

Synthetic Biologics, Inc.
Form 8-K
August 09, 2012

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): **August 6, 2012**

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.)

617 Detroit Street, Suite 100

Ann Arbor, MI 48104

(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.

Exclusive Channel Collaboration Agreement

On August 6, 2012, 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 relating to the identification, design and production of human antibodies and DNA vectors for the development and commercialization of a series of monoclonal antibody therapies for the treatment of certain serious infectious diseases (collectively, the "Program"). The Channel Agreement establishes committees comprised of Company and Intrexon representatives that will govern activities related to the Program in the areas of project establishment, chemistry, manufacturing and controls, clinical and regulatory matters, commercialization efforts and intellectual property.

The Channel Agreement grants the Company a worldwide exclusive license to use specified patents and other intellectual property of Intrexon in connection with the research, development, use, importing, manufacture, sale, and offer for sale of monoclonal antibody therapies for the treatment of eight specific target infectious disease indications (the “Field”). Initially, the Company’s development efforts will target three infectious diseases within the Field. Within the first two years of the collaboration, the Company has the right to exchange its initial three targets on a one-for-one basis with any of the other five targeted infectious diseases in the Field at no additional cost. The Company also has the option, within such two year period, to choose to develop any or all of the other five target diseases in the Field, upon payment of the additional consideration described below. Such license is exclusive with respect to any clinical development, selling, offering for sale or other commercialization of the Company’s products within the Field (“Synthetic Products”), and otherwise is non-exclusive. The Company may not sublicense the rights described without Intrexon’s written consent.

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

Subject to certain expense allocations and other offsets provided in the Channel Agreement, the Company will pay Intrexon royalties on annual net sales of the Synthetic Products, calculated on a Synthetic Product-by-Synthetic Product basis. 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 First Amendment to Registration Rights Agreement (as defined below). The Channel Agreement, Stock Issuance Agreement and First Amendment to Registration Rights Agreements shall collectively be referred to as the “Agreements”.

If any shareholder, exchange, board or member approvals of the issuance of the securities under the Stock Issuance Agreement is not received by 120 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 Program identified by Intrexon that is a “Superior Therapy” as defined in the Channel Agreement upon 60 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 Synthetic 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,
is a subject of at least a Phase 2 or Phase 3 clinical 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 6, 2012, the Company entered into a Stock Issuance Agreement with Intrexon pursuant to which the Company has agreed to issue to Intrexon a number of shares of Company common stock equal to the difference between (i) 19.99% of the number of shares of Common Stock of Company outstanding as of the date of the closing prior to the issuance of such shares, and (ii) the number of shares of Common Stock of Company held by Intrexon immediately prior to the Closing (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 filing of an Investigational New Drug application with the U.S. Food and Drug Administration for a Synthetic Product, or alternatively the filing of the first equivalent regulatory filing with a foreign regulatory agency (both as applicable, the “IND Milestone Event”), to pay Intrexon either (i) two million dollars (\$2M) in cash, or (ii) that number of shares of Common Stock (the “IND Milestone Shares”) having a fair market value equaling two million dollars (\$2M) where such fair market value is determined using published market data of the share price for Common Stock at the close of market on the business day immediately preceding the date of public announcement of attainment of the IND Milestone Event.

The Company has also agreed upon the first to occur of either first commercial sale of a Synthetic Product in a country or the granting of the regulatory approval of that Synthetic Product (both as applicable, the “Approval Milestone Event”), to pay to Intrexon either (i) three million dollars (\$3M) in cash, or (ii) that number of shares of Common Stock (the “Approval Milestone Shares”) having a fair market value equaling three million dollars (\$3M) where such fair market value is determined using published market data of the share price for Common Stock at the close of market on the business day immediately preceding the date of public announcement of attainment of the Approval Milestone Event.

The Company has also agreed that it will pay an optional and varying fee whereby the Company remits a payment, in cash or equity at the Company’s sole discretion, to Intrexon calculated as a multiple of the number of targets in excess of three (3) total that the Company desires to elect (the “Field Expansion Fee”). The Field Expansion Fee must be paid completely in either Common Stock or cash, and will comprise either (i) two million dollars (\$2M) in cash for each target in excess of three (3) total that the Company will elect, or (ii) that number of shares of Common Stock (the “Field Expansion Fee Shares”) having a fair market value equaling two million dollars (\$2M) for each such target that Company will elect in excess of three where such fair market value is determined using published market data establishing the volume-weighted average price for a share of Common Stock over the thirty (30) day period immediately preceding the date of the Field Expansion Fee Closing.

In connection with the transactions contemplated by the Stock Issuance Agreement, and pursuant to the First 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 shares to be issued under the Stock Issuance Agreement need to be registered until April 30, 2013. 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 First 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 First 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 8, 2012 announcing the transactions 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, IND Milestone Shares, Approval Milestone Shares and Field Expansion Fee 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(2) of the Securities Act, based on the Company's belief that the offer and sale of the Technology Access Shares, IND Milestone Shares, Approval Milestone Shares and Field Expansion Fee 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 6, 2012 ** |
| 10.2 | Stock Issuance Agreement by and between Synthetic Biologics, Inc. and Intrexon Corporation dated as of August 6, 2012 |
| 10.3 | First Amendment to Registration Rights Agreement by and between Synthetic Biologics, Inc. and Intrexon Corporation dated as of August 6, 2012 |
| 99.1 | Press Release dated August 8, 2012 |

** 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 9, 2012 SYNTHETIC
BIOLOGICS, INC.
(Registrant)

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

INDEX OF EXHIBITS

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