

Edgar Filing: Synthetic Biologics, Inc. - Form 8-K

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 |
|--------------------|--|
| <u>99.1</u> | <u>Press release issued by Synthetic Biologics, Inc. dated January 3, 2019</u> |

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 |
|---------------------------|--|
| <u>99.1</u> | <u>Press release issued by Synthetic Biologics, Inc. dated January 3, 2019</u> |