Synthetic Biologics, Inc. Form S-3 July 03, 2013

As filed with the Securities and Exchange Commission on July 3, 2013 Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

# **REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

# SYNTHETIC BIOLOGICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Nevada 13-3808303

(State or Other Jurisdiction of (I.R.S. Employer

Incorporation or Organization) Identification Number)

155 Gibbs Street, Suite 412 Rockville, Maryland 20850

(734) 332-7800

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

**Jeffrey Riley** 

**Chief Executive Officer and President** 

| Synthetic Biologics, Inc.  |
|--|
| 155 Gibbs Street, Suite 412<br>Rockville, Maryland 20850   |
| (734) 332-7800   |
| (Name, Address, Including Zip Code, and Telephone Number, Including Area Code of Agent for Service)  |
| With copies to:  |
| Leslie Marlow, Esq.  |
| Gracin & Marlow, LLP   |
| The Chrysler Building  |
| 405 Lexington Avenue, 26th Floor   |
| New York, New York 10174   |
| (212) 907-6457   |
| <b>APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC:</b> From time to time after the effective date of this registration statement.   |
| If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.  |
| If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x |
| If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.   |

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective on filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer " Accelerated filer " Non-accelerated filer " (Do not check if a smaller reporting company) Smaller reporting company x

### **CALCULATION OF REGISTRATION FEE**

|  | Amount to be           |        |      |                  |     |  |
|--|------------------------|--------|------|------------------|-----|--|
|  | registered/proposed    |        |      |                  |     |  |
| Title of each class of securities to be registered | maximum offering price |        |      | Amount of        |     |  |
|  | per unit/proposed      |        |      | registration fee |     |  |
|  | maximum aggregate      |        |      |                  |     |  |
|  | offering price         |        |      |                  |     |  |
| Common Stock, par value \$0.001 per share          |                        | (1)(2) | -    |                  |     |  |
| Warrants   |                        | (1)    | _    |                  |     |  |
| Units  |                        | (1)    | _    |                  |     |  |
| Total  | \$ 50,000,000          | (3)    | \$ 6 | 5,820            | (4) |  |

- An unspecified number of securities or aggregate principal amount, as applicable, is being registered as may from time to time be offered at unspecified prices.
- (2) Includes rights to acquire common stock of the Company under any shareholder rights plan then in effect, if applicable under the terms of any such plan.
  - The proposed maximum aggregate offering price per class of security will be determined from time to time by the Company in connection with the issuance by the Company of the securities registered hereunder and is not specified as to each class of security pursuant to General Instruction II.D. of Form \$3 under the
- is not specified as to each class of security pursuant to General Instruction II.D. of Form S-3 under the Securities Act of 1933, as amended.
- (4) The registration fee has been calculated in accordance with Rule 457(o) under the Securities Act of 1933, as amended.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

### **EXPLANATORY NOTE**

This registration statement contains two prospectuses:

- a base prospectus which covers the offering, issuance and sale by the registrant of up to a maximum aggregate offering price of \$50,000,000 of the registrant's common stock, warrants and/or units; and
- a sales agreement prospectus covering the offering, issuance and sale by the registrant of up to a maximum •aggregate offering price of \$15,000,000 of the registrant's common stock that may be issued and sold under a sales agreement with Cantor Fitzgerald & Co.

The base prospectus immediately follows this explanatory note. The sales agreement prospectus immediately follows the base prospectus. The common stock that may be offered, issued and sold by the registrant under the sales agreement prospectus is included in the \$50,000,000 of securities that may be offered, issued and sold by the registrant under the base prospectus.

| The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. |
|--|
| Subject to Completion, dated July 3, 2013.   |
| PROSPECTUS   |
|  |
|  |
| \$50,000,000   |
| Common Stock   |
| Warrants   |
| Units  |

We may offer and sell up to \$50 million in the aggregate of the securities identified above from time to time in one or more offerings. This prospectus provides you with a general description of the securities.

Each time we offer and sell securities, we will provide a supplement to this prospectus (which includes, but is not limited to, the sales agreement prospectus) that contains specific information about the offering and the amounts, prices and terms of the securities. The supplement may also add, update or change information contained in this prospectus with respect to that offering. You should carefully read this prospectus and the applicable prospectus supplement before you invest in any of our securities.

We may offer and sell the securities described in this prospectus and any prospectus supplement to or through one or more underwriters, dealers and agents, or directly to purchasers, or through a combination of these methods. If any underwriters, dealers or agents are involved in the sale of any of the securities, their names and any applicable purchase price, fee, commission or discount arrangement between or among them will be set forth, or will be calculable from the information set forth, in the applicable prospectus supplement. See the sections of this prospectus

| entitled "About this Prospectus" and "Plan of Distribution" for more information. No securities may be sold without  |
|--|
| delivery of this prospectus and the applicable prospectus supplement describing the method and terms of the offering |
| of such securities.  |

This prospectus may not be used to sell securities unless it is accompanied by a prospectus supplement.

INVESTING IN OUR SECURITIES INVOLVES RISKS. SEE THE "RISK FACTORS" ON PAGE 6 OF THIS PROSPECTUS AND ANY SIMILAR SECTION CONTAINED IN THE APPLICABLE PROSPECTUS SUPPLEMENT CONCERNING FACTORS YOU SHOULD CONSIDER BEFORE INVESTING IN OUR SECURITIES.

Our common stock is listed on the NYSE MKT under the symbol "SYN." On July 1, 2013, the last reported sale price of our common stock on the NYSE MKT was \$1.67 per share.

As of July 2, 2013, the aggregate market value of our outstanding common stock held by non-affiliates was approximately \$45,744,673, based on 44,654,414 shares of outstanding common stock, of which approximately 17,262,394 shares are held by affiliates, and a per share price of \$1.67 based on the closing sale price of our common stock on July 1, 2013. We have not offered any securities during the past twelve months pursuant to General Instruction I.B.6 of Form S-3.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2013

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You should rely only on the information we have provided or incorporated by reference in this prospectus or in any prospectus supplement. We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus or in any prospectus supplement. This prospectus and any prospectus supplement is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information contained in this prospectus and in any prospectus supplement is accurate only as of their respective dates and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any prospective supplement or any sale of securities. The registration statement, including the exhibits and the documents incorporated herein by reference, can be read on the Securities and Exchange Commission website or at the Securities and Exchange Commission offices mentioned under the heading "Where You Can Find More Information."

### ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the U.S. Securities and Exchange Commission, or the SEC, using a "shelf" registration process. By using a shelf registration statement, we may sell securities from time to time and in one or more offerings up to a total dollar amount of \$50 million of securities from time to time as described in this prospectus. Each time that we offer and sell securities, we will provide a prospectus supplement to this prospectus (which term includes, as applicable, the sales agreement prospectus filed with the registration statement of which this prospectus forms a part) that contains specific information about the securities being offered and sold and the specific terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus with respect to that offering. If there is any inconsistency between the information in this prospectus and the applicable prospectus supplement, you should rely on the prospectus supplement. Before purchasing any securities, you should carefully read both this prospectus and the applicable prospectus supplement, together with the additional information described under the heading "Where You Can Find More Information" and "Incorporation of Certain Information by Reference."

You should rely only on the information incorporated by reference or provided in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We will not make an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus and the applicable prospectus supplement to this prospectus is accurate as of the date on its respective cover, and that any information incorporated by reference is accurate only as of the date of the document incorporated by reference, unless we indicate otherwise. Our business, financial condition, results of operations and prospects may have changed since those dates.

Unless otherwise stated or the context otherwise requires, references in this prospectus to "Synthetic," the "Company," "we," "our" and "us" refer to Synthetic Biologics, Inc., a Nevada corporation and its consolidated subsidiaries, unless otherwise specified. When we refer to "you," we mean the holders of the applicable series of securities.

# PROSPECTUS SUMMARY

The items in the following summary are described in more detail elsewhere in this prospectus and in the documents incorporated by reference herein. This summary provides an overview of selected information and does not contain all the information you should consider before investing in our common stock. Therefore, you should read the entire prospectus and any free writing prospectus that we have authorized for use in connection with this offering carefully, including the "Risk Factors" section and other documents or information included or incorporated by reference in this prospectus before making any investment decision.

# **Our Business**

We are a biotechnology company focused on the development of biologics for the prevention and treatment of serious infectious diseases. We are developing an oral enzyme for the prevention of *C. difficile* infections, and a series of monoclonal antibody therapies for the treatment of Pertussis and *Acinetobacter* infections. In addition, we are developing a drug candidate for the treatment of relapsing-remitting multiple sclerosis and cognitive dysfunction in multiple sclerosis, and have partnered the development of a treatment for fibromyalgia.

Product Pipeline:

Summary of Infectious Disease Programs:

Clostridium difficile (C. difficile) infections: In November 2012, we acquired a series of oral beta-lactamase enzymes (P1A, P2A and P3A) and related assets targeting the prevention of C. difficile infections (CDI), the leading cause of hospital acquired infections (HAI), that generally occurs secondary to treatment with intravenous antibiotics. The acquired assets include a pre-Investigational New Drug (IND) package for P3A (SYN-004), Phase I and Phase II clinical data for P1A, manufacturing processes and data, and a portfolio of issued and pending U.S. and international patents intended to support an IND and Biologic License Application (BLA) with the FDA. Utilizing this portfolio of assets, we intend to develop a proprietary oral beta-lactamase enzyme product candidate, SYN-004, previously known as IPSAT P3A. When co-administered with certain intravenous beta-lactam antibiotics, it is expected that SYN-004 can degrade the antibiotic that is excreted in the gastrointestinal (GI) tract, thus preserving the natural balance of the patient's microflora, and preventing opportunistic infections including CDI. Beta-lactam antibiotics are a mainstay in hospital infection management and include the commonly used penicillin and cephalosporin classes of antibiotics. In 2012, 15 million Americans were administered beta-lactam antibiotics.\*

\*This information is an estimate derived from the use of information under license from the following IMS Health Incorporated information service: CDM Hospital database for full year 2012. IMS expressly reserves all rights, including rights of copying, distribution and republication.

