

SYNTHETIC BIOLOGICS, INC.

FORM S-1/A (Securities Registration Statement)

Filed 10/10/18

Address	9605 MEDICAL CENTER DRIVE SUITE 270 ROCKVILLE, MD, 20850
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

AMENDMENT
NO. 3
TO
FORM S-1
REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933



Synthetic Biologics, Inc.

(Exact name of Registrant as specified in its charter)

Nevada
*(State or other jurisdiction of
incorporation or organization)*

2834
*(Primary Standard Industrial
Classification Code Number)*

13-3808303
*(I.R.S. Employer
Identification Number)*

**9605 Medical Center Drive, Suite 270
Rockville, Maryland 20850
(301) 417-4364**
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

**Steven A. Shallcross
Interim Chief Executive Officer and
Chief Financial Officer
Synthetic Biologics, Inc.
9605 Medical Center Drive, Suite 270
Rockville, Maryland 20850
(301) 417-4364**
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

**Leslie Marlow, Esq.
Hank Gracin, Esq.
Patrick J. Egan, Esq.
Gracin & Marlow, LLP
The Chrysler Building
405 Lexington Avenue, 26th Floor
New York, New York 10174
(212) 907-6457**

**Oded Har-Even, Esq.
Robert V. Condon III, Esq.
Zysman, Aharoni, Gayer and
Sullivan & Worcester LLP
1633 Broadway
New York, NY 10019
(212) 660-5000**

Approximate date of commencement of proposed sale to the public : As soon as practicable after the effective date of this registration statement.

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, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act of 1933, 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 of 1933, 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(d) under the Securities Act of 1933, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act of 1934.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered (1)	Proposed maximum aggregate offering price(1)(2)(3)	Amount of registration fee(4)
Class A Units consisting of:(5)	\$ 23,000,000	\$ 2,787.60
(i) Common Stock, par value \$0.001 par value		
(ii) Warrants to purchase shares of Common Stock (6)		
Class B Units consisting of:(5)	\$ 23,000,000	\$ 2,787.60
(i) Series B Convertible Preferred Stock, par value \$0.001 per share		
(ii) Warrants to purchase Common Stock (6)		
(iii) Common Stock issuable upon conversion of the Series B Convertible Preferred Stock(6)		
Common Stock issuable upon exercise of Warrants (7)	\$ 55,200,000	\$ 6,690.24
Total	\$ 101,200,000	\$ 12,265.44(8)

- (1) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(o) of the Securities Act of 1933, as amended (the "Securities Act").
- (2) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional securities as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.
- (3) Includes shares of common stock the underwriters have the option to purchase solely to cover over-allotments, if any.
- (4) Calculated under Section 6(b) of the Securities Act as .00012120 of the proposed maximum aggregate offering price.
- (5) The proposed maximum offering price of the Class A Units proposed to be sold in the offering will be reduced on a dollar-for-dollar basis on the offering price of any Class B Units offered and sold in the offering, and as such the proposed aggregate maximum offering price of the Class A Units and Class B Units if any, is \$23,000,000.
- (6) No additional registration fee is payable pursuant to Rule 457(i) under the Securities Act.
- (7) The Warrants are exercisable at a per share exercise price equal to 120% of the public offering price of one share of Common Stock. The proposed maximum aggregate public offering price of the shares of Common Stock issuable upon exercise of the Warrants was calculated to be \$55,200,000, which is equal to 120% of \$46,000,000.
- (8) A filing fee of \$8,641.56 was previously paid.

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 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to 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 these securities, nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS

SUBJECT TO COMPLETION

DATED OCTOBER 10, 2018

**Up to 9,523,809 Class A Units Consisting of Shares of Common Stock and Warrants
Up to 20,000 Class B Units Consisting of Series B Convertible Preferred Stock and Warrants**

**9,523,809 Shares of Common Stock Underlying the Series B Convertible Preferred Stock and
9,523,809 Shares of Common Stock Underlying the Warrants**



We are offering up to 9,523,809 Class A Units, each Class A Unit consisting of one share of our common stock and one warrant to purchase one share of our common stock at a price of 120% of the public offering price of the Class A Units. Each warrant will be exercisable upon issuance and will expire five years from date of issuance. The shares of common stock and warrants that are part of a Class A Unit are immediately separable and will be issued separately in this offering. We are also offering the shares of common stock issuable upon exercise of warrants sold in Class A Units.

We are also offering to each purchaser whose purchase of Class A Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity in lieu of purchasing Class A Units, to purchase Class B Units. Each Class B Unit will consist of one share of Series B Convertible Preferred Stock, or the Series B Preferred, with a stated value of \$1,000 and convertible into shares of our common stock at the public offering price of the Class A Units, together with the equivalent number of warrants as would have been issued to such purchaser of Class B Units if they had purchased Class A Units based on the public offering price. The Series B Preferred do not generally have any voting rights unless and until converted into shares of common stock. The shares of Series B Preferred and warrants that are part of a Class B Unit are immediately separable and will be issued separately in this offering. The number of shares of our common stock outstanding after this offering will fluctuate depending on how many Class B Units are sold in this offering and whether and to what extent holders of Series B Preferred shares convert their shares to common stock. We are also offering the shares of common stock issuable upon exercise of warrants sold in Class B Units and upon conversion of the Series B Preferred. For each Class B Unit we sell, the number of Class A Units we are offering will be decreased on a dollar-for-dollar basis. Because we will issue a common stock purchase warrant as part of the Class A Unit or Class B unit, the number of warrants sold in this offering will not change as a result of the change in the mix of Class A Units and Class B Units.

Our common stock is listed on the NYSE American under the symbol "SYN". On October 8, 2018, the last reported sale price of our common stock on the NYSE American was \$2.10 per share. The public offering price of the Class A Units will be determined between us, the underwriters and investors based on market conditions at the time of pricing, and may be at a discount to the current market price of our common stock. Therefore, the recent market price used throughout this prospectus may not be indicative of the final offering price. The public offering price of the Class B Units will be \$1,000 per unit. There is no established trading market for the warrants or the Series B Preferred and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the warrants or the Series B Preferred on any national securities exchange or other trading market. Without an active trading market, the liquidity of the warrants and the Series B Preferred will be limited.

Investing in our securities involves risk. See "Risk Factors" beginning on page 15 of this prospectus for a discussion of information that should be considered in connection with an investment in our securities.

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.

	<u>Per Class A Unit</u>	<u>Per Class B Unit</u>	<u>Total</u>
Public offering price	\$	\$	\$
Underwriting discounts and commissions ⁽¹⁾	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

(1) We have also agreed to reimburse the underwriters for certain expenses incurred in connection with this offering. See "Underwriting" beginning on page 47 of this prospectus for a description of the compensation payable to the underwriters.

We have granted a 45-day option to the representative of the underwriters to purchase additional shares of common stock and/or additional warrants in amounts up to 15% of the common stock, warrants and/or common stock issuable upon conversion of the Series B Preferred included in the Class B Units sold in the offering, solely to cover over-allotments, if any.

We expect that delivery of the securities offered hereby against payment will be made on or about _____, 2018.

A.G.P.

The date of this prospectus is _____, 2018.



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You should rely only on the information contained in this prospectus and any free writing prospectus that we have authorized for use in connection with this offering. Neither we nor the underwriters have authorized anyone to provide you with information that is different. We are offering to sell, and seeking offers to buy, the securities covered hereby only in jurisdictions where offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of the securities covered hereby. Our business, financial condition, results of operations and prospects may have changed since that date. We are not, and the underwriters are not, making an offer of these securities in any jurisdiction where the offer is not permitted. You should also read and consider the information in the documents to which we have referred you under the caption “Where You Can Find Additional Information” in the prospectus. In addition, this prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the heading “Where You Can Find Additional Information.”

For investors outside the United States: Neither we nor any of the underwriters have taken any action that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. 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 securities covered hereby and the distribution of this prospectus outside of the United States.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We believe that the data obtained from these industry publications and third-party research, surveys and studies are reliable. We are ultimately responsible for all disclosure included in this prospectus.

Except where the context requires otherwise, in this prospectus the “Company,” “Synthetic Biologics,” “Synthetic,” “we,” “us” and “our” refer to Synthetic Biologics, Inc., a Nevada corporation, and, where appropriate, its wholly owned subsidiaries.

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus or incorporated by reference into this prospectus from our filings with the Securities and Exchange Commission, or SEC, listed in the section of the prospectus entitled “Incorporation of Certain Documents by Reference.” Because it is only a summary, it does not contain all of the information that you should consider before purchasing our securities in this offering and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere or incorporated by reference into this prospectus. You should read the entire prospectus, the registration statement of which this prospectus is a part, and the information incorporated by reference herein in their entirety, including the “Risk Factors” and our financial statements and the related notes incorporated by reference into this prospectus, before purchasing our securities in this offering.

Our Business

Overview

We are a late-stage clinical company focused on developing therapeutics designed to preserve the microbiome to protect and restore the health of patients. Our lead candidates poised for Phase 3 development are: (1) SYN-004 (ribaxamase) which is designed to protect the gut microbiome from the effects of certain commonly used intravenous (IV) beta-lactam antibiotics for the prevention of *C. difficile* infection (CDI), overgrowth of pathogenic organisms and the emergence of antimicrobial resistance (AMR), and (2) SYN-010 which is intended to reduce the impact of methane-producing organisms in the gut microbiome to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C). Our preclinical pursuits include an oral formulation of the enzyme intestinal alkaline phosphatase (IAP) to treat both local GI and systemic diseases as well as monoclonal antibody therapies for the prevention and treatment of pertussis, and novel discovery stage biotherapeutics for the treatment of phenylketonuria (PKU).

Product Pipeline:

Product Candidate	Route (Release)	Target	Preclinical	Phase 1	Phase 2	Phase 3
Antibiotic Degrading Enzymes to Prevent CDI, AMR, aGVHD*						
SYN-004 (ribaxamase)	Oral (duodenum) ¹	IV cephalosporins IV penicillins	→			EOP2 (CDI)
SYN-004 (ribaxamase) NG*	Nasogastric (duodenum) ²	IV cephalosporins IV penicillins	→			NEW Indication (aGVHD)
SYN-007 (ribaxamase) DR	Oral (ileum-cecum) ³	Oral cephalosporins Oral penicillins	→			In-patient e.g. surgery
SYN-006 (carbapenemase)	Oral (duodenum) ¹	IV carbapenems	→			Outpatient e.g. pediatric diarrhea
Treatment of IBS-C (expansion to CIC)						
SYN-010^C	Oral (duodenum, colon)	Methanogens in gut	→			EOP2
Treatment of Specific Colitis Conditions						
SYN-020^M	Oral (small intestine)	Multiple	→			Treat colitis from radiation, IO chemotherapy

¹Designed to degrade excess antibiotic excreted into the GI tract before the antibiotic reaches the colon and causes dysbiosis.

²For use in patients who can't swallow the capsule or its contents.

³Designed to degrade non-absorbed antibiotic remaining in the GI tract before the antibiotic reaches the colon and causes dysbiosis.

C - License and collaboration with Cedars-Sinai Medical Center

M - Scientific collaboration with Massachusetts General Hospital

* Development of nasogastric tube (NG) dosing is based on guidance and recommendations by physicians, surgeons, KOLs, our expert steering committee and the U.S. Food and Drug Administration (FDA).

Summary of Clinical and Preclinical Programs

Therapeutic Area	Product Candidate	Status
Prevention of CDI, overgrowth of pathogenic organisms and AMR (Degrade IV beta-lactam antibiotics)	SYN-004 (ribaxamase) (oral enzyme)	<ul style="list-style-type: none"> ● Reported supportive Phase 1a/1b data (1Q 2015) ● Reported supportive topline data from two Phase 2a clinical trials (4Q 2015 & 2Q 2016) ● Initiated Phase 2b proof-of-concept clinical trial (3Q 2015) ● Received USAN approval of the generic name “ribaxamase” for SYN-004 (July 2016) ● Completed Enrollment of Phase 2b proof-of-concept clinical trial (3Q 2016) ● Awarded contract by the CDC (4Q 2016) ● Announced positive topline data from Phase 2b proof-of-concept clinical trial, including achievement of primary endpoint of significantly reducing CDI (1Q 2017) ● Announced additional results from Phase 2b proof-of-concept clinical trial demonstrating SYN-004 (ribaxamase) protected and maintained the naturally occurring composition of gut microbes from antibiotic-mediated dysbiosis in treated patients (2Q 2017) ● Announced additional results from Phase 2b proof-of-concept clinical trial funded by a contract awarded by the CDC, demonstrating that SYN-004 (ribaxamase) prevented significant change to the presence of certain AMR genes in the gut resistome of patients receiving SYN-004 compared to placebo (3Q 2017) ● Presented additional supportive results regarding several exploratory endpoints from Phase 2b proof-of-concept clinical trial designed to evaluate SYN-004’s (ribaxamase) ability to protect the gut microbiome from opportunistic bacterial infections and prevent the emergence of antimicrobial resistance (AMR) in the gut microbiome (4Q 2017) ● Reached preliminary agreement with the FDA on key elements of a proposed Phase 3 clinical trial program, including de-coupled co-primary endpoints designed to evaluate efficacy separate from safety in a patient population being treated with a representative selection of IV-beta-lactam antibiotics (1H 2018) ● End of Phase 2 meeting with FDA held to solidify remaining elements of planned Phase 3 clinical trial (3Q 2018) ● Expect results from End of Phase 2 meeting with FDA (4Q 2018) ● Clarified market/partner needs and identified potential additional indications for SYN-004 in specialty patient populations such as allogenic hematopoietic cell transplant recipients ● Plan to initiate clinical trial(s) (2H 2019) which may include a broad Phase 3 clinical trial and/or Phase 1/2 clinical trial(s) in a specialty population leading to a subsequent Phase 3 clinical trial
Treatment of IBS-C	SYN-010 (oral modified-release lovastatin lactone)	<ul style="list-style-type: none"> ● Collaboration with Cedars-Sinai Medical Center (“CSMC”) ● Reported supportive topline data from two Phase 2 clinical trials (4Q 2015 & 1Q 2016) ● Received Type C meeting responses from FDA regarding late-stage aspects of clinical pathway (2Q 2016) ● Presented detailed data supporting previously reported positive topline data from two Phase 2 clinical trials at DDW (May 2016)

		<ul style="list-style-type: none"> • Held End of Phase 2 meeting with FDA (July 2016) • Confirmed key elements of Pivotal Phase 2b/3 clinical trial design pursuant to consultations with FDA (1Q 2017) • Announced issuance of key U.S. composition of matter patent providing important intellectual property protection in the U.S until at least 2035 (Q2 2018) • Entered into agreement with CSMC for an investigator-sponsored Phase 2 clinical study of SYN-010 to evaluate SYN-010 dose response and inform Phase 3 clinical development (Q3 2018) • Anticipate dosing first patient in the Phase 2b investigator sponsored clinical study during Q4 2018 • Anticipate data readout from the Phase 2b investigator sponsored clinical study during 2H 2019
Prevention of CDI, overgrowth of pathogenic organisms and AMR (Degrade IV carbapenem antibiotics)	SYN-006 (oral enzyme)	<ul style="list-style-type: none"> • Identified P2A as a potent carbapenemase that is stable in the GI tract • Manufactured and formulated research lot for oral delivery (2017) • Demonstrated microbiome protection in a pig model of ertapenem administration (Q1 2018)
Prevention of CDI, overgrowth of pathogenic organisms and AMR (Degrade oral beta-lactam antibiotics)	SYN-007 (oral enzyme)	<ul style="list-style-type: none"> • Preclinical work ongoing to expand the utility of SYN-004 (ribaxamase) for use with oral beta-lactam antibiotics • Presented supportive data from canine animal model at the Microbiome World Congress, America (Q4 2017) • Reported supportive data from a second canine animal model demonstrating that when co-administered with oral amoxicillin and oral Augmentin, oral SYN-007 did not interfere with systemic absorption of antibiotics but did diminish microbiome damage associated with these antibiotics (2Q 2018)
Preserve gut barrier, treat local GI inflammation, restore gut microbiome	SYN-020 (oral IAP enzyme)	<ul style="list-style-type: none"> • Generated high expressing manufacturing cell lines for intestinal alkaline phosphatase (IAP) (1H 2017) • Identified downstream process and tablet formulations (2H 2017) • Identified three potential clinical indications in areas of unmet medical need including, enterocolitis associated with radiation therapy, enterocolitis associated with checkpoint inhibitor therapy for cancer, and microscopic colitis (2H 2018) • Ongoing preclinical efficacy studies • Anticipated IND filing (Q4 2019) • Plan to initiate Phase 1 clinical trial (Q1 2020)
Prevention and treatment of pertussis	SYN-005 (monoclonal antibody therapies)	<ul style="list-style-type: none"> • Reported supportive preclinical research findings (2014) • The University of Texas at Austin (“UT Austin”) received a grant from the Bill and Melinda Gates Foundation to support a preclinical study to evaluate the prophylactic capability of SYN-005 (4Q 2015) • Reported supportive preclinical data demonstrating hu1B7, a component of SYN-005, provided protection from pertussis for five weeks in neonatal non-human primate study (Q2 2017) • Reported supportive preclinical data demonstrating that an extended half-life version of hu1B7, a component of SYN-005, provided protection from pertussis for five weeks in a non-human neonatal primate study (Q4 2017) • Collaborations with Intrexon and UT Austin

Our Microbiome-Focused Pipeline

Our SYN-004 (ribaxamase) and SYN-010 programs are focused on protecting the healthy function of the gut microbiome, or gut flora, which is composed of billions of microbial organisms including a natural balance of both “good” beneficial species and potentially “bad” pathogenic species. When the natural balance or normal function of these microbial species is disrupted, a person’s health can be compromised. All of our programs are supported by our growing intellectual property portfolio. We are maintaining and building our patent portfolio through: filing new patent applications; prosecuting existing applications; and licensing and acquiring new patents and patent applications. Our plan remains focused on the advancement of our two late-stage clinical programs. We continue to actively manage resources in preparation for the advancement of our two late-stage microbiome-focused clinical programs, including our pursuit of opportunities that will allow us to establish the clinical infrastructure and financial resources necessary to successfully initiate and complete this plan.

SYN-004 (ribaxamase) — Prevention of *C. difficile* infections (CDI), overgrowth by pathogenic organisms, and the emergence of antimicrobial resistance (AMR)

SYN-004 (ribaxamase) is a proprietary oral 75 mg capsule prophylactic therapy designed to degrade certain IV beta-lactam antibiotics excreted into the GI tract and maintain the natural balance of the gut microbiome to prevent CDI, reduce overgrowth of pathogenic organisms, and suppress the emergence of antimicrobial-resistant organisms. Published clinical literature has also suggested that preventing microbiome damage caused by IV beta-lactam antibiotics excreted into the GI tract may have potential therapeutic benefit as a means of preventing acute graft-vs-host disease in hematopoietic cell transplant patients. SYN-004 (ribaxamase) is a beta-lactamase enzyme intended to be administered as two-75 mg capsules which, when released in the proximal small intestine, can degrade beta-lactam antibiotics in the GI tract without altering systemic antibiotic levels. Beta-lactam antibiotics are a mainstay in hospital infection management and include the commonly used penicillin and cephalosporin classes of antibiotics.

In November 2012, we acquired a series of oral beta-lactamase enzymes (P1A, P2A and P3A) and related assets targeting the prevention of CDI, the leading healthcare-associated infection that generally occurs secondary to treatment with IV antibiotics from Prev ABR LLC. The acquired assets include a pre-Investigational New Drug (IND) package for P3A, Phase 1 and Phase 2 clinical data for P1A, manufacturing processes and data, and a portfolio of issued and pending U.S. and foreign patents intended to support an IND and Biologics License Application (BLA) with the FDA. Utilizing this portfolio of assets, we developed a proprietary, second generation oral beta-lactamase enzyme product candidate that we now refer to as SYN-004 or by its generic name “ribaxamase”.

Compared to the first generation oral enzyme candidate of P1A, we believe that the second generation candidate, SYN-004 (ribaxamase), will have activity against a broader spectrum of beta-lactam antibiotics, including both penicillins and certain cephalosporins. Due to the structural similarities between P1A and SYN-004 (ribaxamase), and based on previous discussions with the FDA, certain preclinical data collected on P1A was used in support of an IND application for SYN-004 (ribaxamase).

Specifically, P1A had been evaluated in four Phase 1 and one Phase 2 clinical trials conducted in Europe. In total, 112 patients and 143 healthy volunteers participated in these studies.

C. difficile

C. difficile is the leading type of hospital acquired infection and is frequently associated with IV beta-lactam antibiotic treatment. According to a paper published in BMC Infectious Diseases (Desai K et al. BMC Infect Dis. 2016; 16: 303) the economic cost of CDI was approximately \$5.4 billion in 2016 (\$4.7 billion in healthcare settings; \$725 million in the community) in the U.S., mostly due to hospitalizations. CDI is a rising global hospital acquired infection (HAI) problem in which the toxins produced by *C. difficile* bacteria result in *C. difficile* associated diarrhea (CDAD), and in the most serious cases, pseudomembranous colitis (severe inflammation of the lower GI tract) that can lead to death. The CDC identified *C. difficile* as an “urgent public health threat,” particularly given its resistance to many drugs used to treat other infections. CDI is a major unintended risk associated with the prophylactic or therapeutic use of IV antibiotics, which may alter the natural balance of microflora that normally protect the GI tract, leading to *C. difficile* overgrowth and infection. Other risk factors for CDI include hospitalization, prolonged length of stay (estimated at 7 days), underlying illness, and immune-compromising conditions including the administration of chemotherapy and advanced age. In addition, approximately 20% of patients who have been diagnosed with CDI experience a recurrence of CDI within one to three months.

Limitations of Current Treatments and Market Opportunity

CDI is a widespread and often drug resistant infectious disease. According to an article published in the New England Journal of Medicine (Leffler DA et al. N Engl J Med 2015; 372:1539-1548), it is estimated that 453,000 patients are infected with *C. difficile* annually in the U.S., and it has been reported that approximately 29,000 patients die due to CDI-associated complications each year. Controlling the spread of CDI has proven challenging, as the *C. difficile* spores are easily transferred to patients via normal contact with healthcare personnel and with inanimate objects. There is currently no vaccine or approved product for the prevention of primary (incident) CDI.

According to IMS Health Incorporated,* in 2016, 227 million doses of SYN-004 (ribaxamase)-addressable intravenous Penicillin and Cephalosporin antibiotics were administered in the United States which may contribute to the onset of CDI. Additional data derived from IMS Health Incorporated states that in 2016, the worldwide market for SYN-004 (ribaxamase)-addressable intravenous beta-lactam antibiotics was approximately 7.5 billion doses, which may represent a multi-billion dollar opportunity for us. According to the CDC report *Antibiotic Resistance Threats in the United States, 2013*, at least 2 million people in the U.S. each year acquire serious infections with bacteria that are resistant to one or more of the antibiotics designed to treat those infections, which results in an estimated \$20 billion in excess direct healthcare costs.

* This information is an estimate derived from the use of information under license from the following IMS Health Incorporated information service: IMS Health Analytics for the full year 2016. IMS expressly reserves all rights, including rights of copying, distribution, and republication.

Clinical Update

On April 23, 2018, we announced that we had reached preliminary agreement with the FDA on key elements of a proposed clinical trial program for our planned Phase 3 clinical trial for ribaxamase. In accordance with recommendations and guidance received from the FDA, we expect the Phase 3 trial to evaluate the efficacy and safety of ribaxamase as separate, co-primary endpoints in a patient population being treated with a representative selection of intravenous (IV) beta-lactam antibiotics, which will include ceftriaxone and piperacillin/tazobactam. The inclusion of more than one beta-lactam antibiotic in this trial is intended to evaluate the potential utility of ribaxamase for co-administration with a greater number of cephalosporin and penicillin beta-lactam antibiotics. The proposed Phase 3 clinical trial discussed with the FDA will comprise a global, event-driven clinical trial with a fixed maximum number of patients and will seek to evaluate the efficacy and safety of ribaxamase in a broader patient population by enrolling patients with a variety of underlying infections. We expect the primary efficacy endpoint of the proposed Phase 3 trial will be the reduction in the incidence of CDI in the ribaxamase treatment group compared to placebo. We have also reached preliminary agreement with the FDA to evaluate mortality risk as the primary safety endpoint for this trial, which will be separate from the primary efficacy endpoint of reduction of the incidence of CDI. The designation of efficacy and safety as separate and decoupled endpoints is critical for clinical studies of this nature, where the underlying population is projected to have a comparatively high incidence of safety events that may significantly dilute the smaller number of CDI events.

We plan to continue collaborative discussions with the FDA to solidify the remaining details of the proposed Phase 3 clinical trial program during an anticipated End of Phase 2 meeting with the FDA in the third quarter of 2018. In parallel with clinical and regulatory efforts, we have recently completed a Health Economics Outcomes Research study, which was conducted to generate key insights on how we can expect Health Care Practitioners, or HCPs, to evaluate patient access for ribaxamase while also providing a framework for potential reimbursement strategies. After evaluating findings from the study, and after extensive discussions with pharmaceutical companies, physicians, research institutions and clinical development groups worldwide, we believe that there is significant potential value in exploring the development of SYN-004 (ribaxamase) in a more narrow patient population where the incidence of the disease endpoint is high and the clinical development may be less costly. One potential narrow patient population for SYN-004 could be allogenic hematopoietic cell transplant (HCT) recipients, who have a very high risk of CDI, VRE colonization and potentially fatal bacteremia, and acute-graft-vs-host disease. Published literature has demonstrated a strong association between these adverse outcomes and microbiome damage caused by IV beta-lactam antibiotics in these patients. Further examination and discussions with key opinion leaders (KOLs) who are experts in allogenic HCT are ongoing to evaluate a potential clinical development pathway forward for SYN-004 in such a narrow, specialty patient population.

Contingent on potential interest from prospective partners and/or appropriate funding, we anticipate initiating the Phase 3 clinical trial currently under discussion with the FDA in 2H 2019 which will evaluate SYN-004 (ribaxamase) effects on CDI in a broad and diverse patient population. In parallel, discussions with KOLs are ongoing to determine if further investigation in the form of a potential Phase 1 and/or Phase 2 clinical trial(s) evaluating SYN-004 (ribaxamase) in a specialized patient population such as allogenic HCT patients may also and/or alternatively be pursued in 2H 2019. If it is determined that the clinical advancement of SYN-004 is more favorable and significantly less costly in a specialized patient population, we may elect to prioritize and pursue this strategy in advance of pursuing the broader, Phase 3 clinical program currently under discussion with the FDA. If approved by the FDA, SYN-004 (ribaxamase) would be the first available drug designed to prevent primary *Clostridium difficile* infection by protecting the gut microbiome from antibiotic-mediated dysbiosis.

SYN-010 — Treatment of Irritable Bowel Syndrome with Constipation (IBS-C)

SYN-010 is our proprietary, modified-release formulation of lovastatin lactone that is intended to reduce methane production by certain microorganisms (*M. smithii*) in the gut while minimizing disruption to the microbiome. Methane produced by *M. smithii* is an underlying cause of pain, bloating and constipation associated with IBS-C, and published reports have associated higher intestinal methane production with increased constipation severity in IBS-C patients. SYN-010 is intended to act primarily in the intestinal lumen while avoiding systemic absorption, thereby targeting the major cause of IBS-C, not just the patient's symptoms.

In December 2013, through our subsidiary Synthetic Biomics, Inc. (SYN Biomics), we entered into a worldwide exclusive license agreement with Cedars-Sinai Medical Center (CSMC) and acquired the rights to develop products for therapeutic and prophylactic treatments of acute and chronic diseases, including the development of SYN-010 to target IBS-C. We licensed from CSMC a portfolio of intellectual property comprised of several U.S. and foreign patents and pending patent applications for various fields of use, including IBS-C, obesity and diabetes. An investigational team, led by Mark Pimentel, M.D. at CSMC, discovered that these products may reduce the production of methane gas by certain GI microorganisms.

We believe SYN-010 may reduce the impact of methane producing organisms on IBS-C.

Irritable Bowel Syndrome

IBS is a functional GI disorder characterized by gas, abdominal pain, bloating and diarrhea or constipation, or alternating episodes of both. The illness affects both men and women; however, two-thirds of diagnosed sufferers are women. The onset of IBS can begin anytime from adolescence to adulthood. Four bowel patterns may be seen with IBS including: IBS-C (constipation predominant), IBS-D (diarrhea predominant), IBS-M (mixed diarrhea and constipation) and IBS-U (unsubtyped). According to GlobalData's IBS — Global Drug Forecast and Market Analysis to 2023 (December 2014), the prevalence of IBS in adults in the United States, Europe and Japan was expected to be 41.1 million in 2016, and it has been reported that up to 20 percent of all IBS patients have IBS-C. Extensive studies conducted by Dr. Pimentel and collaborators have shown that overproduction of methane gas is directly associated with bloating, pain and constipation in IBS-C patients. Investigators at CSMC have discovered that inhibiting intestinal methane production may reverse constipation associated with IBS-C, and may be beneficial in treating other major diseases such as obesity, insulin resistance and type 2 diabetes.

Limitations of Current Treatments and Market Opportunity

Currently, the FDA approved therapies for the treatment of IBS-C include prescription and over-the-counter laxatives, which provide patients with temporary symptomatic relief and often cause diarrhea, but are not designed to and do not treat the underlying cause of pain, bloating and constipation associated with IBS-C. Additionally, these same therapies may come with undesirable safety side-effect profiles, the most common of which is diarrhea. As a result, these therapies have struggled to find adoption in several key markets, including Europe. We believe this presents an important opportunity for SYN-010. Towards the end of 2017, we engaged outside consultants to evaluate the potential regulatory pathway towards EMA marketing approval. According to IMS Health Analytics, U.S. sales in 2016 for IBS-C and Chronic Idiopathic Constipation (CIC) therapeutics as well as OTC laxatives/products were approximately \$2.5 billion, representing a constant annual growth rate (CAGR) of 19% from 2012.

Clinical Update

On September 5, 2018, we entered into an agreement with CSMC for an investigator-sponsored Phase 2 clinical study of SYN-010 to be co-funded by us and CSMC (the "Study").

The Study will provide further evaluation of the efficacy and safety of SYN-010, our modified-release reformulation of lovastatin lactone, which is exclusively licensed to us by CSMC. SYN-010 is designed to reduce methane production by certain microorganisms (*M. smithii*) in the gut to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C). The data from this study will provide additional insights into potential SYN-010 clinical efficacy, including dose response and microbiome effects, ideally solidifying existing clinical outcomes data, and potentially simplifying Phase 3 clinical development.

The Study will be conducted out of the Pimentel Laboratory at CSMC and is expected to be a 12-week, placebo-controlled, double-blind, randomized clinical trial to evaluate two dose strengths of oral SYN-010 (21 mg and 42 mg) in approximately 150 patients diagnosed with IBS-C. The investigator-sponsored Study will be led by the gastrointestinal microbiota researcher Ruchi Mathur, M.D., director of Metabolism, Clinical Research and Administrative Operations at the Medically Associated Science and Technology (MAST) Program at CSMC. The Study is expected to begin enrollment during the fourth quarter of 2018, contingent upon approval of the clinical study protocol by the CSMC Institutional Review Board.

The primary objective for the Study will be to determine the efficacy of SYN-010, measured as an improvement from baseline in the weekly average number of complete spontaneous bowel movements (CSBMs) during the 12-week treatment period for SYN-010 21 mg and 42 mg daily doses relative to placebo. Secondary efficacy endpoints for both dose strengths of SYN-010 are expected to measure changes from baseline in abdominal pain, bloating, stool frequency as well as the use of rescue medication relative to placebo. Exploratory outcomes include Adequate Relief and quality of life measures using the well-validated EQ-5D-5L and PAC-SYM patient questionnaires.

We expect that CSMC will dose the first patient in the investigator-sponsored Phase 2b clinical study in Q4 2018. A data readout from this clinical trial study is anticipated in 2H 2019.

Allowance of Key U.S. Patent

On May 1, 2018, the United States Patent and Trademark Office (USPTO) issued U.S. Patent No. 9,956,292 which includes claims related to composition of matter for the use of anti-methanogenic compositions to treat IBS-C. The patent will provide key intellectual property protection in the U.S. for SYN-010 and will expire no later than 2035.

Research Programs

Infectious disease outbreaks are increasing while intervention options are declining due to widespread multidrug-resistant bacteria, increasing numbers of immunocompromised patients (e.g., the elderly and cancer patients) and the isolation of new pathogens.

SYN-007 — Prevention of CDI, overgrowth of pathogenic organisms and the emergence of antimicrobial resistance (AMR)

SYN-007 is a specially formulated version of SYN-004 (ribaxamase) designed to degrade orally administered beta-lactam antibiotics to protect the gut microbiome from antibiotic-mediated dysbiosis. SYN-007 is formulated for release in the distal small intestine to allow systemic absorption of the oral antibiotic while still providing protection upstream of the colon and to the gut microbiome. SYN-007 is designed for patients who have been administered SYN-004 (ribaxamase) in combination with intravenous beta-lactam antibiotics and who are then transferred to an oral beta-lactam antibiotic, thereby extending gut microbiome protection from antibiotic-mediated dysbiosis. Data from a recent canine study completed during the second half of 2017 demonstrated that, when co-administered with oral amoxicillin, oral SYN-007 did not interfere with amoxicillin absorption and did demonstrate protection of the gut microbiome. The data from this canine study were presented during recent microbiome conferences in Q4 2017 and Q1 2018. A second canine study was completed during Q2 2018 in which oral SYN-007 was co-administered with oral amoxicillin and oral Augmentin. Again, SYN-007 did not interfere with systemic absorption of the antibiotics but did diminish the microbiome damage associated with these antibiotics.

SYN-006 — Prevention of CDI, overgrowth of pathogenic organisms and the emergence of antimicrobial resistance (AMR)

The second pipeline product, termed SYN-006, has the potential to further expand the utility of our SYN-004 (ribaxamase) program to a broader spectrum of IV beta-lactam antibiotics in the GI tract to include carbapenem antibiotics. Carbapenems are broad-spectrum beta-lactam antibiotics that have been shown to significantly damage the gut microbiome, incur a high risk for *C. difficile* infection, and enable GI overgrowth with multidrug resistant organisms. Carbapenems are frequently a last line of defense antibiotic, therefore the emergence and spread of carbapenem resistance presents an urgent threat. SYN-006 is a carbapenemase designed to degrade intravenous (IV) carbapenem antibiotics within the GI tract to maintain the natural balance of the gut microbiome for the prevention of CDI, overgrowth of pathogenic organisms and the emergence of antimicrobial resistance (AMR). It is anticipated that, by protecting the gut microbiome from exposure to carbapenem antibiotics, SYN-006 may potentially diminish the spread of such resistance. At the ID Week 2017 conference, we presented a poster demonstrating SYN-006's broad activity against four carbapenem antibiotics as well as efficacy in a canine model. The poster also showed data from a porcine model indicating that the carbapenem, ertapenem, potently damaged gut microbiomes and mediated expansion of antibiotic resistance genes in the GI tract. More recently, we successfully formulated SYN-006 for oral delivery and evaluated it in a porcine efficacy model in conjunction with IV ertapenem. The data, presented at a clinical conference during the first quarter of 2018, demonstrated that SYN-006 did not interfere with serum levels of ertapenem and did diminish antibiotic-mediated dysbiosis.

SYN-005 — Pertussis (Whooping Cough)

The SYN-005 program is developing monoclonal antibodies both as a prophylaxis and a treatment for pertussis. *Bordetella pertussis* (*B. pertussis*) is a gram-negative bacterium that infects the upper respiratory tract, causing uncontrollable and violent coughing. Antibiotic treatment does not have a major effect on the course of pertussis. While such treatment can eliminate the *B. pertussis* bacteria from the respiratory tract, it does not neutralize the pertussis toxin. Infants with pertussis often require hospitalization in pediatric intensive care units, frequently requiring mechanical ventilation. The incidence of pertussis is increasing due to the declining effectiveness of the acellular vaccine introduced in the 1990s, exposure of unvaccinated and under-vaccinated individuals including infants who are not yet fully vaccinated and exposure of individuals whose immunity has diminished over time.

According to the Centers for Disease Control and Prevention (CDC), there were 24.1 million cases of whooping cough worldwide in 2014, and it is estimated that *B. pertussis* infection caused up to 167,700 deaths in children younger than 5 years in 2014.

Intrexon Collaboration and The University of Texas at Austin Agreement

In August 2012, we entered into a worldwide exclusive channel collaboration with Intrexon develop monoclonal antibody (mAb) therapies for the treatment of certain infectious diseases not adequately addressed by existing therapies. In December 2012, we initiated mAb development for the prevention and treatment of pertussis focusing on toxin neutralization. Unlike antibiotics, we are developing a mAb therapy to target and neutralize the pertussis toxin as a prophylaxis for high-risk newborns and in order to shorten the course, diminish the long-term complications, and reduce the mortality rate in infected infants.

To further the development of this potential therapy for pertussis, we entered into an agreement with UT Austin to license the rights to certain research and pending patents related to pertussis antibodies. These research efforts are being conducted at the Cockrell School of Engineering in the laboratory of Associate Professor, Jennifer A. Maynard, Ph.D., the Laurence E. McMakin, Jr. Centennial Faculty Fellow in the McKetta Department of Chemical Engineering. Dr. Maynard brings to the project her expertise in defining the key neutralizing epitopes of pertussis toxin to optimize the potential efficacy of antibody therapeutics.

Preclinical Development

Working with our collaborator, Intrexon, and our academic collaborator, UT Austin, we have established a humanized mAb product candidate, SYN-005, designed to neutralize pertussis toxin, a major cause of pertussis-mediated infant morbidity and mortality. The two humanized mAbs, hu1B7 and hu11E6, bound tightly to the toxin and potently neutralized the toxin. In addition, the antibodies, individually or in combination, were highly efficacious in a murine model of pertussis in which they completely mitigated elevations of the white blood cell count that is characteristic of the illness.

In April 2014, and again in September 2014, we received positive preclinical research findings of SYN-005 for the treatment of pertussis in three non-human primate studies (n = 19). In the latter two pertussis studies in particular, SYN-005 rapidly stopped the rise in white blood cell count that is characteristic of the disease and accelerated its return to baseline.

In September 2014, we received U.S. Orphan Drug Designation from the FDA for SYN-005 for the treatment of pertussis.

In October 2015, the Bill & Melinda Gates Foundation awarded a grant to UT Austin to generate preclinical proof-of-concept data in the neonatal non-human primate model to test the hypothesis that antibody administration at birth may have a role in the prevention of pertussis.

In December 2015, the non-human primate prophylaxis study was initiated by UT Austin to determine if administration of hu1B7, one component of SYN-005, at two days of age could protect animals from a subsequent pertussis infection. On April 19, 2017, we announced supportive preclinical data demonstrating hu1B7 provided five weeks of protection from pertussis in neonatal non-human primates. Control animals (n=6), infected with *Bordetella pertussis* (*B. pertussis*) at five weeks of age, demonstrated marked elevations in white blood cell counts and most exhibited behavioral signs of pertussis, including coughing and diminished activity. In contrast, the experimental animals (n=7), who were treated with hu1B7 at two days of age and then infected five weeks later, had significantly lower peak white blood cell counts (p=0.004) that remained within the normal range or were only slightly elevated. Importantly, all seven of the animals that received prophylactic hu1B7 appeared healthy and none exhibited any behavioral signs of pertussis. Building on this early success, we performed preclinical testing of a modified version of hu1B7 that has the potential to extend the plasma half-life. The modified hu1B7 achieved higher plasma levels at five weeks than the parental hu1B7 antibody and was efficacious in preventing clinical pertussis. The extended half-life antibody has the potential to substantially reduce the required dose and cost for prophylaxis for application in the Developing World. This current study expands the potential clinical utility beyond treatment to also include prophylaxis.

SYN-020 — Oral Intestinal Alkaline Phosphatase

SYN-020 is in the preclinical development stage. SYN-020 is being developed as a modified-release oral dosage form of intestinal alkaline phosphatase (IAP). IAP is an endogenous enzyme expressed in the upper GI tract that functions as a broadly acting phosphatase that generally serves to maintain GI homeostasis and promote commensal microbiota. In animal models, IAP is anti-inflammatory, tightens the gut barrier to diminish “leaky gut,” and accelerates gut microbiome recovery from antibiotic-mediated dysbiosis. Published reports have demonstrated efficacy for several indications with oral IAP in many animal models including colitis, antibiotic-mediated dysbiosis, and metabolic syndrome as well as in a pilot human clinical trial with ulcerative colitis patients.

