

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): January 6, 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

(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 (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. “

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## Item 8.01. Other Events

On January 6, 2020, Synthetic Biologics, Inc. (the “Company”) received official meeting minutes from the U.S. Food and Drug Administration (the “FDA”) following a Type C meeting held on December 2, 2019 at the Company’s request to discuss the development of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant (HCT) recipients who are administered intravenous (IV) beta-lactam antibiotics in response to fever. Based on the final meeting minutes, the Phase 1b/2a study will comprise a single center, randomized, double-blinded, placebo-controlled clinical trial of oral SYN-004 (ribaxamase) in up to 36 evaluable adult allogeneic HCT recipients. The goal of this study is to evaluate the safety, tolerability and potential absorption into the systemic circulation (if any) of 150 mg oral SYN-004 (ribaxamase) administered to allogeneic HCT recipients who receive an IV beta-lactam antibiotic to treat fever. Study participants will be enrolled into three sequential cohorts administered a different study-assigned IV beta-lactam antibiotic. Eight participants in each cohort will receive SYN-004 (ribaxamase) and four will receive placebo. Safety and pharmacokinetic data for each cohort will be reviewed by an independent Data and Safety Monitoring Committee, which will make a recommendation on whether to proceed to the next IV beta-lactam antibiotic. The study will also evaluate potential protective effects of SYN-004 (ribaxamase) on the gut microbiome as well as generate preliminary information on potential therapeutic benefits and patient outcomes of SYN-004 (ribaxamase) in allogeneic HCT recipients. Enrollment is expected to begin during the first quarter of 2020 contingent upon approval of the clinical study protocol by the Washington University School of Medicine’s Institutional Review Board.

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 No.	Description
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<a href="#">99.1</a>	<a href="#">Press release issued by Synthetic Biologics, Inc. dated January 7, 2020</a>
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## 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: January 7, 2020

SYNTHETIC BIOLOGICS, INC.

By: /s/ Steven A. Shallcross

Name: Steven A. Shallcross

Title: Chief Executive Officer  
and Chief Financial Officer

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## EXHIBIT INDEX

Exhibit Number	Description
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