Synthetic Biologics, Inc.
Form 8-K
August 10, 2015

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): August 10, 2015

SYNTHETIC BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Nevada	001-12584	13-3808303
(State or other jurisdiction of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

9605 Medical Center Drive, Suite 270

Rockville, MD 20850

(Address of principal executive offices and zip code)

617 Detroit Street, Ste. 100

Ann Arbor, MI 48104

(Mailing Address and zip code)

Registrant's telephone number, including area code: (734) 332-7800

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the 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 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.

Exclusive Channel Collaboration Agreement

On August 10, 2015, Synthetic Biologics, Inc. (the "Company") expanded its relationship with Intrexon Corporation ("Intrexon") and entered into an Exclusive Channel Collaboration Agreement (the "Channel Agreement") with Intrexon that governs a "channel collaboration" arrangement in which the Company will use Intrexon's technology for development of biotherapeutic products (a "Collaboration Product") for the treatment of phenylketonuria (PKU) in humans by direct administration of a viral construct containing a gene to alter genetic expression of phenyalanine hydroxylase and/or administration of genetically modified bacteria that express an effector directed to the metabolic conversion of phenyalanine (the "Field"). The Channel Agreement establishes committees comprised of Company and Intrexon representatives that will initially govern activities related to the collaboration in the areas of project establishment and intellectual property and optionally, chemistry, clinical and regulatory matters and commercialization efforts.

The Channel Agreement grants the Company a worldwide exclusive license to use the patents and other intellectual property of Intrexon in connection with the research, development, use, importing, manufacture, sale, and offer for sale of Collaboration Products in the Field. Such license is exclusive to both parties within the Field, and otherwise is non-exclusive. The Company may not sublicense the rights described without Intrexon's written consent other than under limited circumstances to third party contractors performing contract manufacturing services or in the case of certain late stage clinical product candidates.

Under the Channel Agreement, and subject to certain exceptions, the Company is responsible for, among other things, the development, commercialization and manufacturing of products.

The Company has agreed to pay Intrexon a technology access fee by the issuance of 937,500 shares of its common stock having a value equal to $3 million as of August 7, 2015 within ten days of approval of the issuance by the NYSE MKT. In addition, upon the achievement of the milestones set forth below, the Company agreed to pay Intrexon milestone payments of up to $27 million for each product developed as follows: (i) $2 million upon first doing of a patient in a Phase 1 clinical trial upon commencement of an IND, payable in stock or cash at the Company's option; (ii) 30 days after achievement of the first commercial sale of a Collaboration Product in the United States or approval of a New Drug Application and/or Biologics License Application for a Collaboration Product by the U.S. Food and Drug Administration ; and (iii) 30 days after achievement of the first commercial sale of a Collaboration Product in a nation subject to the authority of the European Medicines Agency (EMA) or approval of a Marketing Authorization Application for a Collaboration Product by the EMA. The Company will pay Intrexon royalties on annual net sales of Collaboration Products, calculated on a product-by-product basis, equal to a percent of net sales (ranging from mid-single digits on the first $100 million of net sales to mid-teen digits on net sales in excess of $750

million). The Company has likewise agreed to pay Intrexon a percentage of quarterly revenue obtained from a sublicensor in the event of a sublicensing arrangement. In addition, in partial consideration for each party's execution and delivery of the Channel Agreement, the Company entered into the Stock Issuance Agreement (as defined below) and the Second Amendment to Registration Rights Agreement (as defined below). The Channel Agreement, Stock Issuance Agreement and Second Amendment to Registration Rights Agreements shall collectively be referred as the "Agreements".

If any shareholder, exchange, board member approvals of the issuance of the securities under the Stock Issuance Agreement is not received by 90 days after the effective date of the agreement, Intrexon has the right to terminate the Agreements. During the first 18 months, the Company may not terminate the Channel Agreement, except under limited circumstances. Following the first 18 months, the Company may voluntarily terminate the Channel Agreement upon 90 days written notice to Intrexon. Intrexon may also terminate the Channel Agreement if the Company elects not to pursue the development of a Superior Therapy as defined in the Channel Agreement identified by Intrexon that is a "Superior Therapy" as defined in the Channel Agreement upon 90 days notice unless the Company remedies the circumstances giving rise to the termination during such notice period. Each party has the right to terminate the agreement upon 60 days notice if the other party commits a material breach of the Channel Agreement, subject to certain cure periods.