**Pertussis:** In December 2012, in collaboration with Intrexon, we initiated development of a monoclonal antibody (mAb) therapy for the treatment of Pertussis infections, more commonly known as whooping cough. We are developing a mAb therapy, SYN-005, designed to target and neutralize the pertussis toxin, in order to reduce the mortality rate in infants and potentially shorten the duration of chronic cough in afflicted adults. To further the development of this potential therapy for Pertussis, we entered into an agreement with The University of Texas at Austin to license the rights to certain research and pending patents related to pertussis antibodies. According to the World Health Organization, each year, *B. pertussis* infection causes an estimated 300,000 deaths worldwide, primarily among young, unvaccinated infants.

Acinetobacter infections: In September 2012, in collaboration with Intrexon, we initiated efforts to develop a mAb therapy for the treatment of *Acinetobacter* infections. Many strains of *Acinetobacter* are multidrug-resistant and pose an increasing global threat to hospitalized patients, wounded military personnel and those affected by natural disasters. A treatment for *Acinetobacter* infections represents a billion dollar market opportunity.

Summary of Multiple Sclerosis Program:

Trimesta<sup>TM</sup> (oral estriol) is being developed as an oral once-daily treatment for relapsing-remitting multiple sclerosis (MS) in women. Patient enrollment is complete in this two-year, randomized, double-blind, placebo-controlled Phase II clinical trial being conducted at 15 centers in the U.S. The primary endpoint is relapse rate at two years, with top-line results expected in 1H 2014. This trial is supported by grants exceeding \$8 million, which should be sufficient to fund the trial through completion. Annual worldwide sales of current MS therapies are estimated at \$14.1 billion.

Trimesta<sup>TM</sup> is also being developed for the treatment of cognitive dysfunction in female MS patients. This 12-month randomized, double-blind, placebo-controlled Phase II clinical trial is being conducted at the University of California, Los Angeles (UCLA). The primary endpoint is the effect on cognitive function as assessed by Paced Auditory Serial Addition Test (PASAT). Patient enrollment is ongoing. The majority of the costs of this trial are being funded by grants from foundations and charitable organizations and we have pledged approximately \$500,000 to UCLA to partially fund this trial payable over three years. An estimated 50-65% of MS patients are expected to develop disabilities due to cognitive dysfunction and there is currently no approved treatment.

Summary of Fibromyalgia Program:

Effirma<sup>TM</sup> (flupirtine) is being developed for the treatment of fibromyalgia by Meda AB (Meda), a multi-billion dollar international pharmaceutical company. On May 6, 2010, we entered into a sublicense agreement with Meda covering all of our patents' rights on the use of flupirtine for fibromyalgia in the U.S., Canada and Japan. The sublicense agreement provides that all ongoing and future development costs are to borne by Meda and we are entitled to receive certain payments if milestones are achieved and royalties on sales. According to Meda's 2012 Year-End Report filed in February 2013, Meda has received the go-ahead from the FDA to conduct a Phase II proof of concept study for the treatment of fibromyalgia. Meda also announced that the randomized, double-blind, placebo and active-controlled study of patients with fibromyalgia will be conducted at 25 clinics in the U.S. Based on an estimated annual price of \$1,200 per fibromyalgia patient, we estimate that the total market potential in the U.S. is \$6 billion.

In order to further prioritize our focus, we have elected to discontinue further development of AEN-100 for the treatment of amyotrophic lateral sclerosis. However, we are currently seeking development partners for our zinc-based intellectual property and assets including, AEN-100.

Recent Developments

On December 19, 2012, we entered into a Patent License Agreement (the "License Agreement") with The University of Texas at Austin (the "University") for the exclusive license of the right to use, develop, manufacture, market and commercialize certain research and patents related to Pertussis (more commonly known as whooping cough) antibodies developed in the lab of Dr. Jennifer A. Maynard, Assistant Professor of Chemical Engineering. In connection with the License Agreement, we and the University also entered into a Sponsored Research Agreement pursuant to which the University will perform certain research work related to pertussis under the direction of Dr. Jennifer Maynard and we will obtain certain rights to patents and technology developed during the course of such research.

On November 28, 2012, a closing was held for the transaction contemplated by the Asset Purchase Agreement (the "Prev Agreement") we entered into with Prev ABR LLC ("Prev"), pursuant to which we acquired the C. diff program assets of Prev, including pre-Investigational New Drug (IND) package, Phase I and Phase II clinical data, manufacturing process data and all issued and pending U.S. and international patents. Pursuant to the Prev Agreement, we paid Prev an initial cash payment of \$100,000 upon execution of the Prev Agreement and at closing paid an additional cash payment of \$135,000 and issued 625,000 unregistered shares of our common stock to Prev. In addition, upon the achievement of the milestones set forth below, Prev may be entitled to receive additional consideration payable 50% in cash and 50% in our stock, subject to Prev's option to receive the entire payment in shares of our stock, with the exception of the first milestone payments to be paid in cash: (i) upon commencement of an IND; (ii) upon commencement of a Phase I clinical trial; (iii) upon commencement of a Phase II clinical trial; (iv) upon commencement of a Phase III clinical trial; (v) upon Biologic License Application (BLA) filing in the U.S. and for territories outside of the U.S. (as defined in the Prev Agreement); and (vi) upon BLA approval in the U.S. and upon approval in territories outside the-U.S. The future stock issuances are subject to prior approval of the NYSE MKT, LLC. No royalties are payable to Prev under the Prev Agreement. The Prev Agreement also provides that Prev has a right to the return to it of all assets acquired by us under the Prev Agreement if on or prior to the date that is (i) thirty (30) months after the execution of the Prev Agreement, we have not initiated toxicology studies in non-rodent models or (ii) thirty six (36) months have not filed an IND under the program related to the assets and such failure is not due to action or inaction of Prev or breach of its representations or warranties or covenants or if there is a change of control as defined in the Prev Agreement and after such change of control the assets are not further developed; provided however that such thirty (30) and thirty six (36) month periods can be extended by us for an additional twelve (12) months upon payment of a cash milestone payment.

On October 30, 2012, we completed a private placement (the "October 2012 Private Placement") with certain accredited investors, pursuant to which we sold an aggregate of 6,750,000 shares of our common stock at a price per share of \$1.60 (the "Common Shares") for aggregate gross proceeds of \$10.8 million and net proceeds of \$10.1 million. In connection with the October 2012 Private Placement, we filed a registration statement with the SEC which was declared effective on December 20, 2012 for the resale of our common stock owned by certain of the purchasers in the October 2012 Private Placement. In connection with the October 2012 Private Placement, we also entered into an agreement with a certain purchaser that is an affiliate of Intrexon (the "Joinder Agreement") pursuant to which such purchaser agreed to be bound by the terms of and join Intrexon as a party to its registration rights agreement with us entered into in connection with the Second Channel Agreement (the "First Amendment to Registration Rights Agreement") and we registered the shares issued to such purchaser in accordance with the First Amendment to Registration Rights Agreement.

Griffin Securities, Inc. ("Griffin") served as the placement agent for the October 2012 Private Placement. In consideration for services rendered by Griffin in the October 2012 Private Placement, we (i) paid to Griffin cash commissions equal to 6.0% of the gross proceeds received in the October 2012 Private Placement, (ii) issued to Griffin, or its designee, warrants, which are five-year warrants to purchase 635,855 shares of our common stock with an exercise price of \$1.60 per share (the "Agent Warrants"); and (iii) reimbursed Griffin for its reasonable actual out-of-pocket expenses incurred in connection with the October 2012 Private Placement, including reasonable legal fees and disbursements. The common stock underlying the Agent Warrants was registered under the registration statement declared effective on December 20, 2012.

On August 6, 2012, we expanded our relationship with Intrexon and entered into a Second Channel Agreement with Intrexon (the "Second Channel Agreement") that governs an "exclusive channel collaboration" arrangement in which we 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 (the "Program"). The Second Channel Agreement establishes committees comprised of our 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. On October 16, 2012, a closing was held for the transaction contemplated by the Second Channel Agreement. Pursuant to the terms of a Stock Issuance Agreement with Intrexon (the "Second Stock Purchase Agreement"), we issued 3,552,210 shares of our common stock, \$0.001 par value, which issuance is also deemed paid in consideration for the execution and delivery of the Second Channel Agreement, dated August 6, 2012, between ourselves and Intrexon. We registered the shares issued to Intrexon in accordance with the First Amendment to Registration Rights Agreement.

On February 15, 2012, upon stockholder approval, we amended our Articles of Incorporation to change our name to Synthetic Biologics, Inc. Our common stock continues trade on the NYSE MKT (formerly the NYSE Amex and American Stock Exchange), under the symbol "SYN". Prior to this time and since October 16, 2008, our name was Adeona Pharmaceuticals, Inc. and we traded on the NYSE MKT stock exchange under the symbol "AEN". We are incorporated in the State of Nevada.

On December 21, 2011, we announced that the Board of Directors had taken several actions to prioritize our focus on our entry into the emerging field of synthetic biology. In connection with the change in business focus on March 8, 2012, we entered into a Membership Interest Purchase Agreement, and certain related agreements, pursuant to which we sold all of our interest in the Adeona Clinical Laboratory (the "Lab") to Hartlab, LLC, an entity controlled by the Lab's former owner, in consideration for (i) the immediate assignment of the Lab's outstanding accounts receivable up through the date of closing, plus (ii) Seven Hundred Thousand Dollars (\$700,000) payable pursuant to the terms of a two-year non-recourse promissory note secured by all of the assets of the Lab.

