

Synthetic Biologics, Inc.
Form SC 13D/A
October 19, 2012

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

SCHEDULE 13D
(Amendment No. 1)*
Under the Securities Exchange Act of 1934

SYNTHETIC BIOLOGICS, INC.
(Name of Issuer)

Common Stock, par value \$0.001 per share
(Title of Class of Securities)

87163U102
(CUSIP Number)

Third Security, LLC
1881 Grove Avenue
Radford, Virginia 24141
Attention: Marcus E. Smith, Esq.
(540) 633-7900
(Name, Address and Telephone Number of Person
Authorized to Receive Notices and Communications)

Copy to:
Intrexon Corporation
Attention: Legal
20358 Seneca Meadows Parkway
Germantown, Maryland 20876
(301) 556-9809

October 16, 2012
(Date of Event which Requires Filing of this Statement)

If the filing person has previously filed a statement on Schedule 13G to report the acquisition which is the subject of this Schedule 13D, and is filing this schedule because of Rule 13d-1(b)(3) or (4), check the following box o .

NOTE: Schedules filed in paper format shall include a signed original and five copies of the schedule, including all exhibits. See §240.13d-7 for other parties to whom copies are to be sent.

* The remainder of this cover page shall be filled out for a reporting person's initial filing on this form with respect to the subject class of securities, and for any subsequent amendment containing information which would alter

disclosures provided in a prior cover page.

The information required on the remainder of this cover page shall not be deemed to be “filed” for the purpose of Section 18 of the Securities Exchange Act of 1934 (“Act”) or otherwise subject to the liabilities of that section of the Act but shall be subject to all other provisions of the Act (however, see the Notes).



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- 1 NAMES OF REPORTING PERSONS
I.R.S. IDENTIFICATION NO. OF ABOVE PERSONS

Randal J. Kirk

- 2 CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP
(a)
(b)

- 3 SEC USE ONLY

- 4 SOURCE OF FUNDS

PF

- 5 CHECK IF DISCLOSURE OF LEGAL PROCEEDINGS IS REQUIRED
PURSUANT TO ITEM 2(d) OR 2(e)

- 6 CITIZENSHIP OR PLACE OF ORGANIZATION

United States

- 7 SOLE VOTING POWER

0

NUMBER OF
SHARES BENEFICIALLY
OWNED BY
EACH
REPORTING
PERSON WITH

- 8 SHARED VOTING POWER

6,675,768

- 9 SOLE DISPOSITIVE POWER

0

- 10 SHARED DISPOSITIVE POWER

6,675,768

- 11 AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING
PERSON

6,675,768

- 12 CHECK IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES
CERTAIN SHARES

- 13 PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11)
20.0%

- 14 TYPE OF REPORTING PERSON
IN

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- 1 NAMES OF REPORTING PERSONS
I.R.S. IDENTIFICATION NO. OF ABOVE PERSONS

Intrexon Corporation
I.R.S. IDENTIFICATION NO.: 26-0084895

- 2 CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP
(a)
(b)

- 3 SEC USE ONLY

- 4 SOURCE OF FUNDS

WC

- 5 CHECK IF DISCLOSURE OF LEGAL PROCEEDINGS IS REQUIRED
PURSUANT TO ITEM 2(d) OR 2(e)

0

- 6 CITIZENSHIP OR PLACE OF ORGANIZATION

Virginia

- 7 SOLE VOTING POWER

0

NUMBER OF
SHARES 8 SHARED VOTING POWER
BENEFICIALLY
OWNED BY 6,675,768
EACH

- 9 SOLE DISPOSITIVE POWER
PERSON WITH

0

- 10 SHARED DISPOSITIVE POWER

6,675,768

- 11 AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING
PERSON

6,675,768

- 12 CHECK IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES
CERTAIN SHARES

0

- 13 PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11)
20.0%

- 14 TYPE OF REPORTING PERSON
CO

This Amendment No. 1 (the "Amendment") amends and supplements the Statement on Schedule 13D, dated December 7, 2011 and filed on December 12, 2011 (the "Original Schedule 13D"), relating to the Common Stock, par value \$0.001 per share (the "Common Stock"), of Synthetic Biologics, Inc. a Michigan corporation (the "Company"). Mr. Randal J. Kirk ("Mr. Kirk") and Intrexon Corporation, a Virginia corporation ("Intrexon" and, together with Mr. Kirk, the "Reporting Persons"), are filing this Amendment to disclose the acquisition by Intrexon of 3,552,210 shares of Common Stock in connection with the closing on October 16, 2012 (the "Closing") under an Exclusive Channel Collaboration Agreement between the Company and Intrexon dated August 6, 2012 ("Channel Collaboration"). Mr. Kirk could be deemed to have indirect beneficial ownership of the shares of Common Stock directly beneficially owned by Intrexon.

