Synthetic Biologics, Inc.
Form 8-K
January 05, 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 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