



Edgar Filing: Synthetic Biologics, Inc. - Form S-3

(Mailing Address and Zip Code of Administrative Offices)

**Jeffrey Riley**

**Chief Executive Officer and President**

**Synthetic Biologics, Inc.**

**9605 Medical Center Drive, Suite 270  
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**

Approximate date of commencement of proposed sale to the public: 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.

Edgar Filing: Synthetic Biologics, Inc. - Form S-3

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

**CALCULATION OF REGISTRATION FEE**

<b>Title of each class of securities to be registered</b>	<b>Amount to be registered/proposed maximum offering price per unit/proposed maximum aggregate offering price</b>	<b>Amount of registration fee (1)</b>
Common Stock, par value \$0.001 per share		(2)(3) —
Warrants		(2) —
Units		(2) —
<b>Total</b>	<b>\$ 200,000,000</b>	<b>(4) \$ 23,240 (5)</b>

Pursuant to Rule 415(a)(6) under the Securities Act of 1933, as amended (the “Securities Act”), the securities registered pursuant to this Registration Statement include unsold securities previously registered by the Registrant on the Registrant’s Registration Statement (File No. 333-203322), filed on April 10, 2015 and declared effective on April 20, 2015 (the “Prior Registration Statement”). The Prior Registration Statement registered the offer and sale of an indeterminate number of shares of common stock, warrants to purchase common stock, and units consisting of a combination of shares of common stock and warrants (collectively, the “Shelf Securities”) having an aggregate initial offering price not to exceed \$100,000,000, of which \$54,000,001 of Shelf Securities remain unsold (the “Unsold Securities”) as the date of filing of this Registration Statement. The Registrant has determined to include in this Registration Statement the Unsold Securities. Pursuant to Rule 415(a)(6) under the Securities Act, the filing fee of \$6,275 relating to the Unsold Securities under the Prior Registration Statement, which was paid or was deemed to

- (1) have been paid under the Prior Registration Statement, will continue to be applied to the Unsold Securities registered pursuant to this Registration Statement. The Registrant is also registering new securities on this registration statement with an aggregate initial offering price of \$145,999,999 (the “New Securities”), which aggregate offering price is not specified as to each class of security (see footnote (4)). To the extent that, after the filing date hereof and prior to the effectiveness of this Registration Statement, the Registrant sells any Unsold Securities pursuant to the Prior Registration Statement, the Registrant will identify in a pre-effective amendment to this Registration Statement the updated amount of Unsold Securities from the Prior Registration Statement to be included in this Registration Statement pursuant to Rule 415(a)(6) and the updated amount of New Securities to be registered on this Registration Statement. Pursuant to Rule 415(a)(6) under the Securities Act, the offering of the Unsold Securities under the Prior Registration Statement will be deemed terminated as of the date of effectiveness of this Registration Statement.
- (2) 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.
- (3) Includes rights to acquire common stock of the Registrant 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
- (4) Registrant in connection with the issuance by the Registrant of the securities registered hereunder and is not specified as to each class of security pursuant to General Instruction II.D. of Form S-3 under the Securities Act.
- (5) The registration fee has been calculated in accordance with Rule 457(o) under the Securities Act. The filing fee of \$6,275 relating to the Unsold Securities under the Prior Registration Statement, which was paid or deemed to have been paid under the Prior Registration Statement, will continue to be applied to the Unsold Securities registered pursuant to this Registration Statement. A filing fee of \$16,965 with respect to the New Securities is being paid in

connection with the filing of this Registration Statement. See footnote (2) above.

**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 Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

**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 August 10, 2015.**

## **PROSPECTUS**

**\$200,000,000**

**Common Stock**

**Warrants**

**Units**

We may offer and sell up to \$200 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 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 5 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 traded on NYSE MKT under the symbol "SYN". On August 6, 2015, the last reported sale price for the common stock was \$3.10 per share. We urge prospective purchasers of our common stock to obtain current information about the market prices of our common stock.

Our executive offices are located at 9605 Medical Center Drive, Suite 270, Rockville, Maryland 20850 and our administrative offices are located at 617 Detroit Street, Suite 100, Ann Arbor, Michigan 48104. Our telephone number is (734) 332-7800.

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

The date of this prospectus is \_\_\_\_\_, 2015.

