

Synthetic Biologics, Inc.
Form 8-K
November 21, 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): November 21, 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.)	(IRS 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

On November 21, 2018, Synthetic Biologics, Inc. (the “Company”) issued a press release announcing that it has successfully completed an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) to discuss development of SYN-004 (ribaxamase) for the prevention of antibiotic-mediated *Clostridium difficile* infection. Pursuant to the meeting, the FDA has proposed criteria for Phase 3 clinical efficacy and safety which, if achieved, may support submission for marketing approval of SYN-004 (ribaxamase) on the basis of a single Phase 3 clinical trial. Final agreement on these criteria is contingent on FDA evaluation of a detailed Phase 3 clinical trial protocol

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 press release 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 No.	Description
<u>99.1</u>	<u>Press release issued by Synthetic Biologics, Inc. dated November 21, 2018</u>

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.

Dated: November 21, 2018 SYNTHETIC BIOLOGICS, INC.

By: /s/ Steven A. Shallcross

Name: Steven A. Shallcross

Title: Interim Chief Executive Officer and Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
<u>99.1</u>	<u>Press release issued by Synthetic Biologics, Inc. dated November 21, 2018</u>