Upon termination of the Channel Agreement, the Company may continue to develop and commercialize any Collaboration Product that, at the time of termination satisfies one of the following:

- is being commercialized by the Company;
- has received regulatory approval;
- is a subject of an application for regulatory approval that is pending before the applicable regulatory authority; and
- is a subject of at least a Phase 2 trial if such termination is by Intrexon due to a material breach by the Company of the Channel Agreement or by the Company upon 60 days notice after the first 18 months.

The Company's obligation to pay the royalties described above with respect to these "retained" products will survive termination of the Channel Agreement.

Stock Issuance Agreement and Registration Rights Agreement

On August 10, 2015, the Company entered into a Stock Issuance Agreement with Intrexon pursuant to which the Company has agreed to issue to Intrexon 937,500 shares of Company common stock, having a value equal to $3 million as of August 7, 2015 (the "Technology Access Shares"), which issuance will be deemed paid in partial consideration for the execution and delivery of the Channel Agreement.

The Company has also agreed upon the dosing of its first patient in a Phase 1 clinical trial for each product developed to pay Intrexon either (i) two million dollars ($2 million) in cash, or (ii) that number of shares of Company common stock (the "Clinical Milestone Shares") having a fair market value equaling two million dollars ($2 million) where such fair market value is determined using published market data of the share price for the Company's common stock at the close of market on the business day immediately preceding the date of public announcement of attainment of the milestone event as defined in the Channel Agreement.

In connection with the transactions contemplated by the Stock Issuance Agreement, and pursuant to the Second Amendment to Registration Rights Agreement executed and delivered by the parties at the closing, the Company agreed to file a "resale" registration statement (the "Registration Statement") registering the resale of the shares issued and to be issued under the Stock Issuance Agreement. None of the Technology Access Shares to be issued under the Stock Issuance Agreement need to be registered until 120 days after the date of the Second Amendment to Registration Rights Agreement and none of the Milestone Shares need to be registered until 120 days after the achievement or the milestone with respect to each product. Under that agreement, the Company will be obligated to use its reasonable best efforts to cause the "resale" registration statement to be declared effective as promptly as practicable after filing and to maintain the effectiveness of the registration statement until all securities therein are sold or are otherwise can be sold pursuant to Rule 144, without any restrictions.

The foregoing description of each of the Channel Agreement, the Stock Issuance Agreement and the Second Amendment to Registration Rights Agreement is qualified in its entirety by reference to such Agreements, which are filed as Exhibits 10.1, 10.2 and 10.3 to this Current Report, respectively, and are incorporated herein by reference. The benefits of the representations and warranties set forth in the Channel Agreement, the Stock Issuance Agreement and the Second Amendment to Registration Rights Agreement are intended to be relied upon by the parties to such Agreements only and, except as otherwise expressly provided therein, do not constitute continuing representations and warranties to any other party or for any other purpose. The press release dated August 10, 2015 announcing the transaction described above is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 3.02 Unregistered Sales of Equity Securities.

The disclosure in Item 1.01 is incorporated herein by reference thereto. The offer and issuance of the Technology Access Shares will not be registered under the Securities Act of 1933 at the time of issuance, and therefore may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements. For these issuances, the Company intends to rely on the exemption from federal registration under Section 4(a)(2) of the Securities Act, based on the Company's belief that the offer and sale of the Technology Access Shares has not and will not involve a public offering as Intrexon is an "accredited investor" as defined under Section 501 promulgated under the Securities Act and no general solicitation has been involved in the offering.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1	Exclusive Channel Collaboration Agreement by and between Synthetic Biologics, Inc. and Intrexon Corporation dated as of August 10, 2015 **
10.2	Stock Issuance Agreement by and between Synthetic Biologics, Inc. and Intrexon Corporation dated as of August 10, 2015
10.3	Second Amendment to Registration Rights Agreement by and between Synthetic Biologics, Inc. and Intrexon Corporation dated as of August 10, 2015
99.1	Press Release dated August 10, 2015

** 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: August 10, 2015

SYNTHETIC BIOLOGICS, INC.
(Registrant)

By: /s/ Jeffrey Riley
Name: Jeffrey Riley
Title: President and Chief Executive Officer

INDEX OF EXHIBITS

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