## TABLE OF CONTENTS

	Page
<u>About this Prospectus</u>	1
<u>Prospectus Summary</u>	2
<u>Risk Factors</u>	5
<u>Special Note Regarding Forward-Looking Statements</u>	5
<u>Use of Proceeds</u>	5
<u>Dividend Policy</u>	5
<u>Description of Capital Stock</u>	6
<u>Description of Warrants</u>	6
<u>Description of Units</u>	8
<u>Plan of Distribution</u>	8
<u>Legal Matters</u>	9
<u>Experts</u>	10
<u>Where You Can Find More Information</u>	10
<u>Incorporation of Certain Documents by Reference</u>	10
<u>Disclosure of the Securities and Exchange Commission Position on Indemnification for Securities Act Liabilities</u>	10

**The registration statement containing this prospectus, including the exhibits to the registration statement, provides additional information about us and the common stock offered under this prospectus. 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 not an offer or solicitation in respect to these securities in any jurisdiction in which such offer or solicitation would be unlawful. This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission (the “SEC”). The registration statement that contains this prospectus (including the exhibits to the registration statement) contains additional information about our company and the securities offered under this prospectus. That registration statement can be read at the SEC website or at the SEC’s offices listed under the heading “Where You Can Find More Information.” We have not authorized anyone else to provide you with different information or additional information. You should not assume that the information in this prospectus, or any supplement or amendment to this prospectus, is accurate at any date other than the date indicated on the cover page of such documents.

## PROSPECTUS SUMMARY

### Our Business

We are a clinical-stage company developing therapeutics to protect the microbiome while targeting pathogen-specific diseases. Our lead candidates in Phase 2 development include SYN-004 which is designed to protect the gut microbiome (gastrointestinal (GI) microflora) from the effects of certain commonly used intravenous (IV) antibiotics for the prevention of *C. difficile* infection and antibiotic-associated diarrhea (AAD), and SYN-010 which is intended to reduce the impact of methane-producing organisms in the gut microbiome to treat the underlying cause of irritable bowel syndrome with constipation (IBS-C). In addition, we are developing a Phase 2 oral estriol drug, Trimesta™, for the treatment of relapsing-remitting multiple sclerosis (MS) and cognitive dysfunction in MS, and in collaboration with Intrexon Corporation (NYSE:XON), a preclinical stage monoclonal antibody combination for the treatment of Pertussis, and novel discovery stage biotherapeutics for the treatment of phenylketonuria (PKU).

### *Product Pipeline:*

### *Summary of Microbiome Programs:*

***C. difficile* infections (CDI):** We are in clinical development of a novel second-generation oral enzyme, SYN-004, to degrade commonly used IV beta-lactam antibiotics in the GI tract, intended to protect the microbiome and prevent the development of and severe effects from CDI and AAD. CDIs are a leading type of hospital acquired infection (HAI) and are frequently associated with IV antibiotic treatment. Designed to be given orally and co-administered with certain IV beta-lactam antibiotics (e.g., penicillins and cephalosporins), SYN-004 is intended to protect the gut while the IV antibiotics fight the primary infection. SYN-004 is believed to not only have a similar profile to its first-generation predecessor, which demonstrated protection of the microbiome (gut flora) during treatment with certain penicillins, but also has the potential to protect the gut from a broader spectrum of IV beta-lactam antibiotics. Beta-lactam antibiotics are a mainstay in hospital infection management and include the commonly used penicillin and cephalosporin classes of antibiotics. SYN-004's target market is significant and represented by annual U.S. hospitals purchases of approximately 118 million doses of IV beta-lactam antibiotics which are administered to approximately 14 million patients.\* Currently there are no approved treatments designed to protect the gut microbiome from the damaging effects of IV antibiotics. This worldwide market could represent a multi-billion dollar opportunity for us. In November 2014, the U.S. Patent and Trademark Office (USPTO) issued Patent No. 8,894,994 that has claims to compositions of matter and pharmaceutical compositions of beta-lactamases, including

