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 3, 2019

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 8.01. Other Events

On January 3, 2019, Synthetic Biologics, Inc. (the "Company") issued a press release announcing that the first two patients have been enrolled in the SYN-010 Phase 2b investigator-sponsored clinical study. SYN-010 is a proprietary, 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). Cedars-Sinai Medical Center and Synthetic Biologics are co-funding the study, which will further assess the efficacy and safety of SYN-010 in patients diagnosed with IBS-C.

The press release attached as Exhibit 99.1 to this Current Report on Form 8-K, which is incorporated herein by reference, includes "safe harbor" language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained in the press release are "forward-looking" rather than historical.

The Company undertakes no duty or obligation to update or revise information included in this Current Report on Form 8-K or the press release attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Synthetic Biologics, Inc. dated January 3, 2019

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 3, 2019

SYNTHETIC BIOLOGICS, INC.

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release issued by Synthetic Biologics, Inc. dated January 3, 2019

Exhibit 99.1

Synthetic Biologics Announces First Two Patients Enrolled in Phase 2b Investigator-Sponsored Clinical Study of SYN-010, for the Treatment of IBS-C

Rockville, MD, January 03, 2019 – Synthetic Biologics, Inc. (NYSE American: SYN), a late-stage clinical company developing therapeutics designed to preserve the microbiome to protect and restore the health of patients, today announced that the first two patients have been enrolled in SYN-010's Phase 2b investigator-sponsored clinical study. SYN-010 is a proprietary, 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). Cedars-Sinai Medical Center (CSMC) and Synthetic Biologics are co-funding the study, which will further assess the efficacy and safety of SYN-010 in patients diagnosed with IBS-C.

"IBS with constipation can be debilitating for millions of people worldwide, and this study will go a long way toward helping identify whether SYN-010 can become a valuable tool in addressing the underlying causes and offering relief to those patients," said Mark Pimentel, M.D., head of the Pimentel Laboratory and executive director of the Medically Associated Science and Technology (MAST) Program at CSMC.

The Phase 2b study is beng conducted by the MAST Program at CSMC and comprises 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. A data readout from this investigator-sponsored clinical study is expected during the second half of 2019.

"We are very excited to begin enrollment of our SYN-010 Phase 2b investigator-sponsored clinical study," said Steven A. Shallcross, Chief Executive Officer of Synthetic Biologics. "SYN-010 remains an integral component in our portfolio of microbiome-focused assets and represents a promising and differentiated approach to treating the underlying cause of the symptoms commonly associated with IBS-C. This study will be instrumental in our efforts to expand and fortify the already well-established dataset for SYN-010 and may help determine the optimal dose strength of SYN-010 for potential future registration studies."

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.

The patent rights covering the use of SYN-010 are owned by Cedars-Sinai Medical Center and are exclusively licensed by Cedars-Sinai Medical Center to Synthetic Biologics. Both Cedars-Sinai and Dr. Pimentel have a financial interest in Synthetic Biologics.

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 learn more about SYN-010's unique mechanism of action, please click here.

About Cedars-Sinai Medical Center

Cedars-Sinai is a national leader in providing high-quality, patient-centered healthcare encompassing primary care as well as specialized medicine and conducting research that leads to lifesaving discoveries and innovations. Since its beginning in 1902, Cedars-Sinai has evolved to meet the healthcare needs of one of the most diverse regions in the nation, continually setting new standards in quality and innovation in patient care, research, teaching and community service.

Today, Cedars-Sinai is widely known for its national leadership in transforming healthcare for the benefit of patients. Cedars-Sinai impacts the future of healthcare globally by developing new approaches to treatment and educating tomorrow's physicians and other health professionals. At the same time, Cedars-Sinai demonstrates a longstanding commitment to strengthening the Los Angeles community through wide-ranging programs that improve the health of its most vulnerable residents.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE American: 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 late-stage candidates are: (1) SYN-004 (ribaxamase) which is designed to protect the gut microbiome from the effects of certain commonly used intravenous (IV) beta-lactam antibiotics to prevent microbiome damage, *C. difficile* infection (CDI), overgrowth of pathogenic organisms and the emergence of antimicrobial resistance (AMR), and (2) 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). The Company's preclinical pursuits include an oral formulation of the enzyme intestinal alkaline phosphatase (IAP) to treat both local GI and systemic diseases as well as monoclonal antibody therapies for the prevention and treatment of pertussis. For more information, please visit Synthetic Biologics' website at www.syntheticbiologics.com.

This release contains 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 includes statements regarding SYN-010 representing a promising and differentiated approach to treating the underlying cause of the symptoms commonly associated with IBS-C, potential future registration studies, the planned design of the Phase 2b study, the expected data readout from this investigator-sponsored clinical study during the second half of 2019, the potential of SYN-010 to treat the cause of IBS-C not just the symptoms and the study helping to determine the optimal dose strength of SYN-010 for potential future registration studies. 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, many of which are difficult to predict that could cause actual results to differ materially from current expectations and assumptions 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, the ability to received Institutional Board Approval of the Phase 2b trial protocol, the ability to commence the trial when anticipated, the results of the SYN-010 trial demonstrating support for the use of SYN-010 to treat symptoms of IBS-C, Synthetic Biologics' ability to regain compliance with the continued listing standards of the NYSE American by September 2, 2019, Synthetic Biologics' ability to comply with other continued listing requirements of the NYSE American, the ability of its product candidates to demonstrate safety and effectiveness, as well as results that are consistent with prior results, Synthetic Biologics' clinical trials continuing enrollment as expected, a failure to receive the necessary regulatory approvals for commercialization of Synthetic Biologics' therapeutics, including approval of proposed trial designs, a failure of Synthetic Biologics' clinical trials, and those conducted by investigators, for SYN-004 and SYN-010 to be commenced or completed on time or to achieve desired results and benefits, a failure of Synthetic Biologics' clinical trials to continue enrollment as expected or receive anticipated funding, a failure of Synthetic Biologics to successfully develop, market or sell its products, Synthetic Biologics' inability to maintain its material licensing agreements, or a failure by Synthetic Biologics or its strategic partners to successfully commercialize products, Synthetic Biologics' ability to achieve 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, the continued maintenance and growth of Synthetic Biologics' patent estate, Synthetic Biologics becoming and remaining profitable, 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' Form 10-K for the year ended December 31, 2017 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:

Synthetic Biologics, Inc. (Corporate and Investors)
Vincent I. Perrone, Director, Corporate Communication, (240) 660-2000, info@syntheticbiologics.com

Cedars-Sinai
Jonathan Diamond, Senior Communications Specialist, (323) 866-8146, jonathan.diamond@cshs.org

Ogilvy (Media)
Gregory Kelley, Senior Vice President, (404) 836-2302, gregory.kelley@ogilvy.com

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