

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 ☐ o

Check the appropriate box:

- ☐ o Preliminary Proxy Statement
- ☐ o Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))
- ☐ o Definitive Proxy Statement
- ☒ x Definitive Additional Materials
- ☐ o 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.
- ☐ o Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.
  - (1) Title of each class of securities to which transaction applies:
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- ☐ o Fee paid previously with preliminary materials.
- ☐ o Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.
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(2) Form, Schedule or Registration Statement No.:

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September 24, 2013

Dear Fellow Shareholders,

Over the past year, we continued our efforts to develop novel therapeutics that address specific unmet medical needs. The programs within our pipeline have progressively matured, and with leadership from a seasoned management team, strategic collaborations and aggressive research efforts, we have positioned our Company to reach several key milestones in 2014, including the potential to have three programs in the clinic. Our progress this year further validates that we are on track to meet our goals and emerge as a player in the area of targeted biologics for the prevention and treatment of infectious diseases.

The investigator-initiated Phase II clinical trial evaluating *Trimesta*<sup>TM</sup>, our legacy oral estriol candidate for multiple sclerosis (MS), is scheduled to be completed in January 2014, with topline results available shortly thereafter. The principal investigator for the trial is Rhonda Voskuhl, MD, Professor, Department of Neurology, Jack H. Skirball Chair in Multiple Sclerosis Research and Director, Multiple Sclerosis Program at the UCLA School of Medicine. Throughout her career, Dr. Voskuhl has conducted research related to the anticipated therapeutic benefit of oral estriol for MS patients, based on the reduction of relapse rates observed in women during the third trimester of pregnancy, the period of time during which estriol is naturally produced by the placenta.

*Trimesta*'s continued appeal was highlighted during a successful investor day this past June in New York, which attracted a number of investors and key media personnel. Dr. Voskuhl delivered a keynote presentation focusing on MS awareness and the potential of oral estriol's effect on the disease, as well as the current unmet need in the market. We anticipate this study should generate positive results, and we believe *Trimesta* will eventually reach impactful commercial success as a collaborative treatment to address the debilitating effects of MS.

Going forward into next year, the primary focus of our portfolio will be directed toward our anti-infective biologic candidates. Our lead infectious disease candidate, SYN-004, is a novel point-of-care oral enzyme prevention for *C. difficile* (*C. diff*). *C. diff* bacterium is the leading cause of hospital-acquired infections, and in the U.S. alone infects 1.1 million patients, with 30,000 associated deaths each year. Patients treated with IV antibiotics are highly susceptible to acquiring *C. diff*. If they contract *C. diff*, these patients can spend an additional 4-7 days in the hospital, costing the U.S. healthcare system in excess of \$8 billion annually.

SYN-004 is designed to be co-administered with certain IV beta-lactam antibiotics and to neutralize the antibiotics in the gastrointestinal tract, therefore protecting the balance of the microbiome. Roughly 14.4 million patients are administered "SYN-004 target" IV beta-lactam antibiotics annually, representing an estimated target market for SYN-004 of 117.6 million beta-lactam doses purchased by U.S. hospitals. While the final dosing regimen for SYN-004 is yet to be determined, the addressable market is extremely significant. Currently there are no approved treatments designed to protect the microbiome from the damaging effects of IV antibiotics. This worldwide opportunity could represent a potential multi-billion dollar market.

Our other two infectious disease programs are being developed through an ongoing collaboration with Intrexon Corporation (NYSE: XON), a synthetic biology company led by healthcare visionary R.J. Kirk. The first monoclonal antibody (mAb) is intended to neutralize the *Pertussis* toxin. The incidence of *Pertussis*, or whooping cough, increased to 41,000 cases in the U.S. during 2012, and there are approximately 50 million cases worldwide, including 300,000 deaths. To address this growing unmet medical need, we have identified two synergistic mAb candidates designed to target the *Pertussis* toxin. Our mAb candidates are expected to enter an IND-enabling large animal study before year-end and, if successful, into a clinical trial thereafter.

Our discovery stage mAb therapy for the treatment of *Acinetobacter baumannii* infections is also being developed in collaboration with Intrexon. This is an incredibly difficult to treat pathogen due to its rapid and well-established resistance to most antibiotics, producing mortality rates up to 43%. More recently, deadly

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forms of the bacteria have shown up on the military battlefield and in trauma centers. As the urgency to develop a treatment remains very high, we are continuing the development process to seek an effective mAb to combat these deadly bacteria.

We are thrilled to collaborate with Intrexon, and believe that the recent success of their IPO reflects not only their innovative approach and prominence as a thought leader in the field of synthetic biologics, but also the potential of synthetic biology as a whole.

Looking to the future, we believe we are well-positioned for long-term growth as we actively pursue additional candidates to complement our growing pipeline of anti-infective biologics. We remain committed to advancing our current pipeline and we believe this strategy is an effective way to continue to add value to our business.

On behalf of our team, board directors, clinical investigators, patients and their families, thank you for your 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 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 our ability to reach our milestones, the expected results of the Trimesta clinical trial and the market for our 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, a failure of Synthetic Biologics' product candidates to be demonstrably safe and effective or successfully commercialized, the development of competitive products, a failure to initiate animal trials or clinical trials and if initiated a failure to initiate them when planned or achieve the desired results, a failure to obtain regulatory approval for the Company's 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, 2012, 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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