On November 18, 2011, we entered into a Stock Purchase Agreement with Intrexon pursuant to which we issued to Intrexon 3,123,558 shares of our common stock at a purchase price equal to the \$0.001 par value of such shares, which issuance was deemed paid in consideration for the execution and delivery of the channel agreement which was entered into on November 18, 2011 and terminated on April 16, 2013. We also agreed to an equity participation right in future securities offerings.

# **Company Information**

Our predecessor, Sheffield Pharmaceuticals, Inc. was incorporated in 1986, and in 2006 engaged in a reverse merger with Pipex Therapeutics, Inc., a Delaware corporation formed in 2001. After the merger, we changed our name to Pipex Pharmaceuticals, Inc., and in October 2008 we changed our name to Adeona Pharmaceuticals, Inc. On October 15, 2009, we reincorporated in the State of Nevada. After reprioritizing our focus on the emerging area of synthetic biologics and entering into our first collaboration with Intrexon, we amended our Articles of Incorporation to change our name to Synthetic Biologics, Inc. on February 15, 2012.

Our principal executive offices are located at 155 Gibbs Street, Suite 412, Rockville, Maryland 20850. We also maintain an administrative and finance office in Ann Arbor, Michigan.

### THE OFFERING

We may offer shares of our common stock, warrants to purchase any of such securities, either individually or in combination, and/or units consisting of some or all of such securities for total gross proceeds of up to \$50 million, from time to time under this prospectus, together with the applicable prospectus supplement and any related free writing prospectus, at prices and on terms to be determined by market conditions at the time of any offering. Each time we offer a type or series of securities under this prospectus, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities being offered. Below is a summary of the securities we may offer under this prospectus (together with the applicable prospectus supplement).

We may sell the securities directly to investors or to or through agents, underwriters or dealers. We, and our agents or underwriters, reserve the right to accept or reject all or part of any proposed purchase of securities. Each prospectus supplement will set forth the names of any underwriters, dealers or agents involved in the sale of securities described in that prospectus supplement and any applicable fee, commission or discount arrangements with them.

### RISK FACTORS THAT MAY AFFECT FUTURE RESULTS

You should consider carefully the risks discussed under the section captioned "Risk Factors" contained in our annual report on Form 10-K for the year ended December 31, 2012 and in our subsequent quarterly reports on Form 10-Q, as updated by our subsequent filings under the Securities Exchange Act of 1934, as amended, or the Exchange Act, each of which is incorporated by reference in this prospectus in its entirety, together with other information in this prospectus, and the information and documents incorporated by reference in this prospectus, and any free writing prospectus that we have authorized for use in connection with this offering before you make a decision to invest in our common stock. If any of these events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment.

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the documents incorporated by reference in it, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934 as amended, or the Exchange Act. These statements may be made directly in this document or they may be made part of this document by reference to other documents filed with the SEC, which is known as "incorporation by reference." You can find many (but not all) of these statements by looking for words such as "approximates," "believes," "expects," "anticipates," "estimates," "intends," "plans," "would," "could," "may" or other similar

in this prospectus or the documents incorporated by reference.

We caution investors that any forward-looking statements presented in this prospectus or the documents incorporated by reference, or those which we may make orally or in writing from time to time, are based on our beliefs and assumptions, as well as information currently available to us. Such statements are based on assumptions and the actual outcome will be affected by known and unknown risks, trends, uncertainties and factors that are beyond our control or ability to predict. Although we believe that our assumptions are reasonable, they are not guarantees of future performance and some will inevitably prove to be incorrect. As a result, our actual future results can be expected to differ from our expectations, and those differences may be material. Accordingly, investors should use caution in relying on past forward-looking statements, which are based on known results and trends at the time they are made, to anticipate future results or trends.

Some of the risks and uncertainties that may cause our actual results, performance or achievements to differ materially from those expressed or implied by forward-looking statements include the following:

- a failure to continue to undertake preclinical development and clinical trials for our product candidates;
- a failure to expand our research activities with Intrexon relating to monoclonal antibodies for infectious diseases;
- a failure of our product candidates to be demonstrably safe and effective;
- a failure to obtain regulatory approval for our products or to comply with ongoing regulatory requirements;
- a lack of acceptance of our product candidates in the marketplace;
- a failure by us to become or remain profitable;
- an inability by us to obtain the capital necessary to fund our research and development activities; and

a loss of any of our key scientists or management personnel.

This prospectus and all subsequent written and oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We do not undertake any obligation to release publicly any revisions to our forward-looking statements to reflect events or circumstances after the dates that such statements are made.

For more information on the uncertainty of forward-looking statements, see "Risk Factors" in our Annual Reports on Form 10-K and our Quarterly Reports on Form 10-Q and any applicable prospectus supplement.

### **USE OF PROCEEDS**

We intend to use the net proceeds, if any, from the sales of securities offered by this prospectus for general corporate purposes, which may include, among other things, increasing our working capital and funding research and development, and capital expenditures. In addition, we may use a portion of the net proceeds for licensing or acquiring intellectual property to incorporate into our products and product candidates or our research and development programs. We may also use a portion of the net proceeds to in-license, acquire or invest in complementary businesses or products; however, we have no current commitments or obligations to do so.

The amounts and timing of our actual expenditures will depend on numerous factors, including our development and commercialization efforts, as well as the amount of cash used in our operations. We therefore cannot estimate with certainty the amount of net proceeds to be used for the purposes described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds. Pending the uses described above, we plan to invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities.

### DIVIDEND POLICY

We have never paid cash dividends on our common stock. Moreover, we do not anticipate paying periodic cash dividends on our common stock for the foreseeable future. We intend to use all available cash and liquid assets in the operation and growth of our business. Any future determination about the payment of dividends will be made at the discretion of our board of directors and will depend upon our earnings, if any, capital requirements, operating and financial conditions and on such other factors as our board of directors deems relevant.

### DESCRIPTION OF CAPITAL STOCK

### **Authorized Capital**

Our authorized capital consists of 100 million shares of common stock, par value \$0.001 per share, and 10 million shares of preferred stock, par value \$0.001 per share. As of July 2, 2013, 44,654,414 shares of common stock and no shares of preferred stock were outstanding.

#### Common Stock

We may issue shares of our common stock from time to time. Holders of shares of common stock have the right to cast one vote for each share of common stock in their name on the books of our company, whether represented in person or by proxy, on all matters submitted to a vote of holders of common stock, including election of directors. There is no right to cumulative voting in election of directors. Except where a greater requirement is provided by statute, by our articles of incorporation, or by our bylaws, the presence, in person or by proxy duly authorized, of the one or more holders of a majority of the outstanding shares of our common stock constitutes a quorum for the transaction of business. The vote by the holders of a majority of outstanding shares is required to effect certain fundamental corporate changes such as liquidation, merger, or amendment of our articles of incorporation. Upon our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preferences of any outstanding shares of preferred stock.

There are no restrictions in our articles of incorporation or bylaws that prevent us from declaring dividends. We have not declared any dividends, and we do not plan to declare any dividends in the foreseeable future.

Holders of shares of our common stock are not entitled to preemptive or subscription or conversion rights, and no redemption or sinking fund provisions are applicable to our common stock. All outstanding shares of common stock are, and the shares of common stock sold in the offering will when issued be fully paid and non-assessable.

### **DESCRIPTION OF WARRANTS**

#### Warrants

We may issue warrants for the purchase of common stock. We may issue warrants independently or in combination with common stock. In this prospectus, we have summarized certain general features of the warrants. We urge you, however, to read the applicable prospectus supplement (and any related free writing prospectus that we may authorize to be provided to you) related to the particular series of warrants being offered, as well as any warrant agreements and warrant certificates that contain the terms of the warrants. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of warrant and/or the warrant agreement and warrant certificate, as applicable, that contain the terms of the particular series of warrants we are offering, and any supplemental agreements, before the issuance of such warrants.

Any warrants issued under this prospectus may be evidenced by warrant certificates. Warrants also may be issued under an applicable warrant agreement that we enter into with a warrant agent. We will indicate the name and address of the warrant agent, if applicable, in the prospectus supplement relating to the particular series of warrants being offered.

The following description, together with the additional information that we include in any applicable prospectus supplement and in any related free writing prospectus that we may authorize to be distributed to you, summarizes the material terms and provisions of the warrants that we may offer under this prospectus, which may be issued in one or more series. While the terms we have summarized below will apply generally to any warrants that we may offer under this prospectus, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement and in any related free writing prospectus that we may authorize to be distributed to you. The following description of warrants will apply to the warrants offered by this prospectus unless we provide otherwise in the applicable prospectus supplement. The applicable prospectus supplement for a particular series of warrants may specify different or additional terms.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of warrant and/or the warrant agreement and warrant certificate, as applicable, that contain the terms of the particular series of warrants we are offering, and any supplemental agreements, before the issuance of such warrants.

The summary below and that contained in any prospectus supplement is qualified in its entirety by reference to all of the provisions of the warrant and/or the warrant agreement and warrant certificate, as applicable, applicable to a particular series of debt securities. We urge you to read the applicable prospectus supplements and any related free

writing prospectuses related to the warrants that we may offer under this prospectus, as well as the complete warrant and/or the warrant agreement and warrant certificate, as applicable, that contains the terms of the warrants.

