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 5, 2017

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:

☐ 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

Synthetic Biologics, Inc. (the "Company") today issued a press release announcing positive topline data from its Phase 2b clinical trial for SYN-004 (ribaxamase), 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 trial, a randomized, double-blind, placebo controlled trial of 412 patients, met its primary endpoint of significantly reducing *C. difficile* Infection (CDI). Preliminary analysis of the data indicates seven confirmed cases of CDI in the placebo group compared to two cases in the ribaxamase treatment group. Patients receiving ribaxamase achieved a 71.4% relative risk reduction (p-value=0.045) in CDI rates compared to patients receiving placebo. Adverse events reported during this trial were comparable between treatment and placebo arms.

Synthetic Biologics is also in the process of analyzing data from several exploratory endpoints that were designed to evaluate ribaxamase's ability to protect the gut microbiome from colonization by opportunistic bacteria such as *C. difficile* and other antibiotic-resistant pathogens. Preliminary analysis of the data demonstrated a significant reduction in new colonization by vancomycin-resistant enterococci (VRE) for patients receiving ribaxamase compared to placebo (p-value=0.0002). The study included a secondary endpoint to assess ribaxamase's capacity to decrease the incidence of antibiotic-associated diarrhea from all cases. Preliminary analysis of the data suggested a trend towards such a reduction (p-value=0.13), which was due, for the most part, to the reduction of CDI.

These data are consistent with ribaxamase's mechanism of action designed to protect and preserve the natural balance of the gut microbiome from the unintended effects of IV antibiotic use. The Company expects to share additional results from these exploratory endpoints as they become available later this year, including results focused on ribaxamase's ability to prevent the emergence of antimicrobial resistance in the gut microbiome.

The press release is attached as Exhibit 99.1 to this report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Synthetic Biologics, Inc. press release dated January 5, 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: January 5, 2017

SYNTHETIC BIOLOGICS, INC.
(Registrant)

By: /s/ Jeffrey Riley
Name: Jeffrey Riley
Title: President and Chief Executive Officer

Exhibit 99.1

Synthetic Biologics' SYN-004 (ribaxamase) Achieves Primary Endpoint in Phase 2b Trial for *C. difficile* Infection (CDI)

— Presentation Planned for 9:30am (PT), Jan. 9, 2017 at Biotech Showcase in San Francisco —

For Immediate Release

Rockville, MD, January 05, 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 positive topline data from its Phase 2b clinical trial for SYN-004 (ribaxamase), 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 study, a randomized, double-blind, placebo controlled trial of 412 patients, met its primary endpoint of significantly reducing *C. difficile* Infection (CDI). Preliminary analysis of the data indicated seven confirmed cases of CDI in the placebo group compared to two cases in the ribaxamase treatment group. Patients receiving ribaxamase achieved a 71.4% relative risk reduction (p-value=0.045) in CDI rates compared to patients receiving placebo. Adverse events reported during this trial were comparable between treatment and placebo arms.

Synthetic Biologics is also in the process of analyzing data from several exploratory endpoints that were designed to evaluate ribaxamase's ability to protect the gut microbiome from colonization by opportunistic bacteria such as *C. difficile* and other antibiotic-resistant pathogens. Preliminary analysis of the data demonstrated a significant reduction in new colonization by vancomycin-resistant enterococci (VRE) for patients receiving ribaxamase compared to placebo (p-value=0.0002). With agreement from the FDA, the study included a secondary endpoint to assess ribaxamase's capacity to decrease the incidence of antibiotic-associated diarrhea from all causes. Preliminary analysis of the data suggested a trend towards such a reduction (p-value=0.13), which was due, for the most part, to the reduction of CDI.

These data are consistent with ribaxamase's mechanism of action designed to protect and preserve the natural balance of the gut microbiome from the unintended effects of IV antibiotic use. The Company expects to share additional results from these exploratory endpoints as they become available later this year, including results focused on ribaxamase's ability to prevent the emergence of antimicrobial resistance in the gut microbiome.