SYN-004, and carries a patent term to at least 2031. We also have an extensive patent estate on other aspects of this program which includes patent applications that could carry a term to at least 2035. In the fourth quarter of 2014, we initiated our randomized, double-blind placebo-controlled Phase 1a clinical trial, reported positive topline safety and tolerability results from the Phase 1a clinical trial, and initiated the Phase 1b clinical trial evaluating multiple ascending doses of SYN-004. In February 2015, we reported positive topline results from the Phase 1b clinical trial of escalating doses of oral SYN-004, with no safety or tolerability issues reported at dose levels and dose regimens both meeting and exceeding those expected to be studied in upcoming clinical trials. In March 2015, we reported positive pharmacokinetics data from both Phase 1 clinical trials, with supportive evidence that SYN-004 should have no effect on the IV antibiotic in the bloodstream, allowing the antibiotic to fight the primary infection. In March 2015, we also initiated a Phase 2a clinical trial to evaluate the GI antibiotic-degrading effects and the safety of SYN-004. In June 2015, the first participant was dosed in a second Phase 2a clinical trial of SYN-004, to evaluate the GI antibiotic-degrading effects and the safety of SYN-004, in the presence of the proton pump inhibitor (PPI), esomeprazole. Topline data is expected from the first Phase 2a clinical trial during the third quarter of 2015, and from the second Phase 2a clinical trial during the second half of 2015. In July 2015, we reported data from the first four of 12 expected participants in the first Phase 2a open-label clinical trial; the data showed that SYN-004 degraded IV ceftriaxone in the chyme of the four healthy participants with functioning ileostomies without affecting the ceftriaxone in the bloodstream. The initiation of a Phase 2b proof-of-concept clinical trial of SYN-004 is expected in the third quarter of 2015. This randomized, placebo-controlled clinical trial is expected to enroll approximately 370 patients at up to 75 global clinical sites. An interim analysis of blinded data from the Phase 2b clinical trial is anticipated during the second half of 2015. The initiation of pivotal Phase 3 clinical trial(s) are anticipated during 2016.

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.

**IBS-C:** In December 2013, through our majority-owned subsidiary, Synthetic Biomics, Inc., we entered into a worldwide exclusive license agreement with Cedars-Sinai Medical Center (CSMC) for the right to develop products for therapeutic and prophylactic treatments of acute and chronic diseases, including the development of SYN-010 to target IBS-C. SYN-010 is our proprietary modified-release formulation of the classic statin, lovastatin, that is intended to reduce methane-production by certain microorganisms (*M. smithii*) in the gut while minimizing disruption to the microbiome. SYN-010 is intended to act primarily in the intestinal lumen while avoiding systemic absorption, thereby targeting the cause of IBS-C, not just the symptoms. An investigational team led by Mark Pimentel, M.D. at CSMC discovered that lovastatin may reduce the production of methane gas by certain gastrointestinal (GI) microorganisms. Methane produced by these organisms is perceived as an underlying cause of pain, bloating, and constipation associated with IBS-C, and may contribute to the pathology of other diseases. In May 2015, preclinical results were presented in a poster at Digestive Disease Week® (DDW) 2015 demonstrating that lovastatin prevented proliferation of methanogens in the small intestines of rats with minimal impact on remaining microbiome. In his practice, Dr. Pimentel translated the use of statins to reduce methane in humans by evaluating commercial lovastatin formulations in select IBS-C patients, demonstrating that lovastatin prevented methane production by methanogens in human stool. Using stringent disease diagnosis criteria to ensure market relevance and a population most likely to receive a diagnosis and prescription drug treatment, there are an estimated 40.7 million cases of IBS reported in the U.S., Europe and Japan, and it has been reported that up to 20 percent of all IBS patients have IBS-C. The estimated global sales for IBS therapeutics for 2015 are \$669.3 million, and global sales are expected to be greater than \$1.5 billion in 2023\*. A 505(b)(2) regulatory pathway is anticipated for the development of SYN-010. We licensed an intellectual property portfolio from CSMC including granted use patents and pending patent applications for SYN-010. Additional worldwide patent filings having composition of matter claims, which were recently filed by CSMC and licensed to us, could extend patent protection of SYN-010 to 2035. Our Investigational New Drug (IND) application was submitted to the U.S. Food and Drug Administration (FDA) in May 2015. In June 2015, we initiated our first Phase 2 placebo-controlled clinical trial of SYN-010. This clinical trial is expected to enroll approximately 60 patients who will be randomly assigned in a 1:1:1 ratio to one of three groups, including two different SYN-010 dose groups and a placebo group. Patients are scheduled to receive single oral doses of SYN-010 each day for 28 days. The primary objective of this clinical trial is to evaluate the change from baseline in breath methane, as determined by a lactulose breath test, in methane-positive patients with IBS-C after seven days of treatment with one of two formulations of SYN-010 compared with placebo. Secondary endpoints include improvement in the number of complete spontaneous bowel movements (CSBM) per week, and improvement in abdominal pain and bloating per standard scales required per FDA guidance. We anticipate reporting topline results from the first Phase 2 clinical trial during the second half of 2015. We also anticipate initiating the second SYN-010 Phase 2 clinical trial during the second half of 2015, with topline results from this trial expected during the first half of 2016. The primary endpoint of the second Phase 2 is to evaluate the ability of SYN-010 to sustain the reduction in breath methane levels, and secondary endpoints include evaluating pain, bloating and CSBM. The initiation of pivotal Phase 3 clinical trial(s) are anticipated during 2016.

