Synthetic Biologics, Inc.
Form DEFA14A
September 11, 2012

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)

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(1) Amount Previously Paid:

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To Our Shareholders,

The past year has been one of determination, transition and most important, revitalized dedication to the development of synthetic biologics and innovative medicines for unmet medical needs. During this time we have concentrated our efforts on becoming a leader in the emerging field of synthetic biologics, strategically realigning our existing clinical trial pipeline, and strengthening and expanding our management team.

Focused on Synthetic Biologics

Determined to be at the forefront of the synthetic biology movement, we entered into two worldwide exclusive channel collaborations with Intrexon Corporation, a privately-held synthetic biology company. Pursuant to these collaborations, we will have access to Intrexon s comprehensive suite of proprietary technologies for the development of new therapies for serious diseases that currently have limited or no treatment options.

Under our most recent collaboration, we intend to develop fully human monoclonal antibodies (mAbs) for the treatment of infectious diseases a field of medicine that is in crisis due to the rapid decline of effective treatment options. Initially, we will target three large-market infectious disease indications that have become increasingly resistant to antibiotics and other drugs.

In the accompanying 2012 proxy statement, we are seeking shareholder approval to issue common stock in connection with the Intrexon infectious disease collaboration. With such approval, we look forward to utilizing Intrexon s competencies for the development of a series of fully human mAbs to combat the worldwide toll on human life caused by infectious diseases.

We are also pursuing the development of a synthetic DNA-based therapy to treat pulmonary arterial hypertension (PAH) in collaboration with Intrexon. We are evaluating several approaches to deliver therapeutically relevant levels of prostacyclin through the expression of prostacyclin synthase (PGIS) with the expectation of improved patient efficacy and safety outcomes compared to existing PAH treatments.

Advancing Clinical Trial Programs

While our primary focus targets the field of synthetic biologics, we continue to advance our existing clinical programs for the development of treatments for multiple sclerosis (MS) and amyotrophic lateral sclerosis (ALS).

Our investigational oral estriol drug, Trimesta™, a natural hormone, similar to estrogen that is produced during pregnancy and has been scientifically documented to reduce symptoms of certain autoimmune diseases, including MS. Trimesta™ is currently being evaluated in two separate Phase II MS clinical trials. One trial is studying the ability of Trimesta™ to reduce MS relapse rates in women. This trial completed enrollment of 164 patients earlier this year, and patients will each be dosed and monitored for two years. The second trial initiated enrollment of female patients to investigate the effect of Trimesta™ on cognitive dysfunction related to MS. If successful, Trimesta™ can potentially offer patients an oral, disease-modifying treatment to reduce the debilitating effects of MS.

Utilizing our position as a leader in the field of zinc biology, we have transitioned our efforts to target the devastating progressive neurodegenerative disease amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig s disease. Based on a study conducted by the PNA Center for Neurological Research which demonstrated dramatic results in ALS

using oral high dose zinc, we expect to initiate a Phase II clinical trial during 2013. This trial is designed to evaluate our proprietary, gastroretentive, sustained-release, oral zinc-based drug candidate, AEN-100, in the treatment of ALS. It has often been theorized that there is too little available zinc in the brain of people suffering from ALS, and in the absence of available zinc, neurons burn out through a process called excitotoxicity, and are unable to perform necessary repair functions.

Strengthening and Expanding the Management Team

We believe that the opportunity to develop new therapeutics holds so much promise that, in addition to our collaborations with Intrexon and support from its CEO, R.J. Kirk, we have added key members to our team. Over the past eight months we have expanded and strengthened the management team to include: Evan Ballantyne, Chief Financial Officer, formerly the CFO of Clinical Data; Carol Reed, M.D., Sr. Vice President of Clinical & Regulatory Affairs, formerly the CMO of Clinical Data; John Monahan, Ph.D., Sr. Vice President of Research & Development, who was the formerly the founder and CEO of gene therapy company Avigen; and Mike Kaleko, M.D., Ph.D., Scientific Director, who was formerly the co-head of gene therapy at Novartis.

The Future

Although our initial efforts in the field of synthetic biology are focused on the development of fully human mAbs for infectious diseases and a synthetic DNA-based therapy for PAH, we intend to evaluate additional opportunities to enhance our pipeline in the near-term. At the same time, we intend to move our MS and ALS clinical programs forward. We are aware that there is much to be done, and our team is dedicated to reaching our goals of developing synthetic biologics and innovative medicines for unmet medical needs and creating additional value in our Company.

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 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 our plans for our enhanced pipeline and clinical trials. 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, our ability to obtain additional synthetic biologic programs, a failure to initiate clinical trials and if initiated a failure to 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/A for the year ended December 31, 2011, 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.