

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): August 7, 2019

## 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<br>registered |
|--|-------------------|--|
| Common stock, par value \$0.001<br>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 1.01. Entry into a Material Definitive Agreement

On August 7, 2019, Synthetic Biologics, Inc. (the “Company”) entered into a clinical trial agreement (“CTA”) with Washington University School of Medicine in St. Louis (“Washington University”) to conduct a Phase 1b/2a single-center, randomized, double-blinded, placebo-controlled clinical trial designed to evaluate the safety, tolerability and pharmacokinetics of oral SYN-004 (ribaxamase) in up to 36 adult allogeneic hematopoietic cell transplant (HCT) recipients (the “Study”). Under the terms of the CTA, the Company will serve as the sponsor of the Study and supply SYN-004 (ribaxamase), the Company’s first-in-class oral enzyme designed to protect the gut microbiome from disruption caused by commonly used intravenous (IV) beta-lactam antibiotics, as well as compensate Washington University for all research services to be provided in connection with the Study which is estimated to cost approximately \$3,200,000. Dr. Erik R. Dubberke, Professor of Medicine and Clinical Director, Transplant Infectious Diseases at Washington University will serve as the principal investigator of the trial in collaboration with his Washington University colleague Dr. Mark A. Schroeder, Associate Professor of Medicine, Division of Oncology, Bone Marrow Transplantation and Leukemia.

The Phase 1b/2a single-center, randomized, double-blinded, placebo-controlled clinical trial is designed to evaluate the safety, tolerability and pharmacokinetics of oral SYN-004 (ribaxamase) in up to 36 adult allogeneic HCT recipients. 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 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 on the gut microbiome as well as generate preliminary information on potential therapeutic benefits and patient outcomes of SYN-004 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 (IRB) and the U.S. Food & Drug Administration (FDA).

The CTA continues in effect until completion of all obligations under the CTA. Either party may terminate the CTA prior to completion of its obligations (i) if authorization of the study is withdrawn by the FDA; (ii) if the emergence of any adverse reaction or side effect with the Study Drug administered in the Study is of such magnitude or incidence in the opinion of either party to support termination; or (iii) upon a breach of the terms of the CTA if the breaching party fails to cure the breach within 30 days after receipt of notice. The Company has the right to terminate the CTA (i) effective immediately if Washington University fails to perform the study in accordance with the terms of the protocol, the CTA or applicable laws or regulations or if Washington University or the principal investigator become debarred or (ii) upon 14 days written notice and Washington University has the right to terminate the CTA upon 14 days notice if the principal investigator becomes unable to perform or complete the Study and the parties have not, prior to the expiration of such fourteen (14) day period, agreed to an alternative principal investigator.

#### Item 9.01. Financial Statements and Exhibits.

##### (d) Exhibits

| Exhibit<br>No.               | Description  |
|------------------------------|--|
| <a href="#"><u>10.1*</u></a> | <a href="#"><u>Clinical Trial Agreement between Washington University School of Medicine in St. Louis and Synthetic Biologics, Inc. dated August 7, 2019</u></a> |

\*Confidential portions of this exhibit have been omitted from the exhibit.

## 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: August 8, 2019

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

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