Synthetic Biologics, Inc.
Form 8-K
June 16, 2015

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): June 16, 2015

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.) |

**155 Gibbs Street, Ste. 412**

**Rockville, MD 20850**

(Address of principal executive offices and zip code)

**617 Detroit Street, Ste. 100**

**Ann Arbor, MI 48104**

(Mailing Address and zip code)

Registrant's telephone number, including area code: (734) 332-7800

(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 7.01. Regulation FD Disclosure**

Synthetic Biologics, Inc. (the "Company") will be making investor presentations this week. In connection with the presentations, the Company intends to discuss the slide presentation furnished as Exhibit 99.1 hereto, which is incorporated herein by reference.

The slide presentation attached as Exhibit 99.1 to this Report includes "safe harbor" language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained in the slide presentation or in the press release are "forward-looking" rather than historical.

The information included in this Item 7.01 and in Exhibit 99.1 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing. The Company undertakes no duty or obligation to update or revise information included in this Report or any of the Exhibits.

**Item 8.01. Other Events**

The Company's Investigational New Drug (IND) application which was submitted to the U.S. Food and Drug Administration (FDA) in May 2015 is now able to proceed into clinical trials for the development of SYN-010 with the initiation of a Phase 2 clinical trial during the second quarter of 2015, with topline results anticipated to follow during the second half of this year. SYN-010 is the Company's proprietary modified-release formulation of the classic statin, Lovastatin, that is optimal for reducing methane-production by certain microorganisms (*M. smithii*) in the gut while minimizing disruption to the microbiome. Methane produced by *M. smithii* is perceived as the underlying cause of bloating, pain and constipation associated with IBS-C, and may contribute to the pathology of other diseases. SYN-010 is intended to act primarily in the intestinal lumen while avoiding systemic absorption, thereby targeting the cause of IBS-C, not just the symptoms.

On June 12, 2015, the Company announced that the first participant was dosed in a second Phase 2a clinical trial of SYN-004. This trial will evaluate the gastrointestinal (GI) antibiotic-degrading effects and the safety of SYN-004, in the presence of the proton pump inhibitor (PPI), esomeprazole. As of June 15, 2015, two additional clinical sites have opened enrollment in the first Phase 2a clinical trial to evaluate the GI antibiotic-degrading effects and the safety of

SYN-004. SYN-004 is the Company's candidate therapy designed to degrade certain intravenous (IV) beta-lactam antibiotics within the GI tract and maintain the natural balance of the gut microbiome for the prevention of *C. difficile* infection, antibiotic-associated diarrhea (AAD) and secondary antibiotic-resistant infections. In addition, on June 16, 2015, the Company updated the timing it expects to report preliminary data from the first SYN-004 Phase 2a clinical trial to the third quarter of 2015; the timing to initiate the SYN-004 Phase 2b clinical trial remains on track for the third quarter of 2015.

Strategic partnering efforts supported by demonstrated therapeutic potential and safety profile of oral estriol are ongoing for the Company’s relapsing-remitting multiple sclerosis program. The Company has been informed by UCLA that MRI analyses are ongoing to evaluate changes in the brain that correlate with improvements seen in clinical outcomes, and the Company now expects to report topline data 30 days following its receipt from UCLA.

**Item 9.01. Financial Statements and Exhibits**

(d) Exhibits

The following exhibit is being filed as part of this Report.

| **Exhibit Number** | **Description** |
|---|---|
| 99.1 | Presentation materials to be provided at Synthetic Biologics, Inc.’s presentations |

**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.

| | | |
|---|---|---|
| | SYNTHETIC BIOLOGICS, INC. | |
| Date: June 16, 2015 | By: | /s/ Jeffrey Riley |
| | Name: | Jeffrey Riley |
| | Title: | Chief Executive Officer |

**EXHIBIT INDEX**

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