Limitations of Current Treatments and Clinical Update

Despite its therapeutic potential, clinical application of an oral IAP product has been hindered by inefficient manufacturing with a high cost of goods. We have established manufacturing processes with the potential to yield product with a cost of goods which we believe to be suitable for commercialization. Recent advances include cell lines that express up to 3 grams/L along with a chromatographic downstream process and potential tablet formulations. We are currently optimizing these technologies and pursuing animal efficacy studies. During Q2 2018, we completed several preclinical animal studies that support the clinical utility of SYN-020 for multiple gastrointestinal disorders. We are currently evaluating and establishing strategies to advance IAP to and through clinical trials for several novel indications, including enterocolitis associated with radiation therapy for cancer and checkpoint inhibitor therapy for cancer and microscopic colitis, all of which have unmet medical needs and span a range of market sizes. Importantly, we believe that with a small capital commitment, we can begin moving SYN-020 towards an IND. We are targeting filing an IND during Q4 2019 and commencing a Phase 1 clinical trial during Q1 2020.

SYN-200 — Treatment of Phenylketonuria (PKU)

PKU is a genetic disease that begins at birth characterized by a deficiency in the liver enzyme that breaks down the essential amino acid phenylalanine (Phe), a building block of proteins normally obtained through the foods we eat. As a result, Phe accumulates in the body, becoming toxic and leading to serious health consequences, including profound mental retardation, brain damage, mental illness, behavioral problems, seizures, tremors, limited cognitive ability and hyperactivity. If left untreated, the most severe form of PKU leads to permanent cognitive damage. PKU affects more than 14,000 people in the U.S. and 50,000 people in developed nations globally. There is no existing cure for PKU, requiring patients to maintain a life-long treatment program and a carefully controlled diet.

Intrexon Collaboration

In August 2015, we initiated the SYN-200 discovery program for development and commercialization of novel biotherapeutics for the treatment of patients with PKU pursuant to an exclusive channel collaboration with Intrexon. We intend to utilize Intrexon's ActoBiotics platform to provide a proprietary method of delivering therapeutic protein to the GI tract through food-grade microbes. This program is in the discovery stage.

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. Our telephone number is (301) 417-4364, 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.

The Offering

Class A Units offered by us

Up to 9,523,809 Class A Units. Each Class A Unit will consist of one share of our common stock and a warrant to purchase one share of our common stock at an exercise price equal to 120% of the public offering price of the Class A Unit. The Class A Units will not be certificated and the shares of common stock and warrant that are part of such unit will be immediately separable and will be issued separately in this offering. Assuming no exercise of the over-allotment option and we sell all Class A Units (and no Class B Units) being offered in this offering at an assumed public offering price of \$ 2.10 per share (which was the last reported sale price of our common stock on the NYSE American on October 8, 2018), we would issue in this offering an aggregate of 9,523,809 shares of our common stock and warrants to purchase 9,523,809 shares of our common stock. The actual offering price per each Class A Unit will be negotiated between us and the underwriters based on the trading of our common stock prior to the offering, among other things, and may be at a discount to the current market price. We are also offering the shares of common stock issuable upon exercise of warrants sold in Class A Units.

Assumed Public Offering Price Per Class A Unit

\$2.10 per Class A Unit.

Class B Units offered by us

Up to 20,000 Class B Units. We are also offering to each purchaser whose purchase of Class A Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the holder, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, Class B Units, in lieu of Class A Units. Each Class B Unit will consist of one share of our Series B Preferred, with a stated value of \$1,000 and convertible into shares of our common stock, at the public offering price of the Class A Units, together with an equivalent number of warrants as would have been issued to such purchaser if they had purchased Class A Units based on the public offering price of the Class A Units. The Series B Preferred do not generally have any voting rights but are convertible into shares of common stock. The Class B Units will not be certificated and the shares of Series B Preferred and warrants that are part of such unit will be immediately separable and will be issued separately in this offering. We are also offering the shares of common stock issuable upon exercise of warrants sold in Class B Units and upon conversion of the Series B Preferred. For each Class B Unit we sell, the number of Class A Units we are offering will be decreased on a dollar-for-dollar basis. Because we will issue a warrant as part of each Unit, the number of warrants sold in this offering will not change as a result of a change in the mix of the Units sold.

Public Offering Price Per Class B Unit

\$1,000 per Class B Unit.

Warrants offered by us

Each warrant included in the Units will have an exercise price of 120% of the public offering price of the Class A Units, will be exercisable upon issuance and will expire five years from the date of issuance. Each warrant will be exercisable to purchase one share of our common stock. No fractional shares of common stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will round up to the next whole share. The warrants also provide that in the event of a fundamental transaction we are required to cause any successor entity to assume our obligations under the warrants. In addition, the holder of the warrant will be entitled to receive upon exercise of the warrant the kind and amount of securities, cash or property that the holder would have received had the holder exercised the warrant immediately prior to such fundamental transaction. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the warrants. Subject to certain exceptions, the warrants provide for adjustment of the exercise price, which initially will be 120% of the public offering price of the Class A Units, if we or any of our subsidiaries, as applicable, sell or grant any right to reprice, or otherwise dispose of or issue (or announce any offer, sale, grant or any option to purchase or other disposition) any shares of our common stock or common stock equivalents, at an effective price per share that is less than the exercise price then in effect (such lower price, the "Base Share Price" and such issuances collectively, a "Dilutive Issuance"). In the event a Dilutive Issuance occurs, the exercise price shall be reduced to equal the Base Share Price.

Over-allotment option

We have granted the underwriters a 45-day option to purchase up to 1,428,571 additional shares of common stock at an assumed offering price of \$2.10 per share and/or additional warrants to purchase up to an additional 1,428,571 shares of our common stock from us at a price of \$0.01 per warrant, to cover over-allotments, if any, of the shares of common stock, shares of common stock issuable upon conversion of the Series B Preferred and warrants comprising the Units.

Common stock to be outstanding after the offering

16,732,129 shares of our common stock (at an assumed public offering price of \$2.10 per share which was the last reported sale price of our common stock on the NYSE American on October 8, 2018) and assumes that no shares of Series B Preferred are sold in this offering and that none of the warrants are exercised. If the underwriters' over-allotment option is exercised in full, the total number of shares of common stock outstanding immediately after this offering would be 18,160,700 (at an assumed public offering price of \$2.10 per share which was the last reported sale price of our common stock on the NYSE American on October 8, 2018) and assuming all shares of Series B Preferred sold in this offering convert to common stock and that none of the warrants are exercised). This prospectus also includes the shares of our common stock issuable upon conversion of the Series B Preferred and exercise of the warrants.

Series B Convertible Preferred Stock

The Series B Preferred will be convertible into shares of our common stock (subject to adjustment as provided in the related certificate of designation of preferences, rights and limitations) at any time at the option of the holder, at a conversion price equal to the public offering price of the Class A Units. See "Description of Securities We Are Offering— Preferred Stock — Series B Convertible Preferred Stock" for a discussion of the terms of the Series B Preferred.

Use of Proceeds

We intend to use the net proceeds, if any, from the sales of securities offered by this prospectus to fund our and our subsidiaries' preclinical and clinical programs, (including, but not limited to, provide approximately \$5.0-\$7.0 million in funding for manufacturing scale-up activities to progress SYN-004 towards a potential Phase 3 clinical trial (broad indication) and/or initiate a Phase 1/2 clinical trial(s) in a specialty population, approximately \$7.5 million in funding for preclinical development and related manufacturing activities for our IND and Phase 1 clinical trial for our SYN-020 program and required milestone payments) and for working capital and general corporate purposes, including, to acquire, license or invest in complementary businesses, technologies, product candidates or other intellectual property. We have broad discretion in determining how the proceeds of this offering will be used, and our discretion is not limited by the aforementioned possible uses. Our board of directors believes the flexibility in application of the net proceeds is prudent. See "Use of Proceeds."

Risk Factors

See the section entitled "Risk Factors" beginning on page 15 of this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.

Market symbol and trading

Our common stock is listed on the NYSE American under the symbol "SYN". There is no established trading market for the Series B Preferred or warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Series B Preferred or warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the Series B Preferred and warrants will be limited.

The number of shares of common stock shown above to be outstanding after this offering is based on 7,208,320 shares outstanding as of October 8, 2018, and assumes the issuance and sale of 9,523,809 Class A Units in this offering and no Class B Units.

Unless we indicate otherwise, all information in this prospectus is as of October 8, 2018 and:

- reflects a one-for-thirty-five reverse stock split of our issued and outstanding shares of common stock, options and warrants effected on August 10, 2018 and the corresponding adjustment of all common stock prices per share and stock option and warrant exercise prices per share and preferred stock conversion ratios without taking into account fractional shares which are rounded up to the nearest whole number ;
- assumes no exercise by the underwriters of their over-allotment option;
- excludes 634,921 shares of our common stock issuable upon conversion of outstanding shares of preferred stock;
- excludes 347,765 shares of our common stock issuable upon exercise of outstanding options under our equity incentive plans at a weighted-average exercise price of \$54.19 per share;
- excludes 915,854 shares of our common stock reserved for issuance upon the exercise of outstanding warrants with a weighted-average exercise price of \$75.16 per share and assumes no exercise of the warrants issued in this offering;
- assumes no shares of Series B Preferred are sold in this offering; and
- excludes 170,674 shares of our common stock that are reserved for equity awards that may be granted under our equity incentive plans.

To the extent we sell any Class B Units in this offering, the same aggregate number of common stock equivalents resulting from this offering would be convertible under the Series B Preferred issued as part of the Class B Units.

RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained or incorporated by reference in this prospectus, including our consolidated financial statements and the related notes, before making a decision to invest in our securities. You should also consider the risks, uncertainties and assumptions discussed under Item 1A, "Risk Factors," in Part I of our Annual Report on Form 10-K for the year ended December 31, 2017 and Item 1A, "Risk Factors," in Part II of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 and any updates or other risks contained in other filings that we may make with the SEC after the date of this prospectus, all of which are incorporated herein by reference, and may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future and any additional prospectus supplement. If any of these risks actually occur, our business, results of operations and financial condition could suffer. In that case, the market price of our common stock could decline, and you may lose all or part of your investment.

RISKS RELATED TO THIS OFFERING

Investors will experience immediate and substantial dilution in the book value per share of the securities purchased in this offering.

Investors purchasing securities in this offering will incur immediate and substantial dilution in net tangible book value per share of our common stock. After giving effect to the sale of 9,523,809 Class A Units, at an assumed public offering price of \$2.10 per Class A Unit (which was the last reported sale price of our common stock on the NYSE American on October 8, 2018) assuming no sale of any Class B Units and after deducting the estimated underwriting discount and estimated offering expenses payable by us, purchasers of our Class A units in this offering will incur immediate dilution of \$0.10 per share in the net tangible book value of the common stock they acquire. For a further description of the dilution that investors in this offering will experience, see "Dilution".

In addition, to the extent that outstanding stock options or warrants or preferred stock (including the exercise of any warrants) have been or may be exercised or converted or other shares issued, you may experience further dilution.

Our management will have broad discretion over the use of proceeds from this offering and may not use the proceeds effectively.

Our management will have broad discretion over the use of proceeds from this offering. The net proceeds from this offering will be used to fund our and our subsidiaries' preclinical and clinical programs (including, but not limited to, provide approximately \$5.0-\$7.0 in funding for manufacturing scale-up activities to progress SYN-004 towards a potential Phase 3 (broad indication) clinical trial and/or initiate a Phase 1/2 clinical trial(s) in a specialty population, approximately \$7.5 million in funding for preclinical development and related manufacturing activities in preparation for our IND and Phase 1 clinical trial for our SYN-020 program and required milestone payments) and for working capital and general corporate purposes, including, to acquire, license or invest in complementary businesses, technologies, product candidates or other intellectual property. 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 improve our operating results or enhance the value of our common stock.

Even if this offering is successful, we will need to raise additional capital in the future to continue operations, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We have had recurring losses from operations, negative operating cash flow and an accumulated deficit. We do not generate any cash from operations and must raise additional funds in order to continue operating our business. We expect to continue to fund our operations primarily through equity and debt financings in the future. Our cash requirements may vary from those now planned depending upon numerous factors, including the result of future research and development activities. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue research and development activities and initiate and conduct clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. We expect that our existing cash together with the proceeds from this offering, will be sufficient to meet our anticipated cash requirements for the next twelve months. We will, however, require additional financing in order to complete our planned Phase 3 clinical trial for SYN-004 and/or our planned Phase 2b/3 clinical trial for SYN-010. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. There are no other commitments by any person for future financing. Our securities may be offered to other investors at a price lower than the price per share offered to current stockholders, or upon terms which may be deemed more favorable than those offered to current stockholders. In addition, the issuance of securities in any future financing may dilute an investor's equity ownership and have the effect of depressing the market price for our securities. Moreover, we may issue derivative securities, including options and/or warrants, from time to time, to procure qualified personnel or for other business reasons. The issuance of any such derivative securities, which is at the discretion of our board of directors, may further dilute the equity ownership of our stockholders. No assurance can be given as to our ability to procure additional financing, if required, and on terms deemed favorable to us. To the extent additional capital is required and cannot be raised successfully, we may then have to limit our then current operations and/or may have to curtail certain, if not all, of our business objectives and plans.

There is no established market for the Series B Preferred or warrants being offered in this offering.

There is no established trading market for the Series B Preferred or warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Series B Preferred or warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the Series B Preferred or warrants will be limited.

Holders of Series B Preferred will have limited voting rights.

Except with respect to certain material changes in the terms of the Series B Preferred and certain other matters and except as may be required by Nevada law, holders of Series B Preferred will have no voting rights. Holders of Series B Preferred will have no right to vote for any members of our board of directors.

The warrants are speculative and holders of the warrants will not have rights of common stockholders until such warrants are exercised.

The warrants being offered do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the warrants may exercise their right to acquire the common stock and pay an exercise price per share equal to 120% of the public offering price, or \$2.52 per share (assuming a public offering price of \$2.10 per Class A Unit, which was the last reported sale price of our common stock on the NYSE American on October 8, 2018) prior to three years from the date of issuance, after which date any unexercised warrants will expire and have no further value. Moreover, there can also be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants, and consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

The proceeds received from the exercise of the warrants issued in this offering on a cash basis could be decreased upon the occurrence of certain events, which could result in a decrease in our stock price and have a dilutive effect on our existing stockholders.

The warrants being offered do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the warrants may exercise their right to acquire the common stock and pay an exercise price per share equal to 120% of the public offering price, or \$2.52 per share (assuming a public offering price of \$2.10 per Class A Unit, which was the last reported sale price of our common stock on the NYSE American on October 8, 2018) prior to five years from the date of issuance, after which date any unexercised warrants will expire and have no further value. Moreover, there can also be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants, and consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

RISKS RELATING TO OUR BUSINESS

We will need to raise additional capital to operate our business and our failure to obtain funding when needed may force us to delay, reduce or eliminate our development programs or commercialization efforts.

During the six months ended June 30, 2018, our operating activities used net cash of approximately \$10.4 million and as of June 30, 2018 our cash and cash equivalents were \$7.1 million. With the exception of the three months ended June 30, 2010, we have experienced significant losses since inception and have a significant accumulated deficit. As of June 30, 2018, our accumulated deficit totaled approximately \$200.8 million on a consolidated basis. We expect to incur additional operating losses in the future and therefore expect our cumulative losses to increase. With the exception of the quarter ended June 30, 2010, and limited laboratory revenues from Adeona Clinical Laboratory, which we sold in March 2012, we have generated very minimal revenues. We do not expect to derive revenue from any source in the near future until we or our potential partners successfully commercialize our products. We expect our expenses to increase in connection with our anticipated activities, particularly as we continue research and development, initiate and conduct clinical trials, and seek marketing approval for our product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our products and therefore will not have product revenues from the sale of products. For the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing and collaboration fees and grants, if any.

We will need to raise additional capital to fund our operations and meet our current timelines and we cannot be certain that funding will be available on acceptable terms on a timely basis, or at all. Based on our current plans, our cash and cash equivalents together with the proceeds of this offering will not be sufficient to complete our planned Phase 3 clinical trial for SYN-004 or our planned Phase2b/3 clinical trial for SYN-010. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that may impact our ability to conduct our business. A failure otherwise to raise additional funds when needed in the future could result in us being unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. Our ability to raise capital through the sale of securities may be limited by the rules of the SEC and NYSE American that place limits on the number and dollar amount of securities that may be sold. There can be no assurances that we will be able to raise the funds needed, especially in light of the fact that our ability to sell securities registered on our registration statement on Form S-3 will be limited until such time the market value of our voting securities held by non-affiliates is \$75 million or more. We also may be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available.

We expect to continue to incur significant operating and capital expenditures.

Other than with respect to the three months ended December 31, 2017 and June 30, 2010, we have a history of losses and we have incurred, and will continue to incur, substantial losses and negative operating cash flow. Even if we succeed in developing and commercializing one or more of our product candidates, we may still incur substantial losses for the foreseeable future and may not sustain profitability. We expect that our pivotal Phase 2b/3 and Phase 3 clinical trials will enroll a greater number of patients than our prior clinical trials and will be more costly than our prior clinical trials. In addition, we anticipate a need for additional employees as we undertake later stage clinical trials. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will substantially increase in the foreseeable future as we do the following:

- continue to undertake preclinical development and pivotal clinical trials for our product candidates, including SYN-010 and SYN-004 (ribaxamase);
- seek regulatory approvals for our product candidates;
- develop our product candidates for commercialization;
- implement additional internal systems and infrastructure;
- license or acquire additional technologies;
- lease additional or alternative office facilities;
- manufacture product for clinical trials; and
- hire additional personnel, including members of our management team.

We may experience negative cash flow for the foreseeable future as we fund our development and clinical programs with capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our common stock and underlying securities.

We currently have no significant source of revenue and may never generate significant revenue. Currently, we have no products approved for commercial sale.

Our ability to generate revenue depends heavily on:

- our ability to raise additional capital on a timely basis to continue to fund our clinical trials;
- demonstration in current and future clinical trials that our lead product candidates, SYN-010 for the treatment of IBS-C and SYN-004 (ribaxamase) for the prevention of *C. difficile*, are safe and effective;
- our ability to seek and obtain regulatory approvals, including with respect to the indications we are seeking;
- successful manufacture and commercialization of our product candidates; and
- market acceptance of our products.

All of our existing product candidates are in various stages of development and will require extensive additional clinical evaluation, regulatory review and approval, significant marketing efforts and substantial investment before they could provide us with any revenue. As a result, even if we successfully develop, achieve regulatory approval and commercialize our products, we may be unable to generate revenue for many years, if at all. We do not anticipate that we will generate revenue from product sales for at least several years, if at all. If we are unable to generate revenue from product sales, we will not become profitable, and we may be unable to continue our operations.

Our consolidated financial statements have been prepared assuming that we will continue as a going concern.

Our consolidated financial statements as of December 31, 2017 have been prepared under the assumption that we will continue as a going concern for the next twelve months. In addition, our independent registered public accounting firm has issued a report that includes an explanatory paragraph referring to our recurring losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. Our consolidated financial statements as of December 31, 2017 did not include any adjustments that might result from the outcome of this uncertainty.

Our research and development efforts may not succeed in developing commercially successful products and technologies, which may limit our ability to achieve profitability. We are largely dependent on the success of our lead product candidates, SYN-004 (ribaxamase) and SYN-010, which require significant additional clinical testing before we can seek regulatory approval and we cannot be certain that these product candidates will receive regulatory approval or be successfully commercialized.

We must continue to explore opportunities that may lead to new products and technologies. To accomplish this, we must commit substantial efforts, funds, and other resources to research and development. A high rate of failure is inherent in the research and development of new products and technologies. Any such expenditures that we make will be made without any assurance that our efforts will be successful. Failure can occur at any point in the process, including after significant funds have been invested.

The success of our business currently depends on our development, approval and commercialization of our lead product candidates, SYN-004 and SYN-010, which are our only two product candidates for which we have conducted clinical trials. Even though we are pursuing a registration pathway for each of these product candidates based on specific FDA input, there are many uncertainties known and unknown that may affect the outcome of future clinical trials. All of our product candidates, including SYN-004 and SYN-010, will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. Regardless of whether our clinical trials are deemed to be successful, promising new product candidates may fail to reach the market or may only have limited commercial success because of efficacy or safety concerns, failure to achieve positive clinical outcomes, inability to obtain necessary regulatory approvals or satisfy regulatory criteria, limited scope of approved uses, excessive costs to manufacture, the failure to establish or maintain intellectual property rights, or infringement of the intellectual property rights of others. Failure to obtain regulatory approvals of SYN-004 or SYN-010 in a timely manner would have a material adverse impact on our business. Even if we successfully develop SYN-010, SYN-004 or other new products or enhancements, they may be quickly rendered obsolete by changing customer preferences, changing industry standards, or competitors' innovations. Innovations may not be quickly accepted in the marketplace because of, among other things, entrenched patterns of clinical practice or uncertainty over third-party reimbursement. We cannot state with certainty when or whether any of our products under development will be launched, whether we will be able to develop, license, or otherwise acquire drug candidates or products, or whether any products will be commercially successful. Failure to launch successful new products or new indications for existing products may cause our products to become obsolete, which may limit our ability to achieve profitability.

We are actively seeking and may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We are actively seeking and may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

We may not be able to retain rights licensed to us by others to commercialize key products and may not be able to establish or maintain the relationships we need to develop, manufacture, and market our products.

In addition to our own patent applications, we also currently rely on licensing agreements with third party patent holders/licensors for our products. We have an exclusive license agreement with CSMC relating to our IBS-C program. This agreement requires us or our sublicensee to use our best efforts to commercialize each of the technologies as well as meet certain diligence requirements and timelines in order to keep the license agreement in effect. In the event we or our sublicensee are not able to meet our diligence requirements, we may not be able to retain the rights granted under our agreement or renegotiate our arrangement institution on reasonable terms, or at all. If the license were to terminate and we were to lose the right to commercialize our products, our business opportunity would be adversely affected. Furthermore, we currently have very limited product development capabilities, and limited marketing or sales capabilities. For us to research, develop, and test our product candidates, we would need to contract with outside researchers, in most cases those parties that did the original research and from whom we have licensed the technologies. Our ECC agreements with Intrexon provide that Intrexon may terminate an agreement if we do not perform certain specified requirements, including developing therapies considered superior. Our agreement with UT Austin allows the UT Austin to terminate its agreement if we fail to comply with the terms of the agreement. Our agreement with CSMC allows CSMC to terminate its agreement if we fail to comply with the terms of the agreement.

We can give no assurances that any of our issued patents licensed to us or any of our other patent applications will provide us with significant proprietary protection or be of commercial benefit to us. Furthermore, the issuance of a patent is not conclusive as to its validity or enforceability, nor does the issuance of a patent provide the patent holder with freedom to operate without infringing the patent rights of others.

We will incur additional expenses in connection with our arrangements with Intrexon, our development of SYN-004, SYN 010 and SYN-020, and our agreement with CSMC.

Pursuant to our ECC agreements with Intrexon, we are responsible for future research and development expenses of product candidates developed under our collaboration, the effect of which has and will continue to increase the level of our overall research and development expenses going forward. Our agreements with CSMC requires that we initiate certain studies and file or have accepted an NDA within a certain amount of time, each of which are costly and will require additional expenditures. Although all manufacturing, preclinical studies and human clinical trials are expensive and difficult to design and implement, costs associated with the manufacturing, research and development of biologic product candidates are generally greater in comparison to small molecule product candidates. We have added additional personnel to support our ECC agreements with Intrexon, and research and development of our candidates, SYN-004, SYN-010 and SYN-020. In addition, we have commenced or intend to commence manufacturing of SYN-004, SYN-010 and SYN-020 material to support our planned preclinical and clinical studies which will require us to incur additional expenses.

Because our biologic programs are relatively new, we have only recently assumed development responsibility and costs associated with such programs. In addition, because development activities in collaboration with Intrexon are determined pursuant to joint steering committees comprised of Intrexon and ourselves and we have limited product development experience, future development costs associated with these programs may be difficult to anticipate and exceed our expectations. Our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, unanticipated technical challenges, changes in the focus and direction of our development activities or adjustments necessitated by changes in the competitive landscape in which we operate. If we are unable to continue to financially support such collaborations due to our own working capital constraints, we may be forced to delay our activities. If we are unable to obtain additional financing on terms acceptable to us or at all, we may be forced to seek licensing partners or discontinue development.

Developments by competitors may render our products or technologies obsolete or non-competitive.

Companies that currently sell or are developing proprietary products for the prevention and treatment of *C. difficile* infection include: Actelion Pharmaceutical Ltd., Merck & Co. Inc., Merus B.V., Pfizer Inc., and Sanofi S.A. Companies that currently sell or are developing proprietary products for IBS-C include: Actavis plc, Ironwood Pharmaceuticals, Inc., Synergy Pharmaceuticals Inc., and Takeda Pharmaceutical Company Limited. Companies that currently sell or are developing proprietary products for pertussis include: GlaxoSmithKline plc, MitsubishiTanabe Pharma Corporation and Sanofi S.A. Companies that sell or are developing products for the treatment of PKU include: BioMarin Pharmaceutical Inc., Codexis, Inc. and Synlogic, Inc. Many of our competitors have significant financial and human resources. The infectious disease market is highly competitive with many generic and proprietary intravenous and oral formulations available to physicians and their patients. For our monoclonal antibodies, we currently do not expect to be able to deliver our infectious disease candidates via the oral route and may thus be limited to the in-patient and/or acute treatment setting. In addition, academic research centers may develop technologies that compete with our SYN-004, SYN-010, SYN-005, SYN-020 products and our other technologies. Should clinicians or regulatory authorities view alternative therapeutic regimens as more effective than our products, this might delay or prevent us from obtaining regulatory approval for our products, or it might prevent us from obtaining favorable reimbursement rates from payers, such as Medicare, Medicaid, hospitals and private insurers.

We operate in a highly competitive environment.

The pharmaceutical and biotechnology industries, including the monoclonal antibody industry, are characterized by rapidly evolving technology and intense competition. Our competitors include major multi-national pharmaceutical companies and biotechnology companies developing both generic and proprietary therapies to treat serious diseases. Many of our competitors have drugs that have already been commercialized and therefore benefit from being first to market their products. Many of these companies are well-established and possess technical, human, research and development, financial, and sales and marketing resources significantly greater than ours. In addition, many of our potential competitors have formed strategic collaborations, partnerships and other types of joint ventures with larger, well established industry competitors that afford these companies potential research and development and commercialization advantages in the therapeutic areas we are currently pursuing.

Academic research centers, governmental agencies and other public and private research organizations are also conducting and financing research activities which may produce products directly competitive to those being developed by us. In addition, many of these competitors may be able to obtain patent protection, obtain FDA and other regulatory approvals and begin commercial sales of their products before us. These competitors will compete with us in product sales as well as recruitment and retention of qualified scientific and management personnel, establishment of clinical trial sites and patient enrollment for clinical trials, as well as in the acquisition of technologies and technology licenses complementary to our programs or advantageous to our business.

Competitors could develop and/or gain FDA approval of our product candidates for a different indication.

Many of our competitors may have more resources than us. We cannot provide any assurances that our products will be FDA approved prior to those of our competitors. We are subject to the risk that products containing our active ingredients that are already marketed to treat other indications, or future FDA approved products containing our active ingredients that are marketed to treat other indications, may be prescribed by physicians, or that physicians may substitute a competitor's products, to treat the diseases for which we are intending to commercialize; this is commonly referred to as "off-label" use. While under FDA regulations a competitor is not allowed to promote off-label uses of its product, the FDA does not regulate the practice of medicine and, as a result, cannot direct physicians to select certain products for their patients. Consequently, we might be limited in our ability to prevent off-label use of a competitor's product to treat the diseases we are intending to commercialize, even if we have issued method of use patents for that indication. If we are not able to obtain and enforce our patents, if any, or otherwise receive orphan drug protection, a competitor could develop and commercialize similar products for the same indications that we are pursuing. We cannot provide any assurances that a competitor will not obtain FDA approval for a product that contains the same active ingredients as our products.

If the parties we depend on for supplying substance raw materials for our product candidates and certain manufacturing-related services do not timely supply these products and services in sufficient quality or quantity, it may delay or impair our ability to develop, manufacture and market our product candidates.

We rely on suppliers for the substance raw materials of our product candidates and third parties for manufacturing-related services to produce material that meets appropriate content, quality and stability standards and use in clinical trials of our products and, after approval, for commercial distribution. To succeed, clinical trials require adequate supplies of study material, which may be difficult or uneconomical to procure or manufacture and there can be no assurance that we will successfully procure such study material or even if procured, that we can do so in quantities and in a timely manner to allow our clinical trials to proceed as planned. We and our suppliers and vendors may not be able to (i) produce our study material to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us, or (iii) remain in business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or manufacturer which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers and vendors, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

The third-party manufacturers of the active pharmaceutical ingredient (API) and drug product for our lead product candidates, SYN-010 and SYN-004, are established cGMP manufacturers. For all other therapeutic areas we have not yet established cGMP manufacturers for our biologic and drug candidates. We currently have manufacturers for each of our lead product candidates as well as our SYN-020 program, however, we believe additional manufacturers are available, if any of our manufacturers were to limit or terminate production or otherwise fail to meet the quality or delivery requirements needed to satisfy the supply commitments, the process of locating and qualifying alternate sources could require up to several months, during which time our production could be delayed. Any curtailment in the availability of SYN-004 or SYN-010 could have a material adverse effect on our business, financial position and results of operations. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs.

The manufacture of our product candidates requires significant expertise and manufacturers may encounter difficulties in production, particularly in scaling up production. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign regulations. We may experience longer than expected lead times with respect to the manufacture of SYN-004 (ribaxamase), which may result from the increase in manufacturing scale necessary to conduct our anticipated Phase 3 clinical trial(s) and result in trial delays. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of our clinical trials, increase the costs associated with conducting our clinical trials and, depending upon the period of delay, require us to commence new clinical trials at significant additional expense or to terminate a clinical trial.

We are responsible for ensuring that each of our contract manufacturers comply with the cGMP requirements of the FDA and other regulatory authorities from which we seek to obtain product approval. While we oversee compliance, we do not have control over our manufacturers and their compliance with regulatory requirements. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The approval process for NDAs includes a review of the manufacturer's compliance with cGMP requirements. We are responsible for regularly assessing a contract manufacturer's compliance with cGMP requirements through record reviews and periodic audits and for ensuring that the contract manufacturer takes responsibility and corrective action for any identified deviations.

A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. Furthermore, if our manufacturers fail to deliver the required commercial quantities on a timely basis and at commercially reasonable prices, we may be unable to meet demand for any approved products and would lose potential revenues.

We may not be able to manufacture our product candidates in commercial quantities, which would prevent us from commercializing our product candidates.

To date, our product candidates have been manufactured in small quantities for preclinical studies and clinical trials. If any of our product candidates is approved by the FDA or comparable regulatory authorities in other countries for commercial sale, we will need to manufacture such product candidate in larger quantities. We may not be able to increase successfully the manufacturing capacity for any of our product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to increase successfully the manufacturing capacity for a product candidate, the clinical trials as well as the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply. Our product candidates require precise, high quality manufacturing. Our failure to achieve and maintain these high quality manufacturing standards in collaboration with our third-party manufacturers, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could harm our business, financial condition and results of operations.

If we do not obtain the necessary regulatory approvals in the U.S. and/or other countries we will not be able to sell our product candidates.

We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates or any product candidates we acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the U.S. and approvals from the FDA-equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. We will be required to conduct clinical trials that will be costly. We cannot predict whether our clinical trials will demonstrate the safety and efficacy of our product candidates or if the results of any clinical trials will be sufficient to advance to the next phase of development or for approval from the FDA. We also cannot predict whether our research and clinical approaches will result in drugs or therapeutics that the FDA considers safe and effective for the proposed indications. The FDA has substantial discretion in the drug approval process. The approval process may be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may prevent or delay commercialization of, and our ability to derive product revenues from our product candidates; and diminish any competitive advantages that we may otherwise believe that we hold.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs or BLAs. We may never obtain regulatory clearance for any of our product candidates. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by leaving us without a saleable product, and therefore without any source of revenues, until another product candidate can be developed. There is no guarantee that we will ever be able to develop or acquire another product candidate.

In addition, the FDA may require us to conduct additional pre-clinical and clinical testing or to perform post-marketing studies, as a condition to granting marketing approval of a product. The results generated after approval could result in loss of marketing approval, changes in product labeling, and/or new or increased concerns about the side effects or efficacy of a product. The FDA has significant post-market authority, including the explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information, and compliance with FDA-approved risk evaluation and mitigation strategies. The FDA's exercise of its authority has in some cases resulted, and in the future could result, in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements and potential restrictions on sales of approved products.

In foreign jurisdictions, we must also receive approval from the appropriate regulatory authorities before we can commercialize any products, which can be time consuming and costly. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. There can be no assurance that we will receive the approvals necessary to commercialize our product candidate for sale outside the United States.

If the FDA approves any of our product candidates, the labeling, manufacturing, packaging, adverse event reporting, storage, advertising, promotion and record-keeping for our products will be subject to ongoing FDA requirements and continued regulatory oversight and review. Our drug manufacturers and subcontractors that we retain will be required to comply with FDA and other regulations. We may also be subject to additional FDA post-marketing obligations. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates and/or may be subject to product recalls, seizures, suspension of regulatory approval, suspension of production, injunctions or civil or criminal sanctions. The subsequent discovery of previously unknown problems with any marketed product, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the product, and could include withdrawal of the product from the market.

Clinical trials are very expensive, time-consuming, and difficult to design and implement.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. We estimate that clinical trials for our product candidates would take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Commencement and completion of clinical trials may be delayed by several factors, including:

- obtaining an IND application with the FDA to commence clinical trials;
- identification of, and acceptable arrangements with, one or more clinical sites;
- obtaining IRB approval to commence clinical trials;
- unforeseen safety issues;
- determination of dosing;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment;
- inability to obtain supply of our drug candidate in a timely manner;
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- unwillingness of the FDA or IRBs to permit the clinical trials to be initiated.

In addition, we, IRBs or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if IRBs or the FDA finds deficiencies in our submissions or conduct of our trials.

The results of our clinical trials may not support our product candidate claims and the results of preclinical studies and completed clinical trials are not necessarily predictive of future results.

To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our product candidates. Favorable results in our early studies or trials may not be repeated in later studies or trials. Even if our clinical trials are initiated and completed as planned, we cannot be certain that the results will support our product candidate claims. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. Success of our predecessor P1A clinical product or positive topline data from our previous SYN-004 Phase 1 and Phase 2 clinical trials, does not ensure success of SYN-004, and positive topline data for our SYN-010 Phase 2 clinical trials does not ensure success of SYN-010. Furthermore, the FDA could determine that SYN-004 has not demonstrated safety and require additional clinical trials and safety data, despite positive results from our SYN-004 Phase 2b clinical trial and the determination by clinical sites investigators and an independent third party that the adverse events that occurred in the group that received SYN-004 in our Phase 2b clinical trial were not drug related. We cannot be sure that the results of later clinical trials would replicate the results of prior clinical trials and preclinical testing nor that they would satisfy the requirements of the FDA or other regulatory agencies. Clinical trials may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products. Any such failure could cause us or our sublicensee to abandon a product candidate and might delay development of other product candidates. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Any delay in, or termination of, our clinical trials would delay our obtaining FDA approval for the affected product candidate and, ultimately, our ability to commercialize that product candidate.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Delays in patient enrollment may result in increased cost or may adversely affect timing or outcome of planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

We may experience delays in clinical testing of our product candidates. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a clinical trial, in securing clinical trial agreements with prospective sites with acceptable terms, in obtaining institutional review board approval to conduct a clinical trial at a prospective site, in recruiting patients to participate in a clinical trial or in obtaining sufficient supplies of clinical trial materials. Manufacturing considerations for SYN-004 (ribaxamase) and our other product candidates may include an expected several month lead time following a decision to commence any clinical trial(s) and capacity considerations of our third-party contract manufacturers to provide clinical supply of SYN-004 or our other product candidates could cause delays in clinical trials. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, competing clinical trials and new drugs approved for the conditions we are investigating. Clinical investigators will need to decide whether to offer their patients enrollment in clinical trials of our product candidates versus treating these patients with commercially available drugs that have established safety and efficacy profiles. Any delays in completing our clinical trials will increase our costs, slow down our product development and timeliness and approval process and delay our ability to generate revenue.

Patients who are administered our product candidates may experience unexpected side effects or other safety risks that could cause a halt in their clinical development, preclude approval of our product candidates or limit their commercial potential.

Our clinical trials may be suspended at any time for a number of reasons. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, the FDA or other regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients. For example, the FDA could determine that SYN-004 has not demonstrated safety and require additional clinical trials and safety data, despite positive results from our SYN-004 Phase 2b clinical trial and the determination by clinical sites investigators and an independent third party that the adverse events that occurred in the group that received SYN-004 in our Phase 2b clinical trial were not drug related.

Administering any product candidate to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidates for any or all targeted indications. Ultimately, some or all of our product candidates may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials. Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and could substantially increase commercialization costs.

An NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidate.

We plan to submit SYN-010 to the FDA for approval under Section 505(b)(2) of the FDCA. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by, or for, the applicant and on which the applicant has not obtained a right of reference. The 505(b)(2) application would enable us to reference published literature and/or the FDA's previous findings of safety and effectiveness for the branded reference drug. For NDAs submitted under Section 505(b)(2) of the FDCA, the patent certification and related provisions of the Hatch-Waxman Act apply. In accordance with the Hatch-Waxman Act, such NDAs may be required to include certifications, known as paragraph IV certifications, that certify that any patents listed in the Patent and Exclusivity Information Addendum of the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, with respect to any product referenced in the 505(b)(2) application, are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) NDA.

Under the Hatch-Waxman Act, the holder of patents that the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the paragraph IV certification. Filing of a patent infringement lawsuit against the filer of the 505(b)(2) applicant within 45 days of the patent owner's receipt of notice triggers a one-time, automatic, 30-month stay of the FDA's ability to approve the 505(b)(2) NDA, unless patent litigation is resolved in the favor of the paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all. In addition, a 505(b)(2) application will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the branded reference drug, which could be time consuming and could substantially delay our achievement of regulatory approvals for such product candidates. The FDA may also reject our future 505(b)(2) submissions and require us to file such submissions under Section 505(b)(1) of the FDCA, which would require us to provide extensive data to establish safety and effectiveness of the drug for the proposed use and could cause delay and be considerably more expensive and time consuming. These factors, among others, may limit our ability to successfully commercialize our product candidates.

Our product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.

If one of our product candidates is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product by physicians, healthcare professionals and third-party payors and our profitability and growth will depend on a number of factors, including:

- demonstration of safety and efficacy;
- changes in the practice guidelines and the standard of care for the targeted indication;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- budget impact of adoption of our product on relevant drug formularies;
- the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;
- pricing, reimbursement and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or any of our partners' sales and marketing strategies;
- the product labeling or product insert required by the FDA or regulatory authority in other countries; and
- the availability of adequate third-party insurance coverage or reimbursement.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payors, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful.

We depend on third parties, including researchers and sublicensees, who are not under our control. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to seek or obtain regulatory approval for or commercialize our product candidates.

Since we have in-licensed some of our product candidates, have sublicensed a product candidate and have collaboration agreements for the development of other product candidates, we depend upon our sublicensee and independent investigators and scientific collaborators, such as universities and medical institutions or private physician scientists, to advise us and to conduct our preclinical and clinical trials under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs or the timing of their procurement of clinical-trial data or their compliance with applicable regulatory guidelines. Should any of these scientific inventors/advisors or those of our sublicensee become disabled or die unexpectedly, or should they fail to comply with applicable regulatory guidelines, we or our sublicensee may be forced to scale back or terminate development of that program. They may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking those programs ourselves. Failing to devote sufficient time and resources to our drug-development programs, or substandard performance and failure to comply with regulatory guidelines, could result in delay of any FDA applications and our commercialization of the drug candidate involved.

These collaborators may also have relationships with other commercial entities, some of which may compete with us. Our collaborators assisting our competitors could harm our competitive position. For example, we are highly dependent on scientific collaborators for our IBS-C development program, each of whom are employed by third parties.

With respect to our product candidates in collaboration with Intrexon, we are dependent upon Intrexon's synthetic biology facilities and capabilities as we have no such facilities and capabilities of our own. We are also reliant on their vectors, monoclonal antibody discovery, production cell line development and know-how.

With respect to our product candidate for pertussis in collaboration with University of Texas at Austin, we are dependent on its research laboratories as we have no such facilities or capabilities of our own. If any of the foregoing were to become inaccessible or terminated, it would be difficult for us to develop and commercialize our synthetic biologic product candidates.

We have in the past and expect to have in the future agreements with third-party contract research organizations (CROs), under which we have delegated to the CROs the responsibility to coordinate and monitor the conduct of our SYN-004 and SYN-010 clinical trials and to manage data for our clinical programs. We, our CROs and our clinical sites are required to comply with current Good Clinical Practices, or cGCPs, regulations and guidelines issued by the FDA and by similar governmental authorities in other countries where we are conducting clinical trials. We have an ongoing obligation to monitor the activities conducted by our CROs and at our clinical sites to confirm compliance with these requirements. In the future, if we, our CROs or our clinical sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations, and will require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

We currently have no marketing, sales or distribution organization and have no experience in marketing products as a company. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We currently have no marketing, sales or distribution capabilities and have no experience in marketing products. We may develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products; however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

Even if our products are approved, if doctors decide not to prescribe SYN-010 or hospitals decide not to prescribe SYN-004, we may be unable to generate sufficient revenue to sustain our business.

