Synthetic Biologics, Inc.
Form DEFA14A
April 13, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

SCHEDULE 14A

(RULE 14a-101)

INFORMATION REQUIRED IN PROXY STATEMENT

SCHEDULE 14A INFORMATION

Proxy Statement Pursuant to Section 14(a) of the

Securities Exchange Act of 1934

Filed by the Registrant x
Filed by a Party other than the Registrant ¨

Check the appropriate box:

¨ Preliminary Proxy Statement
¨ **Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**
¨ Definitive Proxy Statement
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¨ Soliciting Material under §240.14a-12

SYNTHETIC BIOLOGICS, INC.

(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

x No fee required.

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April 13, 2015

Dear Fellow Shareholders,

Just over two years ago, we began implementing a strategic plan to transform Synthetic Biologics into a company at the forefront of developing pathogen-specific, microbiome-focused product candidates. Our focus is driven by the clinically proven realization that protecting a normal balance in the microbiome is important to maintaining good health, and that traditional approaches to antibiotic development and usage are failing to provide a continuum of care, or in some cases are inflicting unintended damage to the microbiome.

Synthetic Biologics is working to develop radically differentiated products to address large markets with clear unmet needs. Simply put, we are not developing "me too" products. With strong preclinical data, initial clinical data, support from key opinion leaders and a long-term oriented shareholder base, our aggressive and strategic efforts are directed at moving these novel programs forward:

- SYN-004 is designed to be what we believe is the first point-of-care preventive therapy to protect the natural balance of the gut microbiome from the unintended, harmful effects of intravenous (IV) antibiotics and prevent the onset of ***C. difficile*** **infection**, antibiotic-associated diarrhea and secondary antibiotic-resistant infections.

- SYN-010 is intended to reduce the impact of methane-producing organisms and restore normal bowel function. As such, it is designed to treat the cause of pain, bloating and constipation associated with **irritable bowel syndrome with constipation** (IBS-C), not just address the symptoms.

- SYN-005 is a monoclonal antibody (mAb) combination designed to target and neutralize pertussis toxin (not the bacteria), for the treatment of **Pertussis**, more commonly known as whooping cough, in order to reduce morbidity and mortality in infected infants.

- Trimesta™ is an oral estriol drug for the treatment of **relapsing-remitting multiple sclerosis** (MS) and cognitive dysfunction in MS, that in a Phase 2 clinical trial has demonstrated the potential to have a novel dual mechanism of action for both the anti-inflammatory effects that improve relapse rate, and a neuroprotective effect that improves standard measures of disability and cognition.

Over the past year, we made important advances in furthering Synthetic Biologics' goal of building a late-stage portfolio to address serious infections and diseases. In addition to establishing clinical advisory boards, strengthening our intellectual property portfolios, and implementing formulation and manufacturing efforts, we achieved the following key milestones:

Prevention of *C. difficile* infection – SYN-004:

- ü Reported positive topline safety and tolerability data from Phase 1a and 1b clinical trials
- ü Reported positive pharmacokinetics data from both Phase 1 clinical trials, with supportive evidence that SYN-004 should have no effect on the IV antibiotic in the bloodstream, allowing the antibiotic to fight the primary infection
- ü Initiated a Phase 2a clinical trial to evaluate gastrointestinal (GI) antibiotic-degrading effects and safety

IBS-C – SYN-010:

- ü Announced the modified-release, statin-class formulation of SYN-010, along with the anticipated 505(b)(2) regulatory pathway for development

Pertussis (whooping cough) – SYN-005:

- ü Reported positive preclinical research findings from non-human primate studies
- ü Granted U.S. Orphan Drug designation by the FDA

Relapsing-remitting MS – Trimesta:

- ü Efficacy and safety results from the investigator-initiated Phase 2 trial evaluating adjunctive Trimesta in women with relapsing-remitting MS, including the presentation by the lead investigator of positive results on cognitive and disability scores at 12 months, further supporting Trimesta's unique neuroprotective, as well as anti-inflammatory properties

Looking Ahead

Synthetic Biologics is positioned to achieve a number of important milestones during 2015, each one key to advancing us toward FDA registration trials for SYN-004 and SYN-010, non-dilutive funding for SYN-005 and partnering arrangements for Trimesta.

With regard to our SYN-004 *C. difficile* program, topline data is anticipated to be reported from the recently initiated Phase 2a clinical trial during 2Q 2015. Initiation of a Phase 2b proof-of-concept clinical trial is planned during 2H 2015, with topline data expected in 2H 2015.

For our SYN-010 IBS-C program, submission of an Investigational New Drug (IND) application to initiate clinical trials is expected in 1H 2015. Initiation of Phase 2 clinical trials is planned for 2Q 2015, with topline data expected in 2H 2015.

We continue discussions to secure non-dilutive funding to support preclinical and clinical development efforts for our SYN-005 Pertussis program.

And, in our Trimesta MS program, MRI brain scan analyses are underway by the lead investigator to evaluate changes in the brain that correlate with improvements seen in clinical outcomes, with topline data expected from the lead investigator during 1H 2015. Active discussions with a number of groups are ongoing, and a strategic partnership to further the clinical development of Trimesta is anticipated during 2Q 2015.

I would like to again thank our employees for their dedicated work, our clinical advisors for their valuable expertise in our areas of pursuit, our loyal shareholders for their support of our programs and goals, and our collaborators for their scientific prowess and keen clinical insights.

We look forward to reporting our progress to you during what promises to be a very eventful year for Synthetic Biologics.

Sincerely,

Jeffrey Riley

Chief Executive Officer

This letter includes forward-looking statements on Synthetic Biologics' current expectations and projections about future events. In some cases forward-looking statements can be identified by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," and similar expressions. These statements are based upon current beliefs, expectations and assumptions and are subject to a number of risks and uncertainties, many of which are difficult to predict and include statements regarding Synthetic Biologics' ability to successfully execute its goals, the timing of filings and clinical trials and the potential for Synthetic Biologics' product candidates. The forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those set forth or implied by any forward-looking statements. Important factors that could cause actual results to differ materially from those reflected in Synthetic Biologics' forward-looking statements include, among others, inability of Synthetic Biologics' product candidates to be demonstrably safe and effective or successfully commercialized, inability to initiate clinical trials when planned or achieve the desired results, inability to obtain regulatory approval for products or to comply with ongoing regulatory requirements and other factors described in Synthetic Biologics' report on Form 10-K for the year ended December 31, 2014, and any other filings with the SEC. The information in this letter is provided only as of the date written, and Synthetic Biologics undertakes no obligation to update any forward-looking statements contained in this letter on account of new information, future events, or otherwise, except as required by law.