# General

We will describe in the applicable prospectus supplement the terms of the series of warrants being offered, including:

the offering price and aggregate number of warrants offered;

the currency for which the warrants may be purchased;

if applicable, the number of warrants issued with each such security;

the number of shares of common stock, as the case may be, purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;

the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreements and the warrants;

the terms of any rights to redeem or call the warrants;

any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;

the dates on which the right to exercise the warrants will commence and expire;

the manner in which the warrant agreements and warrants may be modified;

a discussion of any material or special U.S. federal income tax considerations of holding or exercising the warrants;

the terms of the securities issuable upon exercise of the warrants; and

any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any:

### **Exercise of Warrants**

Each warrant will entitle the holder to purchase the securities that we specify in the applicable prospectus supplement at the exercise price that we describe in the applicable prospectus supplement. The warrants may be exercised as set forth in the prospectus supplement relating to the warrants offered. Unless we otherwise specify in the applicable prospectus supplement, warrants may be exercised at any time up to the close of business on the expiration date set forth in the prospectus supplement relating to the warrants offered thereby. After the close of business on the expiration date, unexercised warrants will become void.

Upon receipt of payment and the warrant or warrant certificate, as applicable, properly completed and duly executed at the corporate trust office of the warrant agent, if any, or any other office, including ours, indicated in the prospectus supplement, we will, as soon as practicable, issue and deliver the securities purchasable upon such exercise. If less than all of the warrants (or the warrants represented by such warrant certificate) are exercised, a new warrant or a new warrant certificate, as applicable, will be issued for the remaining warrants.

### Enforceability of Rights by Holders of Warrants

Each warrant agent, if any, will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A warrant agent may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

### Governing Law

Unless we otherwise specify in the applicable prospectus supplement, the warrants and any warrant agreements will be governed by and construed in accordance with the laws of the State of New York.

#### **DESCRIPTION OF UNITS**

### Units

We may issue units consisting of any combination of our common stock and warrants. We will issue each unit so that the holder of the unit is also the holder of each security included in the unit. As a result, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

The summary below and that contained in any prospectus supplement is qualified in its entirety by reference to all of the provisions of the unit agreement and/or unit certificate, and depositary arrangements, if applicable. We urge you to read the applicable prospectus supplements and any related free writing prospectuses related to the units that we may offer under this prospectus, as well as the complete unit agreement and/or unit certificate, and depositary arrangements, as applicable, that contain the terms of the units.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of unit agreement and/or unit certificate, and depositary arrangements, as applicable, that contain the terms of the particular series of units we are offering, and any supplemental agreements, before the issuance of such units.

The applicable prospectus supplement, information incorporated by reference or free writing prospectus may describe:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any provisions for the issuance, payment, settlement, transfer, or exchange of the units or of the securities composing the units;
- whether the units will be issued in fully registered or global form; and
- any other terms of the units.

The applicable provisions described in this section, as well as those described under "Common Stock" and "Warrants" above, will apply to each unit and to each security included in each unit, respectively

### PLAN OF DISTRIBUTION

We may sell the securities from time to time pursuant to underwritten public offerings, negotiated transactions, block trades or a combination of these methods or through underwriters or dealers, through agents and/or directly to one or more purchasers. The securities may be distributed from time to time in one or more transactions:

- •at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
  - at prices related to such prevailing market prices; or
- •at negotiated prices.

Each time that we sell securities covered by this prospectus, we will provide a prospectus supplement or supplements that will describe the method of distribution and set forth the terms and conditions of the offering of such securities, including the offering price of the securities and the proceeds to us, if applicable.

Offers to purchase the securities being offered by this prospectus may be solicited directly. Agents may also be designated to solicit offers to purchase the securities from time to time. Any agent involved in the offer or sale of our securities will be identified in a prospectus supplement.

If a dealer is utilized in the sale of the securities being offered by this prospectus, the securities will be sold to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale.

If an underwriter is utilized in the sale of the securities being offered by this prospectus, an underwriting agreement will be executed with the underwriter at the time of sale and the name of any underwriter will be provided in the

prospectus supplement that the underwriter will use to make resales of the securities to the public. In connection with the sale of the securities, we, or the purchasers of securities for whom the underwriter may act as agent, may compensate the underwriter in the form of underwriting discounts or commissions. The underwriter may sell the securities to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for which they may act as agent. Unless otherwise indicated in a prospectus supplement, an agent will be acting on a best efforts basis and a dealer will purchase securities as a principal, and may then resell the securities at varying prices to be determined by the dealer.

Any compensation paid to underwriters, dealers or agents in connection with the offering of the securities, and any discounts, concessions or commissions allowed by underwriters to participating dealers will be provided in the applicable prospectus supplement. Underwriters, dealers and agents participating in the distribution of the securities may be deemed to be underwriters within the meaning of the Securities Act, and any discounts and commissions received by them and any profit realized by them on resale of the securities may be deemed to be underwriting discounts and commissions. We may enter into agreements to indemnify underwriters, dealers and agents against civil liabilities, including liabilities under the Securities Act, or to contribute to payments they may be required to make in respect thereof and to reimburse those persons for certain expenses.

Any common stock will be listed on the NYSE MKT, but any other securities may or may not be listed on a national securities exchange. To facilitate the offering of securities, certain persons participating in the offering may engage in transactions that stabilize, maintain or otherwise affect the price of the securities. This may include over-allotments or short sales of the securities, which involve the sale by persons participating in the offering of more securities than were sold to them. In these circumstances, these persons would cover such over-allotments or short positions by making purchases in the open market or by exercising their over-allotment option, if any. In addition, these persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in the offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. These transactions may be discontinued at any time.

If indicated in the applicable prospectus supplement, underwriters or other persons acting as agents may be authorized to solicit offers by institutions or other suitable purchasers to purchase the securities at the public offering price set forth in the prospectus supplement, pursuant to delayed delivery contracts providing for payment and delivery on the date or dates stated in the prospectus supplement. These purchasers may include, among others, commercial and savings banks, insurance companies, pension funds, investment companies and educational and charitable institutions. Delayed delivery contracts will be subject to the condition that the purchase of the securities covered by the delayed delivery contracts will not at the time of delivery be prohibited under the laws of any jurisdiction in the United States to which the purchaser is subject. The underwriters and agents will not have any responsibility with respect to the validity or performance of these contracts.

We may engage in at the market offerings into an existing trading market in accordance with Rule 415(a)(4) under the Securities Act. In addition, we may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement so indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and, if not identified in this prospectus, will be named in the applicable prospectus supplement (or a post-effective amendment). In addition, we may otherwise loan or pledge securities to a financial institution or other third party that in turn may sell the securities short using this prospectus and an applicable prospectus supplement. Such financial institution or other third party may transfer its economic short position to investors in our securities or in connection with a concurrent offering of other securities.

The specific terms of any lock-up provisions in respect of any given offering will be described in the applicable prospectus supplement.

The underwriters, dealers and agents may engage in transactions with us, or perform services for us, in the ordinary course of business for which they receive compensation.

### **LEGAL MATTERS**

Gracin & Marlow, LLP, New York, New York will pass upon certain legal matters relating to the issuance and sale of the warrants and units offered hereby on behalf of Synthetic Biologics, Inc. and Parsons Behle & Latimer, Reno, Nevada will pass upon certain legal matters relating to the issuance and sale of the common stock and the common stock underlying the warrants offered hereby on behalf of Synthetic Biologics, Inc. Additional legal matters may be passed upon for us or any underwriters, dealers or agents, by counsel that we will name in the applicable prospectus supplement.

### **EXPERTS**

The financial statements as of December 31, 2012 and for the year ended December 31, 2012 incorporated by reference in this prospectus have been so incorporated in reliance on the report of BDO USA, LLP, an independent registered public accounting firm, incorporated herein by reference, given on authority of said firm as experts in auditing and accounting.

The financial statements as of December 31, 2011 and for the year ended December 31, 2011 incorporated by reference in this prospectus have been so incorporated in reliance on the report of Berman & Company, P.A. an independent registered public accounting firm, incorporated herein by reference, given on authority of said firm as experts in auditing and accounting.

#### WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any document we file at the SEC's public reference room located at 100 F Street N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference room. Our public filings are also available to the public at the SEC's web site at http://www.sec.gov.

This prospectus is part of a registration statement on Form S-3 that we have filed with the SEC under the Securities Act. This prospectus does not contain all of the information in the registration statement. We have omitted certain parts of the registration statement, as permitted by the rules and regulations of the SEC. You may inspect and copy the registration statement, including exhibits, at the SEC's public reference room or Internet site.

Additional information about Synthetic Biologics. Inc. is contained at our website, <a href="www.syntheticbiologics.com">www.syntheticbiologics.com</a>. Information on our website is not incorporated by reference into this report. We make available on our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K as soon as reasonably practicable after those reports are filed with the SEC. The following Corporate Governance documents are also posted on our website: Code of Conduct, Code of Ethics for Financial Management and the Charters for the Audit Committee, Compensation Committee and Nominations Committee of the Board of Directors.

### INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" the information we file with it which means that we can disclose important information to you by referring you to those documents instead of having to repeat the information in this prospectus. The information incorporated by reference is considered to be part of this prospectus, and later information that we file with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act between the date of this prospectus and the termination of the offering, however, we are not incorporating by reference any documents or portions thereof, whether specifically listed below or filed in the future, that are not deemed "filed" with the SEC, or any information furnished pursuant to Items 2.02 or 7.01 of Form 8-K or related exhibits furnished pursuant to Item 9.01 of Form 8-K:

Our annual report on Form 10-K for the fiscal year ended December 31, 2012 filed with the SEC on April 16, 2013;

Our quarterly report on Form 10-Q for the quarter ended March 31, 2013 filed with the SEC on May 15, 2013;

Our current report on Form 8-K filed with the SEC on April 19, 2013, and

The description of our common stock set forth in our registration statement on Form 8-A12B, filed with the SEC on June 20, 2007 (File No. 000-12584).