To increase awareness and adoption of our products once approved, we and our collaborators will need to educate doctors and hospitals on the benefits and value of our products through published papers, presentations at scientific conferences and one-on-one education sessions. In addition, we and our collaborators will need to assure doctors of our ability to obtain and maintain adequate reimbursement coverage from third-party payors. We and our collaborators may need to hire additional commercial, scientific, technical, sales and marketing and other personnel to support this process. If our educational efforts fail and medical practitioners do not decide to prescribe our products in sufficient volume, we may be unable to generate sufficient revenue to sustain our business. In addition, factors outside of our control, such as insurance reimbursement are expected to influence market acceptance of our products. Accordingly, even if we receive regulatory approval for the use of our products, we may not be successful in generating revenue from the sale of our products.

Reimbursement may not be available for our product candidates, which would impede sales.

Market acceptance and sales of our product candidates may depend on coverage and reimbursement policies and health care reform measures. Decisions about formulary coverage as well as levels at which government authorities and third-party payors, such as private health insurers and health maintenance organizations, reimburse patients for the price they pay for our products as well as levels at which these payors pay directly for our products, where applicable, could affect whether we are able to commercialize these products. We cannot be sure that reimbursement will be available for any of our products. Also, we cannot be sure that coverage or reimbursement amounts will not reduce the demand for, or the price of, our products. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to commercialize our products.

In recent years, officials have made numerous proposals to change the health care system in the United States. These proposals include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. If our products are or become subject to government regulation that limits or prohibits payment for our products, or that subjects the price of our products to governmental control, we may not be able to generate revenue, attain profitability or commercialize our products.

As a result of legislative proposals and the trend towards managed health care in the United States, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also impose strict prior authorization requirements and/or refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly-approved drugs, which in turn will put pressure on the pricing of drugs.

Healthcare reform measures could hinder or prevent our product candidates' commercial success.

The U.S. government and other governments have shown significant interest in pursuing continued healthcare reform. Any government-adopted reform measures could adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the United States, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably.

If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability lawsuits related to the testing of our product candidates, and will face an even greater risk if we sell our product candidates commercially. Currently, we are not aware of any anticipated product liability claims with respect to our product candidates. In the future, an individual may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- initiation of investigations by regulators;
- substantial monetary awards to patients or other claimants;
- distraction of management's attention from our primary business;
- product recalls;
- loss of revenue; and
- the inability to commercialize our product candidates.

We have clinical trial liability insurance. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates. Our current insurance coverage may prove insufficient to cover any liability claims brought against us. In addition, because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy liabilities that may arise.

We rely on patent applications and various regulatory exclusivities to protect some of our product candidates and our ability to compete may be limited or eliminated if we are not able to protect our products.

The patent positions of pharmaceutical companies are uncertain and may involve complex legal and factual questions. We may incur significant expenses in protecting our intellectual property and defending or assessing claims with respect to intellectual property owned by others. Any patent or other infringement litigation by or against us could cause us to incur significant expenses and divert the attention of our management.

Others may file patent applications or obtain patents on similar technologies or compounds that compete with our products. We cannot predict how broad the claims in any such patents or applications will be, and whether they will be allowed. Once claims have been issued, we cannot predict how they will be construed or enforced. We may infringe intellectual property rights of others without being aware of it. If another party claims we are infringing their technology, we could have to defend an expensive and time consuming lawsuit, pay a large sum if we are found to be infringing, or be prohibited from selling or licensing our products unless we obtain a license or redesign our product, which may not be possible.

We also rely on trade secrets and proprietary know-how to develop and maintain our competitive position. Some of our current or former employees, consultants, scientific advisors, current or prospective corporate collaborators, may unintentionally or willfully disclose our confidential information to competitors or use our proprietary technology for their own benefit. Furthermore, enforcing a claim alleging the infringement of our trade secrets would be expensive and difficult to prove, making the outcome uncertain. Our competitors may also independently develop similar knowledge, methods, and know-how or gain access to our proprietary information through some other means.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, as well as costs associated with lawsuits.

If any other person files patent applications, or is issued patents, claiming technology also claimed by us in pending applications, we may be required to participate in interference proceedings in the U.S. Patent and Trademark Office to determine priority of invention. We, or our licensors, may also need to participate in interference proceedings involving our issued patents and pending applications of another entity.

The intellectual property environment in the monoclonal antibody field is particularly complex, constantly evolving and highly fragmented. We have not conducted freedom-to-use patent searches on all aspects of our product candidates or potential product candidates, and we may be unaware of relevant patents and patent applications of third parties. In addition, the freedom-to-use patent searches that have been conducted may not have identified all relevant issued patents or pending patents. We cannot provide assurance that our proposed products in this area will not ultimately be held to infringe one or more valid claims owned by third parties which may exist or come to exist in the future or that in such case we will be able to obtain a license from such parties on acceptable terms.

We cannot guarantee that the practice of our technologies will not conflict with the rights of others. In some foreign jurisdictions, we could become involved in opposition proceedings, either by opposing the validity of another's foreign patent or by persons opposing the validity of our foreign patents.

We may also face frivolous litigation or lawsuits from various competitors or from litigious securities attorneys. The cost to us of any litigation or other proceeding relating to these areas, even if deemed frivolous or resolved in our favor, could be substantial and could distract management from our business. Uncertainties resulting from initiation and continuation of any litigation could have a material adverse effect on our ability to continue our operations.

If we infringe the rights of others we could be prevented from selling products or forced to pay damages.

If our products, methods, processes, and other technologies are found to infringe the proprietary rights of other parties, we could be required to pay damages, or we may be required to cease using the technology or to license rights from the prevailing party. Any prevailing party may be unwilling to offer us a license on commercially acceptable terms.

We do not have a guarantee of patent term restoration and marketing exclusivity of the ingredients for our drugs even if we are granted FDA approval of our products.

The U.S. Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman) permits the FDA to approve Abbreviated New Drug Applications (ANDAs) for generic versions of innovator drugs, as well as NDAs with less original clinical data, and provides patent restoration and exclusivity protections to innovator drug manufacturers. The ANDA process permits competitor companies to obtain marketing approval for drugs with the same active ingredient and for the same uses as innovator drugs, but does not require the conduct and submission of clinical studies demonstrating safety and efficacy. As a result, a competitor could copy any of our drugs and only need to submit data demonstrating that the copy is bioequivalent to gain marketing approval from the FDA. Hatch-Waxman requires a competitor that submits an ANDA, or otherwise relies on safety and efficacy data for one of our drugs, to notify us and/or our business partners of potential infringement of our patent rights. We and/or our business partners may sue the company for patent infringement, which would result in a 30-month stay of approval of the competitor's application. The discovery, trial and appeals process in such suits can take several years. If the litigation is resolved in favor of the generic applicant or the challenged patent expires during the 30-month period, the stay is lifted and the FDA may approve the application. Hatch-Waxman also allows competitors to market copies of innovator products by submitting significantly less clinical data outside the ANDA context. Such applications, known as Section 505(b)(2) NDAs may rely on clinical investigations not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use and are subject to the ANDA notification procedures described above.

The law also permits restoration of a portion of a product's patent term that is lost during clinical development and NDA review, and provides statutory protection, known as exclusivity, against FDA approval or acceptance of certain competitor applications. Restoration can return up to five years of patent term for a patent covering a new product or its use to compensate for time lost during product development and regulatory review. The restoration period is generally one-half the time between the effective date of an IND and submission of an NDA, plus the time between NDA submission and its approval (subject to the five-year limit), and no extension can extend total patent life beyond 14 years after the drug approval date. Applications for patent term extension are subject to U.S. Patent and Trademark Office (USPTO) approval, in conjunction with FDA. Approval of these applications takes at least nine months, and there can be no guarantee that it will be given at all.

Hatch-Waxman also provides for differing periods of statutory protection for new drugs approved under an NDA. Among the types of exclusivity are those for a “new chemical entity” and those for a new formulation or indication for a previously-approved drug. If granted, marketing exclusivity for the types of products that we are developing, which include only drugs with innovative changes to previously-approved products using the same active ingredient, would prohibit the FDA from approving an ANDA or 505(b)(2) NDA relying on our safety and efficacy data for three years. This three-year exclusivity, however, covers only the innovation associated with the original NDA. It does not prohibit the FDA from approving applications for drugs with the same active ingredient but without our new innovative change. These marketing exclusivity protections do not prohibit the FDA from approving a full NDA, even if it contains the innovative change.

The technology on which our channel partnering arrangements with Intrexon are based on early stage technology.

On August 8, 2012, we announced an exclusive channel collaboration with Intrexon relating to the design, production, testing and commercialization of human recombinant monoclonal antibodies for the treatment of certain infectious diseases. Although monoclonal antibody therapeutics are well established in the biotechnology and pharmaceutical sectors, their use for the treatment of infectious disease is extremely limited. In order for monoclonal antibodies to be effective for infectious diseases, they must not only properly target the organism of interest (or its toxins), but may also need to overcome defenses and forms of resistance of such organisms. To accomplish this may require the use of more than one specific monoclonal antibody, and mixtures of different monoclonal antibodies, which may create additional unforeseen complications, including increased manufacturing complexity and expense. In order to be competitive, monoclonal antibodies will be required to be produced at a low enough cost of goods in order to be profitably marketed. We have very limited development and manufacturing experience in the field of monoclonal antibodies and infectious disease. We cannot assure that any monoclonal antibody candidates will provide satisfactory *in vitro* and *in vivo* nonclinical results sufficient to warrant the expense of cGMP manufacture and clinical testing in human clinical trials.

On August 10, 2015, we expanded our relationship with Intrexon and entered into an ECC that governs a “channel collaboration” arrangement in which we intend to use Intrexon’s technology for development of biotherapeutic products for the treatment of PKU in humans. The strategy is to orally deliver a bacterium, *Lactococcus lactis*, that has been engineered to efficiently degrade phenylalanine in the GI tract to prevent phenylalanine absorption into the blood. The strategy is supported by data from rodent studies. The extent to which the data translate to large animal models and to a human therapeutic remains unknown. While genetically-modified versions of *Lactococcus lactis* have been tested in human clinical trials for other indications, the regulatory paths for recombinant bacterial products have not been fully established.

We do not expect to generate any additional revenue from our sublicense with Meda AB due to recent developments in Europe.

On May 6, 2010, we entered into a sublicense agreement with Meda AB whereby we were given the right to receive certain milestone payments totaling \$17.5 million (including an upfront payment of \$2.5 million that was received in 2010), plus certain royalties on our flupirtine program. Meda AB informed us that due to the decision of the European Medicines Agency (EMA) to limit the use of flupirtine for long-term pill and systemic use, it has postponed its planned fibromyalgia clinical trials in the U.S. Therefore, we do not expect that the various milestones set forth in the sublicense agreement will be achieved by Meda AB, or that Meda AB will develop flupirtine for fibromyalgia in the U.S., Canada or Japan and accordingly we do not expect to receive any additional milestone payments or royalties on sales in connection with the sublicense agreement.

We may fail to retain or recruit necessary personnel, and we may be unable to secure the services of consultants.

As of September 30, 2018, we employed 25 individuals, 24 of whom are full-time employees. We have also engaged clinical consultants to advise us on our clinical programs and regulatory consultants to advise us on our dealings with the FDA and other foreign regulatory authorities. We have been and will be required to retain additional consultants and employees in order to fulfill our obligations under the ECC agreements with Intrexon, our development of SYN 010 and SYN-004 and our agreement with CSMC. Our future performance will depend in part on our ability to successfully integrate newly hired officers into our management team and our ability to develop an effective working relationship among senior management.

Certain of our directors, scientific advisors, and consultants serve as officers, directors, scientific advisors, or consultants of other biopharmaceutical or biotechnology companies that might be developing competitive products to ours. Other than corporate opportunities, none of our directors are obligated under any agreement or understanding with us to make any additional products or technologies available to us. Similarly, we can give no assurances, and we do not expect and stockholders should not expect, that any biomedical or pharmaceutical product or technology identified by any of our directors or affiliates in the future would be made available to us other than corporate opportunities. We can give no assurances that any such other companies will not have interests that are in conflict with our interests.

Losing key personnel or failing to recruit necessary additional personnel would impede our ability to attain our development objectives. There is intense competition for qualified personnel in the drug and biologic development areas, and we may not be able to attract and retain the qualified personnel we would need to develop our business.

We rely on independent organizations, advisors, and consultants to perform certain services for us, including handling substantially all aspects of regulatory approval, clinical management, manufacturing, marketing, and sales. We expect that this will continue to be the case. Such services may not always be available to us on a timely basis when we need them.

We expect to increase the size of our organization, and we may experience difficulties in managing growth.

We are a small company with 25 employees as of September 30, 2018. To continue our clinical trials and commercialize our product candidates, we will need to expand our employee base for managerial, operational, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- manage development efforts effectively;
- manage our commercialization activities effectively;
- integrate additional management, administrative, manufacturing and sales and marketing personnel;
- maintain sufficient administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our financial results and impact our ability to achieve development milestones.

Our management team may invest or spend the proceeds of our prior offerings and future offerings 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 our offerings. The net proceeds from our offerings, including sales made under the sales agreement that we entered into on August 5, 2016 with FBR Capital Markets & Co. now known as B. Riley FBR, Inc. (the “B. Riley FBR Sales Agreement”), will be used primarily for general corporate purposes, which may include, among other things, for clinical trials for our product candidates, paying general and administrative expenses and accounts payable, increasing our working capital, funding research and development and funding capital expenditures. We may also 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 in-license, acquire or invest in complementary businesses or products, although we have no commitments or agreements with respect to any such licenses, acquisitions or investments as of the date of this filing supplement. Our management will have considerable discretion in the application of the net proceeds, and investors will not have the opportunity, as part of their 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. The failure of our management to use funds effectively could have a material adverse effect on our business, cause the market price of our common stock to decline and impair the commercialization of our products and/or delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing instruments and U.S. government securities. These investments may not yield a favorable return to our stockholders.

RISKS RELATING TO OUR SECURITIES

We cannot assure you that our common stock will be liquid or that it will remain listed on the NYSE American. A failure to regain compliance with the NYSE American stockholders equity listing requirements or failure to continue to meet the other listing requirements could result in a de-listing of our common stock.

Our common stock is listed on the NYSE American. The NYSE American’s listing standards generally mandate that we meet certain requirements relating to stockholders’ equity, stock price, market capitalization, aggregate market value of publicly held shares and distribution requirements. We cannot assure you that we will be able to maintain the continued listing standards of the NYSE American. The NYSE American requires companies to meet certain continued listing criteria including a minimum stockholders’ equity of \$6.0 million if an issuer has sustained losses from continuing operations and/or net losses in its five most recent years, as outlined in the NYSE American Company Guide. At June 30, 2018, we had stockholders’ deficit of \$208.8 million. The NYSE American Company Guide also states that the NYSE normally will not consider removing from listing securities of an issuer with total value of market capitalization of at least \$50.0 million and 1,100,000 shares publicly held, a market value of publicly held shares of at least \$15.0 million and 400 round lot shareholders. Although we have more than 1,100,000 shares publicly held and 400 round lot shareholders, our stock price is volatile and, during the first two quarters of 2018, the price of our common stock experienced a sustained decrease resulting in a period where our market capitalization fell below \$50.0 million. Our market capitalization is currently below \$50.0 million.

On March 7, 2018, we announced that we received written communication from the NYSE American stating we were no longer in compliance with certain continued listing standards as set forth in the NYSE American Company Guide. Specifically, based on our annual report on Form 10-K for the year ended December 31, 2017, and filed with the SEC on February 22, 2018, we are below compliance with Part 10, Section 1003(iii) of the NYSE American Company Guide since we reported a stockholders' deficit of \$1.5 million and net losses in five of our most recent fiscal years as of December 31, 2017. On April 3, 2018, we submitted a plan of compliance to the NYSE American outlining our plan to regain compliance with certain continued listing standards as set forth in Part 10, Section 1003(iii) of the NYSE American Company Guide by September 2, 2018, the conclusion of the compliance plan period. There can be no assurance that we can regain compliance with the listing standard of the NYSE American, or that the NYSE American will continue to list our common stock if we regain compliance, or if we continue to fail to maintain the minimum stockholders' equity. In addition, in the future we may not be able to maintain such minimum stockholders' equity and/or issue additional equity securities in exchange for cash or other assets, if available, to maintain certain minimum stockholders' equity required by the NYSE American. If we are delisted from the NYSE American then our common stock will trade, if at all, only on the over-the-counter market, such as the OTC Bulletin Board securities market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. If our common stock is delisted from the NYSE American due to our failure to regain compliance with the listing standards by the end of the compliance period or for any other reason, and the market value of our shares of common stock held by non-affiliates remains below \$15 million, we will likely no longer be eligible to sell common stock pursuant to the B. Riley FBR Sales Agreement or otherwise utilize our shelf registration statement. In addition, delisting of our common stock could depress our stock price, substantially limit liquidity of our common stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from the NYSE American could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities. On May 18, 2018 we received notification from the NYSE American that NYSE Regulation has reviewed our plan of compliance and determined to accept the plan and grant a plan period through September 2, 2019. NYSE Regulation staff will review our company periodically for compliance with the initiatives outlined in the plan. If we are not in compliance with the continued listing standards by September 2, 2019 or if we do not make progress consistent with the plan during the plan period, NYSE Regulation staff will initiate delisting proceeding as appropriate.

If our common stock falls below \$0.20 per share on a 30-trading-day average it will become subject to the continued listing evaluation and follow-up procedures set forth in Section 1009 of the NYSE American Company Guide which could, among other things, result in initiation of immediate delisting procedures. In the event that we were to fail to meet the requirements of NYSE American per share price requirement or stockholders equity requirement and we could not timely cure such deficiency, our listing could become subject to NYSE American continued listing evaluation and follow-up procedures, which could result in delisting procedures. Based on the low stock price on July 28, 2018, our board of directors approved a one-for-thirty-five proportionate reverse stock split of our authorized number of shares of common stock and our outstanding number of shares of common stock that we effected on August 10, 2018. However, there can be no assurance that the reverse stock split will result in a sustained higher stock price that will allow us to meet the NYSE American stock price listing requirements or that the reverse stock split will not inhibit our ability to seek equity financing as a remedy to regain compliance with NYSE American stockholders' equity requirements.

Holders of our warrants issued in our October 2014 offering, and our November 2016 offering, and our Series A Preferred Stock have no rights as common stockholders until they exercise their warrants or convert their Series A Preferred Stock and acquire our common stock.

Until the holders of the warrants we issued in our October 2014 offering and our November 2016 offering and the holders of our Series A Preferred Stock acquire shares of our common stock by exercising their warrants or converting their Series A Preferred Stock, respectively, the holders have no rights as a stockholder with respect to the shares of common stock underlying their securities. Upon exercise of the warrants or conversion of the Series A Preferred Stock, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

Because there is no established public trading market for the October 2014 or November 2016 warrants or the Series A Preferred Stock we issued, the liquidity of each such security is limited. We do not expect a market to develop, nor do we intend to apply to list the October 2014 or November 2016 warrants or the Series A Preferred Stock on any securities exchange. Upon exercise of the October 2014 or November 2016 warrants and conversion of the Series A Preferred Stock, our stockholders will experience dilution.

The fundamental change purchase feature of the warrants we issued in our November 2016 offering may delay or prevent an otherwise beneficial attempt to take over our company.

The terms of the November 2016 warrants require us to offer to purchase the warrants for cash in the event of a fundamental change, as defined. This feature may have the effect of delaying or preventing a takeover of our company that would otherwise be beneficial to investors.

Warrants are a risky investment. Holders of outstanding warrants may not be able to recover the investment in the warrants, and the warrants may expire worthless.

Whether our outstanding warrants will have any value will depend on the market conditions for, and the price of, our common stock, which conditions will depend on factors related and unrelated to the success of our clinical development program, and cannot be predicted at this time.

If our common stock price does not increase to an amount sufficiently above the exercise prices of the warrants during the periods the warrants are exercisable, holders of warrants will be unable to recover any of their investment in the warrants. In fact, the warrants issued in November 2016 that had an exercise price of \$60.20 (post reverse stock split) expired unexercised because their exercise price was above the common stock trading price. There can be no assurance that any of the factors that could impact the trading price of our common stock will result in the trading price increasing to an amount that will exceed the exercise price or the price required for holders of warrants to achieve a positive return on their investment in the warrants.

We may not have the funds necessary to fulfill our obligation to repurchase the November 2016 warrants.

Under certain circumstances, if an extraordinary transaction (as defined in the warrant agreement) occurs, holders of the warrants issued in November 2016 may require us to repurchase the remaining unexercised portion of such warrants for an amount of cash equal to the value of the warrant as determined in accordance with the Black Scholes option pricing model and the terms of the warrants. Our ability to repurchase the warrants depends on our ability to generate cash flow in the future. To some extent, this is subject to general economic, financial, competitive, legislative and regulatory factors and other factors that are beyond our control. We cannot assure you that we will maintain sufficient cash reserves or that our business will generate cash flow from operations at levels sufficient to permit us to repurchase the warrants.

The issuance of shares of common stock upon conversion of the Series A Preferred Stock would reduce the relative voting power of holders of our common stock, would dilute the ownership of such holders and may adversely affect the market price of our common stock.

The conversion of the Series A Preferred Stock to common stock would dilute the ownership interest of existing holders of our common stock, and any sales in the public market of the common stock issuable upon conversion of the Series A Preferred Stock could adversely affect prevailing market prices of our common stock. Sales by such holders of a substantial number of shares of our common stock in the public market, or the perception that such sales might occur, could have a material adverse effect on the price of our common stock.

The holders of shares of the Series A Preferred Stock may exercise significant influence over us.

The holders of the Series A Preferred Stock will own approximately 9% of our shares of common stock on a fully diluted as-converted basis based on the number of shares of common stock outstanding as of the date hereof.

In addition, under the terms of the Certificate of Designation that governs the Series A Preferred Stock, the Series A Preferred Stock generally ranks, with respect to liquidation, dividends and redemption, senior to other securities (including our common stock and Series B Preferred) and, so long as any shares of Series A Preferred Stock remain outstanding, the approval of the holders of a majority of the Series A Preferred Stock outstanding at the time of approval is required in order for us to, among other things, (i) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or alter or amend the Certificate of Designation; (ii) amend our Articles of Incorporation or bylaws in any manner that adversely affects any powers, preferences or rights of the Series A Preferred Stock; (iii) authorize or create any series or class of stock ranking as to redemption, distribution of assets upon a Liquidation Event (as defined in the Certificate of Designation) or dividends senior to, or otherwise *pari passu* with, the Series A Preferred Stock; (iv) declare or make any dividends other than dividend payments on the Series A Preferred Stock or other distributions payable solely in common stock; (v) authorize any increase in the number of shares of Series A Preferred Stock or issue any additional shares of Series A Preferred Stock; or (vi) enter into any agreement with respect to any of the foregoing.

The holders of Series A Preferred Stock have rights, preferences and privileges that are not held by, and are preferential to, the rights of our common stockholders and holders of our Series B Preferred Stock.

Upon our liquidation, dissolution or winding up, the holders of the Series A Preferred Stock will be entitled to receive out of our assets, in preference to the holders of the common stock and any junior preferred stock (including the Series B Preferred offered hereby), an amount per share equal to the greater of (i) the sum of the Accreted Value (as defined in the Certificate of Designation) plus an amount equal to all accrued or declared and unpaid dividends on the Series A Preferred Stock that have not previously been added to the Accrued Value, or (ii) the amount that such shares would have been entitled to receive if they had converted into common stock immediately prior to such liquidation, dissolution or winding up. In addition, upon consummation of a specified change of control transaction, each holder of Series A Preferred Stock will be entitled to have us redeem the Series A Preferred Stock at a price specified in the Certificate of Designation. These provisions may make it more costly for a potential acquirer to engage in a business combination transaction with us. Provisions that have the effect of discouraging, delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock. If there are insufficient assets to pay in full such amounts, then the available assets will be ratably distributed to the holders of the Series A Preferred Stock in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full. This will reduce the remaining amount of our assets, if any, available to distribute to holders of our common stock. The holders of Series A Preferred Stock also have a preferential right to receive cumulative dividends on the Accreted Value of each share of Series A Preferred Stock at an initial rate of 2% per annum, compounded quarterly.

In addition, the holders of the Series A Preferred Stock also have certain redemption and conversion rights.

Our obligations to the holders of Series A Preferred Stock could limit our ability to obtain additional financing or increase our borrowing costs, which could have an adverse effect on our financial condition. These preferential rights could also result in divergent interests between the holders of shares of the Series A Preferred Stock and holders of our common stock and Series B Preferred.

The redemption right of the holders of the Series A Preferred Stock may delay or prevent an otherwise beneficial change of control transaction or result in a depletion of our cash in order to satisfy the redemption right of the holders Series A Preferred Stock.

The terms of the Series A Preferred Stock provide the holders with the right to require us to redeem the stock upon a change of control for cash in the event of a fundamental change, as defined. This feature may have the effect of delaying or preventing a change of control that would otherwise be beneficial to investors or depleting our cash.

The market price of our common stock has been and may continue to be volatile and adversely affected by various factors.

The market price of our common stock could fluctuate significantly in response to various factors and events, including:

- our ability to execute our business plan;
- operating results below expectations;
- announcements concerning product development results, including clinical trial results, or intellectual property rights of others;
- litigation or public concern about the safety of our potential products;
- our issuance of additional securities, including debt or equity or a combination thereof, necessary to fund our operating expenses;
- announcements of technological innovations or new products by us or our competitors;
- loss of any strategic relationship;
- industry developments, including, without limitation, changes in healthcare policies or practices or third-party reimbursement policies;
- economic and other external factors effecting U.S. or Global equity markets;
- period-to-period fluctuations in our financial results; and
- whether an active trading market in our common stock develops and is maintained.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock.

Our articles of incorporation and bylaws and Nevada law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Our articles of incorporation, as amended, our amended and restated bylaws and Nevada law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. The board of directors could authorize the issuance of an additional series of preferred stock that would grant holders preferred rights to our assets upon liquidation, special voting rights, the right to receive dividends before dividends would be declared to common stockholders, and the right to the redemption of such shares, possibly together with a premium, prior to the redemption of the common stock. To the extent that we do issue additional preferred stock, the rights of holders of common stock could be impaired thereby, including without limitation, with respect to liquidation.

Provisions of our articles of incorporation, as amended and our amended and restated bylaws may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, our articles of incorporation, as amended, and amended and restated bylaws, among other things:

- provide the board of directors with the ability to alter the bylaws without stockholder approval; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

Our failure to fulfill all of our registration requirements may cause us to suffer liquidated damages, which may be very costly.

Pursuant to the terms of the registration rights agreement that we entered into with Intrexon and an affiliated entity, we were required to file a registration statement with respect to securities issued and are required to maintain the effectiveness of such registration statement. The failure to do so could result in the payment of damages by us. There can be no assurance that we will be able to maintain the effectiveness of any registration statement, and therefore there can be no assurance that we will not incur damages with respect to such agreements.

Pursuant to the terms of the registration rights agreement that we entered into with holders of our Series A Preferred Stock, we are required to file a registration statement with respect to the securities issued to them upon their request within certain time periods and are required to maintain the effectiveness of such registration statement. The failure to do so could result in the payment of damages by us. There can be no assurance that we will be able to meet the required filing deadlines or maintain the effectiveness of any registration statement, and therefore there can be no assurance that we will not incur damages with respect to such agreements.

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. Our Series A Preferred Stockholders rank senior to our common stockholders with respect to dividends and, subject to any senior rights of the Series A Preferred Stock, the holders of the Series B Preferred will participate, on an as-if-converted-to-common stock basis, in any dividends to the holders of common stock.

Resales of our common stock in the public market 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 future offerings. Any issuance from time to time of new shares of our common stock, or our ability to issue shares of common stock in future offerings, 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.

The shares of common stock offered under the B. Riley FBR Sales Agreement may be sold in “at the market” offerings, and investors who buy shares at different times will likely pay different prices.

Investors who purchase shares that are sold under the B. Riley FBR Sales Agreement at different times will likely pay different prices, and so may experience different outcomes in their investment results. We will have discretion, subject to market demand, to vary the timing, prices, and numbers of shares sold, and there is no minimum or maximum sales price. Investors may experience declines in the value of their shares as a result of share sales made at prices lower than the prices they paid.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain forward-looking statements, including statements regarding the progress and timing of our product development, the goals of our development activities, estimates of the potential markets for our product candidates, estimates of the capacity of manufacturing and other facilities to support our products, our expected future revenues, operations and expenditures and projected cash needs. The forward-looking statements are contained principally in the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business” of this prospectus and the documents incorporated by reference. These statements relate to future events of our financial performance and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. Those risks and uncertainties include, among others:

- our ability to implement our business plan;
- our ability to raise additional capital to meet our liquidity needs;
- our ability to generate sufficient proceeds from this offering;
- our ability to generate product revenues;
- our ability to achieve profitability;
- our ability to satisfy U.S. (including the FDA), and international regulatory requirements;
- our ability to obtain market acceptance of our products;
- our ability to compete in the market;
- our ability to advance our clinical trials;
- our ability to fund, design and implement clinical trials;
- our ability to demonstrate that our product candidates are safe for human use and effective for indicated uses;
- our ability to gain acceptance of physicians and patients for use of our products;
- our dependency on third-party researchers and manufacturers and licensors;
- our ability to establish and maintain strategic partnerships, including for the distribution of products;
- our ability to attract and retain sufficient, qualified personnel;
- our ability to obtain or maintain patents or other appropriate protection for the intellectual property;
- our dependency on the intellectual property licensed to us or possessed by third parties;
- our ability to adequately support future growth;
- our ability to maintain our NYSE American listing; and
- potential product liability or intellectual property infringement claims.

Forward-looking statements include all statements that are not historical facts. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “potential,” or the negative of those terms, and similar expressions and comparable terminology intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements represent our estimates and assumptions only as of the date of this prospectus and, except as required by law, we undertake no obligation to update or review publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this prospectus. You should read this prospectus, the documents incorporated by reference in this prospectus, the documents referenced in this prospectus and the documents filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

USE OF PROCEEDS

We estimate that the net proceeds of this offering will be approximately \$18.0 million, or approximately \$20.8 million if the underwriters exercise in full their over-allotment option, assuming a public offering price of \$2.10 per Class A Unit (which was the last reported sale price of our common stock on the NYSE American on October 8, 2018) and \$1,000 per Class B Unit, after deducting the estimated underwriting discount and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the warrants. The public offering price per Class A Unit will be determined between us, the underwriters and investors based on market conditions at the time of pricing, and may be at a discount to the current market price of our common stock. We will only receive additional proceeds from the exercise of the warrants issuable in connection with this offering if such warrants are exercised at their exercise price of 120% of the public offering price of the Class A Units and the holders of such warrants pay the exercise price in cash upon such exercise and do not utilize the cashless exercise provision of the warrants.

We intend to use the net proceeds, if any, from the sales of securities offered by this prospectus to fund our and our subsidiaries' preclinical and clinical programs (including, but not limited to, provide approximately \$5.0-\$7.0 million in funding for manufacturing scale-up activities to progress SYN-004 towards a potential Phase 3 clinical trial (broad indication) and/or initiate a Phase 1/2 clinical trial(s) in a specialty population, approximately \$7.5 million in funding for preclinical development and related manufacturing activities in preparation for our IND and Phase 1 clinical trial for our SYN-020 program and required milestone payments) and for working capital and general corporate purposes, including, to acquire, license or invest in complementary businesses, technologies, product candidates or other intellectual property. We have broad discretion in determining how the proceeds of this offering will be used, and our discretion is not limited by the aforementioned possible uses. Our board of directors believes the flexibility in application of the net proceeds is prudent.

The expected use of proceeds from this offering represent our current intentions based on present plans and business conditions. 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 reallocate the net proceeds of this offering within the categories listed above or to use the net proceeds for other purposes. Accordingly 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.

CAPITALIZATION

The following table sets forth our capitalization as of June 30, 2018:

- on an actual basis, adjusted to reflect the reverse stock split of one-for-thirty-five effective August 10, 2018;
- on a pro forma basis to give effect to the issuance of 3,485,483 shares of common stock for which we received net proceeds of \$11.8 million from July 1, 2018 through and immediately prior to the date of this prospectus but does not reflect reductions in cash subsequent to June 30, 2018 as a result of expenses incurred in the ordinary course of business; and
- on a pro forma as adjusted basis to give effect to (i) the issuance of 3,485,483 shares of common stock for which we received net proceeds of \$11.8 million from July 1, 2018 through and immediately prior to the date of this prospectus but does not reflect reductions in cash subsequent to June 30, 2018 as a result of expenses incurred in the ordinary course of business and (ii) the sale of 9,523,809 Class A Units in this offering at the assumed public offering price of \$2.10 per Class A Unit (which was the last reported sale price of our common stock on the NYSE American on October 8, 2018), after deducting underwriting discounts and commissions and other estimated offering expenses payable by us. The pro forma as adjusted basis assumes no sale of Class B Units and excludes the proceeds, if any, from the exercise of any warrants issued in this offering.

This Capitalization table should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our historical financial statements and notes to those financial statements that are incorporated by reference in this prospectus.

	As of June 30, 2018 (in thousands)		
	Actual	Pro Forma	Pro Forma As Adjusted
Cash and cash equivalents	\$ 7,129	\$ 18,886	\$ 36,886
Series A convertible preferred stock	12,173	12,173	12,173
Common stock, \$0.001 par value; 35,000,000 shares authorized, 3,722,837, shares issued and outstanding actual; Preferred Stock, \$0.001 par value, 10,000,000 shares authorized, no shares issued and outstanding	130	7	17
Additional paid-in capital	194,186	205,940	223,930
Accumulated deficit	(200,803)	(200,803)	(200,803)
Total Synthetic Biologics, Inc. and Subsidiaries Equity (Deficit)	(6,487)	5,144	23,144
Non-controlling interest	(1,940)	(1,940)	(1,940)
Total Stockholders’ Equity (Deficit)	(8,427)	3,204	21,204
Total Capitalization	\$ (8,427)	\$ 3,204	\$ 21,204

Unless we indicate otherwise, all information in this Capitalization section is as of October 8, 2018 and:

- reflects a one-for-thirty-five reverse stock split of our issued and outstanding shares of common stock, options and warrants effected on August 10, 2018 and the corresponding adjustment of all common stock prices per share and stock option and warrant exercise prices per share and conversion ratios without taking into account fractional shares which are rounded up to the nearest whole number ;
- assumes no exercise by the underwriters of their over-allotment option;
- excludes shares of our common stock issuable upon conversion of outstanding shares of Series A preferred stock;
- excludes 347,765 shares of our common stock issuable upon exercise of outstanding options under our equity incentive plans at a weighted-average exercise price of \$54.19 per share;
- excludes 915,854 shares of our common stock reserved for issuance upon the exercise of outstanding warrants with a weighted-average exercise price of \$75.16 per share and assumes no exercise of the warrants issued in this offering;
- assumes no shares of Series B Preferred are sold in this offering; and
- excludes 170,674 shares of our common stock that are reserved for equity awards that may be granted under our equity incentive plans.

To the extent we sell any Class B Units in this offering, the same aggregate number of common stock equivalents resulting from this offering would be convertible under the Series B Preferred issued as part of the Class B Units.

Each increase (decrease) of 250,000 Class A Units to be purchased at \$2.10 per unit (which was the last reported sale price of our common stock on the NYSE American on October 8, 2018) would increase or (decrease) additional paid-in capital, total stockholders’ deficit and total capitalization by approximately \$0.5 million, assuming the offering price remains at \$2.10 and after deducting estimated underwriters’ discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 500,000 Class A Units to be purchased at \$2.10 per unit (which was the last reported sale price of our common stock on the NYSE American on October 8, 2018) would increase or (decrease) additional paid-in capital, total stockholders’ equity (deficit) and total capitalization by approximately \$1.0 million, assuming the offering price remains at \$2.10 and after deducting estimated underwriters’ discounts and commissions and estimated offering expenses payable by us.

A \$0.25 increase (decrease) in the assumed public offering price of \$2.10 per Class A Unit (which was the last reported sale price of our common stock on the NYSE American on October 8, 2018) would result in an incremental increase (decrease) in each of our additional paid-in capital, total stockholders’ equity (deficit) and total capitalization on a pro forma as adjusted basis by approximately \$2.2 million, assuming that the number of Class A Units sold by us as set forth on the cover page of this prospect remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by

us. A \$0.50 increase (decrease) in the assumed public offering price of \$2.10 per Class A Units (which was the last reported sale price of our common stock on the NYSE American on October 8, 2018) would result in an incremental increase (decrease) in each of our additional paid-in capital, total stockholders' equity (deficit) and total capitalization on a pro forma as adjusted basis by approximately \$4.4 million, assuming that the number of Class A Units sold by us as set forth on the cover page of this prospect remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

DILUTION

If you invest in our securities in this offering, you will experience dilution to the extent of the difference between the public offering price per Class A Unit in this offering and our as adjusted net tangible book value per share immediately after this offering assuming no value is attributed to the warrants, and the warrants are accounted for and classified as equity. This calculation does not reflect any dilution associated with the sale and exercise of the warrants.

Our net tangible book value on June 30, 2018 was approximately \$3.7 million, or \$1.01 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.

Our pro forma net tangible book value as of June 30, 2018 was \$15.5 million or \$2.15 per share of common stock, based upon 7,208,320 shares outstanding, after giving effect to issuances of 3,485,483 shares of common stock for which we received net proceeds of \$11.8 million from July 1, 2018 through and immediately prior to the date of this prospectus but does not reflect reductions in cash subsequent to June 30, 2018 as a result of expenses incurred in the ordinary course of business. After giving effect to the sale by us of 9,523,809 Class A units in this offering at a public offering price of \$2.10 per Class A Unit, (which was the last reported sale price of our common stock on the NYSE American of October 8, 2018) and no Class B Units, and after deducting the estimated underwriting discount and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2018 would have been approximately \$33.5 million, or approximately \$2.00 per share. This represents an immediate decrease in pro forma as adjusted net tangible book value of \$0.15 per share to existing stockholders and an immediate dilution of \$0.10 per share to new investors purchasing Class A Units in this offering. The following table illustrates this per share dilution:

Assumed public offering price per Class A Unit	\$	2.10
Pro forma net tangible book value per share as of June 30, 2018	\$	2.15
Decrease in pro forma net tangible book value per share after this offering	\$	(0.15)
Pro forma as adjusted net tangible book value per share after giving effect to this offering	\$	2.00
Dilution per share to investors purchasing our common stock in this offering	\$	0.10

The information above and below assumes that no shares of Series B Preferred are sold in this offering. The information above assumes that the underwriters do not exercise their over-allotment option. If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value would be \$2.00 per share, representing an immediate decrease to existing stockholders of \$0.15 per share and an immediate dilution of \$0.10 per share to new investors.

To the extent we sell any Class B Units in this offering, the same aggregate number of common stock equivalents resulting from this offering would be convertible under the Series B Preferred issued as part of the Class B Units.

A \$0.25 increase (decrease) in the assumed public offering price of \$2.10 per Class A Unit (which was the last reported sale price of our common stock on the NYSE American on October 8, 2018) would result in an incremental increase (decrease) in our pro forma net tangible book value of approximately \$2.2 million or approximately \$0.13 per share, and would result in an incremental increase (decrease) in the dilution to new investors of approximately \$0.12 per share, assuming that the number of Class A Units sold by us remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. A \$0.50 increase (decrease) in the assumed public offering price of \$2.10 per Class A Unit (which was the last reported sale price of our common stock on the NYSE American on October 8, 2018) would result in an incremental increase (decrease) in our pro forma net tangible book value of approximately \$4.4 million or approximately \$0.26 per share, and would result in an incremental increase (decrease) in the dilution to new investors of approximately \$0.24 per share, assuming that the number of Class A Units sold by us remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

We may also increase or decrease the number of Class A Units we are offering from the assumed number of Class A Units set forth above. An increase (decrease) of 250,000 in the assumed number of Class A Units sold by us in this offering would result in an incremental increase (decrease) in our pro forma net tangible book value of approximately \$0.5 million or approximately \$0.00 per share, and would result in an incremental increase (decrease) in the dilution to new investors of approximately \$0.00 per share, assuming that the assumed public offering price of the common stock remains the same and after deducting the estimated underwriting discount and estimated offering expenses payable by us. An increase (decrease) of 500,000 in the assumed number of Class A Units sold by us in this offering would result in an incremental increase (decrease) in our pro forma net tangible book value of approximately \$1.0 million or approximately \$0.00 per share and would result in an incremental increase (decrease) in the dilution to new investors of approximately \$0.00 per share, assuming that the assumed public offering price of the common stock remains the same and after deducting the estimated.