Except as set forth below, there are no changes to the information set forth in the Original Schedule 13D.

Item 3. Source and Amount of Funds or Other Consideration.

Item 3 of the Original Schedule 13D is hereby amended and supplemented as follows:

On August 6, 2012 the Company entered into an Exclusive Channel Collaboration Agreement ("Channel Agreement") with Intrexon, pursuant to which the Company agreed to issue to Intrexon at the Closing an aggregate of 3,552,210 shares of common stock, at a purchase price of \$0.001 par value of such shares, as partial consideration for the execution and delivery of the Channel Agreement (the "Shares"). The Channel Agreement governs an 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 and Intrexon entered into the Stock Issuance Agreement and the First Amendment to Registration Rights Agreement. The Channel Agreement, Stock Issuance Agreement and First Amendment to Registration Rights Agreements shall collectively be referred as 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; or

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.

On August 6, 2012, the Company entered into a Stock Issuance Agreement with Intrexon pursuant to which the Company 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 was 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), 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 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 were filed as Exhibits 10.1, 10.2 and 10.3 to the Company's Current Report on Form 8-K dated August 6, 2012 and filed on August 9, 2012, 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 was filed as Exhibit 99.1 to the Company's Current Report on Form 8-K dated August 6, 2012 and filed on August 9, 2012 and is incorporated herein by reference.

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On October 16, 2012, the Company completed the Closing. Pursuant to the terms of the Stock Issuance Agreement between the Company and Intrexon dated August 6, 2012, the Company met all of the requisite closing conditions, including the receipt of NYSE MKT approval, and has issued the Shares to Intrexon, which issuance is deemed paid in partial consideration for the execution and delivery of the Channel Agreement. Stockholder approval of such issuance was obtained at the Company's Annual Meeting of Stockholders held on October 5, 2012.

Item 4. Purpose of Transaction.

Item 4 of the Original Schedule 13D is hereby amended and supplemented as follows:

The Reporting Persons acquired the Shares for investment purposes and as partial consideration for the execution and delivery of the Channel Agreement.

Item 5. Interest in Securities of the Issuer.

Items 5(a) and (b) of the Original Schedule 13D are hereby amended and restated to read in its entirety as follows:

(a) and (b) See Items 11 and 13 of the cover pages to this Statement for the aggregate number of shares and percentage of issued and outstanding shares of Common Stock of the Company owned by the Reporting Persons. The percentage ownership is calculated based on 33,395,538 shares of Common Stock outstanding as of August 9, 2012 as disclosed in the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2012, filed on August 14, 2012.

Reporting Person	Amount of Common Stock Beneficially Owned	Percent of Class	Shared			
			Sole Power to Vote or Direct the Vote	Power to Vote or Direct the Vote	Sole Power to Dispose or to Direct the Disposition	Shared Power to Dispose or to Direct the Disposition
Randal J. Kirk	6,675,768	20.0%	—	6,675,768	—	6,675,768
Intrexon Corporation	6,675,768	20.0%	—	6,675,768	—	6,675,768

Mr. Kirk could be deemed to have indirect beneficial ownership of the shares of Common Stock directly beneficially owned by Intrexon.

Item 6. Contracts, Arrangements, Understandings or Relationships with Respect to Securities of the Issuer.

The Reporting Persons' responses to Items 3 and 4 are incorporated herein by reference.

Item 7. Material to be Filed as Exhibits.

Exhibit 1 Exclusive Channel Collaboration Agreement by and between Synthetic Biologics, Inc. and Intrexon Corporation dated as of August 6, 2012 (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, dated August 6, 2012 and filed August 9, 2012) **

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Exhibit 2 Stock Issuance Agreement by and between Synthetic Biologics, Inc. and Intrexon Corporation dated as of August 6, 2012 (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K, dated August 6, 2012 and filed August 9, 2012)

Exhibit 3 First Amendment to Registration Rights Agreement by and between Synthetic Biologics, Inc. and Intrexon Corporation dated as of August 6, 2012 (filed as Exhibit 10.3 to the Company's Current Report on Form 8-K, dated August 6, 2012 and filed August 9, 2012)

Exhibit 4 Press release issued by Synthetic Biologics dated August 8, 2012 (filed as Exhibit 99.1 to the Company's Current Report on Form 8-K, dated August 6, 2012 and filed August 9, 2012)

Exhibit 5 Joint Filing Agreement, dated as of October 19, 2012, by and between Mr. Kirk and Intrexon Corporation

** 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.

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SIGNATURES

After reasonable inquiry and to the best of their knowledge and belief, the undersigned certify that the information set forth in this statement is true, complete and correct.

Date: October 19, 2012

/s/ Randal J. Kirk

Randal J. Kirk

INTREXON CORPORATION

By: /s/ Randal J. Kirk

Randal J. Kirk

Chief Executive Officer

EXHIBIT INDEX

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