You may obtain, free of charge, a copy of any of these documents (other than exhibits to these documents unless the exhibits are specifically incorporated by reference into these documents or referred to in this prospectus) by writing or calling us at the following address and telephone number:

155 Gibbs Street, Ste. 412 Rockville, Maryland 20850

(734) 332-7800

The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

**SUBJECT TO COMPLETION, DATED JULY 3, 2013** 

**PROSPECTUS** 

Up to \$15,000,000 of Shares

**Common Stock** 

We have entered into a sales agreement with Cantor Fitzgerald & Co., relating to shares of our common stock offered by this prospectus. In accordance with the terms of the sales agreement, we may offer and sell shares of our common stock having an aggregate offering price of up to \$15,000,000 from time to time through Cantor Fitzgerald & Co., acting as agent.

Our common stock is listed on the NYSE MKT under the symbol "SYN." On July 2, 2013, the last reported sale price of our common stock on the NYSE MKT was \$1.67 per share.

As of July 1, 2013 the aggregate market value of our outstanding common stock held by non-affiliates was approximately \$45,744,673, based on 44,654,414 shares of outstanding common stock, of which approximately 17,262,394 shares are held by affiliates, and a per share price of \$1.67 based on the closing sale price of our common stock on July 1, 2013. We have not offered any securities during the past twelve months pursuant to General Instruction I.B.6 of Form S-3.

Sales of our common stock, if any, under this prospectus may be made in sales deemed to be "at-the-market" equity offerings as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act, including sales made directly on or through the NYSE MKT, the existing trading market for our common stock, sales

made to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, and/or any other method permitted by law, including in privately negotiated transactions. Cantor Fitzgerald & Co. will act as sales agent on a best efforts basis and use commercially reasonable efforts to sell on our behalf all of the shares of common stock requested to be sold by us, consistent with its normal trading and sales practices, on mutually agreed terms between Cantor Fitzgerald & Co. and us. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

Cantor Fitzgerald & Co. will be entitled to compensation at a fixed commission rate of 3.0% of the gross sales price per share sold. In connection with the sale of our common stock on our behalf, Cantor Fitzgerald & Co. will be deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of Cantor Fitzgerald & Co. will be deemed to be underwriting commissions or discounts.

Investing in our common stock involves a high degree of risk. Before making an investment decision, please read the information under the heading "Risk Factors" beginning on page S-6 of this prospectus and in the documents incorporated by reference into this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2013.

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### ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we have filed with the Securities and Exchange Commission, or SEC, utilizing a "shelf" registration process. Under the shelf registration process, we may offer shares of our common stock having an aggregate offering price of up to \$15,000,000 from time to time under this prospectus at prices and on terms to be determined by market conditions at the time of offering.

We provide information to you about this offering of shares of our common stock in two separate documents that are bound together: (1) this sales agreement prospectus, which describes the specific details regarding this offering; and (2) the accompanying base prospectus, which provides general information, some of which may not apply to this offering. Generally, when we refer to this "prospectus," we are referring to both documents combined. If information in this sales agreement prospectus is inconsistent with the accompanying base prospectus, you should rely on this prospectus. However, if any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference in this prospectus—the statement in the document having the later date modifies or supersedes the earlier statement as our business, financial condition, results of operations and prospects may have changed since the earlier dates.

You should rely only on the information contained in, or incorporated by reference into, this prospectus and in any free writing prospectus that we may authorize for use in connection with this offering. We have not, and Cantor Fitzgerald & Co., or Cantor, has not, authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and Cantor is not, making an offer to sell or soliciting an offer to buy our securities in any jurisdiction in which an offer or solicitation is not authorized or in which the person making that offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make an offer or solicitation. You should assume that the information appearing in this prospectus, the documents incorporated by reference into this prospectus, and in any free writing prospectus that we may authorize for use in connection with this offering, is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus, the documents incorporated by reference into this prospectus, and any free writing prospectus that we may authorize for use in connection with this offering, in their entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the sections of this prospectus entitled "Where You Can Find More Information" and "Incorporation of Certain Information by Reference."

We are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus outside the United States. This prospectus does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

### INDUSTRY AND MARKET DATA

We obtained the industry and market data in this prospectus from our own research as well as from industry and general publications, surveys and studies conducted by third parties. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate is necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors" and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

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#### PROSPECTUS SUMMARY

The items in the following summary are described in more detail elsewhere in this prospectus and in the documents incorporated by reference herein. This summary provides an overview of selected information and does not contain all the information you should consider before investing in our common stock. Therefore, you should read the entire prospectus and any free writing prospectus that we have authorized for use in connection with this offering carefully, including the "Risk Factors" section and other documents or information included or incorporated by reference in this prospectus before making any investment decision.

## **Our Business**

We are a biotechnology company focused on the development of biologics for the prevention and treatment of serious infectious diseases. We are developing an oral enzyme for the prevention of *C. difficile* infections, and a series of monoclonal antibody therapies for the treatment of Pertussis and *Acinetobacter* infections. In addition, we are developing a drug candidate for the treatment of relapsing-remitting multiple sclerosis and cognitive dysfunction in multiple sclerosis, and have partnered the development of a treatment for fibromyalgia.

*Product Pipeline:* 

Summary of Infectious Disease Programs:

•Clostridium difficile (C. difficile) infections: In November 2012, we acquired a series of oral beta-lactamase enzymes (P1A, P2A and P3A) and related assets targeting the prevention of C. difficile infections (CDI), the leading cause of hospital acquired infections (HAI), that generally occurs secondary to treatment with intravenous antibiotics. The acquired assets include a pre-Investigational New Drug (IND) package for P3A (SYN-004), Phase I and Phase II clinical data for P1A, manufacturing processes and data, and a portfolio of issued and pending U.S. and international patents intended to support an IND and Biologic License Application (BLA) with the FDA. Utilizing this portfolio of assets, we intend to develop a proprietary oral beta-lactamase enzyme product candidate, SYN-004, previously known as IPSAT P3A. When co-administered with certain intravenous beta-lactam antibiotics, it is

expected that SYN-004 can degrade the antibiotic that is excreted in the gastrointestinal (GI) tract, thus preserving the natural balance of the patient's microflora, and preventing opportunistic infections including CDI. Beta-lactam antibiotics are a mainstay in hospital infection management and include the commonly used penicillin and cephalosporin classes of antibiotics. In 2012, 15 million Americans were administered beta-lactam antibiotics.\*

\*This information is an estimate derived from the use of information under license from the following IMS Health Incorporated information service: CDM Hospital database for full year 2012. IMS expressly reserves all rights, including rights of copying, distribution and republication.

**Pertussis:** In December 2012, in collaboration with Intrexon Corporation ("Intrexon"), we initiated development of a monoclonal antibody (mAb) therapy for the treatment of Pertussis infections, more commonly known as whooping cough. We are developing a mAb therapy, SYN-005, designed to target and neutralize the pertussis toxin, in order to reduce the mortality rate in infants and potentially shorten the duration of chronic cough in afflicted adults. To further the development of this potential therapy for Pertussis, we entered into an agreement with The University of Texas at Austin to license the rights to certain research and pending patents related to pertussis antibodies. According to the World Health Organization, each year, *B. pertussis* infection causes an estimated 300,000 deaths worldwide, primarily among young, unvaccinated infants.

Acinetobacter infections: In September 2012, in collaboration with Intrexon, we initiated efforts to develop a mAb therapy for the treatment of *Acinetobacter* infections. Many strains of *Acinetobacter* are multidrug-resistant and pose an increasing global threat to hospitalized patients, wounded military personnel and those affected by natural disasters. A treatment for *Acinetobacter* infections represents a billion dollar market opportunity.

Summary of Multiple Sclerosis Program:

Trimesta<sup>TM</sup> (oral estriol) is being developed as an oral once-daily treatment for relapsing-remitting multiple sclerosis (MS) in women. Patient enrollment is complete in this two-year, randomized, double-blind, placebo-controlled Phase II clinical trial being conducted at 15 centers in the U.S. The primary endpoint is relapse rate at two years, with top-line results expected in 1H 2014. This trial is supported by grants exceeding \$8 million, which should be sufficient to fund the trial through completion. Annual worldwide sales of current MS therapies are estimated at \$14.1 billion.

Trimesta<sup>TM</sup> is also being developed for the treatment of cognitive dysfunction in female MS patients. This 12-month randomized, double-blind, placebo-controlled Phase II clinical trial is being conducted at the University of California, Los Angeles (UCLA). The primary endpoint is the effect on cognitive function as assessed by Paced Auditory Serial Addition Test (PASAT). Patient enrollment is ongoing. The majority of the costs of this trial are being funded by grants from foundations and charitable organizations and we have pledged approximately \$500,000 to UCLA to partially fund this trial payable over three years. An estimated 50-65% of MS patients are expected to develop disabilities due to cognitive dysfunction and there is currently no approved treatment.

## Summary of Fibromyalgia Program:

Effirma<sup>TM</sup> (flupirtine) is being developed for the treatment of fibromyalgia by Meda AB (Meda), a multi-billion dollar international pharmaceutical company. On May 6, 2010, we entered into a sublicense agreement with Meda covering all of our patents' rights on the use of flupirtine for fibromyalgia in the U.S., Canada and Japan. The sublicense agreement provides that all ongoing and future development costs are to borne by Meda and we are entitled to receive certain payments if milestones are achieved and royalties on sales. According to Meda's 2012 Year-End Report filed in February 2013, Meda has received the go-ahead from the FDA to conduct a Phase II proof of concept study for the treatment of fibromyalgia. Meda also announced that the randomized, double-blind, placebo and active-controlled study of patients with fibromyalgia will be conducted at 25 clinics in the U.S. Based on an estimated annual price of \$1,200 per fibromyalgia patient, we estimate that the total market potential in the U.S. is \$6 billion.

In order to further prioritize our focus, we have elected to discontinue further development of AEN-100 for the treatment of amyotrophic lateral sclerosis. However, we are currently seeking development partners for our zinc-based intellectual property and assets including, AEN-100.

