Synthetic Biologics, Inc.
Form 8-K
April 23, 2018

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): April 18, 2018

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

9605 Medical Center Drive, Suite 270

Rockville, MD 20850

(Address of principal executive offices and zip code)

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

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:

¨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))

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

Synthetic Biologics, Inc. (the "Company") today issued a press release announcing it has reached preliminary agreement with the U.S. Food & Drug Administration (FDA) on a proposed clinical trial synopsis for its planned Phase 3 clinical trial for SYN-004 (ribaxamase). In accordance with recommendations and guidance from the FDA, the Company expects the Phase 3 trial to include separate co-primary endpoints designed to evaluate the efficacy and safety of ribaxamase in a patient population being treated with a representative selection of intravenous (IV) beta-lactam antibiotics. The Company expects the primary efficacy endpoint will be the reduction in CDI incidence in the ribaxamase treatment group relative to placebo, while the separate, co-primary safety endpoint is expected to be relative mortality risk between the groups. The designation of efficacy and safety as separate and decoupled endpoints is critical for clinical studies of this nature, where the underlying population is projected to have a comparatively high incidence of safety events that may significantly dilute the smaller number of CDI events. The Company also announced that, based on FDA's additional review of additional data submitted by the Company during the development of the proposed Phase 3 clinical trial, the ribaxamase program no longer met the requirements for Breakthrough Therapy Designation due to the numerical imbalance in fatal adverse events observed in the study which could not be fully evaluated due to the limited safety database, and the study's method of statistical treatment of patients who did not complete the study for any reason. As a result, and with the consent of the FDA, the Company has voluntarily withdrawn the Breakthrough Therapy Designation and has reached agreement with the FDA on how each of these factors will be addressed in the Phase 3 trial.

The press release attached as Exhibit 99.1 to this Current Report on Form 8-K, which is incorporated herein by reference includes "safe harbor" language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained in the slide presentation are "forward-looking" rather than historical.

The Company undertakes no duty or obligation to update or revise information included in this Current Report on Form 8-K or the press release attached as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit 99.1 Press Release issued by Synthetic Biologics, Inc. dated April 23, 2018.

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.

SYNTHETIC BIOLOGICS, INC.

Date: April 23, 2018 By: /s/ Steven A. Shallcross
Name: Steven A. Shallcross
Title: Interim Chief Executive Officer/Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Exhibits
99.1	Press Release issued by Synthetic Biologics, Inc. dated April 23, 2018.