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 14, 2021

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) (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 7.01 Regulation FD Disclosure.

On April 14, 2021, Synthetic Biologics, Inc. (the "Company") issued a press release announcing that enrollment has commenced and the first patient has been dosed in its Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant (HCT) recipients for the prevention of acute graft-versus-host-disease (aGVHD). The single-center, randomized, double-blinded, placebo-controlled clinical trial will evaluate the safety, tolerability and potential absorption into the systemic circulation (if any) of 150 mg oral SYN-004 administered to allogeneic HCT recipients who receive an IV beta-lactam antibiotic to treat fever. Study participants will be enrolled into three sequential cohorts, with each receiving a different study-assigned IV beta-lactam antibiotic. Eight participants in each cohort will receive SYN-004 and four will receive placebo. A data readout for the first cohort is anticipated towards the end of 2021.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 and in the press release attached as Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 7.01 and in the press release attached as Exhibit 99.1 shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

The press release attached as Exhibit 99.1 includes "safe harbor" language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained therein are "forward-looking" rather than historical. The Company undertakes no duty or obligation to update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time if its management believes it is appropriate. Any such updating may be made through the filing of other reports or documents with the Securities and Exchange Commission, through press releases or through other public disclosures.

Item 8.01 Other Events.

On April 14, 2021, Synthetic Biologics, Inc. (the "Company") issued a press release announcing that enrollment has commenced and the first patient has been dosed in its Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant (HCT) recipients for the prevention of acute graft-versus-host-disease (aGVHD). A data readout for the first cohort is anticipated towards the end of 2021.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release issued by Synthetic Biologics, Inc., dated April 14, 2021

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: April 14, 2021

SYNTHETIC BIOLOGICS, INC.

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

Synthetic Biologics Announces First Patient Dosed in Phase 1b/2a Clinical Trial of SYN-004 (ribaxamase) in Allogeneic Hematopoietic Cell Transplant Recipients

Rockville, MD, April 14, 2021 – 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 enrollment has commenced and the first patient has been dosed in its Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant (HCT) recipients for the prevention of acute graft-versus-host-disease (aGVHD). Broad spectrum intravenous (IV) beta-lactam antibiotics used to treat infection following conditioning chemotherapy for allogeneic HCT patients is a necessary and oftentimes lifesaving intervention. However, antibiotic-mediated damage of the gut microbiome in this patient population has been strongly associated with adverse outcomes including *C. difficile* infection (CDI), vancomycin-resistant enterococci (VRE) colonization, potentially fatal bacteremia, and aGVHD.

“Allogenic HCT recipients are at very high risk for infection and frequently receive antibiotics,” said Erik Dubberke, MD, Professor of Medicine and Clinical Director of Transplant Infectious Diseases at Washington University School of Medicine in St. Louis. “There is increasing evidence that disruption of the microbiome caused by antibiotics results in additional complications, including further infections. If this trial shows that SYN-004 has a favorable safety profile and is able to protect the microbiome, it would warrant study in larger trials to determine if this treatment can improve outcomes in these highly susceptible patients**.”**

“We are very excited to begin enrollment of our SYN-004 Phase 1b/2a clinical trial in allogeneic HCT recipients,” said Steve A. Shallcross, Chief Executive Officer of Synthetic Biologics. “We are very grateful for the tremendous support from Dr. Dubberke and his team at Washington University. This clinical program is a critical component of our efforts to expand and fortify the already well-established dataset for SYN-004 and our pursuit of a cost-effective development strategy in a highly specialized patient population. We look forward to reporting key clinical milestones as we advance the trial.”

The single-center, randomized, double-blinded, placebo-controlled clinical trial will evaluate the safety, tolerability and potential absorption into the systemic circulation (if any) of 150 mg oral SYN-004 administered four times per day to allogeneic HCT recipients who receive an intravenous (IV) beta-lactam antibiotic to treat fever. Study participants will be enrolled into three sequential cohorts, with each receiving a different study-assigned IV beta-lactam antibiotic. Eight participants in each cohort will receive SYN-004 and four will receive placebo. A data readout for the first cohort is anticipated towards the end of 2021.

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. 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.

Synthetic Biologics will serve as the sponsor of the clinical trial and supply SYN-004 to Washington University. Dr. Dubberke will serve as the principal investigator along with his Washington University colleague, Dr. Mark A. Schroeder, Associate Professor of Medicine, Division of Oncology, Bone Marrow Transplantation and Leukemia.

About the SYN-004 (ribaxamase) Phase 1b/2a Clinical Trial

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 following conditioning therapy. Antibiotic-mediated damage of the gut microbiome in allogeneic HCT recipients may lead to adverse outcomes including CDI, VRE colonization and potentially fatal bacteremia and aGVHD. A previously completed placebo-controlled Phase 2b clinical trial of 412 patients demonstrated SYN-004 protected the gut microbiome from antibiotic-mediated dysbiosis. Patients who received SYN-004 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 diversified clinical-stage company leveraging the microbiome to develop therapeutics designed to prevent and treat gastrointestinal (GI) diseases in areas of high unmet need. 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 (a) microbiome damage, (b) *Clostridioides difficile* infection (CDI), (c) overgrowth of pathogenic organisms, (d) the emergence of antimicrobial resistance (AMR), and (e) acute graft-versus-host-disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) recipients, and (2) SYN-020, a recombinant oral formulation of the enzyme intestinal alkaline phosphatase (IAP) produced under cGMP conditions and intended to treat both local GI and systemic diseases. 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 a data readout from the first cohort towards the end of 2021, the potential of SYN-004 to significantly improve outcomes for allogenic HCT recipient and the intended benefits to be derived from SYN-004 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 provide data towards the end of 2021, the 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-020 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 for the year ended December 31, 2020 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:

Synthetic Biologics, Inc. (Corporate and Investors)
Vincent I. Perrone, Director Corporate Communication, (240) 660-2000, info@syntheticbiologics.com

Ogilvy (Media)
Gregory Kelley, Senior Vice President, (404) 836-2302, gregory.kelley@ogilvy.com

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