

Synthetic Biologics, Inc.
Form 8-K
December 10, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): **December 5, 2013**

Synthetic Biologics, Inc.

(Exact name of registrant as specified in charter)

Nevada

(State or other jurisdiction of incorporation)

01-12584

13-3808303

(Commission File Number) (IRS Employer Identification No.)

155 Gibbs Street, Ste. 412

Rockville, MD 20850

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(Address of principal executive offices and zip code)

(734) 332-7800

(Registrant's telephone number including area code)

N/A

(Former Name and Former Address)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12(b) under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01 Entry into a Material Definitive Agreement.

On December 5, 2013, Synthetic Biologics, Inc. (the “Company”), through its newly formed, majority owned subsidiary, Synthetic Biomics, Inc. (“SYN Biomics”), entered into a worldwide exclusive license agreement (the “License Agreement”) and option agreement (the “Option Agreement”) with Cedars-Sinai Medical Center (“CSMC”) for the right to develop, manufacture, use, and sell products for the human and veterinary therapeutic and prophylactic treatments for acute and chronic diseases discovered by an investigational team led by Mark Pimentel, M.D. at CSMC to be associated with pathogenic gastrointestinal microorganisms, including for example, irritable bowel syndrome (IBS), obesity and type 2 diabetes. The portfolio of intellectual property licensed to SYN Biomics under the License Agreement includes nine issued U.S. patents, one issued European patent validated in 18 countries, one issued European patent validated in three countries, two issued Australian patents, and one issued Japanese patent as well as 13 pending U.S. and international patent applications for most fields of use and modalities (subject to certain agreed-upon exceptions); two pending U.S. patent applications are optioned to SYN Biomics under the Option Agreement.

The License Agreement provides that the Company will issue to CSMC 291,569 unregistered shares of Company common stock, subject to approval by the NYSE MKT, LLC, or in the event such shares are not issued within 30 days, pay to CSMC in the form of cash, an initial license fee and patent reimbursement fee of \$150,000 and \$220,000, respectively. The parties also entered into a Stock Purchase Agreement with respect to such stock issuance and other issuances of unregistered shares of Company common stock that may be issued to CSMC in lieu of cash, including license fees, milestone payments, expense reimbursements and option fees under the License Agreement or Option Agreement. Any and all such stock issuances by the Company shall be subject to the prior approval of the NYSE MKT, LLC. The License Agreement also provides that commencing on the second anniversary of the License Agreement, SYN Biomics will pay an annual maintenance fee, which payment shall be creditable against annual royalty payments owed under the License Agreement. In addition to royalty payments which are a percentage of Net Sales (as defined in the License Agreement) of Licensed Products (as defined in the License Agreement) and Licensed Technology products (as defined in the License Agreement), SYN Biomics is obligated to pay CSMC a percentage of any non-royalty sublicense revenues, as well as additional consideration upon the achievement of the following milestones (the first two of which are payable in cash or unregistered shares of Company stock at the Company’s option): (i) successful Phase I trial completion of the first Licensed Product or first Licensed Technology Product; (ii) successful Phase II trial completion of the first Licensed Product or first Licensed Technology Product; (iii) initiation of Phase III dosing for each additional indication of a Licensed Product or Licensed Technology Product; (iv) successful Phase III trial completion for each Licensed Product and each Licensed Technology Product; (v) the U.S. Food and Drug Administration’s (“FDA”) acceptance of a New Drug Application for each Licensed Product and each Licensed Technology Product; (vi) regulatory approval for each Licensed Product and each Licensed Technology Product; and (vii) the first commercial sale of each Licensed Product and each Licensed Technology Product. The stock issuances are subject to prior approval of the NYSE MKT, LLC.

Prior to the execution of the License Agreement, SYN Biomics issued shares of common stock of SYN Biomics to each of CSMC and Mark Pimentel, M.D. (the primary inventor of the intellectual property), representing 11.5% and

8.5%, respectively, of the outstanding shares of SYN Biomics (the “SYN Biomics Shares”). The Stock Purchase Agreements for the SYN Biomics Shares provide for certain anti-dilution protection until such time as an aggregate of \$3,000,000 in proceeds from equity financings are received by SYN Biomics as well as a right, under certain circumstances in the event that the SYN Biomics Shares are not then freely tradeable, and subject to NYSE MKT, LLC approval, as of the 18 and 36 month anniversary date of the effective date of the Stock Purchase Agreements, for each of CSMC and the Mark Pimentel to exchange up to 50% of their SYN Biomics shares for unregistered shares of the Company’s common stock, with the rate of exchange based upon the relative contribution of the valuation of SYN Biomics to the public market valuation of the Company at the time of each exchange. The Stock Purchase Agreements also provide for tag- along rights in the event of the sale by the Company of its shares of SYN Biomics.

The License Agreement terminates: (i) automatically if SYN Biomics enters into a liquidating bankruptcy or other specified bankruptcy event or if the performance of any term, covenant, condition or provision of the License Agreement will jeopardize the licensure of CMSC, its participation in certain reimbursement programs, its full accreditation by the Joint Commission of Accreditation of Healthcare Organizations or any similar state organizations, its tax exempt status or is deemed illegal; (ii) upon 30 days notice from CMSC if SYN Biomics fails to make a payment or use commercially reasonable efforts to exploit the patent rights; (iii) upon 60 days notice from CMSC if SYN Biomics fails to cure any breach or default of any material obligations under the License Agreement; or (iv) upon 90 days notice from SYN Biomics if CMCS fails to cure any breach or default of any material obligations under the License Agreement. SYN Biomics also has the right to terminate the License Agreement without cause upon 6 months notice to CSMC; however, upon such termination, SYN Biomics is obligated to pay a termination fee with the amount of such fee reduced: (i) if such termination occurs after an Investigational New Drug submission to the FDA but prior to completion of a Phase II clinical trial, (ii) reduced further if such termination occurs after completion of Phase II clinical trial but prior to completion of a Phase II clinical trial; and (iii) reduced to zero if such termination occurs after completion of a Phase III clinical trial.

