Synthetic Biologics, Inc.
Form 8-K
September 06, 2018

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): September 5, 2018

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ¨

If an emerging growth company, indicate by checkmark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

Item 1.01. Entry into a Material Definitive Agreement.

On September 5, 2018, Synthetic Biologics, Inc. (the "Company"), entered into an agreement with Cedars-Sinai Medical Center (CSMC) for an investigator-sponsored Phase 2 clinical study of SYN-010 to be co-funded by the Company and CSMC (the "Study"). The Study will provide further evaluation of the efficacy and safety of SYN-010, the Company's modified-release reformulation of lovastatin lactone, which is exclusively licensed to the Company by CSMC. SYN-010 is 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).

In consideration of the support provided by CSMC for the Study, the Company entered into a Stock Purchase Agreement with CSMC pursuant to which the Company has agreed upon the approval of the Study protocol by the Institutional Review Board to: (i) issue to CSMC Fifty Thousand (50,000) shares of common stock of the Company; and (ii) transfer to CSMC an additional Two Million Four Hundred Twenty Thousand (2,420,000) shares of common stock of its subsidiary Synthetic Biomics, Inc. ("Synbiomics") owned by the Company, such that after such issuance CSMC will own an aggregate of Seven Million Four Hundred Eighty Thousand (7,480,000) shares of common stock of Synbiomics, representing seventeen percent (17%) of the issued and outstanding shares of Synbiomics' common stock.

The Stock Purchase Agreement also provides CSMC with a right, commencing on the six month anniversary of issuance of the stock under certain circumstances in the event that the shares of stock of Synbiomics are not then freely tradeable, and subject to NYSE American, LLC approval, to exchange its Synbiomics shares for unregistered shares of the Company's common stock, with the rate of exchange based upon the relative contribution of the valuation of Synbiomics to the public market valuation of the Company at the time of each exchange. The Stock Purchase Agreement also provides for tag-along rights in the event of the sale by the Company of its shares of Synbiomics.

On September 6, 2018, the Company issued the press release attached hereto as Exhibit 99.1 regarding the agreements described herein.

Item 3.02. Unregistered Sales of Equity Securities.

The information regarding the shares of Company set forth under Item 1.01 of this Current Report on Form 8-K is incorporated by reference in this Item 3.02. The Company issued to CSMC the shares of the Company's common stock in reliance on the exemption from registration provided for under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The Company relied on this exemption from registration for private placements based in part on the representations made by CSMC, including the representations with respect to CSMC's status as an

"accredited investor," as such term is defined in Rule 501(a) of the Securities Act, and CSMC's investment intent.

Item 8.01 Other Events

The Company today issued a press release announcing that the Company has entered into an agreement with Cedars-Sinai Medical Center for an investigator-sponsored Phase 2 clinical study of SYN-010. The study will provide further evaluation of the efficacy and safety of SYN-010, the Company's modified-release reformulation of lovastatin lactone, which is exclusively licensed to the Company by Cedars-Sinai Medical Center. SYN-010 is 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 Phase 2 study will be conducted out of the Pimentel Laboratory at Cedars-Sinai Medical Center and is expected to be comprised of a 12-week, placebo-controlled, double-blind, randomized clinical trial to evaluate two dose strengths of oral SYN-010 (21 mg and 42 mg) in approximately 150 patients diagnosed with IBS-C. The investigator-sponsored Phase 2 clinical study will be led by the gastrointestinal microbiota researcher Ruchi Mathur, M.D., director of Metabolism, Clinical Research and Administrative Operations at the Medically Associated Science and Technology (MAST) Program at CSMC. The Phase 2 study, which will be co-funded by the Company and CSMC, is expected to begin enrollment during the fourth quarter of 2018, contingent upon approval of the clinical study protocol by CSMC's Institutional Review Board. Both CSMC and Dr. Pimentel have a financial interest in the Company.

The primary objective for the study will be to determine the efficacy of SYN-010, measured as an improvement from baseline in the weekly average number of complete spontaneous bowel movements (CSBMs) during the 12-week treatment period for SYN-010 21 mg and 42 mg daily doses relative to placebo. Secondary efficacy endpoints for both dose strengths of SYN-010 are expected to measure changes from baseline in abdominal pain, bloating, stool frequency as well as the use of rescue medication relative to placebo. Exploratory outcomes include Adequate Relief and quality of life measures using the well-validated EQ-5D-5L and PAC-SYM patient questionnaires.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1	Stock Purchase Agreement between Synthetic Biologics, Inc., and Cedars-Sinai Medical Center dated September 5, 2018
99.1	Synthetic Biologics, Inc. press release dated September 6, 2018

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: September 6, 2018 SYNTHETIC BIOLOGICS, INC.
(Registrant)

By: /s/ Steven Shallcross
Name: Steven Shallcross
Title: Interim Chief Executive Officer and Chief Financial Officer