\*GlobalData, Irritable Bowel Syndrome - Global Drug Forecast and Market Analysis to 2023, December 2014

*Summary of Multiple Sclerosis Program:*

**Relapsing-Remitting MS:** We have licensed issued method of treatment patents in the U.S. for MS therapy with estriol and estriol combination therapies (including estriol with Copaxone<sup>®</sup>) from University of California, Los Angeles (UCLA). In April 2014, positive Phase 2 topline efficacy and safety results was presented by the lead principal investigator of the UCLA Phase 2 investigator initiated randomized (n=158) double-blinded placebo trial which evaluated our drug candidate, Trimesta, in woman with relapsing remitting MS at 16 sites in the U.S. In September 2014, the lead principal investigator presented additional Phase 2 clinical outcome data, including more detailed results on improvements in cognitive and disability measures, at the 2014 Joint Americas and European Committees for Treatment and Research in Multiple Sclerosis Meeting (ACTRIMS-ECTRIMS) in Boston. The data as reported by the lead principal investigator for the UCLA-led Phase 2 study supported the potential of Trimesta to have a novel dual mechanism of action for both the anti-inflammatory effects that improve relapse rate, and a neuroprotective effect that improves standard measures of disability and cognition. Numerous new provisional patent applications have been filed based on the Phase 2 clinical results. This investigator-initiated Phase 2 clinical trial was supported by grants exceeding \$8 million, awarded primarily by the National Multiple Sclerosis Society (NMSS) in partnership with the NMSS's Southern California chapter, and the National Institutes of Health. Annual worldwide sales of MS therapies are forecasted to be approximately \$17.8 billion in 2019. In July 2015, through our wholly owned subsidiary, we entered into amended license and clinical trial agreements with The Regents of UCLA. We were also informed by UCLA that MRI analyses are ongoing to evaluate changes in the brain that correlate with improvements seen in clinical outcomes, and we expect to report topline MRI data 30 days following our receipt of this data from UCLA. We continue to engage the neurology community and potential strategic partners, as we determine next steps for Trimesta.

**Cognitive Dysfunction in MS:** Trimesta is also being developed for the treatment of cognitive dysfunction in female MS patients. This 12-month, UCLA-led, randomized, double-blind, placebo-controlled investigator-initiated Phase 2 clinical trial is being conducted at four sites in the United States. 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 through direct funding to the lead principal investigator 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 for this indication.

**Pertussis:** In December 2012, in collaboration with Intrexon Corporation, we initiated development of a monoclonal antibody (mAb) therapy for the treatment of Pertussis infections, more commonly known as whooping cough. Combining two mAbs, SYN-005 is designed to target and neutralize pertussis toxin as a prophylaxis for high-risk newborns and in order to reduce the mortality rate in infected infants. To further the development of this potential therapy for Pertussis, we entered into an agreement with The University of Texas at Austin (UT) to license the rights to certain research and pending patents related to pertussis antibodies. We have patents pending on compositions and uses of SYN-005 and we have an issued U.S. patent on other pertussis mAbs from UT. According to the World Health Organization, each year, *B. pertussis* infection is estimated to cause up to 300,000 deaths worldwide, primarily among unvaccinated infants. Positive preclinical research findings for SYN-005 were reported in April 2014, and again in September 2014, for our proprietary mAb combination therapy for treating Pertussis, in non-human primate studies. In September 2014 we received a U.S. Orphan Drug designation for SYN-005 for the treatment of Pertussis. In April 2015, positive preclinical findings were reported in two posters at ECCMID 2015 (European Congress of Clinical Microbiology and Infectious Diseases). We are seeking non-dilutive funding to support preclinical and clinical development of SYN-005 for prophylaxis and treatment of Pertussis, including the anticipated filing of an IND application and the anticipated initiation of a Phase 1 clinical trial.