Pursuant to the terms of the Option Agreement, SYN Biomics has a period of six months to negotiate an exclusive license to develop, manufacture, use, and sell biologic products relating to the prevention, acute treatment and chronic treatment of irritable bowel syndrome or other indications utilized or derived from certain optioned patent applications, pending completion of certain limited testing of technology embodied in the patent applications. The Option Agreement provides that, within 30 days of the execution of the Option Agreement, the Company is obligated to pay to CSMC a non-refundable option fee of 43,342 shares of unregistered Company stock, or \$50,000 cash in the event such issuance is not approved by NYSE MKT, LLC. In addition, SYN Biomics has the right to extend the option period for an additional six months, for an additional non-refundable extension fee of \$25,000, payable in unregistered shares of the Company's common stock having a market value of 110% of such amount, subject to approval of NYSE MKT, LLC, or in cash. At any time during the 6 or 12 month option period (if so extended) SYN Biomics has the right to exercise the option and negotiate an exclusive license to the optioned patent applications, which shall provide for: (i) a \$50,000 license issue fee plus reimbursement of patent expenses incurred by CSMC prior to the exclusive license, payable to CSMC in unregistered shares of Company stock having a market value of 110% of such amount, subject to approval of the NYSE MKT, LLC, or in cash, (ii) the same milestone payments, royalties and sublicense fees as are payable under the License Agreement dated December 5, 2013 for separately licensed intellectual property, and (iii) such other customary terms and conditions CSMC typically includes in its license agreements.

In collaboration with Intrexon Corporation, and partially utilizing the intellectual property optioned and/or licensed from CSMC described in the Option Agreement, SYN Biomics and the Company intend to develop biologic approaches for the prevention, acute and chronic treatment of a subset of irritable bowel syndrome (IBS) pathologies specifically caused by auto-antibodies. During the option period, SYN Biomics, the Company and Intrexon will seek to create and test a variety of biologic candidates for the treatment of a subset of IBS cases. This biologic program has been selected as the third target under the Company's exclusive channel collaboration with Intrexon Corporation dated August 6, 2012.

The Company has appointed its founder and Licensing Associate, Steve H. Kanzer, CPA, JD, who was responsible for identifying and negotiating the CSMC transaction, to serve as CEO and President of the Company's new SYN Biomics subsidiary, with Mr. Kanzer agreeing to increase his commitment of time from 50% to 80% with an increase in salary from \$150,000 to \$195,000 per annum. The foregoing description of the agreements does not purport to be complete and is qualified in its entirety by reference to the full text of the License Agreement, Option Agreement and the related Stock Purchase Agreements which are filed as Exhibits 10.1, 10.2, 10.3, 10.4 and 10.5 to this Current Report on Form 8-K and incorporated herein by reference.

On December 9, 2013, the Company issued the press releases attached hereto as Exhibits 99.1 and 99.2 regarding the agreements described herein.

Important Notice regarding the Agreement

The agreements have been included as an exhibits to this Current Report on Form 8-K to provide investors and security holders with information regarding its terms. They are not intended to provide any other financial information about the Company. The representations, warranties and covenants contained in the agreements were made only for purposes of those agreements and as of specific dates; were solely for the benefit of the parties to the agreements; may be subject to limitations agreed upon by the parties, including being qualified by disclosures made for the purposes of allocating contractual risk between the parties to the agreements instead of establishing these matters as facts; and may be subject to standards of materiality applicable to the contracting parties that differ from those applicable to investors. Investors should not rely on the representations, warranties and covenants or any description thereof as characterizations of the actual state of facts or condition of the Company. Moreover, information concerning the subject matter of the representations, warranties and covenants may change after the date of the agreements, which subsequent information may or may not be fully reflected in public disclosures by the Company.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1	Exclusive License Agreement between Synthetic Biologics, Inc., Synthetic Biomics, Inc. and Cedars-Sinai Medical Center dated December 5, 2013**
10.2	Exclusive Option Agreement between Synthetic Biologics, Inc., Synthetic Biomics, Inc. and Cedars-Sinai Medical Center dated December 5, 2013**
10.3	Stock Purchase Agreement between Synthetic Biologics, Inc., Synthetic Biomics, Inc. and Cedars-Sinai Medical Center dated December 5, 2013
10.4	Stock Purchase Agreement between Synthetic Biologics, Inc., Synthetic Biomics, Inc. and Mark Pimentel dated December 5, 2013
10.5	Stock Purchase Agreement between Synthetic Biologics, Inc., Synthetic Biomics, Inc. and Cedars-Sinai Medical Center dated December 5, 2013
99.1	Press Release dated December 9, 2013
99.2	Press Release dated December 9, 2013

** Confidential treatment has been requested as to certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: December 10, 2013 SYNTHETIC BIOLOGICS,
INC.
(Registrant)

By: /s/ C. Evan Ballantyne

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Name: C. Evan Ballantyne

Title: Chief Financial

Officer