Synthetic Biologics, Inc.
Form 8-K
January 18, 2017

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