**Phenylketonuria (PKU):** In August 2015, we entered into a third worldwide exclusive channel collaboration with Intrexon Corporation through which we intend to develop and commercialize novel biotherapeutics for the treatment of patients with PKU. We will utilize Intrexon Corporation's ActoBiotics™ platform providing a proprietary method of delivering therapeutic protein and peptides to the gastrointestinal tract through food-grade microbes. This program is in the discovery stage.

**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. This program is in the discovery stage and the generation of a panel of antibodies to treat this infection is ongoing.

All of our programs are supported by growing patent estates that we either own or exclusively license. In total, each potential product has issued patents that provide protection, and we have approximately 100 U.S. and foreign patents and over 55 U.S. and foreign patents pending.

Since our inception in January 2001, our efforts and resources have been focused primarily on acquiring and developing our product candidates, our clinical trials, raising capital, manufacturing and recruiting personnel. To date, we have financed our operations primarily through public and private sales of our common stock, and we expect to continue to seek to obtain the required capital in a similar manner. We have incurred an accumulated deficit of \$127.0 million through June 30, 2015. We cannot provide any assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding, obtain the required regulatory approvals, or complete additional corporate partnering or acquisition transactions.

### ***Recent Developments***

On August 10, 2015, we expanded our relationship with Intrexon Corporation and entered into an Exclusive Channel Collaboration Agreement (the “Channel Agreement”) with Intrexon Corporation that governs a “channel collaboration” arrangement in which we will use Intrexon Corporation’s technology relating to the development and commercialization of novel biotherapeutics (a “Collaboration Product”) for the treatment of patients with PKU. We have agreed to pay Intrexon Corporation a technology access fee by the issuance of 937,500 shares of common stock, having a value equal to \$3 million as of August 7, 2015, within ten days of approval of the issuance by the NYSE MKT. In addition, upon the achievement of certain milestones, we agreed to pay Intrexon Corporation milestone payments of up to \$27 million for each product developed. We will pay Intrexon Corporation royalties on annual net sales of Collaboration Products, calculated on a product-by-product basis equal to a percent of net sales (ranging from mid-single digits on the first \$100 million of net sales to mid-teen digits on net sales in excess of \$750 million).

On July 21, 2015, we completed a public offering of 15.3 million shares of common stock, including the fully exercised over-allotment option by the underwriters covering 2.0 million shares, at an offering price of \$3.00 per share. The total gross proceeds of the offering, including the exercise in full of the over-allotment option, were approximately \$46.0 million. Net proceeds, after deducting the underwriters' discount and other estimated expenses, were approximately \$42.6 million.

On July 8, 2015, Putney Drug Corp., our subsidiary, and The Regents of UCLA, entered into an amendment to the License Agreement, dated July 11, 2005 (as amended previously), and an amendment to the Clinical Trial Agreement, dated as of April 29, 2010.

Since our inception in January 2001, our efforts and resources have been focused primarily on acquiring and developing our product candidates, our clinical trials, raising capital, manufacturing and recruiting personnel. To date, we have financed our operations primarily through public and private sales of our common stock, and we expect to continue to seek to obtain the required capital in a similar manner. We have incurred an accumulated deficit of \$127.0 million through June 30, 2015. We cannot provide any assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding, obtain the required regulatory approvals, or complete additional corporate partnering or acquisition transactions.

## **Company History**

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 engaged in a merger with a wholly owned subsidiary for the purpose of reincorporating 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.

## **Corporate Information**

Our executive offices are located at 9605 Medical Center Drive, Suite 270, Rockville, Maryland 20850. We also maintain an administrative and finance office in Ann Arbor, Michigan. Our telephone number is (732) 332-7800, and our website address is *www.syntheticbiologics.com*. The information contained on our website is not part of, and should not be construed as being incorporated by reference into this prospectus supplement. As used in this prospectus supplement, unless the context otherwise requires, references to “Synthetic,” “we,” “us,” “our,” and similar references refer to Synthetic Biologics, Inc. and our subsidiaries.