#### Recent Developments

On December 19, 2012, we entered into a Patent License Agreement (the "License Agreement") with The University of Texas at Austin (the "University") for the exclusive license of the right to use, develop, manufacture, market and commercialize certain research and patents related to Pertussis (more commonly known as whooping cough) antibodies developed in the lab of Dr. Jennifer A. Maynard, Assistant Professor of Chemical Engineering. In connection with the License Agreement, we and the University also entered into a Sponsored Research Agreement pursuant to which the University will perform certain research work related to pertussis under the direction of Dr. Jennifer Maynard and we will obtain certain rights to patents and technology developed during the course of such research.

On November 28, 2012, a closing was held for the transaction contemplated by the Asset Purchase Agreement (the "Prev Agreement") we entered into with Prev ABR LLC ("Prev"), pursuant to which we acquired the *C. diff* program assets of Prev, including pre-Investigational New Drug (IND) package, Phase I and Phase II clinical data, manufacturing process data and all issued and pending U.S. and international patents. Pursuant to the Prev Agreement, we paid Prev an initial cash payment of \$100,000 upon execution of the Prev Agreement and at closing paid an additional cash payment of \$135,000 and issued 625,000 unregistered shares of our common stock to Prev. In addition, upon the achievement of the milestones set forth below, Prev may be entitled to receive additional consideration payable 50% in cash and 50% in our stock, subject to Prev's option to receive the entire payment in shares of our stock, with the exception of the first milestone payments to be paid in cash: (i) upon commencement of

an IND; (ii) upon commencement of a Phase I clinical trial; (iii) upon commencement of a Phase III clinical trial; (iv) upon Biologic License Application (BLA) filing in the U.S. and for territories outside of the U.S. (as defined in the Prev Agreement); and (vi) upon BLA approval in the U.S. and upon approval in territories outside the-U.S. The future stock issuances are subject to prior approval of the NYSE MKT, LLC. No royalties are payable to Prev under the Prev Agreement. The Prev Agreement also provides that Prev has a right to the return to it of all assets acquired by us under the Prev Agreement if on or prior to the date that is (i) thirty (30) months after the execution of the Prev Agreement, we have not initiated toxicology studies in non-rodent models or (ii) thirty six (36) months have not filed an IND under the program related to the assets and such failure is not due to action or inaction of Prev or breach of its representations or warranties or covenants or if there is a change of control as defined in the Prev Agreement and after such change of control the assets are not further developed; provided however that such thirty (30) and thirty six (36) month periods can be extended by us for an additional twelve (12) months upon payment of a cash milestone payment.

On October 30, 2012, we completed a private placement (the "October 2012 Private Placement") with certain accredited investors, pursuant to which we sold an aggregate of 6,750,000 shares of our common stock at a price per share of \$1.60 (the "Common Shares") for aggregate gross proceeds of \$10.8 million and net proceeds of \$10.1 million. In connection with the October 2012 Private Placement, we filed a registration statement with the SEC which was declared effective on December 20, 2012 for the resale of our common stock owned by certain of the purchasers in the October 2012 Private Placement. In connection with the October 2012 Private Placement, we also entered into an agreement with a certain purchaser that is an affiliate of Intrexon (the "Joinder Agreement") pursuant to which such purchaser agreed to be bound by the terms of and join Intrexon as a party to its registration rights agreement with us entered into in connection with the Second Channel Agreement(the "First Amendment to Registration Rights Agreement") and we registered the shares issued to such purchaser in accordance with the First Amendment to Registration Rights Agreement.

Griffin Securities, Inc. ("Griffin") served as the placement agent for the October 2012 Private Placement. In consideration for services rendered by Griffin in the October 2012 Private Placement, we (i) paid to Griffin cash commissions equal to 6.0% of the gross proceeds received in the October 2012 Private Placement, (ii) issued to Griffin, or its designee, warrants, which are five-year warrants to purchase 635,855 shares of our common stock with an exercise price of \$1.60 per share (the "Agent Warrants"); and (iii) reimbursed Griffin for its reasonable actual out-of-pocket expenses incurred in connection with the October 2012 Private Placement, including reasonable legal fees and disbursements. The common stock underlying the Agent Warrants was registered under the registration statement declared effective on December 20, 2012.

On August 6, 2012, we expanded our relationship with Intrexon and entered into a Second Channel Agreement with Intrexon (the "Second Channel Agreement") that governs an "exclusive channel collaboration" arrangement in which we 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 (the "Program"). The Second Channel Agreement establishes committees comprised of our 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. On October 16, 2012, a closing was held for the transaction contemplated by the Second Channel Agreement. Pursuant to the terms of a Stock Issuance Agreement with Intrexon (the "Second Stock Purchase Agreement"), we issued 3,552,210 shares of our common stock, \$0.001 par value, which issuance is also deemed paid in consideration for the execution and delivery of the Second Channel Agreement, dated August 6, 2012, between ourselves and Intrexon. We registered the shares issued to Intrexon in accordance with the First Amendment to Registration Rights Agreement.

On February 15, 2012, upon stockholder approval, we amended our Articles of Incorporation to change our name to Synthetic Biologics, Inc. Our common stock continues trade on the NYSE MKT (formerly the NYSE Amex and American Stock Exchange), under the symbol "SYN". Prior to this time and since October 16, 2008, our name was Adeona Pharmaceuticals, Inc. and we traded on the NYSE MKT stock exchange under the symbol "AEN". We are incorporated in the State of Nevada.

On December 21, 2011, we announced that the Board of Directors had taken several actions to prioritize our focus on our entry into the emerging field of synthetic biology. In connection with the change in business focus on March 8, 2012, we entered into a Membership Interest Purchase Agreement, and certain related agreements, pursuant to which we sold all of our interest in the Adeona Clinical Laboratory (the "Lab") to Hartlab, LLC, an entity controlled by the Lab's former owner, in consideration for (i) the immediate assignment of the Lab's outstanding accounts receivable up through the date of closing, plus (ii) Seven Hundred Thousand Dollars (\$700,000) payable pursuant to the terms of a two-year non-recourse promissory note secured by all of the assets of the Lab.

On November 18, 2011, we entered into a Stock Purchase Agreement with Intrexon pursuant to which we issued to Intrexon 3,123,558 shares of our common stock at a purchase price equal to the \$0.001 par value of such shares, which issuance was deemed paid in consideration for the execution and delivery of the channel agreement which was entered into on November 18, 2011 and terminated on April 16, 2013. We also agreed to an equity participation right in future securities offerings.

## **Company Information**

Our predecessor, Sheffield Pharmaceuticals, Inc. was incorporated in 1986, and in 2006 engaged in a reverse merger with Pipex Therapeutics, Inc., a Delaware corporation formed in 2001. After the merger, we changed our name to Pipex Pharmaceuticals, Inc., and in October 2008 we changed our name to Adeona Pharmaceuticals, Inc. On October 15, 2009, we reincorporated in the State of Nevada. After reprioritizing our focus on the emerging area of synthetic biologics and entering into our first collaboration with Intrexon, we amended our Articles of Incorporation to change our name to Synthetic Biologics, Inc. on February 15, 2012.

Our principal executive offices are located at 155 Gibbs Street, Suite 412, Rockville, Maryland 20850. We also maintain an administrative and finance office in Ann Arbor, Michigan.

#### THE OFFERING

| Commo   | n stock |
|---------|---------|
| offered | by us   |

Shares of our common stock having an aggregate offering price of up to \$15,000,000.

## Common stock to be outstanding after this offering

Up to 53,636,449 shares (as more fully described in the notes following this table), assuming sales of 8,982,035 shares of our common stock in this offering at an offering price of \$1.67 per share, which was the last reported sale price of our common stock on the NYSE MKT on July 1, 2013. The actual number of shares issued will vary depending on the sales price under this offering.

# Manner of offering

"At-the-market" offering that may be made from time to time through our sales agent, Cantor

Fitzgerald & Co. See "Plan of Distribution" on page S-8.

Use of proceeds

We intend to use the net proceeds from this offering, if any, for general corporate purposes, which may include, among other things, increasing our working capital and funding research and development, and capital expenditures. In addition, we may use a portion of the net proceeds for licensing or acquiring intellectual property to incorporate into our products and product candidates or our research and development programs, and to fund possible investments in and acquisitions of complementary businesses or partnerships. See "Use of Proceeds" on page S-7.

Risk factors

You should read the "Risk Factors" section of this prospectus and in the documents incorporated by reference in this prospectus for a discussion of factors to consider before deciding to purchase shares of our common stock.

NYSE MKT symbol

SYN

The number of shares of common stock shown above to be outstanding after this offering is based on 44,654,414 shares outstanding as of July 1, 2013, and excludes:

- 3,860,136 shares of our common stock issuable upon exercise of outstanding options under our equity incentive plans, at a weighted-average exercise price of \$1.79 per share; and
- 1,632,501 shares of our common stock reserved for issuance upon the exercise of outstanding warrants, each with a weighted-average exercise price of \$1.99 per share.

Unless otherwise stated, all information contained in this prospectus reflects an assumed public offering price of \$1.67 per share, which was the last reported sale price of our common stock on the NYSE MKT on July 1, 2013.

#### **RISK FACTORS**

You should consider carefully the risks described below and discussed under the section captioned "Risk Factors" contained in our annual report on Form 10-K for the year ended December 31, 2012 and in our subsequent quarterly reports on Form 10-Q as updated by our subsequent filings under the Securities Exchange Act of 1934, as amended, or the Exchange Act, each of which is incorporated by reference in this prospectus in their entirety, together with other information in this prospectus, and the information and documents incorporated by reference in this prospectus, and any free writing prospectus that we have authorized for use in connection with this offering before you make a decision to invest in our common stock. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. The risks below are not the only ones we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business operations.

