

Synthetic Biologics, Inc.
Form DEFA14A
July 18, 2017

**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 (Amendment No.)**

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):

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(1) Title of each class of securities to which transaction applies:

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(3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):

(4) Proposed maximum aggregate value of transaction:

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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.

(1) Amount Previously Paid:

(2) Form, Schedule or Registration Statement No.:

(3) Filing Party:

(4) Date Filed:

July 18, 2017

Dear Fellow Shareholders,

2016 was a transformative and momentum building time for Synthetic Biologics. We began our journey together four years ago with an ambitious goal; to develop innovative, novel and simple approaches to complex and unmet medical needs while continuing to build long-term value for our shareholders. In this short time, our company has evolved as a leader in translatable microbiome-focused research and clinical development with two Phase 3-ready programs which may significantly improve health outcomes for millions of underserved patients. The achievement of critical milestones coupled with our operational efficiency continues to catalyze our momentum and we believe we remain well positioned as we continue our work to strengthen our infrastructure as we advance toward Phase 3 trials and look toward commercialization. In martial arts, this state of mind is called *zanshin* wherein a laser-like focus on today is coupled with preparing for the future.

In the past year, we announced several important clinical milestones, including achieving the primary endpoint of significantly reducing the incidence of new *Clostridium difficile* infection (CDI) and demonstrating a significant reduction of new colonization by vancomycin-resistant enterococci (VRE), compared to placebo, in our Phase 2b proof-of-concept clinical trial for SYN-004 (ribaxamase), our first-in-class oral enzyme designed to protect the gut microbiome from disruption caused by certain intravenous (IV) beta-lactam antibiotics. Further analysis of this study funded by a contract from the CDC is ongoing to determine whether ribaxamase may prevent the emergence of antimicrobial resistance (AMR) in the gut microbiome. Most recently, the FDA granted the first ever Breakthrough Therapy Designation to ribaxamase for the prevention of primary CDI, which is expected to expedite development and review timelines as we prepare to advance ribaxamase towards licensure and commercialization. Following collaborative discussions with the FDA, we announced the approval of a Phase 2b/3 adaptive design pivotal trial for SYN-010, our modified-release formulation of lovastatin lactone intended to reduce methane production by certain microorganisms in the gut to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C).

I would like to thank our loyal shareholders for their unwavering support of our innovative programs and goals, our dedicated employees for their purposeful commitment, and our clinical and scientific advisors for their valuable expertise and keen insights in our areas of pursuit. We remain focused on our mission to build a

strong portfolio of novel products with multi-billion-dollar market potential, designed to preserve the microbiome to protect and restore the health of patients. As the year progresses, we look forward to reporting on our progress during what we expect promises to be a very exciting and eventful year.

Sincerely,

Jeffrey Riley
President and Chief Executive Officer

This letter includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, 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, estimates, indicates, and similar expressions. These statements are based on management's 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 belief that we remain well positioned as we continue our work to strengthen our infrastructure, as we aim to complete our Phase 3 trials and look toward commercialization, the expected benefits of Breakthrough Therapy Designation, the size of the market, benefits to be derived from use of ribaxamase and SYN-004, and our execution of our growth strategy. 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, our product candidates demonstrating safety and effectiveness, as well as results that are consistent with prior results, our ability to initiate clinical trials and if initiated, our ability to complete them on time and achieve the desired results and benefits, our clinical trials continuing enrollment as expected, our ability to obtain regulatory approval for our commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to our ability to promote or commercialize our product candidates for the specific indications, acceptance of our product candidates in the marketplace and the successful development, marketing or sale of our products, developments by competitors that render our products obsolete or non-competitive, our ability to maintain our license agreements, the continued maintenance and growth of our patent estate, our ability to become or remain profitable, our ability to establish and maintain collaborations, our ability to obtain or maintain the capital or grants necessary to

fund our research and development activities, a loss of any of our key scientists or management personnel, and other factors described in Synthetic Biologics' annual report on Form 10-K for the year ended December 31, 2016, subsequent quarterly reports on Forms 10-Q and any other filings we make with the SEC. The information in this presentation is provided only as of the date presented, and Synthetic Biologics undertakes no obligation to update any forward-looking statements contained in this presentation on account of new information, future events, or otherwise, except as required by law.
