**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

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**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): **October 2, 2020**

# 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.) | (I.R.S. Employer Identification No.) |

**9605 Medical Center Drive, Suite 270**
**Rockville, Maryland 20850**
(Address of principal executive offices)

**(301) 417-4364**
(Registrant's telephone number, including area code)

**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 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(b) 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))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common stock, par value $0.001 per share | SYN | NYSE American |

Indicate by check mark whether the registrant is an emerging growth company as defined in in Rule 405 of the Securities Act of 1933 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §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 7.01. Regulation FD Disclosure.**

On October 2, 2020, Synthetic Biologics, Inc. (the "Company") issued a press release announcing the results of a planned interim futility analysis of its investigator-sponsored Phase 2b clinical study of SYN-010 being conducted by Cedars-Sinai Medical Center ("CSMC"). Based on the review of the interim analysis, it was concluded that although SYN-010 was well-tolerated, it is unlikely to meet its primary objective by the time enrollment is completed. As a result, CSMC has agreed to discontinue the trial and will conduct a comprehensive review of the final data set and publish its findings.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 and in the press release attached as Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 7.01 and in the press release attached as Exhibit 99.1 shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

The press release attached as Exhibit 99.1 includes "safe harbor" language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained therein are "forward-looking" rather than historical. The Company undertakes no duty or obligation to update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time if its management believes it is appropriate. Any such updating may be made through the filing of other reports or documents with the Securities and Exchange Commission, through press releases or through other public disclosures.

**Item 8.01. Other Events.**

On October 2, 2020, Synthetic Biologics, Inc. (the "Company") announced the results of a planned interim futility analysis of its investigator-sponsored Phase 2b clinical study of SYN-010 being conducted by Cedars-Sinai Medical Center ("CSMC"). Based on the review of the interim analysis, it was concluded that although SYN-010 was well-tolerated, it is unlikely to meet its primary objective by the time enrollment is completed. As a result, CSMC has agreed to discontinue the trial and will conduct a comprehensive review of the final data set and publish its findings.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release issued by Synthetic Biologics, Inc. dated October 2, 2020 |

**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.

Date: October 2, 2020

**SYNTHETIC BIOLOGICS, INC.**

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

**Exhibit 99.1**

**Synthetic Biologics Provides Update on Investigator-Sponsored Phase 2b Clinical Study of SYN-010 in IBS-C Patients**

**For Immediate Release**

**Rockville, MD, October 2, 2020 –** Synthetic Biologics, Inc. (NYSE American: SYN), a diversified clinical-stage company leveraging the microbiome to develop therapeutics designed to prevent and treat gastrointestinal ("GI") diseases in areas of high unmet need, today announced the results of a planned interim futility analysis of the investigator-sponsored Phase 2b clinical study of SYN-010 being conducted by Cedars-Sinai Medical Center ("CSMC"). Based on the review of the interim analysis, it was concluded that although SYN-010 was well-tolerated, it is unlikely to meet its primary objective by the time enrollment is completed. As a result, CSMC has agreed to discontinue the trial and will conduct a comprehensive review of the final data set and publish its findings.

The Phase 2b study was being conducted by the Medically Associated Science and Technology ("MAST") Program at CSMC and designed to evaluate two dose strengths of oral SYN-010 (21 mg and 42 mg) in patients diagnosed with irritable bowel syndrome with constipation (IBS-C). The primary objective of the study was intended 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.

"We are grateful to the patients and Cedars-Sinai who supported this clinical trial. Although the results were disappointing for SYN-010, we remain committed to the development of new life changing medications for GI diseases" said Steven A. Shallcross, Chief Executive Officer of Synthetic Biologics. "Looking forward, we remain focused on working with our clinical development partners to advance the planned Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant (HCT) patients, and to advance the clinical development program for SYN-020 intestinal alkaline phosphatase (IAP) in multiple potential indications."

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.

**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 condition 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 they 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 Synthetic Biologics, Inc.**
Synthetic Biologics, Inc. (NYSE American: SYN) is a clinical-stage company leveraging the microbiome to develop therapeutics designed to prevent and treat gastrointestinal (GI) diseases in areas of high unmet need. The Company's lead clinical candidates are: (1) SYN-004 (ribaxamase) which is designed to degrade certain commonly used intravenous (IV) beta-lactam antibiotics within the gastrointestinal (GI) tract to prevent microbiome damage, *C. difficile* infection (CDI), overgrowth of pathogenic organisms, the emergence of antimicrobial resistance (AMR) and acute graft-versus-host-disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) recipients, 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 is also advancing SYN-020, an oral formulation of the enzyme intestinal alkaline phosphatase (IAP) to treat both local GI and systemic diseases. 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 include statements regarding working with clinical development partners to advance the planned Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant (HCT) patients, and to advance the clinical development program for SYN-020 intestinal alkaline phosphatase (IAP) in multiple potential indications. 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, a failure of additional pre-clinical studies of SYN-020 to achieve similar results to those previously achieved or to provide support for exercise of the option, a failure to receive the necessary regulatory approvals for commercialization of Synthetic Biologics' therapeutics, a failure of Synthetic Biologics' clinical trials, and those conducted by investigators, for SYN-004, SYN-010 and SYN-020 to be commenced or completed on time or to achieve desired results and benefits, especially in light of COVID-19, 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 and other factors described in Synthetic Biologics' Annual Report on Form 10-K for the year ended December 31, 2019 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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