

Synthetic Biologics, Inc.
Form DEFA14A
July 06, 2016

**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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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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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):

No fee required.
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(1) Amount Previously Paid:

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(4) Date Filed:

July 6, 2016

Dear Fellow Shareholders,

The last year was a transformative one for our company. When we set out on our journey to develop pathogen-specific, microbiome-focused product candidates three years ago, our long-term goal was to develop and commercialize clinically relevant and differentiated products in order to address large markets with clear unmet medical needs. Our focus remains to build a strong portfolio of microbiome-focused products while continuing to create value for our shareholders and we feel a great sense of purpose and pride in continuing to develop our two lead, potential multi-billion dollar, microbiome-focused programs. The achievement of important milestones demonstrates our sustained clinical progress, our ability to operate efficiently and that we are well positioned to initiate Phase 3 clinical trials for our lead microbiome-focused drug candidates.

In the past year, we announced results from two Phase 2 clinical trials for SYN-010, our modified-release formulation of lovastatin lactone intended to reduce methane production by certain microorganisms in the gut while minimizing disruption to the microbiome to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C). Data from both trials demonstrate clinically meaningful improvements at both primary and secondary endpoints, including a reduction of breath methane and increases in quality of life scores for abdominal pain and bloating in IBS-C patients. Positive clinical results from two Phase 2a trials for SYN-004, our oral prophylactic therapy designed to degrade certain IV beta-lactam antibiotics within the gastrointestinal (GI) tract to preserve the natural balance of the gut microbiome for the prevention of *Clostridium difficile* infection (CDI), antibiotic-associated diarrhea (AAD) and emergence of antibiotic-resistant organisms, demonstrate a correlation of SYN-004 with the degradation of ceftriaxone in study participants.

Looking ahead, we remain on schedule to hold an end of Phase 2 meeting with the FDA this summer to discuss clinical trial development for the initiation of a Phase 3 clinical trial for SYN-010. Our Phase 2b proof-of-concept clinical trial to evaluate the ability of SYN-004 to prevent CDI and AAD is ongoing and an interim analysis of blinded data performed by an independent data monitoring committee is expected later this year. In addition, our pipeline of discovery and preclinical and therapeutic programs for pertussis (whooping cough), phenylketonuria (PKU) and oral alkaline phosphatase (IAP) remains robust.

I would like to thank our dedicated employees for their purposeful commitment, our clinical advisors for their valuable expertise in our areas of pursuit, our loyal shareholders for their unwavering support of our innovative programs and goals, and our collaborators for their contribution to our efforts. With sustained clinical momentum and support from positive results from multiple clinical trials, Synthetic Biologics continues to pivot from an early-stage clinical company focused on drug development, to a late-stage clinical company focused on Phase 3 initiation and commercial entry. We look forward to reporting our progress to you during what promises to be a very exciting and eventful year for Synthetic Biologics.

Sincerely,

Jeffrey Riley
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 timeline for our SYN-004 and SYN-010 clinical trials and reporting of data, the size of the market, benefits to be derived from use of SYN-004 and SYN-010 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, 2015, subsequent quarterly reports on Forms 10-Q and any other filings we make with the SEC. The information in this letter is provided only as of the date presented, 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.
