Synthetic Biologics, Inc.
Form DEFA14A
May 12, 2014

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
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SYNTHETIC BIOLOGICS, INC.

(Name of Registrant as Specified In Its Charter)

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

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May 12, 2014

Dear Fellow Shareholders,

As we approach mid-2014, Synthetic Biologics (NYSE MKT: SYN) is having an extraordinary year a period of unprecedented achievement in the advancement of the Company's preclinical and clinical programs with the potential to address some of the most urgent public health issues and significant unmet medical needs facing us today. As aggressive and strategic R&D efforts continue, in partnership with our exceptional corporate and medical center collaborators, and our thought-leading clinical advisors, we are uniquely positioned to successfully execute on our ambitious, yet reasonable goal of moving three novel development programs into the clinic over the next 12 months.

A key to Synthetic Biologics success is our pipeline of novel anti-infective biologics and drugs, beginning with SYN-004, a second-generation oral enzyme designed to protect the normal gastrointestinal (GI) microflora, or microbiome, from the unintended effects of intravenous (IV) antibiotics. SYN-004 is intended to prevent *C. difficile* (*C. diff*) infection, the most prevalent hospital-acquired infection in the United States. *C. diff* results from common use of IV antibiotics, and has been identified by the U.S. Centers for Disease Control and Prevention (CDC) as an urgent public health threat, costing the U.S. healthcare system in excess of $8 billion annually. With the potential to become the first approved preventive therapy in this extremely large and readily addressable market, SYN-004 works by neutralizing antibiotics in the gut, and is intended to protect and maintain the balance of bacterial flora in the GI tract, thereby preventing *C. diff* infection. In October 2013, we initiated pre-Investigational New Drug (IND) work to support our planned preclinical and clinical studies, and we continue to expect Phase Ia and Ib trials to begin in the second half of this year.

We are also committed to advancing the constipation-predominant irritable bowel syndrome (C-IBS) program added to Synthetic Biologics pipeline in December 2013. To help catalyze the development process, Mark Pimentel, M.D., an Associate Professor of Medicine at Cedars-Sinai Medical Center, was appointed Chairman of our C-IBS Clinical Advisory Board. Dr. Pimentel led the investigational team whose discoveries established the foundation of our C-IBS program, and are the basis for developing an oral treatment to reduce the impact of methane-producing organisms on conditions such as C-IBS. We are advancing toward preclinical studies, and expect to initiate a Phase II clinical trial during the second half of 2014 under a corporate IND.

Among other recent highlights from our anti-infective programs, we announced positive news in April 2014 from our first monoclonal antibody (mAb) candidate, SYN-005, our proprietary mAb combination therapy to treat Pertussis (whooping cough). SYN-005 is designed to target and neutralize the pertussis toxin in order to reduce morbidity and mortality in infected infants. Antibiotic use does not have a major effect on the course of Pertussis because, while it can eliminate the *B. pertussis* bacteria from the respiratory tract, it unfortunately does not neutralize the pertussis toxin. Worldwide, there are approximately 50 million cases of Pertussis each year, leading to 300,000 deaths, primarily in infants. Under our Exclusive Channel Collaboration with Intrexon Corporation (NYSE: XON), and our academic collaboration with The University of Texas at Austin, we announced positive preclinical data in two non-human primate studies. Based on these findings, and the findings of other key animal studies, we intend to request an Orphan Drug designation for SYN-005 for the treatment of Pertussis, and to file an IND to support the initiation of a Phase I clinical trial during the first half of 2015.

Our most recent pipeline advancement was achieved with Trimesta™, our oral estriol candidate for relapsing-remitting multiple sclerosis (RRMS), the most common form of multiple sclerosis (MS) in women. Positive Phase II topline efficacy and safety results were presented in April 2014 by lead principal investigator, Dr. Rhonda Voskuhl of the UCLA David Geffen School of Medicine at the 66th American Academy of Neurology Annual Meeting. This Phase II, investigator-initiated clinical trial evaluated oral Trimesta as an adjunctive treatment with

injectable Copaxone®, and demonstrated a statistically significant 47 percent decrease in annualized MS relapse rate in the first 12 months of treatment compared to women

receiving placebo plus Copaxone, and a 32 percent decrease in annualized relapse rate compared with placebo plus Copaxone at 24 months. During a conference call, Dr. Voskuhl stated that it is remarkable to see an effect of a drug (Trimesta) within only one year, and particularly to show it in combination with another drug that is already known to be an effective drug. In addition to validating that adjunctive Trimesta was generally safe and well tolerated by women in the study, encouraging efficacy signals were also observed with clinically significant increases in cognitive scores among the women receiving Trimesta plus Copaxone when compared to placebo plus Copaxone. The topline data presented by Dr. Voskuhl, a Professor of Neurology and Chair of the MS Program at the UCLA School of Medicine, provides significant hope and promise for the 260,000 women affected by RRMS in the United States. We look forward to engaging with the neurology community and potential partners, as we determine next steps for Trimesta.

We are committed and excited to continue moving forward with our current pipeline of promising anti-infective candidates targeting specific pathogens that cause serious infections and diseases. We look forward to reporting progress on the development of our novel biologics and drugs, including our oral biologic to protect the GI microflora from the effects of IV antibiotics for the prevention of *C. diff* infection, our oral treatment to reduce the impact of methane-producing organisms on conditions such as C-IBS, and our mAb combination therapy to treat Pertussis (whooping cough). In parallel, we will determine the most strategic pathway for our Trimesta candidate for the treatment of RRMS in women.

On behalf of our team, board of directors, clinical investigators and advisors, we thank our shareholders for their continued support.

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 statemen 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 drug 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, 2013, 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.

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