"These trial results provide a compelling demonstration of the potential of ribaxamase to help address the serious health impacts associated with CDI and infections from other opportunistic bacteria resulting from dysbiosis of the gut microbiome," said Joseph Sliman, MD, SVP, Clinical and Regulatory Affairs. "More than 453,000[1] patients are diagnosed with CDI annually in the U.S., resulting in approximately 29,000[1] deaths as well as significant and sometimes prolonged illness. Ribaxamase has the potential to shorten hospital stays, diminish morbidity and mortality and reduce the emergence of antibiotic-resistant organisms in the gut microbiome by protecting patients from primary *C. difficile* infection resulting from IV antibiotic use."

In addition to causing significant suffering and mortality, CDI adds an estimated economic burden of nearly $1.5 billion[1] to the healthcare system each year, which could potentially be reduced with an effective therapeutic.

1: Leffler DA et al. N Engl J Med 2015; 372: 1539-1548

“The reduction in the relative risk of CDI represents a significant milestone in the clinical development of ribaxamase and we believe provides further validation for our approach to advancing cutting edge microbiome science,” said Jeffrey Riley, President and Chief Executive Officer. “These findings also help further our goals to bring the first ever microbiome-focused therapeutic to patients and to help illuminate the potential of this drug class to address serious diseases and public health concerns. We expect to share additional data from exploratory endpoints in the coming months and look forward to continuing ongoing and productive discussions with both the FDA and CDC on the protocol for Phase 3 pivotal trials for ribaxamase.”

Synthetic Biologics is also continuing to prepare for the initiation of pivotal Phase 2b/3 clinical trials for SYN-010, the Company’s proprietary, modified-release formulation of lovastatin lactone designed to treat the underlying cause of irritable bowel syndrome with constipation (IBS-C).

Presentation Planned for Biotech Showcase 2017 Conference

Date: Monday, January 9, 2016
Time: 9:30 a.m. (PT) / 12:30 p.m. (ET)
Location: Hilton San Francisco Union Square, San Francisco, CA

A live webcast of Synthetic Biologics’ presentation may be accessed by logging onto the internet at https://event.webcasts.com/viewer/event.jsp?ei=1130367. After the presentation, a replay will be archived and accessible for 90 days at the same website.

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, AAD and the emergence of antibiotic-resistant organisms. The Phase 2b proof-of-concept clinical trial is 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 antibiotic-resistant organisms in patients hospitalized with a lower respiratory infection and receiving IV ceftriaxone. A total of 412 subjects were randomized in a 1:1 ratio receiving either 150 mg dose strength of SYN-004 (ribaxamase) or placebo orally QID from Day 1 and until 72 hours following their last treatment of IV ceftriaxone. The sample size was determined to provide 80% power to detect the treatment effect with a one-sided alpha of 0.05. P-values were determined based on a 1-sided z-test for the comparison of the treatment difference as pre-specified in the statistical analysis plan. To access the ribaxamase mechanism of action video on Synthetic Biologics' website, please click here.

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-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), and (2) 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, antibiotic-associated diarrhea (AAD) and the emergence of antibiotic-resistant organisms. 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 help address the serious health impacts associated with CDI and infections from other opportunistic bacteria resulting from dysbiosis of the gut microbiome, the industry data regarding the expected incidence and economic burden of CDI, the potential of ribaxamase to shorten hospital stays, diminish morbidity and mortality and reduce the emergence of antibiotic resistant organisms in the gut microbiome by protecting patients from primary C. difficile infection resulting from IV antibiotic use, the potential to reduce the economic burden to the healthcare system from an effective therapeutic, the suggested trend toward a reduction of incidence of antibiotic-associated diarrhea from all causes, the expected timing of data release of exploratory endpoints of the trial focused on the ability of ribaxamase to prevent the emergence of antibiotic-resistant organisms in the gut microbiome, the continued ongoing discussions with the FDA and CDC, validation for our approach to advancing cutting edge microbiome science, the continued preparation for the initiation of pivotal Phase 2b/3 clinical trials for SYN-010, the potential of the drug class to address serious diseases and public health concerns, the ability of SYN-004 to protect the gut microbiome from the effects of certain commonly used IV beta-lactam antibiotics for the prevention of C. difficile infection, antibiotic-associated diarrhea (AAD) and the emergence of antibiotic-resistant organisms. 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, 2015 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.

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