The foregoing discussion and table do not take into account further dilution to new investors that could occur upon the exercise of outstanding options or warrants or conversion of our outstanding Series A Preferred Stock. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market Information

Our common stock has traded on the NYSE American under the symbol “SYN” since February 16, 2012. Prior to February 16, 2012, our common stock traded under the symbol “AEN” since October 16, 2008. The following table states the range of the high and low sales prices of our common stock for the year ended December 31, 2016, and the year ended December 31, 2017 and the first and second fiscal quarter of 2018 and for the third quarter through October 8, 2018 (as adjusted to reflect the one-for-thirty-five reverse stock split effective August 10, 2018). These quotations represent inter-dealer prices, without retail mark-up, markdown, or commission, and may not represent actual transactions. The last price of our common stock as reported on the NYSE American on October 8, 2018 was \$2.10 per share. As of October 8, 2018, there were approximately 347 stockholders of record of our common stock. This number does not include beneficial owners from whom shares are held by nominees in street name.

On August 1, 2018, we announced a reverse stock split of our shares of common stock at a ratio of one-for-thirty-five. The reverse stock split took effect at 11 p.m. (Eastern Time) on August 10, 2018, and our common stock began to trade on a post-split basis at the market open on August 13, 2018. When the reverse stock split became effective, every 35 shares of our issued and outstanding common stock were combined into one share of common stock. Effecting the reverse stock split reduced the number of issued and outstanding common stock from approximately 132,969,743 shares to approximately 3,799,136. It also subsequently adjusted outstanding options issued under our equity incentive plan, outstanding warrants to purchase common stock and our outstanding preferred stock.

	<u>High</u>	<u>Low</u>
YEAR ENDED DECEMBER 31, 2016		
First Quarter	\$ 82.60	\$ 35.35
Second Quarter	\$ 95.55	\$ 57.40
Third Quarter	\$ 66.85	\$ 54.95
Fourth Quarter	\$ 61.95	\$ 26.60
YEAR ENDED DECEMBER 31, 2017		
First Quarter	\$ 36.05	\$ 20.65
Second Quarter	\$ 26.25	\$ 14.35
Third Quarter	\$ 36.75	\$ 16.10
Fourth Quarter	\$ 33.60	\$ 17.50
YEAR ENDED DECEMBER 31, 2018		
First Quarter	\$ 21.00	\$ 9.80
Second Quarter	\$ 12.95	\$ 6.65
Third Quarter (through October 8, 2018)	\$ 9.10	\$ 1.86

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, subject to terms of any preferred stock or debt securities. Any future determination about the payment of dividends will be made at the discretion of our board of directors and will be subject to the rights of any outstanding preferred stock 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. The Series A Preferred Stock ranks senior to the shares of our common stock with respect to dividend rights and holders of Series A Preferred Stock are entitled to a cumulative dividend at the rate of 2.0% per annum, payable quarterly in arrears, as set forth in the Certificate of Designation of Series A Preferred Stock.

DESCRIPTION OF OUR SECURITIES

Authorized Capital

Our authorized capital currently consists of 200 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 October 8, 2018, 7,208,320 shares of common stock were issued and outstanding, and 120,000 shares of preferred stock were issued and outstanding.

Common Stock

We may issue shares of our common stock from time to time. We currently have authorized 200,000,000 million shares of common stock, par value \$.001 per share. We may offer shares of common stock alone or underlying the registered securities convertible into or exercisable for our common stock.

Voting. The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election.

Dividends. Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation. In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Rights and Preferences. The holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Fully Paid and Nonassessable . All of our outstanding shares of common stock are, and the shares of common stock to be issued under this prospectus will be, fully paid and nonassessable.

In this prospectus, we have summarized certain general features of our common stock under “Description of Our Securities—Common Stock”. 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 any common stock being offered.

Preferred Stock

Our board of directors has the authority, without action by our stockholders, to designate and issue up to 10 million shares of preferred stock in one or more series or classes and to designate the rights, preferences and privileges of each series or class, which may be greater than the rights of our common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock upon the rights of holders of our common stock until our board of directors determines the specific rights of the holders of the preferred stock. However, the effects might include:

- restricting dividends on our common stock;
- diluting the voting power of our common stock;
- impairing liquidation rights of our common stock; or
- delaying or preventing a change in control of us without further action by our stockholders.

The board of directors' authority to issue preferred stock without stockholder approval could make it more difficult for a third-party to acquire control of our company, and could discourage such attempt. We have no present plans to issue any shares of preferred stock.

Series A Preferred

We had 120,000 shares of Series A Preferred Stock outstanding as of October 8, 2018.

The Series A Preferred Stock ranks senior to the shares of our common stock, and any other class or series of stock issued by us with respect to dividend rights, redemption rights and rights on the distribution of assets on our voluntary or involuntary liquidation, dissolution or winding up. Holders of Series A Preferred Stock are entitled to a cumulative dividend at the rate of 2.0% per annum, payable quarterly in arrears, as set forth in the Certificate of Designation of Series A Preferred Stock classifying the Series A Preferred Stock. The Series A Preferred Stock is convertible at the option of the holders at any time into shares of common stock at a conversion price of \$18.90 per share (as adjusted to reflect the 1-for-35 reverse stock split effected August 10, 2018), subject to certain customary anti-dilution adjustments.

Any conversion of Series A Preferred Stock may be settled by us in shares of common stock only.

The holder's ability to convert the Series A Preferred Stock into common stock is subject to (i) a 19.99% blocker provision to comply with NYSE American Listing Rules, (ii) if so elected by the holder, a 4.99% blocker provision that will prohibit beneficial ownership of more than 4.99% of our outstanding shares common stock or voting power at any time, and (iii) applicable regulatory restrictions.

In the event of our liquidation, dissolution or winding-up, holders of the Series A Preferred Stock are entitled to a preference on liquidation equal to the greater of (i) an amount per share equal to the stated value plus any accrued and unpaid dividends on such share of Series A Preferred Stock (the "Accreted Value"), and (ii) the amount such holders would receive in such liquidation if they converted their shares of Series A Preferred Stock (based on the Accreted Value and without regard to any conversion limitation) into shares of the common stock immediately prior to any such liquidation, dissolution or winding-up (the greater of (i) and (ii), is referred to as the "Liquidation Value").

Except as otherwise required by law, the holders of Series A Preferred Stock have no voting rights, other than customary protections against adverse amendments and issuance of *pari passu* or senior preferred stock. Upon certain change of control events involving our company, we will be required to repurchase all of the Series A Preferred Stock at a redemption price equal to the greater of (i) the Accreted Value and (ii) the amount that would be payable upon a change of control (as defined in the Certificate of Designation) in respect of common stock issuable upon conversion of such share of Series A Preferred Stock if all outstanding shares of Series A Preferred Stock were converted into common stock immediately prior to the change of control.

On or at any time after (i) the VWAP (as defined in the Certificate of Designation) for at least 20 trading days in any 30 trading day period is greater than \$70.00 (as adjusted to reflect the 1-for-35 reverse stock split effected August 10, 2018), subject to adjustment in the case of stock split, stock dividends or the like we have the right, after providing notice not less than 6 months prior to the redemption date, to redeem, in whole or in part, on a pro rata basis from all holders thereof based on the number of shares of Series A Preferred Stock then held, the outstanding Series A Preferred Stock, for cash, at a redemption price per share of Series A Preferred Stock of \$7,875.00 (as adjusted to reflect the 1-for-35 reverse stock split effected August 10, 2018), subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Preferred Stock, or (ii) the five year anniversary of the issue date, we have the right to redeem, in whole or in part, on a pro rata basis from all holders thereof based on the number of shares of Series A Preferred Stock then held, the outstanding Series A Preferred Stock, for cash, at a redemption price per share equal to the Liquidation Value.

Warrants

As of October 8, 2018, we had issued and outstanding warrants to purchase a total of 915,857 shares of our common stock outstanding at a weighted-average price of \$75.16 (as adjusted to reflect the 1-for-35 reverse stock split effected August 10, 2018 without taking into account fractional shares which are rounded up to the nearest whole number).

On November 18, 2016, we completed a public offering of 714,286 shares of common stock (as adjusted to reflect the 1-for-35 reverse stock split effected August 10, 2018) in combination with accompanying warrants to purchase an aggregate of 1,428,571 shares of the common stock (as adjusted to reflect the 1-for-35 reverse stock split effected August 10, 2018), of which warrants to purchase 714,286 (as adjusted to reflect the 1-for-35 reverse stock split effected August 10, 2018 without taking into account fractional shares) shares of common stock are outstanding (the "Series A Warrants"). The per share exercise price of the Series A Warrants is \$50.05 (as adjusted to reflect the 1-for-35 reverse stock split effected August 10, 2018) subject to further adjustment as specified in the warrant agreements. The Series A Warrants may be exercised at any time until the four-year anniversary of the issuance date. The warrants include a provision that if we were to enter into a certain transaction, as defined in the agreement, the warrants would be purchased from the holder for cash.

On October 10, 2014, we issued 14,059,616 units at a price of \$1.47 per unit to certain institutional investors in a registered direct offering, each unit consisted of one share of our common stock and a warrant to purchase 0.5 shares of common stock. The warrants, exercisable for an aggregate of 200,852 (as adjusted to reflect the 1-for-35 reverse stock split effected August 10, 2018 without taking into account fractional shares) shares of common stock, have an exercise price of \$61.25 per share (as adjusted to reflect the 1-for-35 reverse stock split effected August 10, 2018) and a life of five years. The warrants vested immediately and expire on October 10, 2019.

Options

As of October 8, 2018, options to purchase an aggregate of 347,765 (as adjusted to reflect the 1-for-35 reverse stock split effected August 10, 2018 without taking into account fractional shares) shares of common stock were outstanding under our equity incentive plans.

Stockholder Registration Rights

We are party to a registration rights agreement (the "Registration Rights Agreement") that provides the holder of the Series A Preferred Stock with certain registration rights. Pursuant to the terms of the Registration Rights Agreement, we agreed to file a registration statement covering resales of the shares of common stock issuable upon conversion of the Series A Preferred Stock with the SEC within 60 days following receipt of a request at any time (as long as the requestor beneficially owns at least ten percent (10%) of our common stock then outstanding or is otherwise deemed our affiliate) and to use reasonable best efforts to have the registration statement declared effective within 120 days following receipt of such request.

We have agreed to pay certain penalties if the registration statement is not declared effective by the SEC on or before the required deadline. After that deadline and until such time as the registration statement is declared effective (or until we are no longer required to cause the registration statement to be declared effective), we will be required to pay additional liquidated damages.

Pursuant to the terms of the registration rights agreement that we entered into with Intrexon and an affiliated entity, we were required to file a registration statement with respect to securities issued and are required to maintain the effectiveness of such registration statement. The failure to do so could result in the payment of damages by us. The registration statement was declared effective on April 29, 2013.

Anti-Takeover Effects of Certain Provisions of our Articles of Incorporation and Bylaws

Our Articles of Incorporation, as amended, and amended and restated bylaws contain certain provisions that may have anti-takeover effects, making it more difficult for or preventing a third party from acquiring control of the Company or changing its board of directors and management. According to our Amended and Restated Bylaws and Articles of Incorporation, neither the holders of our common stock nor the holders of any preferred stock we may issue in the future have cumulative voting rights in the election of our directors. The lack of cumulative voting makes it more difficult for other stockholders to replace our board of directors or for a third party to obtain control of our company by replacing its board of directors.

Authorized but Unissued Shares

Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval. We may use additional shares for a variety of purposes, including future public offerings to raise additional capital, to fund acquisitions and as employee compensation. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Anti-Takeover Effects of Nevada Law

Business Combinations

The “business combination” provisions of Sections 78.411 to 78.444, inclusive, of the Nevada Revised Statute (the “NRS”) generally prohibit a Nevada corporation with at least 200 stockholders from engaging in various “combination” transactions with any interested stockholder for a period of two years after the date of the transaction in which the person became an interested stockholder, unless the transaction is approved by the board of directors prior to the date the interested stockholder obtained such status or the combination is approved by the board of directors and thereafter is approved at a meeting of the stockholders by the affirmative vote of stockholders representing at least 60% of the outstanding voting power held by disinterested stockholders, and extends beyond the expiration of the two-year period, unless:

- the combination was approved by the board of directors prior to the person becoming an interested stockholder or the transaction by which the person first became an interested stockholder was approved by the board of directors before the person became an interested stockholder or the combination is later approved by a majority of the voting power held by disinterested stockholders; or
- if the consideration to be paid by the interested stockholder is at least equal to the highest of: (a) the highest price per share paid by the interested stockholder within the two years immediately preceding the date of the announcement of the combination or in the transaction in which it became an interested stockholder, whichever is higher, (b) the market value per share of common stock on the date of announcement of the combination and the date the interested stockholder acquired the shares, whichever is higher, or (c) for holders of preferred stock, the highest liquidation value of the preferred stock, if it is higher.

A “combination” is generally defined to include mergers or consolidations or any sale, lease exchange, mortgage, pledge, transfer, or other disposition, in one transaction or a series of transactions, with an “interested stockholder” having: (a) an aggregate market value equal to 5% or more of the aggregate market value of the assets of the corporation, (b) an aggregate market value equal to 5% or more of the aggregate market value of all outstanding shares of the corporation, (c) 10% or more of the earning power or net income of the corporation, and (d) certain other transactions with an interested stockholder or an affiliate or associate of an interested stockholder.

In general, an “interested stockholder” is a person who, together with affiliates and associates, owns (or within two years, did own) 10% or more of a corporation’s voting stock. The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire our company even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

Control Share Acquisitions

The “control share” provisions of Sections 78.378 to 78.3793, inclusive, of the NRS apply to “issuing corporations” that are Nevada corporations with at least 200 stockholders, including at least 100 stockholders of record who are Nevada residents, and that conduct business directly or indirectly in Nevada. The control share statute prohibits an acquirer, under certain circumstances, from voting its shares of a target corporation’s stock after crossing certain ownership threshold percentages, unless the acquirer obtains approval of the target corporation’s disinterested stockholders. The statute specifies three thresholds: one-fifth or more but less than one-third, one-third but less than a majority, and a majority or more, of the outstanding voting power. Generally, once an acquirer crosses one of the above thresholds, those shares in an offer or acquisition and acquired within 90 days thereof become “control shares” and such control shares are deprived of the right to vote until disinterested stockholders restore the right. These provisions also provide that if control shares are accorded full voting rights and the acquiring person has acquired a majority or more of all voting power, all other stockholders who do not vote in favor of authorizing voting rights to the control shares are entitled to demand payment for the fair value of their shares in accordance with statutory procedures established for dissenters’ rights.

A corporation may elect to not be governed by, or “opt out” of, the control share provisions by making an election in its articles of incorporation or bylaws, provided that the opt-out election must be in place on the 10th day following the date an acquiring person has acquired a controlling interest, that is, crossing any of the three thresholds described above. We have not opted out of the control share statutes, and will be subject to these statutes if we are an “issuing corporation” as defined in such statutes.

The effect of the Nevada control share statutes is that the acquiring person, and those acting in association with the acquiring person, will obtain only such voting rights in the control shares as are conferred by a resolution of the stockholders at an annual or special meeting. The Nevada control share law, if applicable, could have the effect of discouraging takeovers of our company.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Corporate Stock Transfer, Inc. The transfer agent’s address is 3200 Cherry Creek South Drive, Suite 430, Denver, Colorado 80209. The transfer agent for any series of preferred stock that we may offer under this prospectus will be named and described in the prospectus supplement for that series.

Listing on the NYSE American

Our common stock is listed on the NYSE American under the symbol “SYN”.

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering up to 9,523,809 Class A Units, assuming no exercise of the over-allotment option. We are also offering to each purchaser whose purchase of Class A Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity in lieu of purchasing Class A Units, to purchase Class B Units. Each Class B Unit will consist of one share of Series B Preferred with a stated value of \$1,000 and convertible into shares of our common stock at the public offering price of the Class A Units, together with the equivalent number of warrants as would have been issued to such purchaser of Class B Units if they had purchased Class A Units based on the public offering price. For each Class B Unit we sell, the number of Class A Units we are offering will be decreased on a dollar-for-dollar basis. Because we will issue a warrant as part of each Unit, the number of warrants sold in this offering will not change as a result of a change in the mix of the Units sold. The number of shares of our common stock outstanding after this offering will fluctuate depending on how many Class B Units are sold in this offering and whether and to what extent holders of Series B Preferred shares convert their shares to common stock. We are also offering the shares of common stock issuable upon exercise of warrants sold in Class B Units and upon conversion of the Series B Preferred.

Common Stock

The material terms and provisions of our common stock and each other class of our securities which qualifies or limits our common stock are described under the caption "Description of Our Securities" in this prospectus.

Preferred Stock

Pursuant to the terms of our articles of incorporation, our board of directors has the authority to issue preferred stock in one or more classes or series and to fix the designations, powers, preferences and rights, and the qualifications, limitations or restrictions thereof, including dividend rights, conversion right, voting rights, terms of redemption, liquidation preferences and the number of shares constituting any class or series, without further vote or action by the stockholders.

Series B Convertible Preferred Stock

The following is a summary of the material terms of the Series B Preferred. This summary is not complete. The following summary of the terms and provisions of the Series B Preferred is qualified in its entirety by reference to the Certificate of Designation of the Series B Preferred, the form of which has been filed as an exhibit to the registration statement of which this prospectus is a part.

General. Our board of directors has designated up to _____ shares of the 10,000,000 authorized shares of preferred stock as Series B Convertible Preferred Stock. When issued, the shares of Series B Preferred will be validly issued, fully paid and non-assessable. Each share of Series B Preferred will have a stated value of \$1,000 per share.

Rank. The Series B Preferred will rank junior to the Series A Preferred Stock and on parity to our common stock.

Conversion. Each share of Series B Preferred is convertible into shares of our common stock (subject to adjustment as provided in the related certificate of designation of preferences, rights and limitations) at any time at the option of the holder at a conversion price equal to the stated value of the Series B Preferred of \$1,000 divided by the public offering price of the Class A Units in this offering. Holders of Series B Preferred will be prohibited from converting Series B Preferred into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our common stock then issued and outstanding. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon at least 61 days' prior notice from the holder to us.

Liquidation Preference. Subject to the senior rights of the Series A Preferred Stock, in the event of our liquidation, dissolution or winding-up, holders of Series B Preferred will be entitled to receive if the Series B Preferred were fully converted into shares of our common stock at the conversion price (disregarding for such purposes any conversion limitations) which amounts shall be paid *pari passu* with all holders of common stock.

Voting Rights. Shares of Series B Preferred will generally have no voting rights, except as required by law and except that the affirmative vote of the holders of a majority of the then outstanding shares of Series B Preferred is required to, (a) alter or change adversely the powers, preferences or rights given to the Series B Preferred, (b) amend our articles of incorporation or other charter documents in any manner that materially adversely affects any rights of the holders, (c) increase the number of authorized shares of Series B Preferred, or (d) enter into any agreement with respect to any of the foregoing.

Dividends. Shares of Series B Preferred will not be entitled to receive any dividends, unless and until specifically declared by our board of directors. Subject to any senior rights of the Series A Preferred Stock, the holders of the Series B Preferred will participate, on an as-if-converted-to-common stock basis, in any dividends to the holders of common stock.

Redemption. We are not obligated to redeem or repurchase any shares of Series B Preferred. Shares of Series B Preferred are not otherwise entitled to any redemption rights or mandatory sinking fund or analogous fund provisions.

Exchange Listing. We do not plan on making an application to list the Series B Preferred on the NYSE American, any other national securities exchange or other nationally recognized trading system.

Warrants

The following summary of certain terms and provisions of the warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the warrant agent agreement, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of warrant agent agreement for a complete description of the terms and conditions of the common warrants.

Form. The warrants will be issued in electronic book entry form. The form of warrant is filed as an exhibit to this registration statement.

Exercisability. The warrants are exercisable at any time after their original issuance and will expire on the fifth anniversary of the original issuance date. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. If at the time of exercise, there is no effective registration statement registering, or no current prospectus available for, the issuance of the shares of common stock to the holder, then the common warrant may only be exercised through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant. No fractional shares of common stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the fair market value of any such fractional shares.

Exercise Limitations. Under the warrants, we may not effect the exercise of any warrant, and a holder will not be entitled to exercise any portion of any warrant, which, upon giving effect to such exercise, would cause (i) the aggregate number of shares of our common stock beneficially owned by the holder (together with its affiliates) to exceed [4.99%/9.99%] of the number of shares of our common stock outstanding immediately after giving effect to the exercise, or (ii) the combined voting power of our securities beneficially owned by the holder (together with its affiliates) to exceed [4.99%/9.99%] of the combined voting power of all of our securities then outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon at least 61 days' prior notice from the holder to us.

Exercise Price. The exercise price per whole share of our common stock purchasable upon the exercise of the warrants is 120% of the public offering price of the Class A Units, or \$2.52 per share, based on an assumed offering price of \$2.10 per Class A Unit (which was the last reported sale price of our common stock on the NYSE American on October 8, 2018). The exercise price of the warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders. Subject to certain exceptions, the warrants provide for adjustment of the exercise price if we or any of our subsidiaries, as applicable, sell or grant any right to reprice, or otherwise dispose of or issue (or announce any offer, sale, grant or any option to purchase or other disposition) any shares of our common stock or common stock equivalents, at an effective price per share that is less than the exercise price then in effect (such lower price, the "Base Share Price" and such issuances collectively, a "Dilutive Issuance"). In the event a Dilutive Issuance occurs, the exercise price shall be reduced to equal the Base Share Price.

Transferability. Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing. We do not plan on applying to list the warrants on the NYSE American, any other national securities exchange or any other nationally recognized trading system.

Fundamental Transactions. In the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the common warrants will be entitled to receive upon exercise of the warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction without regard to any limitations on exercise contained in the warrants. In the event of a fundamental transaction, we are required to cause any successor entity to assume all of our obligations under the warrants.

Right as a Stockholder. Except by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

UNDERWRITING

We have entered into an underwriting agreement, dated _____, 2018, with A.G.P., acting as the representative of the several underwriters named below. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and the underwriters have severally agreed to purchase, the number of Units, provided below opposite their respective names.

Underwriters	Number of Class A Units	Number of Class B Units
A.G.P./Alliance Global Partners		
Total		

The underwriters are offering the Units subject to their acceptance of the Units from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the Units offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriter is obligated to purchase all of the Units if any of the securities are purchased, other than those shares covered by the over-allotment option to purchase additional securities described below.

Discount, Commissions and Expenses

The underwriters have advised us that they propose to offer the Units to the public at the public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$ _____ per Unit. The underwriters may allow, and certain dealers may reallocate, a discount from the concession not in excess of \$ _____ per Unit to certain brokers and dealers. After this offering, the public offering price, concession and reallocation to dealers may be changed by the representative. No such change shall change the amount of proceeds to be received by us as set forth on the cover page of this prospectus. The Units are offered by the underwriters as stated herein, subject to receipt and acceptance by them and subject to their right to reject any order in whole or in part. The underwriters have informed us that they do not intend to confirm sales to any accounts over which they exercise discretionary authority.

The following table shows the underwriting discount payable to the underwriters by us in connection with this offering.

	Per Class A Unit	Per Class B Unit	Total	
			Without Over- Allotment	With Over- Allotment
Public offering price	\$	\$	\$	\$
Underwriting discount ⁽¹⁾	\$	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$	\$

We have agreed to reimburse the underwriters for certain out-of-pocket expenses not to exceed \$150,000 in the aggregate without our consent which shall not be unreasonably withheld. We estimate that expenses payable by us in connection with this offering, including reimbursement of the underwriters out-of-pocket expenses, but excluding the underwriting discount referred to above, will be approximately \$ _____.

- (1) The underwriter will receive a discount of 7% to the public offering price with respect to any Class A Units or Class B Units purchased in this offering by investors.

Option To Purchase Additional Shares and Warrants

We have granted to the underwriters an over-allotment option exercisable not later than 45 days after the date of this prospectus to purchase up to _____ additional shares of common stock (15% of the shares included in the Class A Units sold in this offering and the shares of common stock issuable upon conversion of the Series B Preferred included in Class B Units sold in the offering) and/or warrants to purchase a maximum of _____ shares of common stock from us to cover over-allotments, if any. If the underwriters exercise all or part of this option, they will purchase such common stock covered by the option at the public offering price per Class A Unit, minus one cent and the warrants covered by this option at a price of one cent per warrant, in each case less the underwriting discounts and commissions. If this option is exercised in full, the total offering price to the public will be approximately \$ _____ million and the total net proceeds, after expenses, to us will be approximately \$ _____ million.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act and liabilities arising from breaches of representations and warranties contained in the underwriting agreement, or to contribute to payments that the underwriters may be required to make in respect of those liabilities.

Determination of Offering Price

The actual offering price of the securities we are offering will be negotiated between us and the underwriter based on the trading of our shares of common stock prior to the offering, among other things, and may be at a discount to the current market price.

Lock-up Agreements

We, our officers and directors have agreed, subject to limited exceptions, for a period of 90 days after the date of the underwriting agreement, not to offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of, directly or indirectly any shares of common stock or any securities convertible into or exchangeable for our common stock either owned as of the date of the underwriting agreement or thereafter acquired without the prior written consent of the representative. The representative may, in its sole discretion and at any time or from time to time before the termination of the lock-up period, without notice, release all or any portion of the securities subject to lock-up agreements.

Price Stabilization, Short Positions and Penalty Bids

The underwriter may engage in syndicate covering transactions, stabilizing transactions and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of our shares of common stock:

- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriter is concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.
- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specific maximum.
- Penalty bids permit the underwriter to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These syndicate covering transactions, stabilizing transactions and penalty bids may have the effect of raising or maintaining the market prices of our securities or preventing or retarding a decline in the market prices of our securities. As a result, the price of our shares of common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriter make any representation or prediction as to the effect that the transactions described above may have on the price of our shares of common stock. These transactions may be effected on the NYSE American, in the over-the-counter market or on any other trading market and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriter also may engage in passive market making transactions in our shares of common stock in accordance with Regulation M during a period before the commencement of offers or sales of our shares of common stock in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker's bid that bid must then be lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

Neither we nor the underwriter make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the prices of our securities. In addition, neither we nor the underwriter make any representation that the underwriter will engage in these transactions or that any transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

This prospectus in electronic format may be made available on websites or through other online services maintained by one or more of the underwriters, or by their affiliates. Other than this prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

Other

From time to time, certain of the underwriters and/or their affiliates have provided, and may in the future provide, various investment banking and other financial services for us for which services they have received and, may in the future receive, customary fees. In the course of their businesses, the underwriters and their affiliates may actively trade our securities or loans for their own account or for the accounts of customers, and, accordingly, the underwriters and their affiliates may at any time hold long or short positions in such securities or loans. Except for services provided in connection with this offering, no underwriter has provided any investment banking or other financial services to us during the 180-day period preceding the date of this prospectus and we do not expect to retain any underwriter to perform any investment banking or other financial services for at least 90 days after the date of this prospectus.

NOTICE TO INVESTORS

Notice to Investors in Canada

The securities may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 Underwriting Conflicts ("NI 33-105"), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to Investors in the United Kingdom

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State") an offer to the public of any securities which are the subject of the offering contemplated by this prospectus may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any such securities may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- (a) to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- (b) to any legal entity which has two or more of: (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000; and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;
- (c) by the underwriters to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive); or
- (d) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of these securities shall result in a requirement for the publication by the issuer or the underwriters of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any of the securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any such securities to be offered so as to enable an investor to decide to purchase any such securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression "Prospectus Directive" means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

Each underwriter has represented, warranted and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000 (the FSMA)) received by it in connection with the issue or sale of any of the securities in circumstances in which section 21(1) of the FSMA does not apply to the issuer; and
- (b) it has complied with and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the United Kingdom.

European Economic Area

In particular, this document does not constitute an approved prospectus in accordance with European Commission's Regulation on Prospectuses no. 809/2004 and no such prospectus is to be prepared and approved in connection with this offering. Accordingly, in relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (being the Directive of the European Parliament and of the Council 2003/71/EC and including any relevant implementing measure in each Relevant Member State) (each, a Relevant Member State), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the Relevant Implementation Date) an offer of securities to the public may not be made in that Relevant Member State prior to the publication of a prospectus in relation to such securities which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that it may, with effect from and including the Relevant Implementation Date, make an offer of securities to the public in that Relevant Member State at any time:

- to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- to any legal entity which has two or more of: (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000; and (3) an annual net turnover of more than €50,000,000, as shown in the last annual or consolidated accounts; or

- in any other circumstances which do not require the publication by the Issuer of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer of securities to the public” in relation to any of the securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State. For these purposes the securities offered hereby are “securities.”

LEGAL MATTERS

Gracin & Marlow, LLP, New York, New York will pass upon certain legal matters related to the issuance and sale of the pre-funded warrants offered 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. Zysman, Aharoni, Gayer and Sullivan & Worcester LLP, is acting as counsel to the underwriters in this offering.

EXPERTS

The financial statements as of December 31, 2017 and 2016 and for the years then ended and management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2017 incorporated by reference in this Prospectus and in the Registration Statement have been so incorporated in reliance on the reports of BDO USA, LLP, an independent registered public accounting firm (the reports on the financial statements contain an explanatory paragraph regarding the Company's ability to continue as a going concern), incorporated by reference in this Prospectus and in the Registration Statement, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the Securities and Exchange Commission (the "SEC") a registration statement on Form S-1 under the Securities Act with respect to the securities offered by this prospectus. This prospectus, which is part of the registration statement, omits certain information, exhibits, schedules and undertakings set forth in the registration statement. For further information pertaining to us and the securities offered hereby, reference is made to the registration statement and the exhibits and schedules to the registration statement. Statements contained in this prospectus as to the contents or provisions of any documents referred to in this prospectus are not necessarily complete, and in each instance where a copy of the document has been filed as an exhibit to the registration statement, reference is made to the exhibit for a more complete description of the matters involved.

You may read and copy all or any portion of the registration statement without charge at the public reference room of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Copies of the registration statement may be obtained from the SEC at prescribed rates from the public reference room of the SEC at such address. You may obtain information regarding the operation of the public reference room by calling 1-800-SEC-0330. In addition, registration statements and certain other filings made with the SEC electronically are publicly available through the SEC's website at www.sec.gov. The registration statement, including all exhibits and amendments to the registration statement, has been filed electronically with the SEC. You may also read all or any portion of the registration statement and certain other filings made with the SEC on our website at www.syntheticbiologics.com. The information contained in, and that can be accessed through, our website is not incorporated into and is not part of this prospectus.

We are subject to the information and periodic reporting requirements of the Exchange Act and, accordingly, are required to file annual reports containing financial statements audited by an independent public accounting firm, quarterly reports containing unaudited financial data, current reports, proxy statements and other information with the SEC. You will be able to inspect and copy such periodic reports, proxy statements and other information at the SEC's public reference room, the website of the SEC referred to above, and our website at www.syntheticbiologics.com. Except for the specific incorporated reports and documents listed above, no information available on or through our website shall be deemed to be incorporated in this prospectus or the registration statement of which it forms a part.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" certain information that we will 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 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 (Commission File No. 001-35994) after (i) the date of this initial registration statement and prior to effectiveness of this registration statement and (ii) the date of this prospectus and before the completion of the offering of the securities included in this prospectus, however, we will not incorporate by reference any documents or portions thereof 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, 2017 filed with the SEC on February 22, 2018 (File No. 001-12584);
- Our quarterly reports on Form 10-Q for the quarters ended March 31, 2018 and June 30, 2018 filed with the SEC on May 8, 2018 and August 8, 2018, respectively (File No. 001-12584);

- Our current reports on Form 8-K (File No. 001-12584) filed with the SEC on January 8, 2018, March 7, 2018; April 23, 2018, May 7, 2018, May 22, 2018; August 1, 2018, August 13, 2018, September 6, 2018, September 6, 2018, September 26, 2018, October 2, 2018 and October 10, 2018;
- Our definitive proxy statement on Schedule 14A filed with the SEC on August 14, 2018 (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).

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, a copy of any or all of the reports or documents that we incorporate by reference in this prospectus contained in the registration statement (except exhibits to the documents that are not specifically incorporated by reference) at no cost to you, by writing or calling us at the following address and telephone number:

Synthetic Biologics, Inc.
9605 Medical Center Drive, Suite 270, Suite 12
Rockville, Maryland 20850
(301) 417-4364

Information about us is available at our website at www.syntheticbiologics.com. Except for the specific incorporated reports and documents listed above, no information available on or through our website shall be deemed to be incorporated in this prospectus or the registration statement of which it forms a part. Any statement contained in this registration statement or in a document incorporated or deemed to be incorporated by reference in this registration statement shall be deemed to be modified or superseded for purposes of this registration statement to the extent that a statement contained in this registration statement or in any other subsequently filed document which also is or is deemed to be incorporated by reference in this registration statement modifies or supersedes that statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this registration statement.



**Up to 9,523,809 Class A Units Consisting of Shares of Common Stock and Warrants
Up to 20,000 Class B Units Consisting of Series B Convertible Preferred Stock and Warrants**

**9,523,809 Shares of Common Stock Underlying the Series B Convertible Preferred Stock and
9,523,809 Shares of Common Stock Underlying the Warrants**

PROSPECTUS

A.G.P.

, 2018

Through and including , 2018 (25 days after commencement of this offering), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

PART II - INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

We estimate that expenses in connection with the distribution described in this registration statement (other than fees and commissions charged by the underwriters) will be as set forth below. We will pay all of the expenses with respect to the distribution, and such amounts, with the exception of the SEC registration fee and the Financial Industry Regulatory Authority, Inc. (“FINRA”) filing fee, are estimates.

SEC registration fee	\$	12,266
FINRA filing fee		15,680
Accounting fees and expenses		70,000
Printing fees		10,000
Legal fees and expenses		300,000
Underwriters’ out-of-pocket expenses		150,000
Marketing fees		2,500
Other (including transfer agent and warrant agent fees)		39,554
Total	\$	600,000

ITEM 14. 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 or she 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.

In any underwriting agreement we enter into in connection with the sale of the securities being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us, within the meaning of the Securities Act, against certain liabilities.

ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES

The following information sets forth certain information with respect to all securities which we have sold during the last three years.

On January 24, 2018, we issued to a consultant as a partial payment for services, a warrant to purchase 714 shares of our common stock at an exercise price of \$18.55 per share (as adjusted for the reverse split). The issuance of the warrant was exempt from registration provisions of the Securities Act under the exemption provided for by the Section 4(a)(2) thereof for transactions not involving a public offering.

On September 11, 2017, the Company issued 120,000 shares of its Series A Convertible Preferred Stock to an accredited investor in accordance with the terms of the Purchase Agreement. The offer and issuance of the Series A Convertible Preferred Stock and the shares of Common Stock issuable upon conversion of the Series A Convertible Preferred Stock have not been registered under the Securities Act of 1933, as amended (the “Securities Act”), and therefore may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements. For this issuance, the Company is relying on the exemption from federal registration under Section 4(a)(2) of the Securities Act based on the Company’s belief that the offer and sale of such securities does not involve a public offering as the investor is an “accredited investor” as defined under Section 501 promulgated under the Securities Act.

ITEM 16. EXHIBITS

- 1.1 [Form of Underwriting Agreement*](#)
- 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 with the SEC on 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 with the SEC on 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 with the SEC on August 14, 1998 \(File No. 001-12584\).](#)
- 3.2 [Articles of Merger \(Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed with the SEC on October 19, 2009\) \(File No. 001-12584\).](#)
- 3.3 [Certificate of Merger filed with the Secretary of State of Delaware \(Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed with the SEC on October 19, 2009\) \(File No. 001-12584\).](#)
- 3.4 [Articles of Incorporation filed with the Nevada Secretary of State \(Incorporated by reference to Exhibit 3.3 of the Registrant's Current Report on Form 8-K filed with the SEC on October 19, 2009\) \(File No. 001-12584\).](#)
- 3.5 [Amended and Restated Bylaws Adopted and Effective October 31, 2011 \(Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed with the SEC on November 2, 2011\) \(File No. 001-12584\).](#)
- 3.6 [Certificate of Amendment to Articles of Incorporation \(Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed with the SEC on February 16, 2012\) \(File No. 001-12584\).](#)
- 3.7 [Certificate of Amendment to the Articles of Incorporation \(Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed with the SEC on May 18, 2015\) \(File No. 001-12584\).](#)
- 3.8 [Certificate of Amendment to the Articles of Incorporation \(Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed with the SEC on September 8, 2017\) \(File No. 001-12584\).](#)
- 3.9 [Certificate of Designation for Series A Preferred Stock to Certificate of Incorporation \(Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed September 12, 2017, File No. 001-12584.\)](#)
- 3.10 Certificate of Designation for Series B Preferred Stock to Certificate of Incorporation**
- 4.1 [Specimen Stock Certificate evidencing shares of Common Stock \(Incorporated by reference to Exhibit 4.1 of Registrant's registration statement on Form S-3 filed with the SEC on July 3, 2013\) \(File No. 333-189794\).](#)
- 4.2 [Form of Warrant to purchase shares of common stock \(Incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K filed with the SEC on November 15, 2016\) \(File No. 0001-12584\).](#)
- 4.3 [Form of Warrant Agreement \(Incorporated by reference to \(Incorporated by reference to Exhibit 4.3 of our Current Report on Form 8-K filed with the SEC on November 15, 2016\) \(File No. 0001-12584\).](#)
- 4.4 [Form Warrant Agency Agreement and Form of Warrant Certificate*](#)
- 5.1(a) [Legal opinion of Parsons Behle & Latimer**](#)
- 5.1(b) [Legal opinion of Gracin & Marlow, LLP**](#)
- 10.1 [Share Purchase Agreement dated as of September 11, 2017 between Synthetic Biologics, Inc. and MSD Credit Opportunity Master Fund, L.P. \(Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed September 12, 2017, File No. 001-12584\).](#)
- 10.2 [Registration Rights Agreement dated as of September 11, 2017 between Synthetic Biologics, Inc. and MSD Credit Opportunity Master Fund, L.P. \(Incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on September 12, 2017, File No. 001-12584\).](#)
- 23.1 [Consent of Independent Registered Public Accounting Firm \(BDO USA, LLP\)*](#)
- 23.2 [Consent of Parsons Behle & Latimer \(included in Exhibit 5.1\(a\)\)**](#)
- 23.2 [Consent of Gracin & Marlow, LLP \(included in Exhibit 5.1\(b\)\)**](#)
- 24.1 [Powers of Attorney for our directors \(included on the signature page to the initial Registration Statement\)](#)

* Filed herewith

** Previously filed

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, as amended (the "Securities Act");

(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 Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

(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), (ii), and (iii) of this section 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 Commission 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.

(2) That, for the purpose of determining any liability under the Securities Act, 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 to any purchaser: If the registrant is subject to Rule 430C (§230.430C of this chapter), 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 (§230.430A of this chapter), 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 under the Securities Act 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 (§230.424 of this chapter);

(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, 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.

(c) The undersigned registrant hereby undertakes to supplement the prospectus, after the expiration of the subscription period, to set forth the results of the subscription offer, the transactions by the underwriters during the subscription period, the amount of unsubscribed securities to be purchased by the underwriters, and the terms of any subsequent reoffering thereof. If any public offering by the underwriters is to be made on terms differing from those set forth on the cover page of the prospectus, a post-effective amendment will be filed to set forth the terms of such offering.

(d) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Company 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.

(e) For the purpose of determining any liability under the Securities Act, the registrant will treat 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 under Rule 424(b)(1), or (4), or 497(h) under the Securities Act as part of this registration statement as of the time the Commission declared it effective.

(f) For the purpose of determining any liability under the Securities Act, 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, the Registrant has duly caused this Amendment No. 3 to Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Rockville, State of Maryland, October 10, 2018.

SYNTHETIC BIOLOGICS, INC.

By: /s/ Steven A. Shallcross

Name: Steven A. Shallcross

Title: Interim Chief Executive Officer and Chief Financial Officer

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.

<u> /s/ Steven A. Shallcross</u> Steven A. Shallcross	Interim Chief Executive Officer and Chief Financial Officer (Principal Executive Officer and Principal Financial and Accounting Officer)	October 10, 2018
* <u>Jeffrey J. Kraws</u>	Chairman	October 10, 2018
* <u>Scott L. Tarriff</u>	Director	October 10, 2018
* <u>Jeffrey Wolf</u>	Director	October 10, 2018
*By: <u> /s/ Steven A. Shallcross</u> Steven A. Shallcross Attorney-in-Fact		

UNDERWRITING AGREEMENT

between

SYNTHETIC BIOLOGICS, INC.

and

A.G.P./ALLIANCE GLOBAL PARTNERS,

as Representative of the Several Underwriters

SYNTHETIC BIOLOGICS, INC.