## **RISK FACTORS**

*An investment in our common stock involves a high degree of risk. You should consider carefully the risks discussed under the section captioned “Risk Factors” contained in our most recent annual report on Form 10-K 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 (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**

Some of the statements contained or incorporated by reference in this prospectus may include forward-looking statements that reflect our current views with respect to our ongoing and planned clinical trials, business strategy, business plan, financial performance and other future events. These statements include forward-looking statements both with respect to us, specifically, and the biotechnology sector, in general. We make these statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Statements that include the words “expect,” “intend,” “plan,” “believe,” “project,” “estimate,” “may,” “should,” “anticipate,” “will” and similar statements of a future or forward-looking nature identify forward-looking statements for purposes of the federal securities laws or otherwise.

All forward-looking statements involve inherent risks and uncertainties, and there are or will be important factors that could cause actual results to differ materially from those indicated in these statements. We believe that these factors include, but are not limited to, those factors set forth under the caption “Risk Factors” in this prospectus and under the captions “Risk Factors,” “Business,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” in our most recent Annual Report on Form 10-K and our subsequent Quarterly Reports on Form 10-Q, all of which you should review carefully. Please consider our forward-looking statements in light of those risks as you read this prospectus supplement and the accompanying prospectus. We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise.

If one or more of these or other risks or uncertainties materializes, or if our underlying assumptions prove to be incorrect, actual results may vary materially from what we anticipate. All subsequent written and oral forward-looking statements attributable to us or individuals acting on our behalf are expressly qualified in their entirety by this Note. Before purchasing any shares of common stock, you should consider carefully all of the factors set forth or referred to in this prospectus that could cause actual results to differ.

## **USE OF PROCEEDS**

Unless otherwise set forth in the applicable prospectus supplement, 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, payment of general and administrative expenses and accounts payable, increasing our working capital and funding research and development, clinical trials 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, and intellectual property, 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 250 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 August 6, 2015, 88,596,568 and 88,515,086 of common stock were issued and outstanding, and no shares of preferred stock were issued and 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 our books, 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*

As of August 6, 2015, we had issued and outstanding a total of 7,908,899 warrants to purchase our common stock outstanding at a weighted-average price of \$1.79.

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.

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 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;

6

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

## **EXPERTS**

The financial statements of Synthetic Biologics, Inc. as of December 31, 2014 and 2013 and for each of the three years ended in the period ended December 31, 2014 and management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2014 incorporated by reference in this prospectus have been so incorporated in reliance on the reports of BDO USA, LLP, an independent registered 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 SEC. 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.

## **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 (other than any portions of any such documents that are not deemed "filed" under the Exchange Act in accordance with the Exchange Act and applicable SEC rules) 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:

• Our annual report on Form 10-K for the fiscal year ended December 31, 2014 filed with the SEC on March 16, 2015 (File No. 001-12584);

## Edgar Filing: Synthetic Biologics, Inc. - Form S-3

Our quarterly report on Form 10-Q for the quarter ended March 31, 2015 filed with the SEC on May 11, 2015 and our quarterly report on Form 10-Q for the quarter ended June 30, 2015 filed with the SEC on August 10, 2015 (File No. 001-12584);

Our current reports on Form 8-K filed with the SEC on January 12, 2015, March 19, 2015, May 4, 2015, May 18, 2015, June 16, 2015, July 9, 2015, July 17, 2015 and August 10, 2015 (File No. 001-12584);

Our definitive proxy statement on Schedule 14A filed with the SEC on April 13, 2015 (File No. 001-12584); 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: Synthetic Biologics, Inc., 617 Detroit Street, Suite 100 Ann Arbor, Michigan 48104. (734) 332-7800.

### **DISCLOSURE OF SECURITIES AND EXCHANGE COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES**

Our amended and restated bylaws and Articles of Incorporation contain provisions that permit us to indemnify our directors and officers to the full extent permitted by Nevada law, and our Articles of Incorporation, as amended, contains provisions that eliminate the personal liability of our directors in each case for monetary damages to us or our stockholders for breach of their fiduciary duties, except to the extent that Nevada law prohibits indemnification or elimination of liability. These provisions do not limit or eliminate our rights or the rights of any stockholder to seek an injunction or any other non-monetary relief in the event of a breach of a director's or officer's fiduciary duty. In addition, these provisions apply only to claims against a director or officer arising out of his or her role as a director or officer and do not relieve a director or officer from liability if he or she engaged in willful misconduct or a knowing violation of the criminal law or any federal or state securities law.

