sufficient doses of IV meropenem to be evaluable towards the study endpoints. The study is on-going and remains blinded; however, key findings from blinded data for Cohort 1 are included below:

- Adverse events (AEs) and serious adverse events (SAEs) observed in Cohort 1 were typical of those observed in allo-HCT patients and no AEs or SAEs were determined to be related to study drug treatment by the investigators.
    - A total of 13 SAEs were reported among 10 patients, with the most common SAE being infections and infestations including sepsis.
    - One patient died 14 days after the last dose of study drug (within the 30-day reporting period) due to sepsis that was not related to study drug.
- Consistent with previous studies of SYN-004 in healthy volunteers, SYN-004 was not observed in blood samples from the majority of the evaluable patients.
    - A total of 3 plasma samples (~2% of all analyzed samples) had low but quantifiable levels of

SYN-004 using a sensitive ECL assay.
  - None of the 3 ECL positive plasma samples was found to contain active SYN-004 using a functional enzyme activity assay.
- Meropenem pharmacokinetics were as expected for this patient population.

Based on a review of the safety and pharmacokinetic data, the DSMC has recommended that the study may proceed to enroll Cohort 2 in which study drug (SYN-004 or Placebo) will be administered in combination with the IV beta-lactam antibiotic piperacillin/tazobactam.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by Synthetic Biologics, Inc., dated September 27, 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 27, 2022

SYNTHETIC BIOLOGICS, INC.

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