UNDERWRITING AGREEMENT

New York, New York
[], 2018

A.G.P./Alliance Global Partners
As Representative of the several Underwriters named on Schedule 1 attached hereto
590 Madison Avenue, 36th Floor
New York, New York 10022
Ladies and Gentlemen:

The undersigned, Synthetic Biologics, Inc., a corporation formed under the laws of the State of Nevada (collectively with its subsidiaries and affiliates, including, without limitation, all entities disclosed or described in the Registration Statement (as hereinafter defined) as being subsidiaries or affiliates of Synthetic Biologics, Inc., the “**Company**”), hereby confirms its agreement (this “**Agreement**”) with A.G.P./Alliance Global Partners (hereinafter referred to as “you” (including its correlatives) or the “**Representative**”) and with the other underwriters named on Schedule 1 hereto for which the Representative is acting as representative (the Representative and such other underwriters being collectively called the “**Underwriters**” or, individually, an “**Underwriter**”) as follows:

1. Purchase and Sale of Securities.

1.1 Firm Securities.

1.1.1 Nature and Purchase of Firm Securities.

(i) On the basis of the representations and warranties herein contained, but subject to the terms and conditions herein set forth, the Company agrees to issue and sell to the several Underwriters, an aggregate of [] Class A Units (each, a “**Class A Unit**” and collectively, the “**Class A Units**”), each Class A Unit consisting of one share of the Company’s common stock, par value \$0.001 per share (the “**Common Stock**”), and a warrant, in the form filed as an exhibit to the Registration Statement (as defined in Section 2.1.1 below), to purchase one share of Common Stock (each, a “**Warrant**” and collectively, the “**Warrants**”), and an aggregate of [] Class B Units (each, a “**Class B Unit**” and collectively, the “**Class B Units**”), each Class B Unit consisting of one share of Series B Convertible Preferred Stock, par value \$0.001 per share (the “**Preferred Stock**”), each share of Preferred Stock convertible into [] shares of Common Stock at a conversion price of \$[] per share, subject to adjustments and Warrants to purchase up to [] shares of Common Stock. Each Warrant shall be exercisable for a period of five years at an exercise price of \$[] per share, subject to adjustment as provided in the Warrants. The [] Class A Units and the [] Class B Units are collectively referred to herein as the “**Firm Securities**.”

(ii) The Underwriters, severally and not jointly, agree to purchase from the Company the number of Firm Securities set forth opposite their respective names on Schedule 1 attached hereto and made a part hereof at a purchase price of \$[] per Class A Unit (93% of the per Class A Unit offering price) and \$930.00 per Class B Unit (93% of the per Class B Unit offering price).. The Firm Securities are to be offered initially to the public as units at the respective offering prices set forth on the cover page of the Prospectus (as defined in Section 2.1.1 hereof).

1.1.2 Shares Payment and Delivery

(i) Delivery and payment for the Firm Securities shall be made at 10:00 a.m., Eastern time, on the second (2nd) Business Day following the effective date (the “**Effective Date**”) of the Registration Statement (as defined in Section 2.1.1 below) under the Securities Act of 1933, as amended (the “**Securities Act**”) (or the third (3rd) Business Day following the Effective Date if the pricing for the Offering (as defined in Section 2.1.1 below) occurs after 4:01 p.m., Eastern time on the Effective Date) or at such earlier time as shall be agreed upon by the Representative and the Company, at the offices of Zysman, Aharoni, Gayer and Sullivan & Worcester LLP, 1633 Broadway, New York, New York 10019 (“**Representative Counsel**”), or at such other place (or remotely by facsimile or other electronic transmission) as shall be agreed upon by the Representative and the Company. The hour and date of delivery and payment for the Firm Securities is called the “**Closing Date**.” The Warrants shall be issued pursuant to, and shall have the rights and privileges set forth in the form of Warrant and in a warrant agency agreement, dated on or before the Closing Date, between the Company and Corporate Stock Transfer, Inc., as warrant agent (the “**Warrant Agreement**”). The term “**Business Day**” means any day other than a Saturday, a Sunday or a legal holiday or a day on which banking institutions are authorized or obligated by law to close in New York, New York.

(ii) Payment for the Firm Securities shall be made on the Closing Date by wire transfer in Federal (same day) funds, payable to the order of the Company upon delivery of certificates (in form and substance satisfactory to the Underwriters) representing the Firm Securities (or through the facilities of the Depository Trust Company (“**DTC**”). The Firm Securities shall be registered in such name or names and in such authorized denominations as the Representative may request in writing at least one full Business Day prior to the Closing Date. The Company shall not be obligated to sell or deliver the Firm Securities except upon tender of payment by the Representative for all of the Firm Securities.

1.2 Over-allotment Option

1.2.1 Option Securities. For the purposes of covering any over-allotments in connection with the distribution and sale of the Firm Securities, the Company hereby grants to the Representative an option (the “**Over-allotment Option**”) to purchase up to (a) [] additional shares of Common Stock, representing fifteen percent (15%) of the shares of Common Stock sold as part of the Class A Units and the shares of Common Stock issuable upon conversion of the Preferred Stock sold as part of the Class B Units (the “**Option Shares**”), and/or (b) warrants to purchase up to [] shares of Common Stock, representing fifteen percent (15%) of the Warrants sold as part of the Class A Units and the Warrants sold as part of the Class B Units (the “**Option Warrants**” and collectively with the Option Shares, the “**Option Securities**”). The purchase price to be paid per Option Share shall be \$[] and the purchase price to be paid per Option Warrant shall be \$0.0093. The shares of Common Stock issuable upon exercise of the Firm Warrants and the Option Warrants are hereinafter referred to as the “**Warrant Shares**.” The Shares of Common Stock issuable upon conversion of the Preferred Stock are hereinafter referred to as the “**Preferred Conversion Shares**.” The Firm Securities, the Warrant Shares, the Preferred Conversion Shares and the Option Securities are hereinafter referred to together as the “**Public Securities**.” The offering and sale of the Public Securities is hereinafter referred to as the “**Offering**.”

1.2.2 Exercise of Option. The Over-allotment Option granted pursuant to Section 1.2.1 hereof may be exercised by the Representative as to all (at any time) or any part (from time to time) of the Option Securities within 45 days after the Effective Date. The Underwriters shall not be under any obligation to purchase any Option Securities prior to the exercise of the Over-allotment Option. The Over-allotment Option granted hereby may be exercised by the giving of oral notice to the Company from the Representative, which must be confirmed in writing by overnight mail or facsimile or other electronic transmission setting forth the number of Option Securities to be purchased and the date and time for delivery of and payment for the Option Securities (the “**Option Closing Date**”), which shall not be later than five (5) full Business Days after the date of the notice or such other time as shall be agreed upon by the Company and the Representative, at the offices of Representative Counsel or at such other place (including remotely by facsimile or other electronic transmission) as shall be agreed upon by the Company and the Representative. If such delivery and payment for the Option Securities does not occur on the Closing Date, the Option Closing Date will be as set forth in the notice. Upon exercise of the Over-allotment Option with respect to all or any portion of the Option Securities, subject to the terms and conditions set forth herein, (i) the Company shall become obligated to sell to the Underwriters the number of Option Securities specified in such notice and (ii) each of the Underwriters, acting severally and not jointly, shall purchase that portion of the total number of Option Securities then being purchased as set forth in Schedule 1 opposite the name of such Underwriter.

1.2.3 Payment and Delivery. Payment for the Option Securities shall be made on the Option Closing Date by wire transfer in Federal (same day) funds, payable to the order of the Company upon delivery to you of certificates (in form and substance satisfactory to the Underwriters) representing the Option Securities (or through the facilities of DTC) for the account of the Underwriters. The Option Securities shall be registered in such name or names and in such authorized denominations as the Representative may request in writing at least one full Business Days prior to the Option Closing Date. The Company shall not be obligated to sell or deliver the Option Securities except upon tender of payment by the Representative for applicable Option Securities.

2. Representations and Warranties of the Company. The Company represents and warrants to the Underwriters as of the Applicable Time (as defined below), as of the Closing Date and as of the Option Closing Date, if any, as follows:

2.1 Filing of Registration Statement.

2.1.1 Pursuant to the Securities Act. The Company has filed with the U.S. Securities and Exchange Commission (the “**Commission**”) a registration statement, and an amendment or amendments thereto, on Form S-1 (File No. 333-227400), including any related prospectus or prospectuses, for the registration of the Public Securities under the Securities Act, which registration statement and amendment or amendments have been prepared by the Company in all material respects in conformity with the requirements of the Securities Act and the rules and regulations of the Commission under the Securities Act (the “**Securities Act Regulations**”) and will contain all material statements that are required to be stated therein in accordance with the Securities Act and the Securities Act Regulations. Except as the context may otherwise require, such registration statement, as amended, on file with the Commission at the time the registration statement became effective (including the Preliminary Prospectus included in the registration statement, financial statements, schedules, exhibits and all other documents filed as a part thereof or incorporated therein and all information deemed to be a part thereof as of the Effective Date pursuant to paragraph (b) of Rule 430A of the Securities Act Regulations (the “**Rule 430A Information**”), is referred to herein as the “**Registration Statement**.” If the Company files any registration statement pursuant to Rule 462(b) of the Securities Act Regulations, then after such filing, the term “**Registration Statement**” shall include such registration statement filed pursuant to Rule 462(b). The Registration Statement has been declared effective by the Commission on the date hereof.

Each prospectus used prior to the effectiveness of the Registration Statement, and each prospectus that omitted the Rule 430A Information that was used after such effectiveness and prior to the execution and delivery of this Agreement, is herein called a “**Preliminary Prospectus**.” The Preliminary Prospectus, subject to completion, dated [], 2018, that was included in the Registration Statement immediately prior to the Applicable Time is hereinafter called the “**Pricing Prospectus**.” The final prospectus in the form first furnished to the Underwriters for use in the Offering is hereinafter called the “**Prospectus**.” Any reference to the “**most recent Preliminary Prospectus**” shall be deemed to refer to the latest Preliminary Prospectus included in the Registration Statement.

“ **Applicable Time** ” means [5:00 p.m.], Eastern time, on the date of this Agreement.

“ **Issuer Free Writing Prospectus** ” means any “issuer free writing prospectus,” as defined in Rule 433 of the Securities Act Regulations (“ **Rule 433** ”), including without limitation any “free writing prospectus” (as defined in Rule 405 of the Securities Act Regulations) relating to the Public Securities that is (i) required to be filed with the Commission by the Company, (ii) a “road show that is a written communication” within the meaning of Rule 433(d)(8)(i), whether or not required to be filed with the Commission, or (iii) exempt from filing with the Commission pursuant to Rule 433(d)(5)(i) because it contains a description of the Public Securities or of the Offering that does not reflect the final terms, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company’s records pursuant to Rule 433(g).

“ **Issuer General Use Free Writing Prospectus** ” means any Issuer Free Writing Prospectus that is intended for general distribution to prospective investors (other than a “ *bona fide* electronic road show,” as defined in Rule 433), as evidenced by its being specified in Schedule 2-B hereto.

“ **Issuer Limited Use Free Writing Prospectus** ” means any Issuer Free Writing Prospectus that is not an Issuer General Use Free Writing Prospectus.

“ **Pricing Disclosure Package** ” means any Issuer General Use Free Writing Prospectus issued at or prior to the Applicable Time, the Pricing Prospectus and the information included on Schedule 2-A hereto, all considered together.

2.1.2 Pursuant to the Exchange Act. The Common Stock is registered pursuant to Section 12(b) of the Securities Exchange Act of 1934, as amended (the “ **Exchange Act** ”). The Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act, nor has the Company received any notification that the Commission is contemplating terminating such registration.

2.2 Stock Exchange Listing. The shares of Common Stock are listed on the NYSE American (the “ **Exchange** ”), and the Company has taken no action designed to, or likely to have the effect of, delisting the shares of Common Stock from the Exchange, nor has the Company received any notification that the Exchange is contemplating terminating such listing except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus. The Company has submitted the Application for Listing of Additional Shares with the Exchange to list the shares of Common Stock included in the Public Securities (including the Warrant Shares and the Preferred Conversion Shares).

2.3 No Stop Orders, etc. Neither the Commission nor, to the Company’s knowledge, any state regulatory authority has issued any order preventing or suspending the use of the Registration Statement, any Preliminary Prospectus or the Prospectus or has instituted or, to the Company’s knowledge, threatened to institute, any proceedings with respect to such an order. The Company has complied with each request (if any) from the Commission for additional information.

2.4 Disclosures in Registration Statement

2.4.1 Compliance with Securities Act and 10b-5 Representation

(i) Each of the Registration Statement and any post-effective amendment thereto, at the time it became effective, complied in all material respects with the requirements of the Securities Act and the Securities Act Regulations. Each Preliminary Prospectus, including the prospectus filed as part of the Registration Statement as originally filed or as part of any amendment or supplement thereto, and the Prospectus, at the time each was filed with the Commission, complied in all material respects with the requirements of the Securities Act and the Securities Act Regulations. Each Preliminary Prospectus delivered to the Underwriters for use in connection with this Offering and the Prospectus was or will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(ii) Neither the Registration Statement nor any amendment thereto, at its effective time, as of the Applicable Time, at the Closing Date or at any Option Closing Date (if any), contained, contains or will contain an untrue statement of a material fact or omitted, omits or will omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading; *provided*, *however*, that this representation and warranty shall not apply to statements made or statements omitted in reliance upon and in conformity with written information furnished to the Company with respect to the Underwriters by the Representative expressly for use in the Registration Statement, the Pricing Prospectus, the Pricing Disclosure Package or the Prospectus or any amendment thereof or supplement thereto. The parties acknowledge and agree that such information provided by or on behalf of any Underwriter consists solely of the following statements concerning the Underwriters (the “**Underwriters Information**”) contained in “Underwriting” section of the Prospectus: (i) the first, second, third and sixth sentences of the section entitled “Discount, Commissions and Expenses”; and (ii) the section entitled “Price Stabilization, Short Positions and Penalty Bids”.

(iii) The Pricing Disclosure Package, as of the Applicable Time, at the Closing Date or at any Option Closing Date (if any), did not, does not and will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; and any Issuer Limited Use Free Writing Prospectus hereto does not conflict with the information contained in the Registration Statement, any Preliminary Prospectus, the Pricing Prospectus or the Prospectus, and each such Issuer Limited Use Free Writing Prospectus, as supplemented by and taken together with the Prospectus as of the Applicable Time, did not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading; *provided*, *however*, that this representation and warranty shall not apply to the Underwriters Information.

(iv) Neither the Prospectus nor any amendment or supplement thereto (including any prospectus wrapper), as of its issue date, at the time of any filing with the Commission pursuant to Rule 424(b), at the Closing Date or at any Option Closing Date, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; *provided*, *however*, that this representation and warranty shall not apply to the Underwriters’ Information.

(v) The documents incorporated by reference in the Registration Statement, the Pricing Prospectus, the Pricing Disclosure Package and the Prospectus, when they became effective or were filed with the Commission, as the case may be, conformed in all material respects to the requirements of the Securities Act or the Exchange Act, as applicable, and the rules and regulations of the Commission thereunder and none of such documents contained any untrue statement of a material fact or omitted to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; and any further documents so filed and incorporated by reference in the Registration Statement, the Pricing Prospectus, the Pricing Disclosure Package and the Prospectus, when such documents become effective or are filed with the Commission, as the case may be, will conform in all material respects to the requirements of the Securities Act or the Exchange Act, as applicable, and the rules and regulations of the Commission thereunder, and will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

2.4.2 Disclosure of Agreements. The agreements and documents described in the Registration Statement, the Pricing Disclosure Package and the Prospectus conform in all material respects to the descriptions thereof contained or incorporated by reference therein and there are no agreements or other documents required by the Securities Act and the Securities Act Regulations to be described in the Registration Statement, the Pricing Disclosure Package and the Prospectus or to be filed with the Commission as exhibits to the Registration Statement or to be incorporated by reference in the Registration Statement, the Pricing Disclosure Package or the Prospectus, that have not been so described or filed or incorporated by reference. Each agreement or other instrument (however characterized or described) to which the Company is a party or by which it is or may be bound or affected and (i) that is referred to or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus, or (ii) is material to the Company's business, has been duly authorized and validly executed by the Company, is in full force and effect in all material respects and is enforceable against the Company and, to the Company's knowledge, the other parties thereto, in accordance with its terms, except (x) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally, (y) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws, and (z) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefor may be brought. None of such agreements or instruments has been assigned by the Company, and neither the Company nor, to the Company's knowledge, any other party is in default thereunder and, to the Company's knowledge, no event has occurred that, with the lapse of time or the giving of notice, or both, would constitute a default thereunder except for a default or event which would not reasonably be expected to result in a Material Adverse Change (as such term is defined in Section 2.5.1 below). To the Company's knowledge, performance by the Company of the material provisions of such agreements or instruments will not result in a violation of any existing applicable law, rule, regulation, judgment, order or decree of any governmental agency or court, domestic or foreign, having jurisdiction over the Company or any of its assets or businesses (each, a " **Governmental Entity** "), including, without limitation, those relating to environmental laws and regulations.

2.4.3 Prior Securities Transactions. Since September 1, 2015, no securities of the Company have been sold by the Company or by or on behalf of, or for the benefit of, any person or persons controlling, controlled by or under common control with the Company, except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

2.4.4 Regulations. The disclosures in the Registration Statement, the Pricing Disclosure Package and the Prospectus concerning the effects of federal, state, local and all foreign regulation on the Offering and the Company's business as currently contemplated are correct in all material respects and no other such regulations are required to be disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus which are not so disclosed.

2.4.5 No Other Distribution of Offering Materials. The Company has not, directly or indirectly, distributed and will not distribute any offering material in connection with the Offering other than any Preliminary Prospectus, the Pricing Prospectus, the Pricing Disclosure Package, the Prospectus and other materials, if any, permitted under the Securities Act and consistent with Section 3.2 below.

2.5 Changes After Dates in Registration Statement.

2.5.1 No Material Adverse Change. Since the respective dates as of which information is given in the Registration Statement, the Pricing Disclosure Package and the Prospectus, except as otherwise specifically stated therein: (i) there has been no material adverse change in the financial position or results of operations of the Company, nor any change or development that, singularly or in the aggregate, would involve a material adverse change, in or affecting the condition (financial or otherwise), results of operations, business, assets or prospects of the Company (a “**Material Adverse Change**”); (ii) there have been no material transactions entered into by the Company, other than as contemplated pursuant to this Agreement; and (iii) no officer or director of the Company has resigned from any position with the Company.

2.5.2 Recent Securities Transactions, etc. Subsequent to the respective dates as of which information is given in the Registration Statement, the Pricing Disclosure Package and the Prospectus, and except as may otherwise be indicated or contemplated herein or disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has not: (i) issued any securities other than securities issuable upon the exercise or conversion of then outstanding options, warrants and/or convertible securities, or incurred any liability or obligation, direct or contingent, for borrowed money; or (ii) declared or paid any dividend or made any other distribution on or in respect to its capital stock.

2.6 Disclosures in Commission Filings. None of the Company’s filings with the Commission contained any untrue statement of a material fact or omitted to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Company has made all filings with the Commission required under the Exchange Act and the rules and regulations of the Commission promulgated thereunder (the “**Exchange Act Regulations**”).

2.7 Independent Accountants. To the knowledge of the Company, BDO USA, LLP (the “**Auditor**”), whose report is filed with the Commission and included or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus, is an independent registered public accounting firm as required by the Securities Act and the Securities Act Regulations and the Public Company Accounting Oversight Board. The Auditor has not, during the periods covered by the financial statements included or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus, provided to the Company any non-audit services, as such term is used in Section 10A(g) of the Exchange Act.

2.8 Financial Statements, etc. The financial statements, including the notes thereto and supporting schedules included or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus, fairly present in all material respects the financial position and the results of operations of the Company at the dates and for the periods to which they apply; and such financial statements have been prepared in conformity with U.S. generally accepted accounting principles (“GAAP”), consistently applied throughout the periods involved (provided that unaudited interim financial statements are subject to year-end audit adjustments that are not expected to be material in the aggregate and do not contain all footnotes required by GAAP); and the supporting schedules included or incorporated by reference in the Registration Statement present fairly the information required to be stated therein. The pro forma financial statements and the related notes, if any, included or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus have been properly compiled and prepared in accordance with the applicable requirements of the Securities Act, the Securities Act Regulations, the Exchange Act or the Exchange Act Regulations and present fairly the information shown therein or incorporated therein, and the assumptions used in the preparation thereof are reasonable and the adjustments used therein are appropriate to give effect to the transactions and circumstances referred to therein. Except as included therein, no historical or pro forma financial statements are required to be included in the Registration Statement, the Pricing Disclosure Package or the Prospectus under the Securities Act, the Securities Act Regulations, the Exchange Act or the Exchange Act Regulations. The pro forma and pro forma as adjusted financial information and the related notes, if any, included or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus have been properly compiled and prepared in accordance with the applicable requirements of the Securities Act, the Securities Act Regulations, the Exchange Act or the Exchange Act Regulations and present fairly the information shown therein, and the assumptions used in the preparation thereof are reasonable and the adjustments used therein are appropriate to give effect to the transactions and circumstances referred to therein. All disclosures contained in the Registration Statement, the Pricing Disclosure Package or the Prospectus, or incorporated or deemed incorporated by reference therein, regarding “non-GAAP financial measures” (as such term is defined by the rules and regulations of the Commission), if any, comply in all material respects with Regulation G of the Exchange Act and Item 10 of Regulation S-K of the Securities Act, to the extent applicable. Each of the Registration Statement, the Pricing Disclosure Package and the Prospectus discloses all material off-balance sheet transactions, arrangements, obligations (including contingent obligations), and other relationships of the Company with unconsolidated entities or other persons that may have a material current or future effect on the Company’s financial condition, changes in financial condition, results of operations, liquidity, capital expenditures, capital resources, or significant components of revenues or expenses. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, (a) neither the Company nor any of its direct and indirect subsidiaries, including each entity disclosed or described in the Registration Statement, the Pricing Disclosure Package and the Prospectus as being a subsidiary of the Company (each, a “**Subsidiary**” and, collectively, the “**Subsidiaries**”), has incurred any material liabilities or obligations, direct or contingent, or entered into any material transactions other than in the ordinary course of business, (b) the Company has not declared or paid any dividends or made any distribution of any kind with respect to its capital stock, (c) there has not been any change in the capital stock of the Company or any of its Subsidiaries, or, other than in the course of business or any grants under any stock compensation plan, and (d) there has not been any Material Adverse Change in the Company’s long-term or short-term debt.

2.9 Authorized Capital: Options, etc. The Company had, at the date or dates indicated in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the duly authorized, issued and outstanding capitalization as set forth therein. Based on the assumptions stated in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company will have on the Closing Date the adjusted stock capitalization set forth therein. Except as set forth in, or contemplated by, the Registration Statement, the Pricing Disclosure Package and the Prospectus, on the Effective Date, as of the Applicable Time and on the Closing Date and any Option Closing Date, there will be no stock options, warrants, or other rights to purchase or otherwise acquire any authorized, but unissued shares of Common Stock of the Company or any security convertible or exercisable into shares of Common Stock of the Company, or any contracts or commitments to issue or sell shares of Common Stock or any such options, warrants, rights or convertible securities.

2.10 Valid Issuance of Securities, etc.

2.10.1 Outstanding Securities. Since July 23, 2013, all issued and outstanding securities of the Company issued prior to the transactions contemplated by this Agreement have been duly authorized and validly issued and are fully paid and non-assessable; the holders thereof have no rights of rescission with respect thereto, and are not subject to personal liability by reason of being such holders; and none of such securities were issued in violation of the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company. The authorized shares of Common Stock conform in all material respects to all statements relating thereto contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus. The offers and sales of the outstanding shares of Common Stock were at all relevant times either registered under the Securities Act and the applicable state securities or “blue sky” laws or, based in part on the representations and warranties of the purchasers of such Shares, exempt from such registration requirements. The description of the Company’s stock option, stock bonus and other stock plans or arrangements, and the options or other rights granted thereunder, as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, accurately and fairly present, in all material respects, the information required to be shown with respect to such plans, arrangements, options and rights.

2.10.2 Securities Sold Pursuant to this Agreement. The Public Securities have been duly authorized for issuance and sale and, when issued and paid for in accordance with their respective terms, will be validly issued, fully paid and non-assessable; the holders thereof are not and will not be subject to personal liability by reason of being such holders; the Public Securities are not and will not be subject to the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company; and all corporate action required to be taken for the authorization, issuance and sale of the Public Securities has been duly and validly taken. The Public Securities conform in all material respects to all statements with respect thereto contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus. All corporate action required to be taken for the authorization, issuance and sale of the Preferred Stock (or, with respect to the Series B Preferred Shares, will have been taken prior to the Closing Date, including the filing of the certificate of designation of the Preferred Stock (the “**Certificate of Designation** ”)), the Warrants and the Option Warrants has been duly and validly taken; the Preferred Conversion Shares and the Warrant Shares have been duly authorized and reserved for issuance by all necessary corporate action on the part of the Company and when paid for and issued in accordance with the Certificate of Designation and the Warrant Agreement, respectively, such shares of Common Stock will be validly issued, fully paid and non-assessable; the holders thereof are not and will not be subject to personal liability by reason of being such holders; and such shares of Common Stock, Preferred Conversion Shares and Warrant Shares are not and will not be subject to the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company.

2.11 Registration Rights of Third Parties. Except as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus, no holders of any securities of the Company or any rights exercisable for or convertible or exchangeable into securities of the Company have the right to require the Company to register any such securities of the Company under the Securities Act or to include any such securities in a registration statement to be filed by the Company.

2.12 Validity and Binding Effect of Agreements. This Agreement and the Warrant Agreement have been duly and validly authorized by the Company, and, when executed and delivered, will constitute, the valid and binding agreements of the Company, enforceable against the Company in accordance with their respective terms, except in each case: (i) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors’ rights generally; (ii) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws; and (iii) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefor may be brought.

2.13 No Conflicts, etc. The execution, delivery and performance by the Company of this Agreement, the Warrant Agreement and all ancillary documents related to this Offering, the consummation by the Company of the transactions herein and therein contemplated and the compliance by the Company with the terms hereof and thereof do not and will not, with or without the giving of notice or the lapse of time or both: (i) result in a breach of, or conflict with any of the terms and provisions of, or constitute a default under, or result in the creation, modification, termination or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to the terms of any agreement or instrument to which the Company is a party; (ii) result in any violation of the provisions of the Company's Certificate of Incorporation (as the same may be amended or restated from time to time, the "**Charter**") or the by-laws of the Company (as the same may be amended or restated from time to time); or (iii) violate any existing applicable law, rule, regulation, judgment, order or decree of any Governmental Entity as of the date hereof (including, without limitation, those promulgated by the Food and Drug Administration of the U.S. Department of Health and Human Services (the "**FDA**") or by any foreign, federal, state or local regulatory authority performing functions similar to those performed by the FDA); except in the case of clause (i) or (iii) above, for such breaches, conflicts or violations which would not reasonably be expected to result in a Material Adverse Change.

2.14 No Defaults: Violations. No material default exists in the due performance and observance of any term, covenant or condition of any material license, contract, indenture, mortgage, deed of trust, note, loan or credit agreement, or any other agreement or instrument evidencing an obligation for borrowed money, or any other material agreement or instrument to which the Company is a party or by which the Company may be bound or to which any of the properties or assets of the Company is subject. The Company is not in violation of any term or provision of its Charter or by-laws, or in violation of any franchise, license, permit, applicable law, rule, regulation, judgment or decree of any Governmental Entity.

2.15 Corporate Power; Licenses; Consents.

2.15.1 Conduct of Business. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus or as would not result in a Material Adverse Change, the Company has all requisite corporate power and authority, and has all necessary authorizations, approvals, orders, licenses, certificates and permits of and from all governmental regulatory officials and bodies that it needs as of the date hereof to conduct its business purpose as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

2.15.2 Transactions Contemplated Herein. The Company has all corporate power and authority to enter into this Agreement and the Warrant Agreement and to carry out the provisions and conditions hereof, and all consents, authorizations, approvals and orders required in connection therewith have been obtained. No consent, authorization or order of, and no filing with, any court, government agency or other body is required for the valid issuance, sale and delivery of the Public Securities and the consummation of the transactions and agreements contemplated by this Agreement and the Warrant Agreement and as contemplated by the Registration Statement, the Pricing Disclosure Package and the Prospectus, except with respect to applicable federal and state securities laws and the rules and regulations of the Exchange and the Financial Industry Regulatory Authority, Inc. ("**FINRA**").

2.16 D&O Questionnaires. To the Company's knowledge, all information contained in the questionnaires (the "**Questionnaires**") completed by each of the Company's directors and officers immediately prior to the Offering (the "**Insiders**"), as supplemented by all information concerning the Company's directors, officers and principal shareholders as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, as well as in the Lock-Up Agreement (as defined in Section 2.27 below) provided to the Underwriters, is true and correct in all material respects and the Company has not become aware of any information which would cause the information disclosed in the Questionnaires to become materially inaccurate and incorrect.

2.17 Litigation: Governmental Proceedings. There is no action, suit, proceeding, inquiry, arbitration, investigation, litigation or governmental proceeding pending or, to the Company's knowledge, threatened against, or involving the Company or, to the Company's knowledge, any executive officer or director, including any proceeding before the FDA or comparable federal, state, local or foreign governmental bodies (it being understood that the interaction between the Company and the FDA and such comparable governmental bodies relating to the clinical development and product approval process shall not be deemed proceedings for purposes of this representation), which has not been disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus which is required to be disclosed.

2.18 Good Standing. The Company has been duly organized and is validly existing as a corporation and is in good standing under the laws of the State of Nevada as of the date hereof, and is duly qualified to do business and is in good standing in each other jurisdiction in which its ownership or lease of property or the conduct of business requires such qualification, except where the failure to qualify, singularly or in the aggregate, would not have or reasonably be expected to result in a Material Adverse Change.

2.19 Insurance. The Company carries or is entitled to the benefits of insurance, with reputable insurers, in such amounts and covering such risks which the Company believes are adequate, and all such insurance is in full force and effect. The Company has no reason to believe that it will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not result in a Material Adverse Change.

2.20 Transactions Affecting Disclosure to FINRA.

2.20.1 Finder's Fees. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, there are no claims, payments, arrangements, agreements or understandings relating to the payment of a finder's, consulting or origination fee by the Company or any Insider with respect to the sale of the Public Securities hereunder or any other arrangements, agreements or understandings of the Company with respect to the sale of the Public Securities hereunder or, to the Company's knowledge, any of its shareholders that may affect the Underwriters' compensation, as determined by FINRA.

2.20.2 Payments Within Six (6) Months. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus or the amount of fees to a FINRA members with respect to its at-market facility, the Company has not made any direct or indirect payments (in cash, securities or otherwise) to: (i) any person, as a finder's fee, consulting fee or otherwise, in consideration of such person raising capital for the Company or introducing to the Company persons who raised or provided capital to the Company; (ii) any FINRA member; or (iii) any person or entity that has any direct or indirect affiliation or association with any FINRA member, within the six (6) months prior to the date of this Agreement, other than the payment to the Underwriters as provided hereunder in connection with the Offering.

2.20.3 Use of Proceeds. None of the net proceeds of the Offering will be paid by the Company to any participating FINRA member or its affiliates, except as specifically authorized herein.

2.20.4 FINRA Affiliation. Except as disclosed in their FINRA confirmations, there is no (i) officer or director of the Company, or, to the Company's knowledge, (ii) beneficial owner of 5% or more of any class of the Company's securities or (iii) beneficial owner of the Company's unregistered equity securities which were acquired during the 180-day period immediately preceding the filing of the Registration Statement that is an affiliate or associated person of a FINRA member participating in the Offering (as determined in accordance with the rules and regulations of FINRA).

2.20.5 Information. All information provided by the Company in its FINRA questionnaire to Representative Counsel specifically for use by Representative Counsel in connection with its Public Offering System filings (and related disclosure) with FINRA is true, correct and complete in all material respects.

2.21 Foreign Corrupt Practices Act. None of the Company and its Subsidiaries or, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company and its Subsidiaries or any other person acting on behalf of the Company and its Subsidiaries, has, directly or indirectly, given or agreed to give any money, gift or similar benefit (other than legal price concessions to customers in the ordinary course of business) to any customer, supplier, employee or agent of a customer or supplier, or official or employee of any governmental agency or instrumentality of any government (domestic or foreign) or any political party or candidate for office (domestic or foreign) or other person who was, is, or may be in a position to help or hinder the business of the Company (or assist it in connection with any actual or proposed transaction) that (i) might subject the Company to any damage or penalty in any civil, criminal or governmental litigation or proceeding, (ii) if not given in the past, might have had a Material Adverse Change or (iii) if not continued in the future, might adversely affect the assets, business, operations or prospects of the Company. The Company has taken reasonable steps to ensure that its accounting controls and procedures are sufficient to cause the Company to comply in all material respects with the Foreign Corrupt Practices Act of 1977, as amended.

2.22 Compliance with OFAC. None of the Company and its Subsidiaries or, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company and its Subsidiaries or any other person acting on behalf of the Company and its Subsidiaries, is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury ("OFAC"), and the Company will not, directly or indirectly, use the proceeds of the Offering hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity, for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

2.23 Forward-Looking Statements. No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) contained in either the Registration Statement, Pricing Disclosure Package or Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.

2.24 Money Laundering Laws. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any Governmental Entity (collectively, the "**Money Laundering Laws**"); and no action, suit or proceeding by or before any Governmental Entity involving the Company with respect to the Money Laundering Laws is pending or, to the best knowledge of the Company, threatened.

2.25 Regulatory. All preclinical studies and clinical trials conducted by or on behalf of the Company that are material to the Company and its Subsidiaries, taken as a whole, are or have been adequately described in the Registration Statement, the Pricing Disclosure Package and the Prospectus in all material respects. The preclinical studies and clinical trials conducted by or on behalf of the Company and its Subsidiaries that are described in the Registration Statement, the Pricing Disclosure Package and the Prospectus or the results of which are referred to in the Registration Statement, the Pricing Disclosure Package and the Prospectus were and, if still ongoing, are being conducted in material compliance with all laws and regulations applicable thereto in the jurisdictions in which they are being conducted and with all laws and regulations applicable to preclinical studies and clinical trials from which data will be submitted to support marketing approval. The descriptions in the Registration Statement, the Pricing Disclosure Package and the Prospectus of the results of such studies are accurate and complete in all material respects and fairly present the data derived from such studies, and the Company has no knowledge of, or reason to believe that, any large well-controlled clinical study the aggregate results of which are inconsistent with or otherwise call into question the results of any clinical study conducted by or on behalf of the Company that are described in the Registration Statement, the Pricing Disclosure Package and the Prospectus or the results of which are referred to in the Registration Statement, the Pricing Disclosure Package and the Prospectus. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has not received any written notices or statements from the FDA, the European Medicines Agency (“**EMA**”) or any other governmental agency or authority imposing, requiring, requesting or suggesting a clinical hold, termination, suspension or material modification for or of any preclinical studies and clinical trials that are described in the Registration Statement, the Pricing Disclosure Package and the Prospectus or the results of which are referred to in the Registration Statement, the Pricing Disclosure Package and the Prospectus. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has not received any written notices or statements from the FDA, the EMA or any other governmental agency, and otherwise has no knowledge of, or reason to believe that, (i) any investigational new drug application for any potential product of the Company is or has been rejected or placed on clinical hold; and (ii) any license, approval, permit or authorization to conduct any clinical trial of any potential product of the Company has been, will be or may be suspended, revoked, modified or limited. To the Company’s knowledge, the Company and each of its directors, officers, employees and agents, is and has been in material compliance with applicable health care laws, including, to the extent applicable, without limitation, the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.), the federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)), the civil False Claims Act (31 U.S.C. § 3729 et seq.), the criminal False Claims Law (42 U.S.C. § 1320a-7b(a)), the Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a), the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (42 U.S.C. § 17921 et seq.), the exclusion laws (42 U.S.C. § 1320a-7), Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act), and the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, including without limitation the Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h), and the regulations promulgated pursuant to such laws, and comparable state laws (collectively, the “**Health Care Laws**”). The Company has not received notice of any ongoing claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental authority or third party alleging that any product operation or activity is in material violation of any Health Care Laws. The Company has filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments thereto as required by any Health Care Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete, correct and not misleading on the date filed (or were corrected or supplemented by a subsequent submission). To the Company’s knowledge, the manufacturing facilities and operations of its suppliers are in compliance in all material respects with all applicable statutes, rules, and regulations of the FDA and comparable regulatory agencies outside of the United States to which the Company or its contractors and supplies are subject. The Company is not distributing or promoting any product in a way that would violate the advertising and promotional requirements of the FDA or any other federal, state or foreign regulatory authority, including the FDA’s current regulations and policies related to “off-label” marketing and promotion of prescription drugs and medical devices, consistent with the current scope of the Company’s marketing authorization and product labeling.

2.26 Officers' Certificate. Any certificate signed by any duly authorized officer of the Company and delivered to you or to Representative Counsel shall be deemed a representation and warranty by the Company to the Underwriters as to the matters covered thereby.

2.27 Lock-Up Agreements. Schedule 3 hereto contains a complete and accurate list of the Company's officers and directors (collectively, the "**Lock-Up Parties** "). The Company has caused each of the Lock-Up Parties to deliver to the Representative an executed Lock-Up Agreement, in the form attached hereto as Exhibit A (the "**Lock-Up Agreement** "), prior to the execution of this Agreement.

2.28 Subsidiaries. All direct and indirect Subsidiaries of the Company are duly organized and in good standing under the laws of the place of organization or incorporation, and each Subsidiary is in good standing in each jurisdiction in which its ownership or lease of property or the conduct of business requires such qualification, except where the failure to qualify would not have a Material Adverse Change. The Company's ownership and control of each Subsidiary is as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

2.29 Related Party Transactions.

2.29.1 Business Relationships. There are no business relationships or related party transactions involving the Company or any other person required to be described in the Registration Statement, the Pricing Disclosure Package and the Prospectus that have not been described as required.

2.29.2 No Relationships with Customers and Suppliers. No relationship, direct or indirect, exists between or among the Company on the one hand, and the directors, officers, 5% or greater stockholders, customers or suppliers of the Company or any of the Company's affiliates on the other hand, which is required to be described in the Pricing Disclosure Package and the Prospectus or a document incorporated by reference therein and which is not so described.

2.29.3 No Unconsolidated Entities. There are no transactions, arrangements or other relationships between and/or among the Company, any of its affiliates (as such term is defined in Rule 405 of the Securities Act) and any unconsolidated entity, including, but not limited to, any structured finance, special purpose or limited purpose entity that could reasonably be expected to materially affect the Company's liquidity or the availability of or requirements for its capital resources required to be described in the Pricing Disclosure Package and the Prospectus or a document incorporated by reference therein which have not been described as required.

2.29.4 No Loans or Advances to Affiliates. There are no outstanding loans, advances (except normal advances for business expenses in the ordinary course of business) or guarantees or indebtedness by the Company to or for the benefit of any of the officers or directors of the Company or any of their respective family members, except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

2.30 Board of Directors. The Board of Directors of the Company is comprised of the persons disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus. The qualifications of the persons serving as board members and the overall composition of the board comply with the Exchange Act, the Exchange Act Regulations, the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder (the "**Sarbanes-Oxley Act** ") applicable to the Company and the listing rules of the Exchange. At least one member of the Audit Committee of the Board of Directors of the Company qualifies as an "audit committee financial expert," as such term is defined under Regulation S-K and the listing rules of the Exchange. In addition, at least a majority of the persons serving on the Board of Directors qualify as "independent," as defined under the listing rules of the Exchange.

2.31 Sarbanes-Oxley Compliance.

2.31.1 Disclosure Controls. Except as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has developed and currently maintains disclosure controls and procedures that will comply with Rule 13a-15 or 15d-15 under the Exchange Act Regulations, and such controls and procedures are effective to ensure that all material information concerning the Company will be made known on a timely basis to the individuals responsible for the preparation of the Company's Exchange Act filings and other public disclosure documents.

2.31.2 Compliance. Except as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company is, or at the Applicable Time and on the Closing Date will be, in material compliance with the provisions of the Sarbanes-Oxley Act applicable to it, and has implemented or will implement such programs and taken reasonable steps to ensure the Company's future compliance (not later than the relevant statutory and regulatory deadlines therefor) with all of the material provisions of the Sarbanes-Oxley Act.

2.32 Accounting Controls. Except as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company and its Subsidiaries maintain systems of "internal control over financial reporting" (as defined under Rules 13a-15 and 15d-15 under the Exchange Act Regulations) that comply with the requirements of the Exchange Act and have been designed by, or under the supervision of, their respective principal executive and principal financial officers, or persons performing similar functions, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including, but not limited to, internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company is not aware of any material weaknesses in its internal controls. The Company's auditors and the Audit Committee of the Board of Directors of the Company have been advised of: (i) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are known to the Company's management and that have adversely affected or are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and (ii) any fraud known to the Company's management, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls over financial reporting.

2.33 No Investment Company Status. The Company is not and, after giving effect to the Offering and the application of the proceeds thereof as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, will not be, required to register as an "investment company," as defined in the Investment Company Act of 1940, as amended.