## **Additional Risks Relating To The Offering**

Our management team may invest or spend the proceeds of this offering in ways with which you may not agree or in ways which may not yield a significant return.

Our management will have broad discretion over the use of proceeds from this offering. The net proceeds from this offering will be used for general corporate purposes, which may include, among other things, increasing our working capital and funding research and development, and capital expenditures. In addition, we may use a portion of the net proceeds for licensing or acquiring intellectual property to incorporate into our products and product candidates or our research and development programs, and to fund possible investments in and acquisitions of complementary businesses or partnerships. Our management will have considerable discretion in the application of the net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. The net proceeds may be used for corporate purposes that do not increase our operating results or enhance the value of our common stock.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in this offering. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future

could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in this offering.

We do not intend to pay dividends in the foreseeable future.

We have never paid cash dividends on our common stock. We currently intend to retain our future earnings, if any, to finance the operation and growth of our business and currently do not plan to pay any cash dividends in the foreseeable future. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if the market price of our common stock price appreciates.

Resales of our common stock in the public market during this offering by our stockholders may cause the market price of our common stock to fall.

We may issue common stock from time to time in connection with this offering. This issuance from time to time of these new shares of our common stock, or our ability to issue these shares of common stock in this offering, could result in resales of our common stock by our current stockholders concerned about the potential dilution of their holdings. In turn, these resales could have the effect of depressing the market price for our common stock.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the documents incorporated by reference in it, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934 as amended, or the Exchange Act. These statements may be made directly in this document or they may be made part of this document by reference to other documents filed with the SEC, which is known as "incorporation by reference." You can find many (but not all) of these statements by looking for words such as "approximates," "expects," "anticipates," "estimates," "plans," "would," "could," "may" or other similar in this prospectus or the documents incorporated by reference.

We caution investors that any forward-looking statements presented in this prospectus or the documents incorporated by reference, or those which we may make orally or in writing from time to time, are based on our beliefs and assumptions, as well as information currently available to us. Such statements are based on assumptions and the actual outcome will be affected by known and unknown risks, trends, uncertainties and factors that are beyond our control or ability to predict. Although we believe that our assumptions are reasonable, they are not guarantees of future performance and some will inevitably prove to be incorrect. As a result, our actual future results can be expected to

differ from our expectations, and those differences may be material. Accordingly, investors should use caution in relying on past forward-looking statements, which are based on known results and trends at the time they are made, to anticipate future results or trends.

Some of the risks and uncertainties that may cause our actual results, performance or achievements to differ materially from those expressed or implied by forward-looking statements include the following:

Some of the risks and uncertainties that may cause our actual results, performance or achievements to differ materially from those expressed or implied by forward-looking statements include the following:

- a failure to continue to undertake preclinical development and clinical trials for our product candidates;
- a failure to expand our research activities with Intrexon relating to monoclonal antibodies for infectious diseases;
- a failure of our product candidates to be demonstrably safe and effective;
- a failure to obtain regulatory approval for our products or to comply with ongoing regulatory requirements;
- a lack of acceptance of our product candidates in the marketplace;
- a failure by us to become or remain profitable;
- an inability by us to obtain the capital necessary to fund our research and development activities; and
- a loss of any of our key scientists or management personnel.

This prospectus and all subsequent written and oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We do not undertake any obligation to release publicly any revisions to our forward-looking statements to reflect events or circumstances after the dates that such statements are made.

For more information on the uncertainty of forward-looking statements, see "Risk Factors" in our Annual Reports on Form 10-K and our Quarterly Reports on Form 10-Q and any applicable prospectus supplement.

## **USE OF PROCEEDS**

The amount of proceeds from this offering will depend upon the number of shares of our common stock sold and the market price at which they are sold. There can be no assurance that we will be able to sell any shares under or fully utilize the sales agreement with Cantor as a source of financing. We intend to use the net proceeds, if any, from this offering for general corporate purposes, which may include, among other things, increasing our working capital and funding research and development, and capital expenditures. In addition, we may use a portion of the net proceeds for licensing or acquiring intellectual property to incorporate into our products and product candidates or our research and development programs. We may also use a portion of the net proceeds to in-license, acquire or invest in complementary businesses or products; however, we have no current commitments or obligations to do so.

The amounts and timing of our actual expenditures will depend on numerous factors, including our development and commercialization efforts, as well as the amount of cash used in our operations. We therefore cannot estimate with certainty the amount of net proceeds to be used for the purposes described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds. Pending the uses described above, we plan to invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities.

#### **DILUTION**

If you invest in our common stock, your interest will be diluted immediately to the extent of the difference between the public offering price and the adjusted net tangible book value per share of our common stock after this offering.

Our net tangible book value on March 31, 2013 was approximately \$11.5 million, or \$0.26 per share. "Net tangible book value" is total assets minus the sum of liabilities and intangible assets. "Net tangible book value per share" is net tangible book value divided by the total number of shares outstanding.

After giving effect to the sale of \$15 million of common stock in this offering at an assumed offering price of \$1.67 per share, which was the closing price of our common stock as reported on NYSE MKT on July 1, 2013, and after deducting estimated offering commissions and expenses payable by us, our net tangible book value as of March 31, 2013 would have been approximately \$25.9 million, or \$0.48 per share of common stock. This represents an immediate increase in net tangible book value of \$0.22 per share to our existing stockholders and an immediate dilution in net tangible book value of \$0.48 per share to investors participating in this offering. The following table illustrates this dilution per share to investors participating in this offering:

| Assumed offering price per share  |        | \$1.67 |
|---|--------|--------|
| Net tangible book value per share as of March 31, 2013                                  | \$0.26 |        |
| Increase in net tangible book value per share attributable to new investors in offering | \$0.22 |        |
| Pro forma net tangible book value per share after giving effect to the offering         | \$0.48 |        |
| Dilution per share to new investors   |        | \$1.19 |

The above illustration of dilution per share to investors participating in this offering assumes no exercise of outstanding options to purchase our common stock or outstanding warrants to purchase shares of our common stock.

The above discussion and table are based on shares of our common stock issued and outstanding as of March 31, 2013, which does not include the following, all as of March 31, 2013:

4,221,247 shares issuable upon the exercise of outstanding stock options with a weighted-average exercise price of \$1.82 per share; and

1,632,501 shares of our common stock reserved for issuance upon the exercise of outstanding warrants, each with a weighted-average exercise price of \$1.99 per share.

To the extent that any of these outstanding options are exercised, there will be further dilution to new investors.

## PLAN OF DISTRIBUTION

We have entered into a Controlled Equity Offering<sup>SM</sup> sales agreement with Cantor under which we may issue and sell shares of our common stock having an aggregate gross sales price of up to \$15,000,000 from time to time through Cantor acting as agent. The sales agreement has been filed as an exhibit to our registration statement on Form S-3 of which this prospectus forms a part.

Upon delivery of a placement notice and subject to the terms and conditions of the sales agreement, Cantor may sell our common stock by any method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act, including sales made directly on the NYSE MKT, on any other existing trading market for our common stock or to or through a market maker. Cantor may also sell our common stock by any other method permitted by law, including in privately negotiated transactions. We may instruct Cantor not to sell common stock if the sales cannot be effected at or above the price designated by us from time to time. We or Cantor may suspend the offering of common stock upon notice and subject to other conditions.

We will pay Cantor commissions, in cash, for its services in acting as agent in the sale of our common stock. Cantor will be entitled to compensation at a fixed commission rate of 3.0% of the gross sales price per share sold. Because there is no minimum offering amount required as a condition to close this offering, the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time. We have also agreed to reimburse Cantor for certain specified expenses, including the fees and disbursements of its legal counsel in an amount not to exceed \$50,000. We estimate that the total expenses for the offering, excluding compensation and reimbursements payable to Cantor under the terms of the sales agreement, will be approximately \$100,000.

Settlement for sales of common stock will occur on the third business day following the date on which any sales are made, or on some other date that is agreed upon by us and Cantor in connection with a particular transaction, in return for payment of the net proceeds to us. Sales of our common stock as contemplated in this prospectus will be settled through the facilities of The Depository Trust Company or by such other means as we and Cantor may agree upon. There is no arrangement for funds to be received in an escrow, trust or similar arrangement.

Cantor will use its commercially reasonable efforts, consistent with its sales and trading practices, to solicit offers to purchase the common stock shares under the terms and subject to the conditions set forth in the sales agreement. In connection with the sale of the common stock on our behalf, Cantor will be deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of Cantor will be deemed to be underwriting commissions or discounts. We have agreed to provide indemnification and contribution to Cantor against certain civil liabilities, including liabilities under the Securities Act.

The offering of our common stock pursuant to the sales agreement will terminate upon the earlier of (i) the sale of all shares of our common stock subject to the sales agreement, or (ii) termination of the sales agreement as permitted therein. We and Cantor may each terminate the sales agreement at any time upon ten days' prior notice.

Cantor and its affiliates may in the future provide various investment banking, commercial banking and other financial services for us and our affiliates, for which services they may in the future receive customary fees. To the extent required by Regulation M, Cantor will not engage in any market making activities involving our common stock while the offering is ongoing under this prospectus.

This prospectus in electronic format may be made available on a website maintained by Cantor and Cantor may distribute this prospectus electronically.

#### **LEGAL MATTERS**

Parsons Behle & Latimer, Reno, Nevada will pass upon certain legal matters relating to the issuance and sale of the common stock offered hereby on behalf of Synthetic Biologics, Inc. Cantor is being represented in connection with this offering by Reed Smith LLP, New York, New York.

#### **EXPERTS**

The financial statements as of December 31, 2012 and for the year ended December 31, 2012 incorporated by reference in this prospectus have been so incorporated in reliance on the report of BDO USA, LLP, an independent registered public accounting firm, incorporated herein by reference, given on authority of said firm as experts in auditing and accounting.