The rights of indemnification provided in our amended and restated bylaws are not exclusive of any other rights that may be available under any insurance or other agreement, by vote of stockholders or disinterested directors or otherwise.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC this type of indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

**PART II****INFORMATION NOT REQUIRED IN THE PROSPECTUS****Item 14. *Other Expenses of Issuance and Distribution.***

The following table sets forth the estimated fees and expenses in connection with the shelf registration of the common stock registered under this registration statement, other than any underwriting discounts and commissions. The actual amounts of such fees and expenses will be determined from time to time. All amounts shown are estimates except for the Securities and Exchange Commission (the "SEC") registration fee.

SEC registration fee	\$23,240	(1)
Legal fees and expenses		(2)
Accounting fees and expenses		(2)
Transfer agent and registrar fees and expenses		(2)
Printing and engraving expenses		(2)
Miscellaneous		(2)
<b>Total</b>	\$	(2)

(1) \$6,275 was previously paid.

(2) 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 believe his conduct was unlawful.

#### **Item 16. Exhibits**

- 3.1 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 (File No. 001-12584), (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 (File No. 001-12584) 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 (File No. 001-12584).
- 3.2 Articles of Merger (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 19, 2009 (File No. 001-12584)).
- 3.3 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 (File No. 001-12584)).
- 3.4 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 (File No. 001-12584)).
- 3.5 By-Laws (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 (File No. 001-12584)).
- 3.6 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 (File No. 001-12584)).

- 3.7 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 (File No. 001-12584)).
- 3.8 Certificate of Amendment to the Articles of Incorporation Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed May 18, 2015 (File No. 001-12584)).
- 4.1 Specimen Stock Certificate evidencing shares of Common Stock (Incorporated by reference to Exhibit 4.1 of Registrant's registration statement on Form S-3 filed on July 3, 2013 (File No. 333-189794)).
- 4.2 Form of Warrant#
- 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\*
- 21 List of Subsidiaries (Incorporated by reference to Exhibit 21 to the Registrant's Annual Report on Form 10-K filed on March 16, 2015 (File No. 001-12584))
- 23.1 Consent of Independent Registered Public Accounting Firm (BDO USA, LLP)\*
- 23.2 Consent of Gracin & Marlow, LLP (included in Exhibit 5.1(a))\*
- 23.3 Consent of Parson 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 as an amendment to a document to be incorporated by reference herein in connection with an Offering of Securities to the extent applicable.

**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 a 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 the undertakings set forth in paragraphs (1)(i), (1)(ii) and (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.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) 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

(ii) 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. Provided, however, 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; and

(iii) Each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness; *provided, however,* 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 first use, 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 date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the 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 containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication 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 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.

(c) 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 of 1933 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 of 1933 and will be governed by the final adjudication of such issue.

(6) If this registration statement is permitted by Rule 430A, that:

(i) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b) (1) or (4) or 497(h) under the Securities Act of 1933 shall be deemed to be part of this registration statement as of the time it was declared effective.

(ii) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus 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.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, 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, August 10, 2015.

SYNTHETIC BIOLOGICS,  
INC.

By: /s/ Jeffrey Riley  
Chief Executive Officer,

President and Director  
(Principal Executive Officer)

By: /s/ Steven A. Shallcross  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

## POWER OF ATTORNEY

We, the undersigned hereby severally constitute and appoint each of Jeffrey Riley and Steven A. Shallcross 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 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                      Chief Executive Officer,

Edgar Filing: Synthetic Biologics, Inc. - Form S-3

Jeffrey Riley	President and Director (Principal Executive Officer)	August 10, 2015
/s/ Steven A. Shallcross Steven A. Shallcross	Chief Financial Officer (Principal Financial and Accounting Officer)	August 10, 2015
/s/ Jeffrey J. Kraws Jeffrey J. Kraws	Chairman	August 10, 2015
/s/ Scott L. Tarriff Scott L. Tarriff	Director	August 10, 2015
/s/ Jeffrey Wolf Jeffrey Wolf	Director	August 10, 2015