2.34 No Labor Disputes. No labor dispute with the employees of the Company or any of its Subsidiaries exists or, to the knowledge of the Company, is imminent. The Company is not aware that any key employee or significant group of employees of the Company plans to terminate employment with the Company.

2.35 Intellectual Property Rights. To the knowledge of the Company, the Company or its Subsidiaries owns or possesses or has valid rights to use all patents, patent applications, trademarks, service marks, trade names, trademark registrations, service mark registrations, copyrights, licenses, inventions, trade secrets and similar rights (“ **Intellectual Property Rights** ”) necessary for the conduct of the business of the Company and its Subsidiaries as currently carried on and as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus. To the knowledge of the Company, no action or use by the Company or any of its Subsidiaries necessary for the conduct of its business as currently carried on and as described in the Registration Statement and the Prospectus will involve or give rise to any infringement of, or license or similar fees (other than license or similar fees described or contemplated in the Registration Statement, the Pricing Disclosure Package and the Prospectus) for, any Intellectual Property Rights of others. Neither the Company nor any of its Subsidiaries has received any written notice alleging any such infringement of, license or similar fees for, or conflict with, any asserted Intellectual Property Rights of others. Except as would not reasonably be expected to result, individually or in the aggregate, in a Material Adverse Change, (i) to the knowledge of the Company, there is no infringement, misappropriation or violation by third parties of any of the Intellectual Property Rights owned by the Company; (ii) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others challenging the rights of the Company in or to any such Intellectual Property Rights, and the Company is unaware of any facts which would form a reasonable basis for any such claim, that would, individually or in the aggregate, together with any other claims in this Section 2.35, reasonably be expected to result in a Material Adverse Change; (iii) the Intellectual Property Rights owned by the Company and, to the knowledge of the Company, the Intellectual Property Rights licensed to the Company, have not been adjudged by a court of competent jurisdiction invalid or unenforceable, in whole or in part, and there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Intellectual Property Rights, and the Company is unaware of any facts which would form a reasonable basis for any such claim that would, individually or in the aggregate, together with any other claims in this Section 2.35, reasonably be expected to result in a Material Adverse Change; (iv) there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others that the Company infringes, misappropriates or otherwise violates any Intellectual Property Rights or other proprietary rights of others, the Company has not received any written notice of such claim and the Company is unaware of any other facts which would form a reasonable basis for any such claim that would, individually or in the aggregate, together with any other claims in this Section 2.35, reasonably be expected to result in a Material Adverse Change; and (v) to the Company’s knowledge, no employee of the Company is in or has ever been in violation in any material respect of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee’s employment with the Company, or actions undertaken by the employee while employed with the Company and could reasonably be expected to result, individually or in the aggregate, in a Material Adverse Change. To the Company’s knowledge, all material technical information developed by and belonging to the Company which has not been disclosed in a filed patent application has been kept confidential. The Company is not a party to or bound by any options, licenses or agreements with respect to the Intellectual Property Rights of any other person or entity that are required to be set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus and are not described therein. The Registration Statement, the Pricing Disclosure Package and the Prospectus contain in all material respects the same description of the matters set forth in the preceding sentence. None of the technology employed by the Company has been obtained or is being used by the Company in violation of any contractual obligation binding on the Company or, to the Company’s knowledge, any of its officers, directors or employees, or otherwise in violation of the rights of any persons.

2.36 Taxes. Each of the Company and its Subsidiaries has filed all returns (as hereinafter defined) required to be filed with taxing authorities prior to the date hereof or has duly obtained extensions of time for the filing thereof. Each of the Company and its Subsidiaries has paid all taxes (as hereinafter defined) shown as due on such returns that were filed and has paid all taxes imposed on or assessed against the Company or such respective Subsidiary except as would not be reasonably expected to have a Material Adverse Change. The provisions for taxes payable, if any, shown on the financial statements filed with or as part of the Registration Statement are sufficient for all accrued and unpaid taxes, whether or not disputed, and for all periods to and including the dates of such consolidated financial statements. Except as disclosed in writing to the Underwriters, (i) no issues have been raised (and are currently pending) by any taxing authority in connection with any of the returns or taxes asserted as due from the Company or its Subsidiaries, and (ii) no waivers of statutes of limitation with respect to the returns or collection of taxes have been given by or requested from the Company or its Subsidiaries. There are no tax liens against the assets, properties or business of the Company or its Subsidiaries. The term “**taxes**” mean all federal, state, local, foreign and other net income, gross income, gross receipts, sales, use, ad valorem, transfer, franchise, profits, license, lease, service, service use, withholding, payroll, employment, excise, severance, stamp, occupation, premium, property, windfall profits, customs, duties or other taxes, fees, assessments or charges of any kind whatever, together with any interest and any penalties, additions to tax or additional amounts with respect thereto. The term “**returns**” means all returns, declarations, reports, statements and other documents required to be filed in respect to taxes.

2.37 ERISA Compliance. The Company and any “employee benefit plan” (as defined under the Employee Retirement Income Security Act of 1974, as amended, and the regulations and published interpretations thereunder (collectively, “**ERISA**”)) established or maintained by the Company or its “ERISA Affiliates” (as defined below) are in compliance in all material respects with ERISA. “**ERISA Affiliate**” means, with respect to the Company, any member of any group of organizations described in Sections 414(b),(c),(m) or (o) of the Internal Revenue Code of 1986, as amended, and the regulations and published interpretations thereunder (the “**Code**”) of which the Company is a member. No “reportable event” (as defined under ERISA) has occurred or is reasonably expected to occur with respect to any “employee benefit plan” established or maintained by the Company or any of its ERISA Affiliates. No “employee benefit plan” established or maintained by the Company or any of its ERISA Affiliates, if such “employee benefit plan” were terminated, would have any “amount of unfunded benefit liabilities” (as defined under ERISA). Neither the Company nor any of its ERISA Affiliates has incurred or reasonably expects to incur any material liability under (i) Title IV of ERISA with respect to termination of, or withdrawal from, any “employee benefit plan” or (ii) Sections 412, 4971, 4975 or 4980B of the Code. Each “employee benefit plan” established or maintained by the Company or any of its ERISA Affiliates that is intended to be qualified under Section 401(a) of the Code is so qualified and, to the knowledge of the Company, nothing has occurred, whether by action or failure to act, which would cause the loss of such qualification.

2.38 Licenses or Permits. The Company possesses all licenses, certificates, registrations, authorizations and permits required by the FDA and other governmental or regulatory authorities performing functions similar to those performed by the FDA and have made all declarations and filings with, the appropriate local, state, federal or foreign governmental or regulatory agencies or bodies (including, without limitation, those administered by the FDA or by any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA) that are necessary for the ownership or lease of their respective properties or the conduct of their respective businesses as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus (collectively, the “**Governmental Permits**”) except where any failures to possess or make the same would not, singularly or in the aggregate, have a Material Adverse Change. The Company is in compliance with all such Governmental Permits, including with all conditions and limitations on the commercial rights granted by such Governmental Permits; all such Governmental Permits are valid and in full force and effect, except where the validity or failure to be in full force and effect would not, singularly or in the aggregate, have a Material Adverse Change. The Company has not received notification of any revocation, modification, suspension, termination or invalidation (or proceedings related thereto) of any such Governmental Permit and the Company has no reason to believe that any such Governmental Permit will not be renewed.

2.39 Compliance with Laws. The Company: (i) is and at all times has been in compliance with all statutes, rules, or regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, storage or disposal of any product manufactured or distributed by the Company (“ **Applicable Laws** ”), except as could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Change; (ii) has not received any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence or written notice from the FDA or any other governmental authority alleging or asserting noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws (“ **Authorizations** ”); (iii) possesses all material Authorizations and such Authorizations are valid and in full force and effect and are not in material violation of any term of any such Authorizations; (iv) has not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental authority or third party alleging that any product operation or activity is in violation of any Applicable Laws or Authorizations and has no knowledge that any such governmental authority or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding, except as could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Change; (v) has not received written notice that any governmental authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations and has no knowledge that any such governmental authority is considering such action, except as could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Change; and (vi) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and correct in all material respects on the date filed (or were corrected or supplemented by a subsequent submission).

2.40 Environmental Laws. The Company and its Subsidiaries are in compliance in all material respects with all foreign, federal, state and local rules, laws and regulations relating to the use, treatment, storage and disposal of hazardous or toxic substances or waste and protection of health and safety or the environment which are applicable to their businesses (“ **Environmental Laws** ”), except where the failure to comply would not, singularly or in the aggregate, result in a Material Adverse Change. There has been no storage, generation, transportation, handling, treatment, disposal, discharge, emission, or other release of any kind of toxic or other wastes or other hazardous substances by, due to, or caused by the Company or any of its Subsidiaries (or, to the Company’s knowledge, any other entity for whose acts or omissions the Company or any of its Subsidiaries is or may otherwise be liable) upon any of the property now or previously owned or leased by the Company or any of its Subsidiaries, or upon any other property, in violation of any law, statute, ordinance, rule, regulation, order, judgment, decree or permit or which would, under any law, statute, ordinance, rule (including rule of common law), regulation, order, judgment, decree or permit, give rise to any liability, except for any violation or liability which would not have, singularly or in the aggregate with all such violations and liabilities, a Material Adverse Change; and there has been no disposal, discharge, emission or other release of any kind onto such property or into the environment surrounding such property of any toxic or other wastes or other hazardous substances with respect to which the Company has knowledge, except for any such disposal, discharge, emission, or other release of any kind which would not have, singularly or in the aggregate with all such discharges and other releases, a Material Adverse Change. On the basis of such reviews, the Company and its Subsidiaries have reasonably concluded that such associated costs and liabilities would not have, singularly or in the aggregate, a Material Adverse Change.

2.41 Real Property. Except as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company and each of its Subsidiaries have good and marketable title in fee simple to, or have valid rights to lease or otherwise use, all items of real or personal property which are material to the business of the Company and its Subsidiaries taken as a whole, in each case free and clear of all liens, encumbrances, security interests, claims and defects that do not, singly or in the aggregate, materially affect the value of such property and do not interfere with the use made and proposed to be made of such property by the Company or any of its Subsidiaries; and all of the leases and subleases material to the business of the Company and its subsidiaries, considered as one enterprise, and under which the Company or any of its subsidiaries holds properties described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, are in full force and effect, and neither the Company nor any Subsidiary has received any notice of any material claim of any sort that has been asserted by anyone adverse to the rights of the Company or any Subsidiary under any of the leases or subleases mentioned above, or affecting or questioning the rights of the Company or such Subsidiary to the continued possession of the leased or subleased premises under any such lease or sublease which would result in a Material Adverse Change.

2.42 Contracts Affecting Capital. There are no transactions, arrangements or other relationships between and/or among the Company, any of its affiliates (as such term is defined in Rule 405 of the Securities Act Regulations) and any unconsolidated entity, including, but not limited to, any structured finance, special purpose or limited purpose entity that could reasonably be expected to materially affect the Company's or any of its Subsidiaries' liquidity or the availability of or requirements for their capital resources required to be described or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus which have not been described or incorporated by reference as required.

2.43 Loans to Directors or Officers. There are no outstanding loans, advances (except normal advances for business expenses in the ordinary course of business) or guarantees or indebtedness by the Company to or for the benefit of any of the officers or directors of the Company, or any of their respective family members, except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

2.44 Ineligible Issuer. At the time of filing the Registration Statement and any post-effective amendment thereto, at the time of effectiveness of the Registration Statement and any amendment thereto, at the earliest time thereafter that the Company or another offering participant made a bona fide offer (within the meaning of Rule 164(h)(2) of the Securities Act Regulations) of the Public Securities and at the date hereof, the Company was not and is not an "ineligible issuer," as defined in Rule 405, without taking account of any determination by the Commission pursuant to Rule 405 that it is not necessary that the Company be considered an ineligible issuer.

2.45 Accelerated Filer. As of the time of the initial filing of the Registration Statement and as of the date hereof, the Company was an "accelerated filer," as defined in Rule 12b-2 of the Exchange Act Regulations; however on June 30, 2018, the Company's non-affiliate float was below \$75,000,000 .

2.46 Industry Data. The statistical and market-related data included in each of the Registration Statement, the Pricing Disclosure Package and the Prospectus are based on or derived from sources that the Company reasonably and in good faith believes are reliable and accurate or represent the Company's good faith estimates that are made on the basis of data derived from such sources.

2.47 Margin Securities. The Company owns no “margin securities” as that term is defined in Regulation U of the Board of Governors of the Federal Reserve System (the “**Federal Reserve Board**”), and none of the proceeds of Offering will be used, directly or indirectly, for the purpose of purchasing or carrying any margin security, for the purpose of reducing or retiring any indebtedness which was originally incurred to purchase or carry any margin security or for any other purpose which might cause any of the shares of Common Stock to be considered a “purpose credit” within the meanings of Regulation T, U or X of the Federal Reserve Board.

2.48 Exchange Act Reports. The Company has filed in a timely manner all reports required to be filed pursuant to Sections 13(a), 13(e), 14 and 15(d) of the Exchange Act during the preceding 12 months (except to the extent that Section 15(d) requires reports to be filed pursuant to Sections 13(d) and 13(g) of the Exchange Act, which shall be governed by the next clause of this sentence); and the Company has filed in a timely manner all reports required to be filed pursuant to Sections 13(d) and 13(g) of the Exchange Act since July 23, 2013, except where the failure to timely file could not reasonably be expected, individually or in the aggregate, to have a Material Adverse Change.

2.49 Minute Books. The minute books of the Company have been made available to the Underwriters and counsel for the Underwriters, and such books (i) contain a complete summary of all meetings and actions of the board of directors (including each board committee) and stockholders of the Company (or analogous governing bodies and interest holders, as applicable), and each of its Subsidiaries since the time of its respective incorporation or organization through the date of the latest meeting and action, and (ii) accurately in all material respects reflect all transactions referred to in such minutes. There are no material transactions, agreements, dispositions or other actions of the Company that are not properly approved and/or accurately and fairly recorded in the minute books of the Company, as applicable.

2.50 Confidentiality and Non-Competition. To the Company’s knowledge, no director, officer, key employee or consultant of the Company is subject to any confidentiality, non-disclosure, non-competition agreement or non-solicitation agreement with any employer or prior employer that could reasonably be expected to materially affect his ability to be and act in his respective capacity of the Company or be expected to result in a Material Adverse Change.

2.51 Stabilization. Neither the Company nor, to its knowledge, any of its employees, directors or stockholders (without the consent of the Representative) has taken, directly or indirectly, any action designed to or that has constituted or that might reasonably be expected to cause or result in, under Regulation M of the Exchange Act, or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Public Securities.

2.52 Integration. Neither the Company, nor any of its affiliates, nor any person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause the Offering to be integrated with prior offerings by the Company for purposes of the Securities Act that would require the registration of any such securities under the Securities Act.

3. Covenants of the Company. The Company covenants and agrees as follows:

3.1 Amendments to Registration Statement. The Company shall deliver to the Representative, prior to filing, any amendment or supplement to the Registration Statement, Preliminary Prospectus, Pricing Disclosure Package or Prospectus proposed to be filed after the Effective Date and not file any such amendment or supplement to which the Representative shall reasonably object in writing.

3.2 Federal Securities Laws.

3.2.1 Compliance. The Company, subject to Section 3.2.2, shall comply with the requirements of Rule 424(b) and Rule 430A of the Securities Act Regulations, and will notify the Representative promptly, and confirm the notice in writing, (i) when any post-effective amendment to the Registration Statement or any amendment or supplement to any Preliminary Prospectus, the Pricing Disclosure Package or the Prospectus shall have been filed and when any post-effective amendment to the Registration Statement shall become effective; (ii) of the receipt of any comments from the Commission; (iii) of any request by the Commission for any amendment to the Registration Statement or any amendment or supplement to any Preliminary Prospectus, the Pricing Disclosure Package or the Prospectus or for additional information; (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment or of any order preventing or suspending the use of any Preliminary Prospectus, the Pricing Disclosure Package or the Prospectus, or of the suspension of the qualification of the Public Securities for offering or sale in any jurisdiction, or of the initiation or threatening of any proceedings for any of such purposes or of any examination pursuant to Section 8(d) or 8(e) of the Securities Act concerning the Registration Statement; and (v) if the Company becomes the subject of a proceeding under Section 8A of the Securities Act in connection with the Offering of the Public Securities. The Company shall effect all filings required under Rule 424(b) of the Securities Act Regulations, in the manner and within the time period required by Rule 424(b) (without reliance on Rule 424(b)(8)), and shall take such steps as it deems necessary to ascertain promptly whether the form of prospectus transmitted for filing under Rule 424(b) was received for filing by the Commission and, in the event that it was not, it will promptly file such prospectus. The Company shall use its best efforts to prevent the issuance of any stop order, prevention or suspension and, if any such order is issued, to obtain the lifting thereof at the earliest possible moment.

3.2.2 Continued Compliance. The Company shall comply with the Securities Act, the Securities Act Regulations, the Exchange Act and the Exchange Act Regulations so as to permit the completion of the distribution of the Public Securities as contemplated in this Agreement and in the Registration Statement, the Pricing Disclosure Package and the Prospectus. If at any time when a prospectus relating to the Public Securities is (or, but for the exception afforded by Rule 172 of the Securities Act Regulations (“ **Rule 172** ”), would be) required by the Securities Act to be delivered in connection with sales of the Public Securities, any event shall occur or condition shall exist as a result of which it is necessary, in the opinion of counsel for the Underwriters or for the Company, to (i) amend the Registration Statement in order that the Registration Statement will not include an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading; (ii) amend or supplement the Pricing Disclosure Package or the Prospectus in order that the Pricing Disclosure Package or the Prospectus, as the case may be, will not include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein not misleading in the light of the circumstances existing at the time it is delivered to a purchaser or (iii) amend the Registration Statement or amend or supplement the Pricing Disclosure Package or the Prospectus, as the case may be, in order to comply with the requirements of the Securities Act or the Securities Act Regulations, the Company will promptly (A) give the Representative notice of such event; (B) prepare any amendment or supplement as may be necessary to correct such statement or omission or to make the Registration Statement, the Pricing Disclosure Package or the Prospectus comply with such requirements and, a reasonable amount of time prior to any proposed filing or use, furnish the Representative with copies of any such amendment or supplement and (C) file with the Commission any such amendment or supplement; *provided, however*, that the Company shall not file or use any such amendment or supplement to which the Representative or counsel for the Underwriters shall reasonably object. The Company will furnish to the Underwriters such number of copies of such amendment or supplement as the Underwriters may reasonably request. The Company has given the Representative notice of any filings made pursuant to the Exchange Act or the Exchange Act Regulations within 48 hours prior to the Applicable Time. The Company shall give the Representative notice of its intention to make any such filing from the Applicable Time until the later of the Closing Date and the exercise in full or expiration of the Over-allotment Option specified in Section 1.2 hereof and will furnish the Representative with copies of the related document(s) a reasonable amount of time prior to such proposed filing, as the case may be, and will not file or use any such document to which the Representative or counsel for the Underwriters shall reasonably object.

3.2.3 Exchange Act Registration. For a period of three (3) years after the date of this Agreement, the Company shall use its best efforts to maintain the registration of the shares of Common Stock under the Exchange Act provided that such provision shall not prevent a sale, merger or similar transaction involving the Company. The Company shall not deregister the shares of Common Stock under the Exchange Act without the prior written consent of the Representative which consent shall not be unreasonably withheld and provided that such provision shall not prevent a sale, merger or similar transaction involving the Company.

3.2.4 Free Writing Prospectuses. The Company agrees that, unless it obtains the prior written consent of the Representative, it shall not make any offer relating to the Public Securities that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a “free writing prospectus,” or a portion thereof, required to be filed by the Company with the Commission or retained by the Company under Rule 433; *provided, however*, that the Representative shall be deemed to have consented to each Issuer General Use Free Writing Prospectus hereto and any “road show that is a written communication” within the meaning of Rule 433(d)(8)(i) that has been reviewed by the Representative. The Company represents that it has treated or agrees that it will treat each such free writing prospectus consented to, or deemed consented to, by the Underwriters as an “issuer free writing prospectus,” as defined in Rule 433, and that it has complied and will comply with the applicable requirements of Rule 433 with respect thereto, including timely filing with the Commission where required, legending and record keeping. If at any time following issuance of an Issuer Free Writing Prospectus there occurred or occurs an event or development as a result of which such Issuer Free Writing Prospectus conflicted or would conflict with the information contained in the Registration Statement or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Underwriters and will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission.

3.3 Delivery to the Underwriters of Registration Statements. The Company has delivered or made available or shall deliver or make available to the Representative and counsel for the Representative, without charge, signed copies of the Registration Statement as originally filed and each amendment thereto (including exhibits filed therewith or incorporated by reference therein and documents incorporated or deemed to be incorporated by reference therein) and signed copies of all consents and certificates of experts, and will also deliver to the Underwriters, without charge, a conformed copy of the Registration Statement as originally filed and each amendment thereto (without exhibits) for each of the Underwriters. The copies of the Registration Statement and each amendment thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

3.4 Delivery to the Underwriters of Prospectuses. The Company has delivered or made available or will deliver or make available to each Underwriter, without charge, as many copies of each Preliminary Prospectus as such Underwriter reasonably requested, and the Company hereby consents to the use of such copies for purposes permitted by the Securities Act. The Company will furnish to each Underwriter, without charge, during the period when a prospectus relating to the Public Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the Securities Act, such number of copies of the Prospectus (as amended or supplemented) as such Underwriter may reasonably request. The Prospectus and any amendments or supplements thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

3.5 Events Requiring Notice to the Representative. The Company shall use its best efforts to cause the Registration Statement to remain effective with a current prospectus for at least three years after the Applicable Time, and shall notify the Representative immediately and confirm the notice in writing: (i) of the issuance by the Commission of any stop order or of the initiation, or the threatening, of any proceeding for that purpose; (ii) of the issuance by any state securities commission of any proceedings for the suspension of the qualification of the Public Securities for offering or sale in any jurisdiction or of the initiation, or the threatening, of any proceeding for that purpose; (iii) of the mailing and delivery to the Commission for filing of any amendment or supplement to the Registration Statement or Prospectus; (iv) of the receipt of any comments or request for any additional information from the Commission; and (v) of the happening of any event during the period described in this Section 3.5 that, in the judgment of the Company, makes any statement of a material fact made in the Registration Statement, the Pricing Disclosure Package or the Prospectus untrue or that requires the making of any changes in (a) the Registration Statement in order to make the statements therein not misleading, or (b) in the Pricing Disclosure Package or the Prospectus in order to make the statements therein, in light of the circumstances under which they were made, not misleading. If the Commission or any state securities commission shall enter a stop order or suspend such qualification at any time, the Company shall make every reasonable effort to obtain promptly the lifting of such order.

3.6 Review of Financial Statements. For a period of three years after the date of this Agreement, the Company, at its expense, shall cause its regularly engaged independent registered public accounting firm to review (but not audit) the Company's financial statements for each of the three fiscal quarters immediately preceding the announcement of any quarterly financial information; provided that such provision shall not prevent a sale, merger or similar transaction involving the Company.

3.7 Listing. The Company shall use its best efforts to maintain the listing of the shares of Common Stock (including the shares of Common Stock included in the Public Securities, the Warrant Shares and the Preferred Conversion Shares) on the Exchange for at least three years from the date of this Agreement provided that such provision shall not prevent a sale, merger or similar transaction involving the Company;.

3.8 Intentionally Omitted

3.9 Reports to the Representative.

3.9.1 Periodic Reports, etc. For a period of three (3) years after the date of this Agreement, the Company shall furnish to the Representative copies of such financial statements and other periodic and special reports as the Company from time to time furnishes generally to holders of any class of its securities and also promptly furnish to the Representative: (i) a copy of each periodic report the Company shall be required to file with the Commission under the Exchange Act and the Exchange Act Regulations; (ii) a copy of every press release and every news item and article with respect to the Company or its affairs which was released by the Company; (iii) a copy of each Form 8-K prepared and filed by the Company; (iv) five copies of each registration statement filed by the Company under the Securities Act; (v) a copy of each report or other communication furnished to stockholders and (vi) such additional documents and information with respect to the Company and the affairs of any future subsidiaries of the Company as the Representative may from time to time reasonably request; *provided, however*, the Representative shall sign, if requested by the Company, a Regulation FD compliant confidentiality agreement which is reasonably acceptable to the Representative and Representative Counsel in connection with the Representative's receipt of such information. Documents filed with the Commission pursuant to its EDGAR system or otherwise publicly filed or made available shall be deemed to have been delivered to the Representative pursuant to this Section 3.9.1.

3.9.2 Transfer Agent; Transfer Sheets. For a period of three years after the date of this Agreement, the Company shall retain a transfer agent and registrar acceptable to the Representative (the “ **Transfer Agent** ”) and for a period of one year after the date of this Agreement shall furnish to the Representative at the Company’s sole cost and expense such transfer sheets of the Company’s securities as the Representative may reasonably request, including the daily and monthly consolidated transfer sheets of the Transfer Agent and DTC; provided that such provision shall not prevent a sale, merger or similar transaction involving the Company. Continental Stock Transfer & Trust Company is acceptable to the Representative to act as Transfer Agent for the shares of Common Stock.

3.9.3 Trading Reports. For a period of one (1) year after the date of this Agreement, the Company shall provide to the Representative, at the Company’s expense, such reports published by Exchange relating to price trading of the Public Securities, as the Representative shall reasonably request; provided that such provision shall not prevent a sale, merger or similar transaction involving the Company.

3.9.4 Warrant Agent. For so long as the Warrants and the Option Warrants are outstanding, the Company shall retain a warrant agent reasonably acceptable to the Representative (the “ **Warrant Agent** ”). Corporate Stock Transfer, Inc. is acceptable to the Representative to act as Warrant Agent for the Warrants and the Option Warrants.

3.10 Payment of Expenses. The Company hereby agrees to pay on each of the Closing Date and the Option Closing Date, if any, to the extent not paid at the Closing Date, all expenses incident to the performance of the obligations of the Company under this Agreement, including, but not limited to: (i) all filing fees and communication expenses relating to the registration of the Public Securities with the Commission; (ii) all Public Filing System filing fees associated with the review of the Offering by FINRA; (iii) all fees and expenses relating to the listing of such Public Securities on the Exchange and such other stock exchanges as the Company and the Representative together determine; (iv) all fees, expenses and disbursements relating to the registration, qualification or exemption of the Public Securities under the “blue sky” securities laws of such states and other jurisdictions as the Representative may reasonably designate; (v) all fees, expenses and disbursements relating to the registration, qualification or exemption of the Public Securities under the securities laws of such foreign jurisdictions as the Representative may reasonably designate; (vi) the costs of all mailing and printing of the underwriting documents (including, without limitation, the Underwriting Agreement, the Warrant Agreement, any Blue Sky Surveys and, if appropriate, any Agreement Among Underwriters, Selected Dealers’ Agreement, Underwriters’ Questionnaire and Power of Attorney), Registration Statements, Prospectuses and all amendments, supplements and exhibits thereto and as many preliminary and final Prospectuses as the Representative may reasonably deem necessary; (vii) the costs of preparing, printing and delivering certificates representing the Public Securities; (viii) filing fees related to the Certificate of Designation and fees and expenses of the transfer agent for the shares of Common Stock and Preferred Stock and the Warrant Agent for the Warrants and Option Warrants; (ix) stock transfer and/or stamp taxes, if any, payable upon the transfer of securities from the Company to the Underwriters; (x) the fees and expenses of the Company’s accountants; (xi) the fees and expenses of the Company’s legal counsel and other agents and representatives; (xii) the fees and expenses of the Underwriters’ legal counsel not to exceed \$100,000; (xiii) up to \$25,000 associated with the Representative’s use of IPREO’s book-building, prospectus tracking and compliance software for the Offering; (xiv) up to \$25,000 of the Representative’s actual accountable marketing and “road show” expenses for the Offering.; and (xv) up to \$5,000 for expenses for background checks incurred by the Representative. The Representative may deduct from the net proceeds of the Offering payable to the Company on the Closing Date, or the Option Closing Date, if any, the expenses set forth herein to be paid by the Company to the Underwriters.

3.11 Application of Net Proceeds. The Company shall apply the net proceeds from the Offering received by it in a manner consistent with the application thereof described under the caption "Use of Proceeds" in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

3.12 Delivery of Earnings Statements to Security Holders. The Company shall make generally available to its security holders as soon as practicable, but not later than the first day of the fifteenth (15th) full calendar month following the date of this Agreement, an earnings statement (which need not be certified by independent registered public accounting firm unless required by the Securities Act or the Securities Act Regulations, but which shall satisfy the provisions of Rule 158(a) under Section 11(a) of the Securities Act) covering a period of at least twelve (12) consecutive months beginning after the date of this Agreement.

3.13 Stabilization. Neither the Company nor, to its knowledge, any of its employees, directors or shareholders (without the consent of the Representative) has taken or shall take, directly or indirectly, any action designed to or that has constituted or that might reasonably be expected to cause or result in, under Regulation M of the Exchange Act, or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Public Securities.

3.14 Internal Controls. The Company shall maintain a system of internal accounting controls sufficient to provide reasonable assurances that: (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary in order to permit preparation of financial statements in accordance with GAAP and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

3.15 Accountants. As of the date of this Agreement, the Company shall continue to retain a nationally recognized independent registered public accounting firm for a period of at least three (3) years after the date of this Agreement. The Representative acknowledges that the Auditor is acceptable to the Representative.

3.16 FINRA. The Company shall advise the Representative (who shall make an appropriate filing with FINRA) if it is or becomes aware that (i) any officer or director of the Company, (ii) any beneficial owner of 5% or more of any class of the Company's securities or (iii) any beneficial owner of the Company's unregistered equity securities which were acquired during the 180 days immediately preceding the filing of the Registration Statement is or becomes an affiliate or associated person of a FINRA member participating in the Offering (as determined in accordance with the rules and regulations of FINRA).

3.17 No Fiduciary Duties. The Company acknowledges and agrees that the Underwriters' responsibility to the Company is solely contractual in nature and that none of the Underwriters or their affiliates or any selling agent shall be deemed to be acting in a fiduciary capacity, or otherwise owes any fiduciary duty to the Company or any of its affiliates in connection with the Offering and the other transactions contemplated by this Agreement.

3.18 Company Lock-Up Agreements. The Company, on behalf of itself and any successor entity, agrees that, without the prior written consent of the Representative, it will not for a period of ninety (90) days after the date of this Agreement (the “**Lock-Up Period**”), (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for shares of capital stock of the Company; (ii) file or cause to be filed any registration statement with the Commission relating to the offering of any shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for shares of capital stock of the Company; or (iii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of capital stock of the Company, whether any such transaction described in clause (i), (ii) or (iii) above is to be settled by delivery of shares of capital stock of the Company or such other securities, in cash or otherwise.

The restrictions contained in this Section 3.18 shall not apply to (i) the shares of Common Stock, Preferred Conversion Shares, Warrants or Option Warrants to be sold hereunder or issuance of common stock upon conversion or exercise of any of the foregoing, (ii) the issuance by the Company of shares of Common Stock upon the exercise of a stock option or warrant or the conversion of a security outstanding on the date hereof, which is disclosed in the Registration Statement, Pricing Disclosure Package and Prospectus, or pursuant to the exercise of the Warrants or the conversion of the Preferred Stock, (iii) the issuance by the Company of stock options or other awards under any equity compensation plan of the Company, or (iv) the issuance of securities in connection with a business acquisition, joint venture or partnership (so long as the purpose of such issuance is not solely for capital raising).

3.19 Blue Sky Qualifications. The Company shall use its best efforts, in cooperation with the Underwriters, if necessary, to qualify the Public Securities for offering and sale under the applicable securities laws of such states and other jurisdictions (domestic or foreign) as the Representative may designate with the consent of the Company and to maintain such qualifications in effect so long as required to complete the distribution of the Public Securities; *provided*, *however*, that the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise so subject.

3.20 Reporting Requirements. The Company, during the period when a prospectus relating to the Public Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the Securities Act, will file all documents required to be filed with the Commission pursuant to the Exchange Act within the time periods required by the Exchange Act and Exchange Act Regulations. Additionally, the Company shall report the use of proceeds from the issuance of the Public Securities as may be required under Rule 463 under the Securities Act Regulations.

3.21 Press Releases. Prior to the 41st day following the Closing Date, the Company shall not issue any press release or other communication directly or indirectly or hold any press conference with respect to the Company, its condition, financial or otherwise, or earnings, business affairs or business prospects (except for routine communications in the ordinary course of business and of which the Representative is notified), without the prior written consent of the Representative, which consent shall not be unreasonably withheld, unless in the judgment of the Company and its counsel, and after notification to the Representative, such press release or communication is required by law.

3.22 Sarbanes-Oxley. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company shall at all times comply with all applicable provisions of the Sarbanes-Oxley Act in effect from time to time.

3.23 [Reserved].

4. Conditions of Underwriters' Obligations. The obligations of the Underwriters to purchase and pay for the Public Securities, as provided herein, shall be subject to (i) the continuing accuracy of the representations and warranties of the Company as of the date hereof and as of each of the Closing Date and the Option Closing Date, if any; (ii) the accuracy of the statements of officers of the Company made pursuant to the provisions hereof; (iii) the performance by the Company of its obligations hereunder; and (iv) the following conditions:

4.1 Regulatory Matters.

4.1.1 Commission Actions; Required Filings. The Registration Statement has become effective not later than 5:00 p.m., Eastern time, on the date of this Agreement or such later date and time as shall be consented to in writing by you. At each of the Closing Date and any Option Closing Date, no stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto shall have been issued under the Securities Act, no order preventing or suspending the use of any Preliminary Prospectus or the Prospectus shall have been issued and no proceedings for any of those purposes shall have been instituted or are pending or, to the Company's knowledge, contemplated by the Commission. The Company has complied with each request (if any) from the Commission for additional information. The prospectus containing the Rule 430A Information shall have been filed with the Commission in the manner and within the time frame required by Rule 424(b) under the Securities Act Regulations (without reliance on Rule 424(b)(8)) or a post-effective amendment providing such information shall have been filed with, and declared effective by, the Commission in accordance with the requirements of Rule 430A under the Securities Act Regulations. the Public Securities. At the time of such filing, the Company met the requirements of Form S-1 under the Securities Act. The Registration Statement meets the requirements set forth in Rule 415(a)(1)(iii) under the Securities Act with respect to the Warrant Shares and the Preferred Conversion Shares and complies with said Rule.

4.1.2 FINRA Clearance. On or before the date of this Agreement, the Representative shall have received clearance from FINRA as to the amount of compensation allowable or payable to the Underwriters as described in the Registration Statement.

4.1.3 Exchange Stock Market Clearance. On or before the Closing Date, the shares of Common Stock included in the Public Securities, the Preferred Conversion Shares and the Warrant Shares shall have been approved for listing on the Exchange, subject to official notice of issuance.

4.2 Company Counsel Matters.

4.2.1 Closing Date Opinion of Counsel. On the Closing Date, the Representative shall have received the favorable opinion and negative assurance letter of Gracin & Marlow, LLP, counsel to the Company, dated the Closing Date and addressed to the Representative, in form and substance reasonably acceptable to the Representative.

4.2.2 Opinion of Special Intellectual Property Counsel for the Company. On the Closing Date, the Representative shall have received the favorable opinion letter of Morgan, Lewis & Bockius LLP, as special intellectual property counsel for the Company, dated the Closing Date and addressed to the Representative, in form and substance reasonably acceptable to the Representative.

4.2.3 Opinion of Special Regulatory Counsel for the Company. On the Closing Date, the Representative shall have received the favorable opinion letter of Cooley LLP, as special regulatory counsel for the Company, dated the Closing Date and addressed to the Representative, in form and substance reasonably acceptable to the Representative.

4.2.4 Opinion of Nevada Counsel. On the Closing Date, the Representative shall have received the favorable opinion letter of Parsons Behle & Latimer, as special Nevada counsel for the Company, dated the Closing Date and addressed to the Representative, in form and substance reasonably acceptable to the Representative

4.2.3 Option Closing Date Opinions of Counsel. On the Option Closing Date, if any, the Representative shall have received the favorable opinions and negative assurance letters of each counsel listed in Sections 4.2.1, 4.2.2, 4.2.3 and 4.2.4, dated the Option Closing Date, addressed to the Representative and in form and substance reasonably satisfactory to the Representative, confirming as of the Option Closing Date, the statements made by such counsels in their respective opinions delivered on the Closing Date.

4.2.4 Reliance. In rendering such opinions, such counsel may rely: (i) as to matters involving the application of laws other than the laws of the United States and jurisdictions in which they are admitted, to the extent such counsel deems proper and to the extent specified in such opinion, if at all, upon an opinion or opinions (in form and substance reasonably satisfactory to the Representative) of other counsel reasonably acceptable to the Representative, familiar with the applicable laws; and (ii) as to matters of fact, to the extent they deem proper, on certificates or other written statements of officers of the Company and officers of departments of various jurisdictions having custody of documents respecting the corporate existence or good standing of the Company; *provided* that copies of any such statements or certificates shall be delivered to Representative Counsel if requested. The opinions of each of Gracin & Marlow, LLP, Morgan, Lewis & Bockius LLP, Cooley LLP and Parsons, Behle & Latimer and any opinion relied upon by any of Gracin & Marlow, LLP, Morgan, Lewis & Bockius LLP, Cooley LLP and Parsons, Behle & Latimer shall include a statement to the effect that it may be relied upon by Representative Counsel in its opinion delivered to the Underwriters.

4.2.5 Certificate of Designation. On or prior to the Closing Date, the Representative shall have received evidence of the filing and acceptance of the Certificate of Designation of the Preferred Stock from the Secretary of State of Nevada.

4.3 Comfort Letters.

4.3.1 Cold Comfort Letter. At the time this Agreement is executed you shall have received a cold comfort letter containing statements and information of the type customarily included in accountants' comfort letters with respect to the financial statements and certain financial information contained or incorporated or deemed incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus, addressed to the Representative and in form and substance satisfactory in all respects to you and to the Auditor, dated as of the date of this Agreement.

4.3.2 Bring-down Comfort Letter. At each of the Closing Date and the Option Closing Date, if any, the Representative shall have received from the Auditor a letter, dated as of the Closing Date or the Option Closing Date, as applicable, to the effect that the Auditor reaffirms the statements made in the letter furnished pursuant to Section 4.3.1, except that the specified date referred to shall be a date not more than three (3) business days prior to the Closing Date or the Option Closing Date, as applicable.

4.4 Officers' Certificates

4.4.1 Officers' Certificate. The Company shall have furnished to the Representative a certificate, dated the Closing Date and any Option Closing Date (if such date is other than the Closing Date), of its interim Chief Executive Officer who also serves as its Chief Financial Officer stating that (i) such officers have carefully examined the Registration Statement, the Pricing Disclosure Package, any Issuer Free Writing Prospectus and the Prospectus and, in their opinion, the Registration Statement and each amendment thereto, as of the Applicable Time and as of the Closing Date (or any Option Closing Date if such date is other than the Closing Date) did not include any untrue statement of a material fact and did not omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, and the Pricing Disclosure Package, as of the Applicable Time and as of the Closing Date (or any Option Closing Date if such date is other than the Closing Date), any Issuer Free Writing Prospectus as of its date and as of the Closing Date (or any Option Closing Date if such date is other than the Closing Date), and the Prospectus and each amendment or supplement thereto, as of the respective date thereof and as of the Closing Date, did not include any untrue statement of a material fact and did not omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances in which they were made, not misleading, (ii) since the Applicable Time, no event has occurred which should have been set forth in a supplement or amendment to the Registration Statement, the Pricing Disclosure Package or the Prospectus, (iii) to the best of their knowledge after reasonable investigation, as of the Closing Date (or any Option Closing Date if such date is other than the Closing Date), the representations and warranties of the Company in this Agreement are true and correct in all material respects (except for those representations and warranties which refer to facts existing at a specific date, which shall be true and correct as of such date) and the Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied hereunder at or prior to the Closing Date (or any Option Closing Date if such date is other than the Closing Date), and (iv) there has not been, subsequent to the date of the most recent audited financial statements included or incorporated by reference in the Pricing Disclosure Package, any material adverse change in the financial position or results of operations of the Company, or any change or development that, singularly or in the aggregate, would involve a material adverse change or a prospective material adverse change, in or affecting the condition (financial or otherwise), results of operations, business, assets or prospects of the Company, except as set forth in the Prospectus.

4.4.2 Secretary's Certificate. At each of the Closing Date and the Option Closing Date, if any, the Representative shall have received a certificate of the Company signed by the Secretary of the Company, dated the Closing Date or the Option Date, as the case may be, respectively, certifying: (i) that each of the Charter and Bylaws is true and complete, has not been modified and is in full force and effect; (ii) that the resolutions of the Company's Board of Directors relating to the Offering are in full force and effect and have not been modified; (iii) as to the accuracy and completeness of all correspondence between the Company or its counsel and the Commission; and (iv) as to the incumbency of the officers of the Company. The documents referred to in such certificate shall be attached to such certificate.

