

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): May 15, 2017

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:

- 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))
-

Item 8.01. Other Events

On May 11, 2017, Synthetic Biologics, Inc., a Nevada corporation, (the “Registrant”) issued the attached press release that included notification that the U.S. Food and Drug Administration (FDA) has granted a Breakthrough Therapy Designation for SYN-004 (ribaxamase) for the prevention of *Clostridium difficile* infection. A copy of the press release is attached as Exhibit 99.1 to this Report on Form 8-K and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit

<u>No.</u>	<u>Description</u>
99.1	Synthetic Biologics, Inc. press release dated May 11, 2017

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: May 15, 2017

SYNTHETIC BIOLOGICS, INC.
(Registrant)

By: /s/ Steven Shallcross
Name: Steven Shallcross
Title: Chief Financial Officer



SYN-004 (Ribaxamase) Receives Breakthrough Therapy Designation from U.S. Food and Drug Administration for Prevention of *Clostridium difficile* Infection

-- FDA Action Marks First Breakthrough Therapy Designation for Clinical Program Designed to Prevent Primary *Clostridium difficile* Infection --

-- Type-B Meeting Anticipated to Discuss Potential for Expedited Drug Development Strategy --

For Immediate Release

Rockville, MD, May 11, 2017 – Synthetic Biologics, Inc. (NYSE MKT: SYN), a late-stage clinical company developing therapeutics that preserve the microbiome to protect and restore the health of patients, today announced that the U.S. Food and Drug Administration (FDA) has granted a Breakthrough Therapy Designation for SYN-004 (ribaxamase) for the prevention of *Clostridium difficile* infection. SYN-004 (ribaxamase) is the Company's first-in-class oral enzyme designed to protect the gut microbiome from disruption caused by certain intravenous (IV) beta-lactam antibiotics.

The Breakthrough Therapy Designation is based on data from the successful Phase 2b clinical trial of ribaxamase, which met its primary endpoint of significantly reducing CDI. FDA Breakthrough Therapy Designation is intended to expedite development and review timelines when preliminary clinical evidence indicates that a drug may demonstrate substantial improvement on one or more clinically significant endpoints over available therapies for serious or life threatening diseases. If approved by the FDA, SYN-004 (ribaxamase) would be the first available drug designed to prevent *Clostridium difficile* infection by protecting the gut microbiome from antibiotic-mediated dysbiosis.

"We are delighted by the FDA's recognition of ribaxamase's potential to prevent CDI, and the dire need to fill the current void of an approved intervention," said Jeffrey Riley, President and Chief Executive Officer. "Following this announcement, we have been asked and anticipate requesting a Type-B multidisciplinary meeting with the Agency for a comprehensive discussion on the overarching, high-level drug development plan and pathway to licensure for ribaxamase. We look forward to working closely with the FDA throughout the development and review process and remain dedicated to bringing this potentially paradigm-shifting approach to antibiotic therapy to patients in critical need."

About *Clostridium difficile* Infection

Clostridium difficile infection is the number one hospital acquired infection in the U.S., with more than 453,000¹ patients diagnosed annually. CDI results in approximately 29,000¹ deaths, \$1.5 billion¹ in additional healthcare costs, as well as significant and sometimes prolonged illness.

About SYN-004 (ribaxamase) and the Phase 2b Study

SYN-004 (ribaxamase) is a first-in-class oral enzyme 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 CDI, pathogenic overgrowth and the emergence of antimicrobial resistance (AMR). Synthetic Biologics initiated a Phase 2b proof-of-concept clinical trial intended to evaluate the effectiveness of ribaxamase to prevent the onset of primary *C. difficile* infection (CDI), antibiotic-associated diarrhea (AAD) and the emergence of antimicrobial resistance (AMR) in patients hospitalized with a lower respiratory infection and receiving IV ceftriaxone. Results from this trial indicate that patients receiving ribaxamase achieved a 71.4% relative risk reduction (p-value=0.045) in CDI rates compared to patients receiving placebo. Analysis of the data also demonstrated a significant reduction in new colonization by vancomycin-resistant enterococci (VRE) for patients receiving ribaxamase compared to placebo (p-value=0.0002). Adverse events reported during this trial were comparable between treatment and placebo arms. Analysis of data from several exploratory endpoints designed to evaluate ribaxamase's ability to prevent the emergence and proliferation of AMR in the gut microbiome is ongoing.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE MKT: SYN) is a late-stage clinical company developing therapeutics that preserve the microbiome to protect and restore the health of patients. The Company's lead candidates poised for Phase 3 development are: (1) SYN-004 (ribaxamase) which is designed to protect the gut microbiome from the effects of certain commonly used intravenous (IV) beta-lactam antibiotics for the prevention of *C. difficile* infection, pathogenic overgrowth and the emergence of antimicrobial resistance (AMR), 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 developing preclinical stage monoclonal antibody therapies for the prevention and treatment of pertussis and novel discovery stage biotherapeutics for the treatment of phenylketonuria (PKU). For more information, please visit Synthetic Biologics' website at www.syntheticbiologics.com.

This release includes 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 include statements regarding the potential of ribaxamase to prevent CDI, the anticipated request for a Type-B multidisciplinary meeting with the Agency for a comprehensive discussion on the overarching, high-level drug development plan and pathway to licensure for ribaxamase, the intended expedited development of ribaxamase due to Breakthrough Therapy Designation, the potentially paradigm-shifting approach to antibiotic therapy to patients in critical need, and the ability of SYN-004 to protect the gut microbiome from the disruption caused by certain intravenous (IV) beta-lactam antibiotic and the industry data regarding the expected incidence and economic burden of CDI. 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 that could cause actual results to differ materially 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' product candidates demonstrating safety and effectiveness, as well as results that are consistent with prior results, Synthetic Biologics' ability to initiate clinical trials and if initiated, to complete them on time and achieve desired results and benefits, Synthetic Biologics' clinical trials continuing enrollment as expected, Synthetic Biologics' ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to Synthetic Biologics' ability to promote or commercialize its product candidates for specific indications, 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, Synthetic Biologics' ability to maintain its license agreements, the continued maintenance and growth of Synthetic Biologics' patent estate, Synthetic Biologics becoming and remaining profitable, Synthetic Biologics' ability to establish and maintain collaborations, 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' Annual Report on Form 10-K for the year ended December 31, 2016 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, excepted 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

Feinstein Kean Healthcare (Media)

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

###
