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	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 (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. ☐

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
99.1	Press release issued by Synthetic Biologics, Inc. dated January 7, 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.

Dated: January 7, 2020

SYNTHETIC BIOLOGICS, INC.

By: /s/ Steven A. Shallcross
Name: Steven A. Shallcross
Title: Chief Executive Officer
and Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release issued by Synthetic Biologics, Inc. dated January 7, 2020

Exhibit 99.1

Synthetic Biologics Receives FDA Guidance at Type C Meeting for SYN-004 (ribaxamase)
Phase 1b/2a Clinical Trial in Allogeneic HCT Recipients

Rockville, MD, January 7, 2020 – Synthetic Biologics, Inc. (NYSE American: SYN), a diversified clinical-stage company leveraging the microbiome to develop therapeutics designed to prevent and treat gastrointestinal (GI) diseases in areas of high unmet need, today announced the receipt of official meeting minutes from the U.S. Food and Drug Administration (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.

"Our discussion with the FDA was extremely productive and reinforces our optimism in the potential of SYN-004 (ribaxamase) to prevent dysbiosis of the gut microbiome and significantly improve outcomes for patients who undergo allogeneic HCT and are treated with IV beta-lactam antibiotics," said Steven A. Shallcross, Chief Executive and Financial Officer of Synthetic Biologics. "We remain focused on working with the distinguished team at the Washington University School of Medicine in St. Louis to finalize the clinical program protocol in anticipation of the commencement of the Phase 1b/2a clinical study during the first quarter of 2020."

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 (IRB).

About SYN-004 (ribaxamase)

SYN-004 (ribaxamase) is an oral prophylactic therapy designed to degrade certain IV beta-lactam antibiotics within the GI tract and maintain the natural balance of the gut microbiome for the prevention of *Clostridioides difficile* infection (CDI), overgrowth of pathogenic organisms, the emergence of antimicrobial resistance (AMR) and acute graft-versus-host-disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) recipients. Allogeneic HCT recipients routinely receive long courses of IV beta-lactam antibiotics to treat infection. Antibiotic-mediated damage of the gut microbiome in allogeneic HCT recipients has been strongly associated with adverse outcomes including CDI, vancomycin-resistant enterococci (VRE) colonization and potentially fatal bacteremia and aGVHD. A previously completed placebo-controlled Phase 2b clinical trial of 412 patients demonstrated SYN-004 (ribaxamase) protected the gut microbiome from antibiotic-mediated dysbiosis. Patients receiving SYN-004 (ribaxamase) also demonstrated significantly better maintenance and recovery of the gut microbiome as well as lower incidences of new colonization by opportunistic and potentially pathogenic microorganisms such as VRE.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE American: SYN) is a clinical-stage company developing therapeutics that preserve the microbiome to protect and restore the health of patients. The Company's lead candidates are: (1) SYN-004 (ribaxamase) which is designed to degrade certain commonly used intravenous (IV) beta-lactam antibiotics within the gastrointestinal (GI) tract to prevent microbiome damage, *C. difficile* infection (CDI), overgrowth of pathogenic organisms, the emergence of antimicrobial resistance (AMR) and acute graft-versus-host-disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) recipients, and (2) SYN-010, which is intended to reduce the impact of methane-producing organisms in the gut microbiome to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C). The Company is also advancing SYN-020, an oral formulation of the enzyme intestinal alkaline phosphatase (IAP) to treat both local GI and systemic diseases, and has completed proof-of-concept studies with monoclonal antibody therapies for the prevention and treatment of pertussis. For more information, please visit Synthetic Biologics' website at www.syntheticbiologics.com.

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases forward-looking statements can be identified by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions, and includes statements regarding 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 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 intended benefits to be derived from SYN-004, SYN-010 and SYN-020. These forward-looking statements are based on management's expectations and assumptions as of the date of this press release and are subject to a number of risks and uncertainties, many of which are difficult to predict that could cause actual results to differ materially from current expectations and assumptions from those set forth or implied by any forward-looking statements. Important factors that could cause actual results to differ materially from current expectations include, among others, Synthetic Biologics' ability to continue to comply with continued listing requirements of the NYSE American, the ability of its product candidates to demonstrate safety and effectiveness, as well as results that are consistent with prior results, Synthetic Biologics' clinical trials continuing and/or beginning enrollment as expected, a failure to receive the necessary regulatory approvals for commencement of clinical trials and commercialization of Synthetic Biologics' therapeutics, including approval of proposed trial designs, a failure of Synthetic Biologics' clinical trials, and those conducted by investigators, for SYN-004 and SYN-010 to be commenced or completed on time or to achieve desired results and benefits, a failure of Synthetic Biologics' clinical trials to continue enrollment as expected or receive anticipated funding, a failure of Synthetic Biologics to successfully develop, market or sell its products, Synthetic Biologics' inability to maintain its material licensing agreements, or a failure by Synthetic Biologics or its strategic partners to successfully commercialize products, Synthetic Biologics' ability to achieve acceptance of its product candidates in the marketplace and the successful development, marketing or sale of Synthetic Biologics' products by competitors that render Synthetic Biologics' products obsolete or non-competitive, the continued maintenance and growth of Synthetic Biologics' patent estate, Synthetic Biologics becoming and remaining profitable, Synthetic Biologics' ability to obtain or maintain the capital or grants necessary to fund its research and development activities, a loss of any of Synthetic Biologics' key scientists or management personnel and other factors described in Synthetic Biologics' Form 10-K and 10-K/A for the year ended December 31, 2018 and its other filings with the SEC, including subsequent periodic reports on Forms 10-Q and 8-K. The information in this release is provided only as of the date of this release, and Synthetic Biologics undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

For further information, please contact:

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