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 18, 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 confirming plans to initiate a Phase 2b/3 adaptive pivotal trial for SYN-010, the Company's modified-release reformulation of lovastatin lactone designed to reduce methane production by certain microorganisms (*M. smithii)* in the gut to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C). The Company anticipates initiating this trial during the first quarter of 2017.

In accordance with collaborative discussions with the FDA, key components of the SYN-010 Phase 2b/3 adaptive pivotal trial will include:

- A 12-week, multi-center, double-blind, placebo-controlled, adaptive design clinical trial
- A study population of approximately 840 adult subjects diagnosed with IBS-C
- Evaluation of efficacy and safety of two dose strengths of SYN-010 (21 mg and 42 mg) compared to placebo
- Conducted in approximately 150 clinical sites in North America
- Study subjects will be randomized in a 1:1:1 ratio, receiving either 21 mg of SYN-010, 42 mg of SYN-010, or placebo
- Enrollment open to all IBS-C patients; breath-methane will be measured at baseline to ensure a comparable ratio of high-to-low breath methane IBS-C patients in each treatment arm
- An interim futility analysis may be conducted when approximately 50% of patients in each dosing arm have completed treatment

Consistent with FDA written guidance, the primary objective for this study is to determine the efficacy of SYN-010, measured as an improvement from baseline in the percentage of overall weekly responders[1] during the 12-week treatment period for SYN-010 21 mg and 42 mg daily doses compared to placebo. Secondary efficacy endpoints for both dose strengths of SYN-010 will measure changes from baseline in abdominal pain, bloating, bowel movement frequency and stool consistency. Exploratory outcomes include Adequate Relief and quality of life measures using the well-validated EQ-5D-5L and PAC-SYM patient questionnaires.

[1] An overall 12-week responder is defined as a subject with a weekly response in at least 50% of the weeks of treatment (6 of 12 weeks). Weekly Responder is defined as a patient who experiences a decrease in weekly average score for worst abdominal pain in the past 24 hours of at least 30% compared with Study 1 Baseline and a stool frequency increase of 1 or more CSBM per week compared with Study 1 Baseline.

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 18, 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 18, 2017

SYNTHETIC BIOLOGICS, INC.
(Registrant)

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

Exhibit 99.1

Synthetic Biologics Confirms Key Features of Pivotal Phase 2b/3 Trial of SYN-010 Pursuant to Consultations with FDA

-- Enrollment in SYN-010 Pivotal Trial Will Be Open to All IBS-C Patients --

For Immediate Release

Rockville, MD, January 18, 2017 – Synthetic Biologics, Inc. (NYSE MKT: SYN), a late-stage clinical company developing therapeutics designed to preserve the microbiome to protect and restore the health of patients, today confirmed plans to initiate a Phase 2b/3 adaptive pivotal trial for SYN-010, the Company's modified-release reformulation of lovastatin lactone designed to reduce methane production by certain microorganisms (*M. smithii)* in the gut to treat the underlying cause of irritable bowel syndrome with constipation (IBS-C). The Company anticipates initiating this trial by the end of the first quarter of 2017.

In accordance with collaborative discussions with the FDA, key components of the SYN-010 Phase 2b/3 adaptive pivotal trial will include:

- A 12-week, multi-center, double-blind, placebo-controlled, adaptive design clinical trial
- A study population of approximately 840 adult subjects diagnosed with IBS-C
- Evaluation of efficacy and safety of two dose strengths of SYN-010 (21 mg and 42 mg) compared to placebo
- Conducted in approximately 150 clinical sites in North America
- Study subjects will be randomized in a 1:1:1 ratio, receiving either 21 mg of SYN-010, 42 mg of SYN-010, or placebo
- Enrollment is open to all IBS-C patients; breath-methane will be measured at baseline to ensure a comparable ratio of high-to-low breath methane IBS-C patients in each treatment arm
- An interim futility analysis may be conducted when approximately 50% of patients in each dosing arm have completed treatment

"We are pleased with the direction that we received from the FDA on the clinical trial design for SYN-010," said Jeffrey Riley, President and Chief Executive Officer. "With a clear path forward for SYN-010's clinical development, we are one step closer to achieving our goal of providing patients with a novel, potentially best-in-class therapy that directly targets a cause of IBS-C, thereby alleviating symptoms and preventing their recurrence."

Consistent with FDA written guidance, the primary objective for this study is to determine the efficacy of SYN-010, measured as an improvement from baseline in the percentage of overall weekly responders[1] during the 12-week treatment period for SYN-010 21 mg and 42 mg daily doses compared to placebo. Secondary efficacy endpoints for both dose strengths of SYN-010 will measure changes from baseline in abdominal pain, bloating, bowel movement frequency and stool consistency. Exploratory outcomes include Adequate Relief and quality of life measures using the well-validated EQ-5D-5L and PAC-SYM patient questionnaires.

[1] An overall 12-week responder is defined as a subject with a weekly response in at least 50% of the weeks of treatment (6 of 12 weeks). Weekly Responder is defined as a patient who experiences a decrease in weekly average score for worst abdominal pain in the past 24 hours of at least 30% compared with Study 1 Baseline and a stool frequency increase of 1 or more CSBM per week compared with Study 1 Baseline.

Synthetic Biologics also recently announced the achievement of the primary endpoint from its Phase 2b proof-of-concept clinical trial of SYN-004 (ribaxamase). Preliminary analysis of the data demonstrated a statistically significant reduction in both *C. difficile* infection (CDI) (p-value=0.045; relative risk reduction of 71.4%) and new colonization by vancomycin-resistant enterococci (VRE) (p-value=0.0002) for patients receiving ribaxamase compared to placebo.

About Irritable Bowel Syndrome

IBS affects an estimated 10 to 15 percent of the population, or as many as 45 million people in North America. The illness affects both men and women; however, two-thirds of diagnosed sufferers are women. It has been reported that up to 20 percent of all IBS patients have IBS-C and current FDA-approved therapies for the treatment of IBS-C, which include prescription and over-the-counter laxatives, do little to treat the underlying cause of the disease. These products provide patients with temporary relief from the symptoms of constipation by elevating the amount of water which passes through the gastrointestinal tract, but tend to cause an IBS-C patient to swing from suffering from constipation, to suffering from diarrhea.

About SYN-010

SYN-010 is a proprietary, modified-release formulation of lovastatin lactone that is intended to reduce methane production by certain microorganisms (*M. smithii*) in the gut while minimizing disruption to the microbiome to treat an underlying cause of IBS-C. SYN-010 is intended to act primarily in the intestinal lumen while avoiding systemic absorption, thereby targeting a major cause of IBS-C, not just the symptoms. To access the SYN-010 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 designed to 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 (CDI), antibiotic-associated diarrhea (AAD) and the emergence of antimicrobial-resistance (AMR). 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 plans to initiate a Phase 2b/3 adaptive pivotal trial for SYN-010 towards the end of quarter 1 2017, the size of the market, potential of SYN-010 to reduce methane production for the treatment of IBS-C and *to protect the microbiome*, and *the size of the market 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.*

For further information, please contact:

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