4.5 No Material Changes. Prior to and on each of the Closing Date and each Option Closing Date, if any: (i) there shall have been no material adverse change or development involving a prospective material adverse change in the condition or prospects or the business activities, financial or otherwise, of the Company from the latest dates as of which such condition is set forth in the Registration Statement and no change in the capital stock or debt of the Company, the Pricing Disclosure Package and the Prospectus; (ii) no action, suit or proceeding, at law or in equity, shall have been pending or threatened against the Company or any director or officer before or by any court or federal or state commission, board or other administrative agency wherein an unfavorable decision, ruling or finding may materially adversely affect the business, operations, prospects or financial condition or income of the Company, except as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus; (iii) no stop order shall have been issued under the Securities Act and no proceedings therefor shall have been initiated or threatened by the Commission; (iv) no action shall have been taken and no law, statute, rule, regulation or order shall have been enacted, adopted or issued by any Governmental Entity which would prevent the issuance or sale of the Public Securities or materially and adversely affect or potentially materially and adversely affect the business or operations of the Company; (v) no injunction, restraining order or order of any other nature by any federal or state court of competent jurisdiction shall have been issued which would prevent the issuance or sale of the Public Securities or materially and adversely affect or potentially materially and adversely affect the business or operations of the Company and (vi) the Registration Statement, the Pricing Disclosure Package and the Prospectus and any amendments or supplements thereto shall contain all material statements which are required to be stated therein in accordance with the Securities Act and the Securities Act Regulations and shall conform in all material respects to the requirements of the Securities Act and the Securities Act Regulations, and neither the Registration Statement, the Pricing Disclosure Package, the Prospectus nor any amendment or supplement thereto shall contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

4.6 No Material Misstatement or Omission. The Underwriters shall not have discovered and disclosed to the Company on or prior to the Closing Date and any Option Closing Date that the Registration Statement or any amendment or supplement thereto contains an untrue statement of a fact which, in the opinion of counsel for the Underwriters, is material or omits to state any fact which, in the opinion of such counsel, is material and is required to be stated therein or is necessary to make the statements therein not misleading, or that the Registration Statement, Pricing Disclosure Package or the Prospectus or any amendment or supplement thereto contains an untrue statement of fact which, in the opinion of such counsel, is material or omits to state any fact which, in the opinion of such counsel, is material and is necessary in order to make the statements, in the light of the circumstances under which they were made, not misleading.

4.7 Corporate Proceedings. All corporate proceedings and other legal matters incident to the authorization, form and validity of each of this Agreement, the Public Securities, the Registration Statement, the Pricing Disclosure Package and the Prospectus and all other legal matters relating to this Agreement and the transactions contemplated hereby and thereby shall be reasonably satisfactory in all material respects to counsel for the Underwriters, and the Company shall have furnished to such counsel all documents and information that they may reasonably request to enable them to pass upon such matters.

4.8 Delivery of Agreements.

4.8.1 Lock-Up Agreements. On or before the date of this Agreement, the Company shall have delivered to the Representative executed copies of the Lock-Up Agreements from each of the persons listed in Schedule 3 hereto.

4.8.2 Warrant Agreement. As of the date hereof, the Company and the Warrant Agent shall have executed the Warrant Agreement and the Warrant Agreement shall be in full force and effect.

4.9 Additional Documents. At the Closing Date and at each Option Closing Date (if any) Representative Counsel shall have been furnished with such documents and opinions as they may require for the purpose of enabling Representative Counsel to deliver an opinion to the Underwriters, or in order to evidence the accuracy of any of the representations or warranties, or the fulfillment of any of the conditions, herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Public Securities as herein contemplated shall be satisfactory in form and substance to the Representative and Representative Counsel.

5. Indemnification .

5.1 Indemnification of the Underwriters.

5.1.1 General . Subject to the conditions set forth below, the Company agrees to indemnify and hold harmless each Underwriter, its affiliates and each of its and their respective directors, officers, members, employees, representatives, partners, shareholders, affiliates, counsel and agents and each person, if any, who controls any such Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act (collectively the “**Underwriter Indemnified Parties**,” and each an “**Underwriter Indemnified Party**”), against any and all loss, liability, claim, damage and expense whatsoever (including but not limited to any and all legal or other expenses reasonably incurred in investigating, preparing or defending against any litigation, commenced or threatened, or any claim whatsoever, whether arising out of any action between any of the Underwriter Indemnified Parties and the Company or between any of the Underwriter Indemnified Parties and any third party, or otherwise) to which they or any of them may become subject under the Securities Act, the Exchange Act or any other statute or at common law or otherwise or under the laws of foreign countries (a “**Claim**”), (i) arising out of or based upon any untrue statement or alleged untrue statement of a material fact contained in (A) the Registration Statement, the Pricing Disclosure Package, the Preliminary Prospectus, the Prospectus or any Issuer Free Writing Prospectus (as from time to time each may be amended and supplemented); (B) any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the Offering, including any “road show” or investor presentations made to investors by the Company (whether in person or electronically); or (C) any application or other document or written communication (in this Section 5, collectively called “**application**”) executed by the Company or based upon written information furnished by the Company in any jurisdiction in order to qualify the Public Securities under the securities laws thereof or filed with the Commission, any state securities commission or agency, the Exchange or any other national securities exchange; or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, unless such statement or omission was made in reliance upon, and in conformity with, the Underwriters’ Information, or (ii) otherwise arising in connection with or allegedly in connection with the Offering. The Company also agrees that it will reimburse each Underwriter Indemnified Party for all fees and expenses (including but not limited to any and all legal or other expenses reasonably incurred in investigating, preparing or defending against any litigation, commenced or threatened, or any claim whatsoever, whether arising out of any action between any of the Underwriter Indemnified Parties and the Company or between any of the Underwriter Indemnified Parties and any third party, or otherwise) (collectively, the “**Expenses**”), and further agrees wherever and whenever possible to advance payment of Expenses as they are incurred by an Underwriter Indemnified Party in investigating, preparing, pursuing or defending any Claim.

5.1.2 Procedure . If any action is brought against an indemnified party in respect of which indemnity may be sought against an indemnifying party pursuant to Section 5.1.1 or 5.2, such indemnified party shall promptly notify the indemnifying party in writing of the institution of such action and the indemnifying party shall assume the defense of such action, including the employment and fees of counsel (subject to the approval of such indemnified party) and payment of actual expenses. Such indemnified party shall have the right to employ its or their own counsel in any such case, but the fees and expenses of such counsel shall be at the expense of the indemnified party unless (A) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (B) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (C) a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party) or (D) the indemnifying party has not in fact employed counsel to assume the defense of such action or counsel satisfactory to the indemnified party, in each case, within a reasonable time after receiving notice of the commencement of the action; in each of which cases the reasonable fees, disbursements and other charges of counsel will be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees, disbursements and other charges of more than one separate firm admitted to practice in such jurisdiction (plus local counsel) at any one time for all such indemnified party or parties. All such fees, disbursements and other charges will be reimbursed by the indemnifying party promptly as they are incurred. An indemnifying party will not, in any event, be liable for any settlement of any action or claim effected without its written consent. In addition, the indemnifying party shall not, without the prior written consent of the the indemnified party, settle, compromise or consent to the entry of any judgment in or otherwise seek to terminate any pending or threatened action in respect of which advancement, reimbursement, indemnification or contribution may be sought hereunder (whether or not such indemnified party is a party thereto) unless such settlement, compromise, consent or termination (i) includes an unconditional release of each indemnified party, acceptable to such indemnified party, from all liabilities, expenses and claims arising out of such action for which indemnification or contribution may be sought and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act, by or on behalf of any indemnified party.

5.2 Indemnification of the Company. Each Underwriter, severally and not jointly, agrees to indemnify and hold harmless the Company, its directors, its officers who signed the Registration Statement and persons who control the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any and all loss, liability, claim, damage and expense described in the foregoing indemnity from the Company to the several Underwriters, as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions made in the Registration Statement, any Preliminary Prospectus, the Pricing Disclosure Package or Prospectus or any amendment or supplement thereto or in any application, in reliance upon, and in strict conformity with, the Underwriters' Information. In case any action shall be brought against the Company or any other person so indemnified based on any Preliminary Prospectus, the Registration Statement, the Pricing Disclosure Package or Prospectus or any amendment or supplement thereto or any application, and in respect of which indemnity may be sought against any Underwriter, such Underwriter shall have the rights and duties given to the Company, and the Company and each other person so indemnified shall have the rights and duties given to the several Underwriters by the provisions of Section 5.1.2. The Company agrees promptly to notify the Representative of the commencement of any litigation or proceedings against the Company or any of its officers, directors or any person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, in connection with the issuance and sale of the Public Securities or in connection with the Registration Statement, the Pricing Disclosure Package, the Prospectus or any Issuer Free Writing Prospectus.

5.3 Contribution.

5.3.1 Contribution Rights. If the indemnification provided for in this Section 5 shall for any reason be unavailable to or insufficient to hold harmless an indemnified party under Section 5.1 or 5.2 in respect of any loss, claim, damage or liability, or any action in respect thereof, referred to therein, then each indemnifying party shall, in lieu of indemnifying such indemnified party, contribute to the amount paid or payable by such indemnified party as a result of such loss, claim, damage or liability, or action in respect thereof, (i) in such proportion as shall be appropriate to reflect the relative benefits received by the Company, on the one hand, and the Underwriters, on the other, from the Offering of the Public Securities, or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Underwriters, on the other, with respect to the statements or omissions that resulted in such loss, claim, damage or liability, or action in respect thereof, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Underwriters, on the other, with respect to such Offering shall be deemed to be in the same proportion as the total net proceeds from the Offering of the Public Securities purchased under this Agreement (before deducting expenses) received by the Company, as set forth in the table on the cover page of the Prospectus, on the one hand, and the total underwriting discounts and commissions received by the Underwriters with respect to the shares of the Common Stock purchased under this Agreement, as set forth in the table on the cover page of the Prospectus, on the other hand. The relative fault shall be determined by reference to whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or the Underwriters, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to this Section 5.3.1 were to be determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, damage or liability, or action in respect thereof, referred to above in this Section 5.3.1 shall be deemed to include, for purposes of this Section 5.3.1, any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this Section 5.3.1 in no event shall an Underwriter be required to contribute any amount in excess of the amount by which the total underwriting discounts and commissions received by such Underwriter with respect to the Offering of the Public Securities exceeds the amount of any damages that such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation.

5.3.2 Contribution Procedure. Within fifteen (15) days after receipt by any party to this Agreement (or its representative) of notice of the commencement of any action, suit or proceeding, such party will, if a claim for contribution in respect thereof is to be made against another party (“contributing party”), notify the contributing party of the commencement thereof, but the failure to so notify the contributing party will not relieve it from any liability which it may have to any other party other than for contribution hereunder. In case any such action, suit or proceeding is brought against any party, and such party notifies a contributing party or its representative of the commencement thereof within the aforesaid 15 days, the contributing party will be entitled to participate therein with the notifying party and any other contributing party similarly notified. Any such contributing party shall not be liable to any party seeking contribution on account of any settlement of any claim, action or proceeding affected by such party seeking contribution on account of any settlement of any claim, action or proceeding affected by such party seeking contribution without the written consent of such contributing party. The contribution provisions contained in this Section 5.3.2 are intended to supersede, to the extent permitted by law, any right to contribution under the Securities Act, the Exchange Act or otherwise available. Each Underwriter’s obligations to contribute pursuant to this Section 5.3 are several and not joint.

6. Default by an Underwriter.

6.1 Default Not Exceeding 10% of Firm Securities or Option Securities. If any Underwriter or Underwriters shall default in its or their obligations to purchase the Firm Securities or the Option Securities, if the Over-allotment Option is exercised hereunder, and if the number of the Firm Securities or Option Securities with respect to which such default relates does not exceed in the aggregate 10% of the number of Firm Securities or Option Securities that all Underwriters have agreed to purchase hereunder, then such Firm Securities or Option Securities to which the default relates shall be purchased by the non-defaulting Underwriters in proportion to their respective commitments hereunder.

6.2 Default Exceeding 10% of Firm Securities or Option Securities. In the event that the default addressed in Section 6.1 relates to more than 10% of the Firm Securities or Option Securities, you may in your discretion arrange for yourself or for another party or parties to purchase such Firm Securities or Option Securities to which such default relates on the terms contained herein. If, within one (1) Business Day after such default relating to more than 10% of the Firm Securities or Option Securities, you do not arrange for the purchase of such Firm Securities or Option Securities, then the Company shall be entitled to a further period of one (1) Business Day within which to procure another party or parties satisfactory to you to purchase said Firm Securities or Option Securities on such terms. In the event that neither you nor the Company arrange for the purchase of the Firm Securities or Option Securities to which a default relates as provided in this Section 6, this Agreement will automatically be terminated by you or the Company without liability on the part of the Company (except as provided in Sections 3.9 and 5 hereof) or the several Underwriters (except as provided in Section 5 hereof); *provided, however*, that if such default occurs with respect to the Option Securities, this Agreement will not terminate as to the Firm Securities; and *provided, further*, that nothing herein shall relieve a defaulting Underwriter of its liability, if any, to the other Underwriters and to the Company for damages occasioned by its default hereunder.

6.3 Postponement of Closing Date. In the event that the Firm Securities or Option Securities to which the default relates are to be purchased by the non-defaulting Underwriters, or are to be purchased by another party or parties as aforesaid, you or the Company shall have the right to postpone the Closing Date or Option Closing Date for a reasonable period, but not in any event exceeding five (5) Business Days, in order to effect whatever changes may thereby be made necessary in the Registration Statement, the Pricing Disclosure Package or the Prospectus or in any other documents and arrangements, and the Company agrees to file promptly any amendment to the Registration Statement, the Pricing Disclosure Package or the Prospectus that in the opinion of counsel for the Underwriter may thereby be made necessary. The term “**Underwriter**” as used in this Agreement shall include any party substituted under this Section 6 with like effect as if it had originally been a party to this Agreement with respect to such shares of Common Stock.

7. Additional Covenants.

7.1 Board Composition and Board Designations. The Company shall ensure that: (i) the qualifications of the persons serving as members of the Board of Directors and the overall composition of the Board comply with the Sarbanes-Oxley Act, with the Exchange Act and with the listing rules of the Exchange or any other national securities exchange, as the case may be, in the event the Company seeks to have its Public Securities listed on another exchange or quoted on an automated quotation system, and (ii) if applicable, at least one member of the Audit Committee of the Board of Directors qualifies as an “audit committee financial expert,” as such term is defined under Regulation S-K and the listing rules of the Exchange.

7.2 Prohibition on Press Releases and Public Announcements. The Company shall not issue press releases or engage in any other publicity, without the Representative’s prior written consent, for a period ending at 5:00 p.m., Eastern time, on the first (1st) Business Day following the forty-fifth (45th) day after the Closing Date, other than normal and customary releases or releases required under applicable laws or the NYSE American.

8. Effective Date of this Agreement and Termination Thereof.

8.1 Effective Date. This Agreement shall become effective when both the Company and the Representative have executed the same and delivered counterparts of such signatures to the other party.

8.2 Termination. The Representative shall have the right to terminate this Agreement at any time prior to any Closing Date, (i) if any domestic or international event or act or occurrence has materially disrupted, or in your opinion will in the immediate future materially disrupt, general securities markets in the United States; or (ii) if trading on the New York Stock Exchange or the Nasdaq Stock Market LLC shall have been suspended or materially limited, or minimum or maximum prices for trading shall have been fixed, or maximum ranges for prices for securities shall have been required by FINRA or by order of the Commission or any other government authority having jurisdiction; or (iii) if the United States shall have become involved in a new war or an increase in major hostilities; or (iv) if a banking moratorium has been declared by a New York State or federal authority; or (v) if a moratorium on foreign exchange trading has been declared which materially adversely impacts the United States securities markets; or (vi) if the Company shall have sustained a material loss by fire, flood, accident, hurricane, earthquake, theft, sabotage or other calamity or malicious act which, whether or not such loss shall have been insured, will, in your opinion, make it inadvisable to proceed with the delivery of the Firm Securities or Option Securities; or (vii) if the Company is in material breach of any of its representations, warranties or covenants hereunder; or (viii) if the Representative shall have become aware after the date hereof of such a material adverse change in the conditions or prospects of the Company, or such adverse material change in general market conditions as in the Representative's judgment would make it impracticable to proceed with the offering, sale and/or delivery of the Public Securities or to enforce contracts made by the Underwriters for the sale of the Public Securities.

8.3 Expenses. Notwithstanding anything to the contrary in this Agreement, except in the case of a default by the Underwriters, pursuant to Section 6.2 above, in the event that this Agreement shall not be carried out for any reason whatsoever, within the time specified herein or any extensions thereof pursuant to the terms herein, the Company shall be obligated to pay to the Underwriters their actual and accountable out-of-pocket expenses related to the transactions contemplated herein then due and payable (including the fees and disbursements of Representative Counsel) up to \$75,000 and upon demand the Company shall pay the full amount thereof to the Representative on behalf of the Underwriters; *provided, however*, that such expense cap in no way limits or impairs the indemnification and contribution provisions of this Agreement.

8.4 Survival of Indemnification. Notwithstanding any contrary provision contained in this Agreement, any election hereunder or any termination of this Agreement, and whether or not this Agreement is otherwise carried out, the provisions of Section 5 shall remain in full force and effect and shall not be in any way affected by, such election or termination or failure to carry out the terms of this Agreement or any part hereof.

8.5 Representations, Warranties, Agreements to Survive. All representations, warranties and agreements contained in this Agreement or in certificates of officers of the Company submitted pursuant hereto, shall remain operative and in full force and effect regardless of (i) any investigation made by or on behalf of any Underwriter or its Affiliates or selling agents, any person controlling any Underwriter, its officers or directors or any person controlling the Company or (ii) delivery of and payment for the Public Securities.

9. Miscellaneous.

9.1 Notices. All communications hereunder, except as herein otherwise specifically provided, shall be in writing and shall be mailed (registered or certified mail, return receipt requested), personally delivered or sent by facsimile transmission and confirmed and shall be deemed given when so delivered or faxed and confirmed or if mailed, two (2) days after such mailing.

If to the Representative:

A.G.P./Alliance Global Partners
590 Madison Avenue, 36th Floor
New York, New York 10022
Attn: Mr. David Bocchi, Head of Investment Banking
Fax No.: (212) 813-1047

with a copy (which shall not constitute notice) to:

Zysman, Aharoni, Gayer and Sullivan & Worcester LLP
1633 Broadway
New York, New York 10019
Attention: Oded Har-Even, Esq.
Fax No.: (212) 660-3000

If to the Company:

Synthetic Biologics, Inc.
9605 Medical Center Drive, Suite 270
Rockville, Maryland 20850
Attention: Steven A. Shallcross, Chief Executive Officer
Fax No: []

with a copy (which shall not constitute notice) to:

Gracin & Marlow, LLP
The Chrysler Building
405 Lexington Avenue, 26th Floor
New York, New York 10174
Attention: Leslie Marlow, Esq.
Fax No: (212) 208-4657

9.2 Research Analyst Independence. The Company acknowledges that each Underwriter's research analysts and research departments are required to be independent from its investment banking division and are subject to certain regulations and internal policies, and that such Underwriter's research analysts may hold views and make statements or investment recommendations and/or publish research reports with respect to the Company and/or the offering that differ from the views of their investment banking division. The Company acknowledges that each Underwriter is a full service securities firm and as such from time to time, subject to applicable securities laws, rules and regulations, may effect transactions for its own account or the account of its customers and hold long or short positions in debt or equity securities of the Company; *provided, however*, that nothing in this Section 9.2 shall relieve the Underwriter of any responsibility or liability it may otherwise bear in connection with activities in violation of applicable securities laws, rules or regulations.

9.3 Headings. The headings contained herein are for the sole purpose of convenience of reference, and shall not in any way limit or affect the meaning or interpretation of any of the terms or provisions of this Agreement.

9.4 Amendment. This Agreement may only be amended by a written instrument executed by each of the parties hereto.

9.5 Entire Agreement. This Agreement (together with the other agreements and documents being delivered pursuant to or in connection with this Agreement) constitutes the entire agreement of the parties hereto with respect to the subject matter hereof and thereof, and supersedes all prior agreements and understandings of the parties, oral and written, with respect to the subject matter hereof.

9.6 Binding Effect. This Agreement shall inure solely to the benefit of and shall be binding upon the Representative, the Underwriters, the Company and the controlling persons, directors and officers referred to in Section 5 hereof, and their respective successors, legal representatives, heirs and assigns, and no other person shall have or be construed to have any legal or equitable right, remedy or claim under or in respect of or by virtue of this Agreement or any provisions herein contained. The term "successors and assigns" shall not include a purchaser, in its capacity as such, of securities from any of the Underwriters.

9.7 Governing Law; Consent to Jurisdiction; Trial by Jury. This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of New York, without giving effect to conflict of laws principles thereof. The Company hereby agrees that any action, proceeding or claim against it arising out of, or relating in any way to this Agreement shall be brought and enforced in the New York Supreme Court, County of New York, or in the United States District Court for the Southern District of New York, and irrevocably submits to such jurisdiction, which jurisdiction shall be exclusive. The Company hereby waives any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum. Any such process or summons to be served upon the Company may be served by transmitting a copy thereof by registered or certified mail, return receipt requested, postage prepaid, addressed to it at the address set forth in Section 9.1 hereof. Such mailing shall be deemed personal service and shall be legal and binding upon the Company in any action, proceeding or claim. The Company agrees that the prevailing party(ies) in any such action shall be entitled to recover from the other party(ies) all of its reasonable attorneys' fees and expenses relating to such action or proceeding and/or incurred in connection with the preparation therefor. The Company (on its behalf and, to the extent permitted by applicable law, on behalf of its stockholders and affiliates) and each of the Underwriters hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

9.8 Execution in Counterparts. This Agreement may be executed in one or more counterparts, and by the different parties hereto in separate counterparts, each of which shall be deemed to be an original, but all of which taken together shall constitute one and the same agreement, and shall become effective when one or more counterparts has been signed by each of the parties hereto and delivered to each of the other parties hereto. Delivery of a signed counterpart of this Agreement by facsimile or email/pdf transmission shall constitute valid and sufficient delivery thereof.

9.9 Waiver, etc. The failure of any of the parties hereto to at any time enforce any of the provisions of this Agreement shall not be deemed or construed to be a waiver of any such provision, nor to in any way effect the validity of this Agreement or any provision hereof or the right of any of the parties hereto to thereafter enforce each and every provision of this Agreement. No waiver of any breach, non-compliance or non-fulfillment of any of the provisions of this Agreement shall be effective unless set forth in a written instrument executed by the party or parties against whom or which enforcement of such waiver is sought; and no waiver of any such breach, non-compliance or non-fulfillment shall be construed or deemed to be a waiver of any other or subsequent breach, non-compliance or non-fulfillment.

[Signature Page Follows]

If the foregoing correctly sets forth the understanding between the Underwriters and the Company, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement between us.

Very truly yours,

SYNTHIETIC BIOLOGICS, INC.

By: _____
Name:
Title:

Confirmed as of the date first written above mentioned, on behalf of itself and as Representative of the several Underwriters named on Schedule 1 hereto:

A.G.P./ALLIANCE GLOBAL PARTNERS

By: _____
Name:
Title:

[SIGNATURE PAGE]

SYNTHETIC BIOLOGICS, INC. – UNDERWRITING AGREEMENT

SCHEDULE 1

Underwriter	Number of Class A Units	Number of Class B Units	Number of Option Shares to be Purchased if the Over-Allotment Option is Fully Exercised by the Representative	Number of Option Warrants to be Purchased if the Over- Allotment Option is Fully Exercised by the Representative
A.G.P./Alliance Global Partners				
TOTAL				

SCHEDULE 2-A
Pricing Information

Number of Class A Units:

Number of Class B Units:

Number of Option Shares:

Number of Option Warrants:

Public Offering Price per Class A Unit: \$

Public Offering Price per Class B Unit: \$1,000.00

Warrant Exercise Price: \$

Underwriting Discount per Class A Unit: \$

Underwriting Discount per Class B Unit: \$70.00

Underwriting Discount per Option Share: \$

Underwriting Discount per Option Warrant: \$0.0007

Proceeds to Company per Class A Unit (before expenses): \$

Proceeds to Company per Class B Unit (before expenses): \$930.00

Proceeds to Company per Option Share (before expenses): \$

Proceeds to Company per Option Warrant (before expenses): \$0.0093

SCHEDULE 2-B

Issuer General Use Free Writing Prospectuses

SCHEDULE 3

List of Lock-Up Parties

Steven A. Shallcross

Joseph Sliman

Jeffrey J. Kraws

Scott L. Tarriff

Jeffrey Wolf

EXHIBIT A

Form of Lock-Up Agreement

A.G.P./Alliance Global Partners
590 Madison Avenue, 36th Floor
New York, New York 10022

As Representative (the “**Representative**”) of the several Underwriters named in the Underwriting Agreement referenced below

Ladies and Gentlemen:

The undersigned understands that you and certain other firms (the “**Underwriters**”) propose to enter into an Underwriting Agreement (the “**Underwriting Agreement**”) providing for the purchase by the Underwriters of securities (the “**Securities**”), including Common Stock, par value \$0.001 per share (the “**Common Stock**”), of Synthetic Biologics, Inc., a Nevada corporation (the “**Company**”), and that the Underwriters propose to reoffer the Securities to the public (the “**Offering**”).

In consideration of the execution of the Underwriting Agreement by the Underwriters, and for other good and valuable consideration, the undersigned hereby irrevocably agrees that, without the prior written consent of the Representative, on behalf of the Underwriters, the undersigned will not, directly or indirectly, (1) offer for sale, sell, pledge, or otherwise transfer or dispose of (or enter into any transaction or device that is designed to, or could be expected to, result in the transfer or disposition by any person at any time in the future of) any Common Stock (including, without limitation, Common Stock that may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations of the Securities and Exchange Commission and Common Stock that may be issued upon exercise of any options or warrants) or securities convertible into or exercisable or exchangeable for Common Stock, (2) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of Common Stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or other securities, in cash or otherwise, (3) except as provided for below, make any demand for or exercise any right or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any Common Stock or securities convertible into or exercisable or exchangeable for Common Stock or any other securities of the Company, or (4) publicly disclose the intention to do any of the foregoing for a period commencing on the date hereof and ending on the 90th day after the closing of the Offering (such 90-day period, the “**Lock-Up Period**”).

The foregoing paragraph shall not apply to (a) transactions relating to Common Stock or other securities acquired in the open market after the completion of the Offering, *provided* that no filing under Section 16(a) of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), shall be required or shall be voluntarily made in connection with such transfers; (b) bona fide gifts, sales or other dispositions of shares of any class of the Company’s capital stock or any security convertible into Common Stock, in each case that are made exclusively between and among the undersigned or members of the undersigned’s family, or affiliates of the undersigned, including its partners (if a partnership) or members (if a limited liability company); (c) any transfer of Common Stock or any security convertible into Common Stock by will or intestate succession upon the death of the undersigned; (d) transfer of Common Stock or any security convertible into Common Stock to an immediate family member (for purposes of this Lock-Up Letter Agreement, “immediate family” shall mean any relationship by blood, marriage or adoption, not more remote than first cousin) or any trust, limited partnership, limited liability company or other entity for the direct or indirect benefit of the undersigned or any immediate family member of the undersigned; *provided* that, in the case of clauses (b)- (d) above, it shall be a condition to any such transfer that (i) the transferee/donee agrees to be bound by the terms of this Lock-Up Letter Agreement (including, without limitation, the restrictions set forth in the preceding sentence) to the same extent as if the transferee/donee were a party hereto, (ii) each party (donor, donee, transferor or transferee) shall not be required by law (including without limitation the disclosure requirements of the Securities Act of 1933, as amended (the “**Securities Act**”), and the Exchange Act) to make, and shall agree to not voluntarily make, any filing or public announcement of the transfer or disposition prior to the expiration of the 90-day period referred to above, and (iii) the undersigned notifies the Representative at least two business days prior to the proposed transfer or disposition; (e) the transfer of Common Stock to the Company to satisfy withholding obligations for any equity award granted pursuant to the terms of the Company’s stock option/incentive plans, such as upon exercise, vesting, lapse of substantial risk of forfeiture, or other similar taxable event, in each case on a “cashless” or “net exercise” basis (which, for the avoidance of doubt shall not include “cashless” exercise programs involving a broker or other third party), *provided* that as a condition of any transfer pursuant to this clause (e), that if the undersigned is required to file a report under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock during the Lock-Up Period, the undersigned shall include a statement in such report, and if applicable an appropriate disposition transaction code, to the effect that such transfer is being made as a stock delivery or forfeiture in connection with a net value exercise, or as a forfeiture or sale of shares solely to cover required tax withholding, as the case may be; (f) transfers of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock pursuant to a bona fide third party tender offer made to all holders of the Common Stock, merger, consolidation or other similar transaction involving a change of control (as defined below) of the Company, including voting in favor of any such transaction or taking any other action in connection with such transaction, *provided* that in the event that such merger, tender offer or other transaction is not completed, the Common Stock and any security convertible into or exercisable or exchangeable for Common Stock shall remain subject to the restrictions set forth herein; (g) the exercise of warrants or the exercise of stock options granted pursuant to the Company’s stock option/incentive plans or otherwise outstanding on the date hereof; *provided* , that the restrictions shall apply to Common Stock issued upon such exercise or conversion; (h) the establishment of any contract, instruction or plan that satisfies all of the requirements of Rule 10b5-1 (a “**Rule 10b5-1 Plan**”) under the Exchange Act; *provided* , *however* , that no sales of Common Stock or securities convertible into, or exchangeable or exercisable for, Common Stock, shall be made pursuant to a Rule 10b5-1 Plan prior to the expiration of the Lock-Up Period; *provided further* , that the Company is not required to report the establishment of such Rule 10b5-1 Plan in any public report or filing with the Commission under the Exchange Act during the lock-up period and does not otherwise voluntarily effect any such public filing or report regarding such Rule 10b5-1 Plan; and (i) any demands or requests for, exercise any right with respect to, or take any action in preparation of, the registration by the Company under the Act of the undersigned’s Common Stock, *provided* that no transfer of the undersigned’s Common Stock registered pursuant to the exercise of any such right and no registration statement shall be filed under the Act with respect to any of the undersigned’s Common Stock during the Lock-Up Period. For purposes of clause (f) above, “change of control” shall mean the consummation of any bona fide third party tender offer, merger, purchase, consolidation or other similar transaction the result of which is that any “person” (as defined in Section 13(d)(3) of the Exchange Act), or group of persons, becomes the beneficial owner (as defined in Rules 13d-3 and 13d-5 of the Exchange Act) of a majority of total voting power of the voting stock of the Company.

The undersigned also agrees and consents to the entry of stop transfer instructions with the Company’s transfer agent and registrar against the transfer of the undersigned’s securities subject to this Lock-Up Letter Agreement except in compliance with this Lock-Up Letter Agreement.

It is understood that, if the Company notifies the Underwriters that it does not intend to proceed with the Offering, if the Underwriting Agreement does not become effective, or if the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Securities, the undersigned will be released from its obligations under this Lock-Up Letter Agreement.

The undersigned understands that the Company and the Underwriters will proceed with the Offering in reliance on this Lock-Up Letter Agreement.

Whether or not the Offering actually occurs depends on a number of factors, including market conditions. Any Offering will only be made pursuant to an Underwriting Agreement, the terms of which are subject to negotiation between the Company and the Underwriters.

This Lock-Up Letter Agreement shall automatically terminate upon the earliest to occur, if any, of (1) the termination of the Underwriting Agreement before the sale of any Securities to the Underwriters or (2) December 17, 2018, in the event that the Underwriting Agreement has not been executed by that date.

[Signature page follows]

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Lock-Up Letter Agreement and that, upon request, the undersigned will execute any additional documents necessary in connection with the enforcement hereof. Any obligations of the undersigned shall be binding upon the heirs, personal representative, successors and assigns of the undersigned.

Very truly yours,

(Name - Please Print)

(Signature)

(Name of Signatory, in the case of entities - Please Print)

(Title of Signatory, in the case of entities - Please Print)

Address: _____

Synthetic Biologics, Inc.

and

Corporate Stock Transfer, Inc., as
Warrant Agent

Warrant Agency Agreement

Dated as of [], 2018

WARRANT AGENCY AGREEMENT

WARRANT AGENCY AGREEMENT, dated as of [], 2018 (“Agreement”), between Synthetic Biologics, Inc., a Nevada corporation (the “Company”), and Corporate Stock Transfer, Inc., a [] corporation (the “Warrant Agent”).

WITNESSETH

WHEREAS, pursuant to a registered offering by the Company of an aggregate of [] Class A Units (each, a “Class A Unit” and collectively, the “Class A Units”), each Class A Unit consisting of one share of the Company’s common stock, par value \$0.001 per share (the “Common Stock”), and a warrant to purchase one share of Common Stock (each, a “Warrant” and collectively, the “Warrants”), and an aggregate of [] Class B Units (each, a “Class B Unit” and collectively, the “Class B Units”), each Class B Unit consisting of one share of Series B Convertible Preferred Stock, par value \$0.001 per share (the “Preferred Stock”), and a Warrant to purchase the number of shares as would have been issued to such purchaser if they had purchased Class A Units based on the public offering price, pursuant to an effective registration statement on Form S-1 (File No. 333-227400) (the “Registration Statement”), the Company wishes to issue the Warrants in book entry form entitling the respective holders of the Warrants (the “Holders”, which term shall include a Holder’s transferees, successors and assigns and “Holder” shall include, if the Warrants are held in “street name,” a Participant (as defined below) or a designee appointed by such Participant) to purchase an aggregate of up to [] shares of Common Stock upon the terms and subject to the conditions hereinafter set forth (the “Offering”);

WHEREAS, the shares of Common Stock, Preferred Stock and Warrants to be issued in connection with the Offering shall be immediately separable and will be issued separately, but will be purchased together in the Offering; and

WHEREAS, the Company wishes the Warrant Agent to act on behalf of the Company, and the Warrant Agent is willing so to act, in connection with the issuance, registration, transfer, exchange, exercise and replacement of the Warrants and, in the Warrant Agent’s capacity as the Company’s transfer agent, the delivery of the Warrant Shares (as defined below).

NOW, THEREFORE, in consideration of the premises and the mutual agreements herein set forth, the parties hereby agree as follows:

Section 1. Certain Definitions. For purposes of this Agreement, the following terms have the meanings indicated:

- (a) “Business Day” means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which the New York Stock Exchange is authorized or required by law or other governmental action to close.
- (b) “Close of Business” on any given date means 5:00 p.m., New York City time, on such date; provided, however, that if such date is not a Business Day it means 5:00 p.m., New York City time, on the next succeeding Business Day.
- (c) “Person” means an individual, corporation, association, partnership, limited liability company, joint venture, trust, unincorporated organization, government or political subdivision thereof or governmental agency or other entity.

- (d) “Warrant Certificate” means a certificate issued to a Holder, representing such number of Warrant Shares as is indicated therein.
- (e) “Warrant Shares” means the shares of Common Stock underlying the Warrants and issuable upon exercise of the Warrants.

All other capitalized terms used but not otherwise defined herein shall have the meaning ascribed to such terms in the Warrant.

Section 2. Appointment of Warrant Agent. The Company hereby appoints the Warrant Agent to act as agent for the Company in accordance with the terms and conditions hereof, and the Warrant Agent hereby accepts such appointment. The Company may from time to time appoint a Co-Warrant Agent as it may, in its sole discretion, deem necessary or desirable. The Warrant Agent shall have no duty to supervise, and will in no event be liable for the acts or omissions of, any co-Warrant Agent.

Section 3. Global Warrants.

(a) The Warrants shall be issuable in book entry form (the “Global Warrants”). All of the Warrants shall initially be represented by one or more Global Warrants deposited with the Warrant Agent and registered in the name of Cede & Co., a nominee of The Depository Trust Company (the “Depository”), or as otherwise directed by the Depository. Ownership of beneficial interests in the Warrants shall be shown on, and the transfer of such ownership shall be effected through, records maintained by (i) the Depository or its nominee for each Global Warrant or (ii) institutions that have accounts with the Depository (such institution, with respect to a Warrant in its account, a “Participant”).

(b) If the Depository subsequently ceases to make its book-entry settlement system available for the Warrants, the Company may instruct the Warrant Agent regarding other arrangements for book-entry settlement. In the event that the Warrants are not eligible for, or it is no longer necessary to have the Warrants available in, book-entry form, the Warrant Agent shall provide written instructions to the Depository to deliver to the Warrant Agent for cancellation each Global Warrant, and the Company shall instruct the Warrant Agent to deliver to each Holder a Warrant Certificate.

(c) A Holder has the right to elect at any time or from time to time a Warrant Exchange (as defined below) pursuant to a Warrant Certificate Request Notice (as defined below). Upon written notice by a Holder to the Warrant Agent for the exchange of some or all of such Holder’s Global Warrants for a Warrant Certificate evidencing the same number of Warrants, which request shall be in the form attached hereto as Annex A (a “Warrant Certificate Request Notice” and the date of delivery of such Warrant Certificate Request Notice by the Holder, the “Warrant Certificate Request Notice Date” and the deemed surrender upon delivery by the Holder of a number of Global Warrants for the same number of Warrants evidenced by a Warrant Certificate, a “Warrant Exchange”), the Warrant Agent shall promptly effect the Warrant Exchange and shall promptly issue and deliver to the Holder a Warrant Certificate for such number of Warrants in the name set forth in the Warrant Certificate Request Notice. Such Warrant Certificate shall be dated the original issue date of the Warrants and shall be manually executed by an authorized signatory of the Company. In connection with a Warrant Exchange, the Company agrees to deliver, or to direct the Warrant Agent to deliver, the Warrant Certificate to the Holder within three (3) Business Days of the Warrant Certificate Request Notice pursuant to the delivery instructions in the Warrant Certificate Request Notice (“Warrant Certificate Delivery Date”). If the Company fails for any reason to deliver to the Holder the Warrant Certificate subject to the Warrant Certificate Request Notice by the Warrant Certificate Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Warrant Shares evidenced by such Warrant Certificate (based on the VWAP (as defined in the Warrant) of the Common Stock on the Warrant Certificate Request Notice Date), \$10 per Business Day (increasing to \$20 per Business Day on the fifth Business Day after such liquidated damages begin to accrue) for each Business Day after such Warrant Certificate Delivery Date until such Warrant Certificate is delivered or, prior to delivery of such Warrant Certificate, the Holder rescinds such Warrant Exchange. The Company covenants and agrees that, upon the date of delivery of the Warrant Certificate Request Notice, the Holder shall be deemed to be the holder of the Warrant Certificate and, notwithstanding anything to the contrary set forth herein, the Warrant Certificate shall be deemed for all purposes to contain all of the terms and conditions of the Warrants evidenced by such Warrant Certificate and the terms of this Agreement, other than Section 3(c), which shall not apply to the Warrants evidenced by a Warrant Certificate. In the event a beneficial owner requests a Warrant Exchange, upon issuance of the paper Warrant Certificate, the Company shall act as warrant agent and the terms of the paper Warrant Certificate so issued shall exclusively govern in respect thereof. For purposes of clarity, if there is a conflict between the express terms of this Agreement and any Warrant Certificate with respect to the terms of the Warrants, the terms of such Warrant Certificate shall govern and control.

Section 4. Form of Warrant. The Warrants, together with the form of election to purchase Common Stock (the “Exercise Notice”) and the form of assignment to be printed on the reverse thereof, whether a Warrant Certificate or a Global Warrant, shall be substantially in the form of Exhibit 1 hereto.

Section 5. Countersignature and Registration. The Warrants shall be executed on behalf of the Company by its Chief Executive Officer or Chief Financial Officer, either manually or by facsimile signature, and have affixed thereto the Company’s seal or a facsimile thereof which shall be attested by the Secretary or an Assistant Secretary of the Company, either manually or by facsimile signature. The Warrants shall be countersigned by the Warrant Agent either manually or by facsimile signature and shall not be valid for any purpose unless so countersigned. In case any officer of the Company who shall have signed a Warrant shall cease to be such officer of the Company before countersignature by the Warrant Agent and issuance and delivery by the Company, such Warrant, nevertheless, may be countersigned by the Warrant Agent, issued and delivered with the same force and effect as though the person who signed such Warrant had not ceased to be such officer of the Company; and any Warrant may be signed on behalf of the Company by any person who, at the actual date of the execution of such Warrant, shall be a proper officer of the Company to sign such Warrant, although at the date of the execution of this Warrant Agreement any such person was not such an officer.

The Warrant Agent will keep or cause to be kept, at one of its offices, or at the office of one of its agents, books for registration and transfer of the Warrant Certificates issued hereunder. Such books shall show the names and addresses of the respective Holders of the Warrant Certificates, the number of warrants evidenced on the face of each of such Warrant Certificate and the date of each of such Warrant Certificate. The Warrant Agent will create a special account for the issuance of Warrant Certificates.

