

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): October 2, 2020

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
(I.R.S. Employer Identification No.)

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

(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 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(b) 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).

company ☐ Emerging growth

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 October 2, 2020, Synthetic Biologics, Inc. (the “Company”) issued a press release announcing the results of a planned interim futility analysis of its investigator-sponsored Phase 2b clinical study of SYN-010 being conducted by Cedars-Sinai Medical Center (“CSMC”). Based on the review of the interim analysis, it was concluded that although SYN-010 was well-tolerated, it is unlikely to meet its primary objective by the time enrollment is completed. As a result, CSMC has agreed to discontinue the trial and will conduct a comprehensive review of the final data set and publish its findings.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 and in the press release attached 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. The information contained in this Item 7.01 and in the press release attached as Exhibit 99.1 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 attached as Exhibit 99.1 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. The Company undertakes no duty or obligation to update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time if its management believes it is appropriate. Any such updating may be made through the filing of other reports or documents with the Securities and Exchange Commission, through press releases or through other public disclosures.

Item 8.01. Other Events.

On October 2, 2020, Synthetic Biologics, Inc. (the “Company”) announced the results of a planned interim futility analysis of its investigator-sponsored Phase 2b clinical study of SYN-010 being conducted by Cedars-Sinai Medical Center (“CSMC”). Based on the review of the interim analysis, it was concluded that although SYN-010 was well-tolerated, it is unlikely to meet its primary objective by the time enrollment is completed. As a result, CSMC has agreed to discontinue the trial and will conduct a comprehensive review of the final data set and publish its findings.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Synthetic Biologics, Inc. dated October 2, 2020

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.

Date: October 2, 2020

SYNTHETIC BIOLOGICS, INC.

By: /s/ Steven Shallcross

Name: Steven Shallcross

Title: Chief Executive Officer and Chief Financial
Officer