The financial statements as of December 31, 2011 and for the year ended December 31, 2011 incorporated by reference in this prospectus have been so incorporated in reliance on the report of Berman & Company, P.A. an independent registered public accounting firm, incorporated herein by reference, given on authority of said firm as experts in auditing and accounting.

#### WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-3 under the Securities Act, of which this prospectus forms a part. The rules and regulations of the SEC allow us to omit from this prospectus certain information included in the registration statement. For further information about us and the securities we are offering under this prospectus, you should refer to the registration statement and the exhibits and schedules filed with the registration statement. With respect to the statements contained in this prospectus regarding the contents of any agreement or any other document, in each instance, the statement is qualified in all respects by the complete text of the agreement or document, a copy of which has been filed as an exhibit to the registration statement.

We file reports, proxy statements and other information with the SEC under the Exchange Act. You may read and copy this information from the Public Reference Room of the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, at prescribed rates. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is <a href="https://www.sec.gov">www.sec.gov</a>.

## INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" the information we file with it which means that we can disclose important information to you by referring you to those documents instead of having to repeat the information in this prospectus. The information incorporated by reference is considered to be part of this prospectus, and later information that we file with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act between the date of this prospectus and the termination of the offering however, we are not incorporating by reference any documents or portions thereof, whether specifically listed below or filed in the future, that are not deemed "filed" with the SEC, or any information furnished pursuant to Items 2.02 or 7.01 of Form 8-K or related exhibits furnished pursuant to Item 9.01 of Form 8-K:

Our annual report on Form 10-K for the fiscal year ended December 31, 2012 filed with the SEC on April 16, 2013;

Our quarterly report on Form 10-Q for the quarter ended March 31, 2013 filed with the SEC on May 15, 2013;

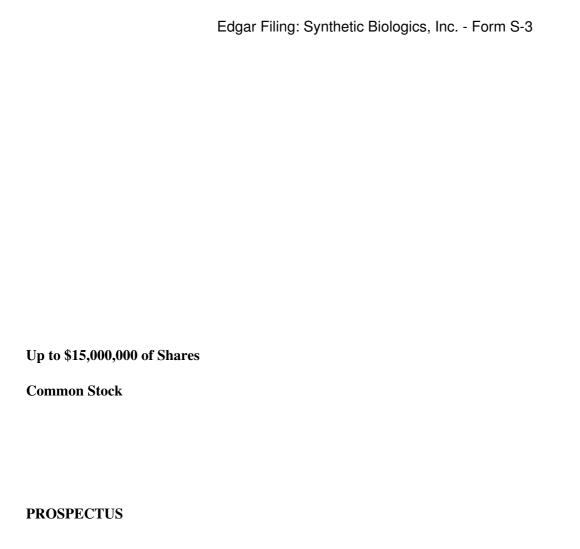
Our current report on Form 8-K filed with the SEC on April 19, 2013; and

The description of our common stock set forth in our registration statement on Form 8-A12B, filed with the SEC on June 20, 2007 (File No. 000-12584).

You may obtain, free of charge, a copy of any of these documents (other than exhibits to these documents unless the exhibits are specifically incorporated by reference into these documents or referred to in this prospectus) by writing or calling us at the following address and telephone number:

155 Gibbs Street, Ste. 412 Rockville, Maryland 20850

(734) 332-7800



, 2013

#### **PART II**

## INFORMATION NOT REQUIRED IN PROSPECTUS

## Item 14. Other Expenses of Issuance and Distribution

The following is an estimate of the expenses (all of which are to be paid by the registrant) that we may incur in connection with the securities being registered hereby.

| SEC registration fee         | \$6,820 |
|------------------------------|---------|
| FINRA fee                    | \$8,000 |
| Legal fees and expenses      | \$(1)   |
| Printing expenses            | \$(1)   |
| Accounting fees and expenses | \$(1)   |
| Miscellaneous                | \$(1)   |
|                              |         |
| Total                        | \$(1)   |

(1) These fees are calculated based on the securities offered and the number of issuances and accordingly cannot be estimated at this time.

## Item 15. Indemnification of Directors and Officers.

Section 78.138 of the Nevada Revised Statute provides that a director or officer is not individually liable to the corporation or its stockholders or creditors for any damages as a result of any act or failure to act in his capacity as a director or officer unless it is proven that (1) his act or failure to act constituted a breach of his fiduciary duties as a director or officer and (2) his breach of those duties involved intentional misconduct, fraud or a knowing violation of law.

This provision is intended to afford directors and officers protection against and to limit their potential liability for monetary damages resulting from suits alleging a breach of the duty of care by a director or officer. As a consequence of this provision, stockholders of our company will be unable to recover monetary damages against directors or officers for action taken by them that may constitute negligence or gross negligence in performance of their duties unless such conduct falls within one of the foregoing exceptions. The provision, however, does not alter the applicable standards governing a director's or officer's fiduciary duty and does not eliminate or limit the right of our company or any stockholder to obtain an injunction or any other type of non-monetary relief in the event of a breach of fiduciary duty.

The Registrant's Articles of Incorporation, as amended, and amended and restated bylaws provide for indemnification of directors, officers, employees or agents of the Registrant to the fullest extent permitted by Nevada law (as amended from time to time). Section 78.7502 of the Nevada Revised Statute provides that such indemnification may only be provided if the person acted in good faith and in a manner he reasonably believed to be in, or not opposed to, the best interest of the Registrant and, with respect to any criminal action or proceeding, had no reasonable cause to behave his conduct was unlawful.

## Item 16. Exhibits.

- 1.1#Form of Underwriting Agreement
- 1.2\* Sales Agreement, dated July 3, 2013, by and between Synthetic Biologics, Inc. and Cantor Fitzgerald & Co.
- Certificate of Incorporation, as amended (Incorporated by reference to (i) Exhibit 3.1 of the Registrant's Current
  Report on Form 8-K filed October 16, 2008; (ii) Exhibit 3.1 of the Registrant's Quarterly Report on Form 10-Q for
  the quarterly period ended June 30, 2001 filed August 14, 2001; and (iii) Exhibits 3.1, 4.1 and 4.2 of the
  Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 1998 filed August 14, 1998.)
- Articles of Merger (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 19, 2009.)
- Certificate of Merger filed with the Secretary of State of Delaware (Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed October 19, 2009.)
- Articles of Incorporation filed with the Nevada Secretary of State (Incorporated by reference to Exhibit 3.3 of the Registrant's Current Report on Form 8-K filed October 19, 2009.)

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- Bylaws (Incorporated by reference to (i) Exhibit 3.4 of the Registrant's Current Report on Form 8-K filed October 19, 2009 and (ii) Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed June 3, 2010.)
- Amended and Restated Bylaws Adopted and Effective October 31, 2011 (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed November 2, 2011.)
- Certificate of Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed February 16, 2012.)
- 4.1\* Specimen stock certificate evidencing the shares of common stock.

Form of Warrant

- 4.2#
- 4.3# Form of Warrant Agreement
- 4.4# Form of Unit
- 4.5# Form of Unit Agreement
- 5.1(a)\* Legal opinion of Gracin & Marlow, LLP
- 5.1(b)\*Legal opinion of Parsons Behle & Latimer
- 23.1\* Consent of Independent Registered Public Accounting Firm -BDO USA, LLP
- 23.2\* Consent of Independent Registered Public Accounting Firm -Berman & Company, P.A.
- 23.3 Consent of Gracin & Marlow, LLP (included in Exhibit 5.1(a))
- 23.4 Consent of Parsons Behle & Latimer (included in Exhibit 5.1(b))
- 24.1\* Powers of Attorney for our directors (included on signature page)
- \* Filed herewith

#To be filed by amendment or incorporated by reference in connection with the offering of the securities.

#### Item 17. Undertakings

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement: (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933; (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; provided, however, that paragraphs (a)(1)(i), (a)(1)(ii), and (a)(1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is a part of the registration statement. (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

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| (5) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:  |
|--|
| (A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and   |
| (B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. <i>Provided</i> , <i>however</i> , that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date. |
| (6) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of securities:  |
| The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:   |
| (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;   |
| (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;   |

- (iii) The portion of any other free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
- (iv) Any other communications that is an offer in the offering made by the undersigned registrant to the purchaser.
- (b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- (h) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

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#### **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Rockville, State of Maryland, July 3, 2013.

SYNTHETIC BIOLOGICS, INC.

By: /s/ Jeffrey Riley

Chief Executive Officer,

President and Director (Principal Executive Officer)

By: /s/ C. Evan Ballantyne

Chief Financial Officer

(Principal Financial and

Accounting Officer)

#### POWER OF ATTORNEY

We, the undersigned hereby severally constitute and appoint each of Jeffrey Riley and C. Evan Ballantyne our true and lawful attorney and agent, with full power to each to sign for us, and in our names in the capacities indicated below, any and all amendments to this registration statement, any subsequent registration statements pursuant to Rule 462 of the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof. This power of attorney may be executed in counterparts.

Pursuant to the requirements of the Securities Act 1933, this report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

| /s/ Jeffrey Riley Jeffrey Riley              | Chief Executive Officer, President and Director (Principal Executive Officer) | July 3, 2013 |
|--|---|--------------|
| /s/ C. Evan Ballantyne<br>C. Evan Ballantyne | Chief Financial Officer and<br>(Principal Financial and Accounting Officer)   | July 3, 2013 |
| /s/ Jeffrey J. Kraws Jeffrey J. Kraws        | Chairman  | July 3, 2013 |
| /s/ Steve H. Kanzer<br>Steve H. Kanzer       | Director  | July 3, 2013 |
| /s/ Scott L. Tarriff Scott L. Tarriff        | Director  | July 3, 2013 |
| /s/ Jeffrey Wolf Jeffrey Wolf                | Director  | July 3, 2013 |

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