Section 6. Transfer, Split Up, Combination and Exchange of Warrant Certificates; Mutilated, Destroyed, Lost or Stolen Warrant Certificates. Subject to the provisions of the Warrant and the last sentence of this first paragraph of Section 6 and subject to applicable law, rules or regulations, or any “stop transfer” instructions the Company may give to the Warrant Agent, at any time after the closing date of the Offering, and at or prior to the Close of Business on the Termination Date, any Warrant Certificate or Warrant Certificates or Global Warrant or Global Warrants may be transferred, split up, combined or exchanged for another Warrant Certificate or Warrant Certificates or Global Warrant or Global Warrants, entitling the Holder to purchase a like number of shares of Common Stock as the Warrant Certificate or Warrant Certificates or Global Warrant or Global Warrants surrendered then entitled such Holder to purchase. Any Holder desiring to transfer, split up, combine or exchange any Warrant Certificate or Global Warrant shall make such request in writing delivered to the Warrant Agent, and shall surrender the Warrant Certificate or Warrant Certificates to be transferred, split up, combined or exchanged at the principal office of the Warrant Agent, provided that no such surrender is applicable to the Holder of a Global Warrant. Any requested transfer of Warrants, whether a Global Warrant or a Warrant Certificate, shall be accompanied by reasonable evidence of authority of the party making such request that may be required by the Warrant Agent. Thereupon the Warrant Agent shall, subject to the last sentence of this first paragraph of Section 6, countersign and deliver to the Person entitled thereto any Warrant Certificate or Global Warrant, as the case may be, as so requested. The Company may require payment from the Holder of a sum sufficient to cover any tax or governmental charge that may be imposed in connection with any transfer, split up, combination or exchange of Warrants. The Company shall compensate the Warrant Agent per the fee schedule mutually agreed upon by the parties hereto and provided separately on the date hereof.

Upon receipt by the Warrant Agent of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of a Warrant Certificate, which evidence shall include an affidavit of loss, or in the case of mutilated certificates, the certificate or portion thereof remaining, and, in case of loss, theft or destruction, of indemnity in customary form and amount, and satisfaction of any other reasonable requirements established by Section 8-405 of the Uniform Commercial Code as in effect in the State of Nevada, and reimbursement to the Company and the Warrant Agent of all reasonable expenses incidental thereto, and upon surrender to the Warrant Agent and cancellation of the Warrant Certificate if mutilated, the Company will make and deliver a new Warrant Certificate of like tenor to the Warrant Agent for delivery to the Holder in lieu of the Warrant Certificate so lost, stolen, destroyed or mutilated.

Section 7. Exercise of Warrants; Exercise Price; Termination Date.

(a) The Warrants shall be exercisable commencing on the Initial Exercise Date. The Warrants shall cease to be exercisable and shall terminate and become void, and all rights thereunder and under this Agreement shall cease, at or prior to the Close of Business on the Termination Date. Subject to the foregoing and to Section 7(b) below, the Holder of a Warrant may exercise the Warrant in whole or in part upon providing the items required by Section 7(c) below to the Warrant Agent at the principal office of the Warrant Agent or to the office of one of its agents as may be designated by the Warrant Agent from time to time. In the case of the Holder of a Global Warrant, the Holder shall deliver the executed Exercise Notice and payment of the Exercise Price pursuant to Section 2(a) of the Warrant. Notwithstanding any other provision in this Agreement, a holder whose interest in a Global Warrant is a beneficial interest in a Global Warrant held in book-entry form through the Depository (or another established clearing corporation performing similar functions), shall effect exercises by delivering to the Depository (or such other clearing corporation, as applicable) the appropriate instruction form for exercise, complying with the procedures to effect exercise that are required by the Depository (or such other clearing corporation, as applicable). The Company acknowledges that the bank accounts maintained by the Warrant Agent in connection with the services provided under this Agreement will be in its name and that the Warrant Agent may receive investment earnings in connection with the investment at Warrant Agent risk and for its benefit of funds held in those accounts from time to time. Neither the Company nor the Holders will receive interest on any deposits or Exercise Price.

(b) Upon receipt of an Exercise Notice for a cashless exercise pursuant to Section 2(c) of the Warrant (each, a “Cashless Exercise”), the Company will promptly calculate and transmit to the Warrant Agent the number of Warrant Shares issuable in connection with such Cashless Exercise and deliver a copy of the Exercise Notice to the Warrant Agent, which shall issue such number of Warrant Shares in connection with such Cashless Exercise.

(c) Upon the Warrant Agent’s receipt, at or prior to the Close of Business on the Termination Date set forth in a Warrant, of the executed Exercise Notice, accompanied by payment of the Exercise Price pursuant to Section 2(a) of the Warrant, the shares to be purchased (other than in the case of a Cashless Exercise), an amount equal to any applicable tax, governmental charge or expense reimbursement referred to in Section 6 in cash, or by certified check or bank draft payable to the order of the Company and, in the case of an exercise of a Warrant in the form of a Warrant Certificate for all of the Warrant Shares represented thereby, the Warrant Agent shall cause the Warrant Shares underlying such Warrant to be delivered to or upon the order of the Holder of such Warrant, registered in such name or names as may be designated by such Holder, no later than the Warrant Share Delivery Date. If the Company is then a participant in the DWAC system of the Depository and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) the Warrant is being exercised via Cashless Exercise, then the certificates for Warrant Shares shall be transmitted by the Warrant Agent to the Holder by crediting the account of the Holder’s broker with the Depository through its DWAC system. For the avoidance of doubt, if the Company becomes obligated to pay any amounts to any Holders pursuant to Section 2(d)(i) or 2(d)(iv) of the Warrant, such obligation shall be solely that of the Company and not that of the Warrant Agent. Notwithstanding anything else to the contrary in this Agreement, except in the case of a Cashless Exercise, if any Holder fails to duly deliver payment to the Warrant Agent of an amount equal to the aggregate Exercise Price of the Warrant Shares to be purchased upon exercise of such Holder’s Warrant as set forth in Section 7(a) hereof, the Warrant Agent will not be obligated to deliver certificates representing any such Warrant Shares (via DWAC or otherwise) until following receipt of such payment, and the applicable Warrant Share Delivery Date shall be deemed extended by one day for each day (or part thereof) until such payment is delivered to the Warrant Agent.

(d) The Warrant Agent shall deposit all funds received by it in payment of the Exercise Price for all Warrants in the account of the Company maintained with the Warrant Agent for such purpose (or to such other account as directed by the Company in writing) and shall advise the Company via telephone at the end of each day on which funds for the exercise of any Warrant are received of the amount so deposited to its account. The Warrant Agent shall promptly confirm such telephonic advice to the Company in writing.

(e) In case the Holder of any Warrant Certificate exercises fewer than all Warrants evidenced thereby and surrenders such Warrant Certificate in connection with such partial exercise, a new Warrant Certificate evidencing the number of Warrant Shares equivalent to the number of Warrant Shares remaining unexercised may be issued by the Warrant Agent to the Holder of such Warrant Certificate or to his duly authorized assigns in accordance with Section 2(d)(ii) of the Warrant, subject to the provisions of Section 6 hereof.

Section 8. Cancellation and Destruction of Warrant Certificates. All Warrant Certificates surrendered for the purpose of exercise, transfer, split up, combination or exchange shall, if surrendered to the Company or to any of its agents, be delivered to the Warrant Agent for cancellation or in canceled form, or, if surrendered to the Warrant Agent, shall be canceled by it, and no Warrant Certificates shall be issued in lieu thereof except as expressly permitted by any of the provisions of this Agreement. The Company shall deliver to the Warrant Agent for cancellation and retirement, and the Warrant Agent shall so cancel and retire, any other Warrant Certificate purchased or acquired by the Company otherwise than upon the exercise thereof. The Warrant Agent shall deliver all canceled Warrant Certificates to the Company, or shall, at the written request of the Company, destroy such canceled Warrant Certificates, and in such case shall deliver a certificate of destruction thereof to the Company, subject to any applicable law, rule or regulation requiring the Warrant Agent to retain such canceled certificates.

Section 9. Certain Representations; Reservation and Availability of Shares of Common Stock or Cash.

(a) This Agreement has been duly authorized, executed and delivered by the Company and, assuming due authorization, execution and delivery hereof by the Warrant Agent, constitutes a valid and legally binding obligation of the Company enforceable against the Company in accordance with its terms, and the Warrants have been duly authorized, executed and issued by the Company and, assuming due authentication thereof by the Warrant Agent pursuant hereto and payment therefor by the Holders as provided in the Registration Statement, constitute valid and legally binding obligations of the Company enforceable against the Company in accordance with their terms and entitled to the benefits thereof; in each case except as enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium and other similar laws relating to or affecting creditors' rights generally or by general equitable principles (regardless of whether such enforceability is considered in a proceeding in equity or at law).

(b) As of the date hereof and prior to the Offering, the authorized capital stock of the Company consists of (i) [] shares of authorized Common Stock, of which [] shares of Common Stock are issued and outstanding, and (ii) [] shares of authorized preferred stock of which 0 are issued and outstanding. As of the date hereof there are [] shares of Common Stock reserved for issuance upon exercise of the Warrants inclusive of any Warrants the Underwriter may acquire upon exercise of its over-allotment option described in the Registration Statement. Except as disclosed in the Registration Statement, there are no other outstanding obligations, warrants, options or other rights to subscribe for or purchase from the Company any class of capital stock of the Company.

(c) The Company covenants and agrees that it will cause to be reserved and kept available out of its authorized and unissued shares of Common Stock or its authorized and issued shares of Common Stock held in its treasury, free from preemptive rights, the number of shares of Common Stock that will be sufficient to permit the exercise in full of all outstanding Warrants.

(d) The Warrant Agent will create a special account for the issuance of Common Stock upon the exercise of Warrants.

(e) The Company further covenants and agrees that it will pay when due and payable any and all federal and state transfer taxes and charges which may be payable in respect of the original issuance or delivery of the Warrant Certificates or certificates evidencing Common Stock upon exercise of the Warrants. The Company shall not, however, be required to pay any tax or governmental charge which may be payable in respect of any transfer involved in the transfer or delivery of Warrant Certificates or the issuance or delivery of certificates for Common Stock in a name other than that of the Holder of the Warrant Certificate evidencing Warrants surrendered for exercise or to issue or deliver any certificate for shares of Common Stock upon the exercise of any Warrants until any such tax or governmental charge shall have been paid (any such tax or governmental charge being payable by the Holder of such Warrant Certificate at the time of surrender) or until it has been established to the Company's reasonable satisfaction that no such tax or governmental charge is due.

Section 10. Common Stock Record Date. Each Holder shall be deemed to have become the holder of record for the Warrant Shares pursuant to Section 2(d)(i) of the Warrants.

Section 11. Adjustment of Exercise Price, Number of Shares of Common Stock or Number of the Company Warrants. The Exercise Price, the number of shares covered by each Warrant and the number of Warrants outstanding are subject to adjustment from time to time as provided in Section 3 of the Warrant. In the event that at any time, as a result of an adjustment made pursuant to Section 3 of the Warrant, the Holder of any Warrant thereafter exercised shall become entitled to receive any shares of capital stock of the Company other than shares of Common Stock, thereafter the number of such other shares so receivable upon exercise of any Warrant shall be subject to adjustment from time to time in a manner and on terms as nearly equivalent as practicable to the provisions with respect to the shares contained in Section 3 of the Warrant, and the provisions of Sections 7, 9 and 13 of this Agreement with respect to the shares of Common Stock shall apply on like terms to any such other shares. All Warrants originally issued by the Company subsequent to any adjustment made to the Exercise Price pursuant to the Warrant shall evidence the right to purchase, at the adjusted Exercise Price, the number of shares of Common Stock purchasable from time to time hereunder upon exercise of the Warrants, all subject to further adjustment as provided herein.

Section 12. Certification of Adjusted Exercise Price or Number of Shares of Common Stock. Whenever the Exercise Price or the number of shares of Common Stock issuable upon the exercise of each Warrant is adjusted as provided in Section 11 or 13, the Company shall (a) promptly prepare a certificate setting forth the Exercise Price of each Warrant as so adjusted, and a brief statement of the facts accounting for such adjustment, (b) promptly file with the Warrant Agent and with each transfer agent for the Common Stock a copy of such certificate and (c) instruct the Warrant Agent to send a brief summary thereof to each Holder of a Warrant.

Section 13. Fractional Shares of Common Stock.

(a) The Company shall not issue fractions of Warrants or distribute a Global Warrant or Warrant Certificates that evidence fractional Warrants. Whenever any fractional Warrant would otherwise be required to be issued or distributed, the actual issuance or distribution shall reflect a rounding of such fraction either up or down to the nearest whole Warrant.

(b) The Company shall not issue fractions of shares of Common Stock upon exercise of Warrants or distribute stock certificates that evidence fractional shares of Common Stock. Whenever any fraction of a share of Common Stock would otherwise be required to be issued or distributed, the actual issuance or distribution in respect thereof shall be made in accordance with Section 2(d)(v) of the Warrant.

Section 14. Conditions of the Warrant Agent's Obligations. The Warrant Agent accepts its obligations herein set forth upon the terms and conditions hereof, including the following to all of which the Company agrees and to all of which the rights hereunder of the Holders from time to time of the Warrant shall be subject:

(a) Compensation and Indemnification. The Company agrees promptly to pay the Warrant Agent the compensation detailed on Exhibit 2 hereto for all services rendered by the Warrant Agent and to reimburse the Warrant Agent for reasonable out-of-pocket expenses (including reasonable counsel fees) incurred without gross negligence, bad faith or willful misconduct by the Warrant Agent in connection with the services rendered hereunder by the Warrant Agent. The Company also agrees to indemnify the Warrant Agent for, and to hold it harmless against, any loss, liability or expense incurred without gross negligence, bad faith or willful misconduct on the part of the Warrant Agent, arising out of or in connection with its acting as Warrant Agent hereunder, including the reasonable costs and expenses of defending against any claim of such liability.

(b) Agent for the Company. In acting under this Warrant Agreement and in connection with the Warrant Certificates, the Warrant Agent is acting solely as agent of the Company and does not assume any obligations or relationship of agency or trust for or with any of the Holders of Warrant Certificates or beneficial owners of Warrants.

(c) Counsel. The Warrant Agent may consult with counsel satisfactory to it, which may include counsel for the Company, and the written advice of such counsel shall be full and complete authorization and protection in respect of any action taken, suffered or omitted by it hereunder in good faith and in accordance with the advice of such counsel.

(d) Documents. The Warrant Agent shall be protected and shall incur no liability for or in respect of any action taken or omitted by it in reliance upon any Warrant Certificate, notice, direction, consent, certificate, affidavit, statement or other paper or document reasonably believed by it to be genuine and to have been presented or signed by the proper parties.

(e) Certain Transactions. The Warrant Agent, and its officers, directors and employees, may become the owner of, or acquire any interest in, Warrants, with the same rights that it or they would have if it were not the Warrant Agent hereunder, and, to the extent permitted by applicable law, it or they may engage or be interested in any financial or other transaction with the Company and may act on, or as depositary, trustee or agent for, any committee or body of Holders of Warrant Securities or other obligations of the Company as freely as if it were not the Warrant Agent hereunder. Nothing in this Warrant Agreement shall be deemed to prevent the Warrant Agent from acting as trustee under any indenture to which the Company is a party.

(f) No Liability for Interest. Unless otherwise agreed with the Company, the Warrant Agent shall have no liability for interest on any monies at any time received by it pursuant to any of the provisions of this Agreement or of the Warrant Certificates.

(g) No Liability for Invalidity. The Warrant Agent shall have no liability with respect to any invalidity of this Agreement or any of the Warrant Certificates (except as to the Warrant Agent's countersignature thereon).

(h) No Responsibility for Representations. The Warrant Agent shall not be responsible for any of the recitals or representations herein or in the Warrant Certificates (except as to the Warrant Agent's countersignature thereon), all of which are made solely by the Company.

(i) No Implied Obligations. The Warrant Agent shall be obligated to perform only such duties as are herein and in the Warrants specifically set forth and no implied duties or obligations shall be read into this Agreement or the Warrants against the Warrant Agent. The Warrant Agent shall not be under any obligation to take any action hereunder which may tend to involve it in any expense or liability, the payment of which within a reasonable time is not, in its reasonable opinion, assured to it. The Warrant Agent shall not be accountable or under any duty or responsibility for the use by the Company of any of the Warrants authenticated by the Warrant Agent and delivered by it to the Company pursuant to this Agreement or for the application by the Company of the proceeds of the Warrants. The Warrant Agent shall have no duty or responsibility in case of any default by the Company in the performance of its covenants or agreements contained herein or in the Warrants or in the case of the receipt of any written demand from a Holder of a Warrant Certificate with respect to such default, including, without limiting the generality of the foregoing, any duty or responsibility to initiate or attempt to initiate any proceedings at law.

Section 15. Purchase or Consolidation or Change of Name of Warrant Agent. Any corporation into which the Warrant Agent or any successor Warrant Agent may be merged or with which it may be consolidated, or any corporation resulting from any merger or consolidation to which the Warrant Agent or any successor Warrant Agent shall be party, or any corporation succeeding to the corporate trust business of the Warrant Agent or any successor Warrant Agent, shall be the successor to the Warrant Agent under this Agreement without the execution or filing of any paper or any further act on the part of any of the parties hereto, provided that such corporation would be eligible for appointment as a successor Warrant Agent under the provisions of Section 17. In case at the time such successor Warrant Agent shall succeed to the agency created by this Agreement any of the Warrants shall have been countersigned but not delivered, any such successor Warrant Agent may adopt the countersignature of the predecessor Warrant Agent and deliver such Warrants so countersigned; and in case at that time any of the Warrants shall not have been countersigned, any successor Warrant Agent may countersign such Warrants either in the name of the predecessor Warrant Agent or in the name of the successor Warrant Agent; and in all such cases such Warrants shall have the full force provided in the Warrants and in this Agreement.

In case at any time the name of the Warrant Agent shall be changed and at such time any of the Warrants shall have been countersigned but not delivered, the Warrant Agent may adopt the countersignature under its prior name and deliver Warrants so countersigned; and in case at that time any of the Warrants shall not have been countersigned, the Warrant Agent may countersign such Warrants either in its prior name or in its changed name; and in all such cases such Warrants shall have the full force provided in the Warrants and in this Agreement.

Section 16. Duties of Warrant Agent. The Warrant Agent undertakes the duties and obligations imposed by this Agreement upon the following terms and conditions, all of which the Company, by its acceptance hereof, shall be bound:

(a) The Warrant Agent may consult with legal counsel reasonably acceptable to the Company (who may be legal counsel for the Company), and the opinion of such counsel shall be full and complete authorization and protection to the Warrant Agent as to any action taken or omitted by it in good faith and in accordance with such opinion.

(b) Whenever in the performance of its duties under this Agreement the Warrant Agent shall deem it necessary or desirable that any fact or matter be proved or established by the Company prior to taking or suffering any action hereunder, such fact or matter (unless other evidence in respect thereof be herein specifically prescribed) may be deemed to be conclusively proved and established by a certificate signed by the Chief Executive Officer or Chief Financial Officer of the Company; and such certificate shall be full authentication to the Warrant Agent for any action taken or suffered in good faith by it under the provisions of this Agreement in reliance upon such certificate.

(c) Subject to the limitation set forth in Section 14, the Warrant Agent shall be liable hereunder only for its own gross negligence, bad faith or willful misconduct, or for a breach by it of this Agreement.

(d) The Warrant Agent shall not be liable for or by reason of any of the statements of fact or recitals contained in this Agreement or in the Warrants (except its countersignature thereof) by the Company or be required to verify the same, but all such statements and recitals are and shall be deemed to have been made by the Company only.

(e) The Warrant Agent shall not be under any responsibility in respect of the validity of this Agreement or the execution and delivery hereof (except the due execution hereof by the Warrant Agent) or in respect of the validity or execution of any Warrant (except its countersignature thereof); nor shall it be responsible for any breach by the Company of any covenant or condition contained in this Agreement or in any Warrant; nor shall it be responsible for the adjustment of the Exercise Price or the making of any change in the number of shares of Common Stock required under the provisions of Section 11 or 13 or responsible for the manner, method or amount of any such change or the ascertaining of the existence of facts that would require any such adjustment or change (except with respect to the exercise of Warrants evidenced by Warrant Certificates after actual notice of any adjustment of the Exercise Price); nor shall it by any act hereunder be deemed to make any representation or warranty as to the authorization or reservation of any shares of Common Stock to be issued pursuant to this Agreement or any Warrant or as to whether any shares of Common Stock will, when issued, be duly authorized, validly issued, fully paid and nonassessable.

(f) Each party hereto agrees that it will perform, execute, acknowledge and deliver or cause to be performed, executed, acknowledged and delivered all such further and other acts, instruments and assurances as may reasonably be required by the other party hereto for the carrying out or performing by any party of the provisions of this Agreement.

(g) The Warrant Agent is hereby authorized to accept instructions with respect to the performance of its duties hereunder from the Chief Executive Officer or Chief Financial Officer of the Company, and to apply to such officers for advice or instructions in connection with its duties, and it shall not be liable and shall be indemnified and held harmless for any action taken or suffered to be taken by it in good faith in accordance with instructions of any such officer, provided Warrant Agent carries out such instructions without gross negligence, bad faith or willful misconduct.

(h) The Warrant Agent and any shareholder, director, officer or employee of the Warrant Agent may buy, sell or deal in any of the Warrants or other securities of the Company or become pecuniarily interested in any transaction in which the Company may be interested, or contract with or lend money to the Company or otherwise act as fully and freely as though it were not Warrant Agent under this Agreement. Nothing herein shall preclude the Warrant Agent from acting in any other capacity for the Company or for any other legal entity.

(i) The Warrant Agent may execute and exercise any of the rights or powers hereby vested in it or perform any duty hereunder either itself or by or through its attorney or agents, and the Warrant Agent shall not be answerable or accountable for any act, default, neglect or misconduct of any such attorney or agents or for any loss to the Company resulting from any such act, default, neglect or misconduct, provided reasonable care was exercised in the selection and continued employment thereof.

Section 17. Change of Warrant Agent. The Warrant Agent may resign and be discharged from its duties under this Agreement upon 30 days' notice in writing sent to the Company and to each transfer agent of the Common Stock, and to the Holders of the Warrant Certificates. The Company may remove the Warrant Agent or any successor Warrant Agent upon 30 days' notice in writing, sent to the Warrant Agent or successor Warrant Agent, as the case may be, and to each transfer agent of the Common Stock, and to the Holders of the Warrant Certificates. If the Warrant Agent shall resign or be removed or shall otherwise become incapable of acting, the Company shall appoint a successor to the Warrant Agent. If the Company shall fail to make such appointment within a period of 30 days after such removal or after it has been notified in writing of such resignation or incapacity by the resigning or incapacitated Warrant Agent or by the Holder of a Warrant Certificate (who shall, with such notice, submit his Warrant Certificate for inspection by the Company), then the Holder of any Warrant Certificate may apply to any court of competent jurisdiction for the appointment of a new Warrant Agent. Any successor Warrant Agent, whether appointed by the Company or by such a court, shall be a corporation organized and doing business under the laws of the United States or of a state thereof, in good standing, which is authorized under such laws to exercise corporate trust powers and is subject to supervision or examination by federal or state authority and which has at the time of its appointment as Warrant Agent a combined capital and surplus of at least \$50,000,000. After appointment, the successor Warrant Agent shall be vested with the same powers, rights, duties and responsibilities as if it had been originally named as Warrant Agent without further act or deed; but the predecessor Warrant Agent shall deliver and transfer to the successor Warrant Agent any property at the time held by it hereunder, and execute and deliver any further assurance, conveyance, act or deed necessary for the purpose. Not later than the effective date of any such appointment, the Company shall file notice thereof in writing with the predecessor Warrant Agent and each transfer agent of the Common Stock, and mail a notice thereof in writing to the Holders of the Warrant Certificates. However, failure to give any notice provided for in this Section 17, or any defect therein, shall not affect the legality or validity of the resignation or removal of the Warrant Agent or the appointment of the successor Warrant Agent, as the case may be.

Section 18. Issuance of New Warrants. Notwithstanding any of the provisions of this Agreement or of the Warrants to the contrary, the Company may, at its option, issue a new Global Warrant or Warrant Certificates, if any, evidencing Warrants in such form as may be approved by its Board of Directors to reflect any adjustment or change in the Exercise Price per share and the number or kind or class of shares of stock or other securities or property purchasable under the Global Warrant or Warrant Certificates, if any, made in accordance with the provisions of this Agreement.

Section 19. Notices. Notices or demands authorized by this Agreement to be given or made (i) by the Warrant Agent or by the Holder of any Warrant Certificate to or on the Company, (ii) subject to the provisions of Section 17, by the Company or by the Holder of any Warrant Certificate to or on the Warrant Agent or (iii) by the Company or the Warrant Agent to the Holder of any Warrant Certificate, shall be deemed given (a) on the date delivered, if delivered personally, (b) on the first Business Day following the deposit thereof with Federal Express or another recognized overnight courier, if sent by Federal Express or another recognized overnight courier, (c) on the fourth Business Day following the mailing thereof with postage prepaid, if mailed by registered or certified mail (return receipt requested), and (d) the time of transmission, if such notice or communication is delivered via facsimile or email attachment at or prior to 5:30 p.m. (New York City time) on a Business Day and (e) the next Business Day after the date of transmission, if such notice or communication is delivered via facsimile or email attachment on a day that is not a Business Day or later than 5:30 p.m. (New York City time) on any Business Day, in each case to the parties at the following addresses (or at such other address for a party as shall be specified by like notice):

(a) If to the Company, to:

Synthetic Biologics, Inc.
9605 Medical Center Drive, Suite 270
Rockville, Maryland 20850
Attention:

(b) If to the Warrant Agent, to:

Corporate Stock Transfer, Inc.
3200 Cherry Creek South Drive, Suite 430
Denver, Colorado 80209
Attention:

For any notice delivered by email to be deemed given or made, such notice must be followed by notice sent by overnight courier service to be delivered on the next business day following such email, unless the recipient of such email has acknowledged via return email receipt of such email.

(c) If to the Holder of any Warrant Certificate, to the address of such Holder as shown on the registry books of the Company. Any notice required to be delivered by the Company to the Holder of any Warrant may be given by the Warrant Agent on behalf of the Company. Notwithstanding any other provision of this Agreement, where this Agreement provides for notice of any event to a Holder of any Warrant Certificate, for a Global Warrant, such notice shall be sufficiently given if given to the Depositary (or its designee) pursuant to the procedures of the Depositary or its designee.

Section 20. Supplements and Amendments.

(a) The Company and the Warrant Agent may from time to time supplement or amend this Agreement without the approval of any Holders of Warrant Certificates in order to cure any ambiguity, to correct or supplement any provision contained herein which may be defective or inconsistent with any other provisions herein, or to make any other provisions with regard to matters or questions arising hereunder which the Company and the Warrant Agent may deem necessary or desirable and which shall not adversely affect the interests of the Holders of the Warrants Certificates in any material respect.

(b) In addition to the foregoing, with the consent of Holders of Warrants, the Company and the Warrant Agent may modify this Agreement for the purpose of adding any provisions to or changing in any manner or eliminating any of the provisions of this Warrant Agreement or modifying in any manner the rights of the Holders of the Warrant Certificates; provided, however, that no modification of the terms (including but not limited to the adjustments described in Section 11) upon which the Warrants are exercisable or reducing the percentage required for consent to modification of this Agreement may be made without the consent of the Holder of each outstanding warrant certificate affected thereby. As a condition precedent to the Warrant Agent's execution of any amendment, the Company shall deliver to the Warrant Agent a certificate from a duly authorized officer of the Company that states that the proposed amendment complies with the terms of this Section 20.

Section 21. Successors. All covenants and provisions of this Agreement by or for the benefit of the Company or the Warrant Agent shall bind and inure to the benefit of their respective successors and assigns hereunder.

Section 22. Benefits of this Agreement. Nothing in this Agreement shall be construed to give any Person other than the Company, the Holders of Warrant Certificates and the Warrant Agent any legal or equitable right, remedy or claim under this Agreement; but this Agreement shall be for the sole and exclusive benefit of the Company, the Warrant Agent and the Holders of the Warrant Certificates.

Section 23. Governing Law. This Agreement and each Warrant issued hereunder shall be governed by, and construed in accordance with, the laws of the State of New York without giving effect to the conflicts of law principles thereof.

Section 24. Counterparts. This Agreement may be executed in any number of counterparts and each of such counterparts shall for all purposes be deemed to be an original, and all such counterparts shall together constitute but one and the same instrument.

Section 25. Captions. The captions of the sections of this Agreement have been inserted for convenience only and shall not control or affect the meaning or construction of any of the provisions hereof.

Section 26. Information. The Company agrees to promptly provide to the Holders of the Warrants any information it provides to all holders of the Common Stock, except to the extent any such information is publicly available on the EDGAR system (or any successor thereof) of the Securities and Exchange Commission.

Section 27. Force Majeure. Notwithstanding anything to the contrary contained herein, Warrant Agent shall not be liable for any delays or failures in performance resulting from acts beyond its reasonable control including, without limitation, acts of God, terrorist acts, shortage of supply, breakdowns or malfunctions, interruptions or malfunction of computer facilities, or loss of data due to power failures or mechanical difficulties with information storage or retrieval systems, labor difficulties, war, or civil unrest, it being understood that the Warrant Agent shall use reasonable best efforts which are consistent with accepted practices in the banking industry to resume performance as soon as practicable under the circumstances.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the day and year first above written.

SYNTHETIC BIOLOGICS, INC.

By: _____
Name:
Title:

CORPORATE STOCK TRANSFER, INC.

By: _____
Name:
Title:

Annex A: Form of Warrant Certificate Request Notice

WARRANT CERTIFICATE REQUEST NOTICE

To: Corporate Stock Transfer, Inc. as Warrant Agent for Synthetic Biologics, Inc. (the "Company")

The undersigned Holder of Common Stock Purchase Warrants ("Warrants") in the form of Global Warrants issued by the Company hereby elects to receive a Warrant Certificate evidencing the Warrants held by the Holder as specified below:

1. Name of Holder of Warrants in form of Global Warrants: _____
2. Name of Holder in Warrant Certificate (if different from name of Holder of Warrants in form of Global Warrants): _____
3. Number of Warrants in name of Holder in form of Global Warrants: _____
4. Number of Warrants for which Warrant Certificate shall be issued: _____
5. Number of Warrants in name of Holder in form of Global Warrants after issuance of Warrant Certificate, if any: _____
6. Warrant Certificate shall be delivered to the following address:

The undersigned hereby acknowledges and agrees that, in connection with this Warrant Exchange and the issuance of the Warrant Certificate, the Holder is deemed to have surrendered the number of Warrants in form of Global Warrants in the name of the Holder equal to the number of Warrants evidenced by the Warrant Certificate.

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____

COMMON STOCK PURCHASE WARRANT

SYNTHETIC BIOLOGICS, INC.

Warrant Shares: _____ Initial Exercise Date: _____, 2018

THIS COMMON STOCK PURCHASE WARRANT (the “Warrant”) certifies that, for value received, _____ or its assigns (the “Holder”) is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after _____, 2018 (the “Initial Exercise Date”) and on or prior to 5:00 p.m. (New York City time) on _____, 2023 (the “Termination Date”) but not thereafter, to subscribe for and purchase from Synthetic Biologics, Inc., a Nevada corporation (the “Company”), up to _____ shares (as subject to adjustment hereunder, the “Warrant Shares”) of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b). This Warrant shall initially be issued and maintained in the form of a security held in book-entry form and the Depository Trust Company or its nominee (“DTC”) shall initially be the sole registered holder of this Warrant, subject to a Holder’s right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agency Agreement, in which case this sentence shall not apply.

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

“Affiliate” means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

“Bid Price” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the “Pink Sheets” published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

“Board of Directors” means the board of directors of the Company.

“Business Day” means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

“Commission” means the United States Securities and Exchange Commission.

“Common Stock” means the common stock of the Company, par value \$0.001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

“Common Stock Equivalents” means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“Exempt Issuance” means the issuance of (a) shares of Common Stock or options to employees, officers or directors of the Company pursuant to any stock or option plan duly adopted for such purpose, by a majority of the non-employee members of the Board of Directors or a majority of the members of a committee of non-employee directors established for such purpose for services rendered to the Company, (b) securities upon the exercise or exchange of or conversion of any securities issued under the Registration Statement and/or other securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date of this Warrant, provided that such securities have not been amended since the date of this Warrant to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities (other than in connection with stock splits or combinations) or to extend the term of such securities, (c) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, provided that such securities are issued as “restricted securities” (as defined in Rule 144) and carry no registration rights that require or permit the filing of any registration statement in connection therewith, and provided that any such issuance shall only be to a Person (or to the equity holders of a Person) which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities, and (d) securities issued pursuant to any at-the-market or similar agreement, including but not limited to, the sales the Company entered into on August 5, 2016 (as such agreement may be amended or replaced) with FBR Capital Markets & Co. now known as B. Riley FBR, Inc.

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Registration Statement” means the Company’s registration statement on Form S-1 (File No. 333-227400).

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Trading Day” means a day on which the Common Stock is traded on a Trading Market.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the New York Stock Exchange, OTCQB or OTCQX (or any successors to any of the foregoing).

“Transfer Agent” means Corporate Stock Transfer, Inc., the current transfer agent of the Company, with a mailing address of 3200 Cherry Creek South Drive, Suite 430, Denver, Colorado 80209 and a facsimile number of 303-282-5800, and any successor transfer agent of the Company.

“VWAP” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the “Pink Sheets” published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

“Warrant Agency Agreement” means that certain warrant agency agreement, dated on or about the Initial Exercise Date, between the Company and the Warrant Agent.

“Warrant Agent” means the Transfer Agent and any successor warrant agent of the Company.

“Warrants” means this Warrant and other Common Stock purchase warrants issued by the Company pursuant to the Registration Statement.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed facsimile copy or PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the “Notice of Exercise”). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the shares specified in the applicable Notice of Exercise by wire transfer or cashier’s check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Trading Day of receipt of such notice. The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.

Notwithstanding the foregoing in this Section 2(a), a holder whose interest in this Warrant is a beneficial interest in certificate(s) representing this Warrant held in book-entry form through DTC (or another established clearing corporation performing similar functions), shall effect exercises made pursuant to this Section 2(a) by delivering to DTC (or such other clearing corporation, as applicable) the appropriate instruction form for exercise, complying with the procedures to effect exercise that are required by DTC (or such other clearing corporation, as applicable), subject to a Holder's right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agency Agreement, in which case this sentence shall not apply, provided, however, a beneficial holder shall have all of the rights and remedies of a "Holder" hereunder.

b) Exercise Price. The exercise price per share of the Common Stock under this Warrant shall be \$[], subject to adjustment hereunder (the "Exercise Price").

c) Cashless Exercise. If at any time after the date hereof, there is no effective registration statement registering, or no current prospectus available for, the issuance of the Warrant Shares to the Holder, then this Warrant may only be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b)(64) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. as of the time of the Holder's execution of the applicable Notice of Exercise if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of "regular trading hours" on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of "regular trading hours" on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

Notwithstanding anything herein to the contrary, on the Termination Date, this Warrant shall be automatically exercised via cashless exercise pursuant to this Section 2(c).

d) Mechanics of Exercise.

- i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company of the Notice of Exercise, (ii) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company and (iii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date"), all subject to receipt of any cash payments required by the Holder. Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), \$10 per Trading Day (increasing to \$20 per Trading Day on the fifth Trading Day after such liquidated damages begin to accrue) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise.
- ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

- iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.
- iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of \$11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of \$10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder \$1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.
- v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

- vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.
- vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% (or, upon election by a Holder prior to the issuance of and Warrants, 9.99%) of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) Adjustment Upon Issuance of Shares of Common Stock. If the Company or any Subsidiary thereof, as applicable, at any time while this Warrant is outstanding, shall sell or grant any option to purchase, or otherwise dispose of or issue any Common Stock or Common Stock Equivalents, at an effective price per share less than the Exercise Price then in effect (such lower price, the “Base Share Price” and such issuances collectively, a “Dilutive Issuance”) (it being understood and agreed that if the Company sells securities as a unit, any warrant included in the unit shall be deemed to have an effective price equal to its exercise price and any common stock include in the unit shall be deemed to have an effective price equal to the unit price and if the holder of the Common Stock or Common Stock Equivalents so issued shall at any time, whether by operation of purchase price adjustments, reset provisions, floating conversion, exercise or exchange prices or otherwise, or due to warrants, options or rights per share which are issued in connection with such issuance, be entitled to receive shares of Common Stock at an effective price per share that is less than the Exercise Price, such issuance shall be deemed to have occurred for less than the Exercise Price on such date of the Dilutive Issuance at such effective price), then simultaneously with the consummation of each Dilutive Issuance the Exercise Price shall be reduced and only reduced to equal the Base Share Price. Notwithstanding the foregoing, no adjustments shall be made, paid or issued under this Section 3(a) in respect of an Exempt Issuance. The Company shall notify the Holder, in writing, no later than the Trading Day following the issuance or deemed issuance of any Common Stock or Common Stock Equivalents subject to this Section 3(a), indicating therein the applicable issuance price, or applicable reset price, exchange price, conversion price and other pricing terms (such notice, the “Dilutive Issuance Notice”). For purposes of clarification, whether or not the Company provides a Dilutive Issuance Notice pursuant to this Section 3(a), upon the occurrence of any Dilutive Issuance, the Holder is entitled to receive a number of Warrant Shares based upon the Base Share Price regardless of whether the Holder accurately refers to the Base Share Price in the Notice of Exercise. The Company shall have no right to voluntarily lower the exercise or conversion price of any security outstanding on the date of issuance of the Warrant below the Exercise Price other than in accordance with the terms of such security without the approval of holders of a majority of the Warrants.

b) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(b) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

c) Subsequent Rights Offerings. In addition to any adjustments pursuant to Sections 3(a) and 3(b) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, that, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, that, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation). To the extent that this Warrant has not been partially or completely exercised at the time of such Distribution, such portion of the Distribution shall be held in abeyance for the benefit of the Holder until the Holder has exercised this Warrant.

e) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a “Fundamental Transaction”), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the “Alternate Consideration”) receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the “Successor Entity”) to assume in writing all of the obligations of the Company under this Warrant in accordance with the provisions of this Section 3(e) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant referring to the “Company” shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant with the same effect as if such Successor Entity had been named as the Company herein.

f) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

g) Notice to Holder.

- i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.
- ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least 5 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice; provided further that no notice shall be required if the information is disseminated in a press release or document filed with the SEC. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

a) Transferability. This Warrant and all rights hereunder are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the original issuance date and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Warrant Agent (or, in the event a Holder elects to receive a Warrant in certificated form, the Company) shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Warrant Agent and the Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then, such action may be taken or such right may be exercised on the next succeeding Business Day.

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) **Governing Law.** All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against a party hereto or their respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) **Restrictions.** The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by facsimile or e-mail, or sent by a nationally recognized overnight courier service, addressed to the Company, at Synthetic Biologics, Inc., 9605 Medical Center Drive, Suite 270, Rockville, Maryland 20850 Attention: Chief Executive Officer, email address: sshallcross@syntheticbiologics.com, or such other facsimile number, email address or address as the Company may specify for such purposes by notice to the Holders. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by facsimile or e-mail, or sent by a nationally recognized overnight courier service addressed to each Holder at the facsimile number, e-mail address or address of such Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via facsimile at the facsimile number or via e-mail at the e-mail address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the time of transmission, if such notice or communication is delivered via facsimile at the facsimile number or via e-mail at the e-mail address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

h) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

i) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

j) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

k) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

l) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

m) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

n) Warrant Agency Agreement. If this Warrant is held in global form through DTC (or any successor depository), this Warrant is issued subject to the Warrant Agency Agreement. To the extent any provision of this Warrant conflicts with the express provisions of the Warrant Agency Agreement, the provisions of this Warrant shall govern and be controlling.

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

SYNTHETIC BIOLOGICS, INC.

By: _____
Name:
Title:

NOTICE OF EXERCISE

TO: []

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

in lawful money of the United States; or

if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

The Warrant Shares shall be delivered to the following DWAC Account Number:

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: _____
(Please Print)

Address: _____
(Please Print)

Phone Number:

Email Address:

Dated: _____, _____

Holder's Signature: _____

Holder's Address: _____

Consent of Independent Registered Public Accounting Firm

Synthetic Biologics, Inc.
Rockville, Maryland

We hereby consent to the incorporation by reference in the Prospectus constituting a part of this Registration Statement of our reports dated February 22, 2018 relating to the consolidated financial statements and the effectiveness of internal control over financial reporting of Synthetic Biologics, Inc., appearing in the Company's Annual Report on Form 10-K for the year ended December 31, 2017. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

We also consent to the reference to us under the caption "Experts" in the Prospectus.

/s/ BDO USA, LLP
McLean, Virginia

October 10, 2018
