Synthetic Biologics, Inc.
Form 10-K
March 02, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2016

OR

¨TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES ACT OF 1934

For the transition period from to

Commission File Number: 1-12584

SYNTHETIC BIOLOGICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Nevada	**13-3808303**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification Number)*

9605 Medical Center Drive, Ste. 270 **Rockville, MD**	**20850**
(Address of Principal Executive Offices)	*(Zip Code)*

Registrant's telephone number, including area code:
(301) 417-4364

Securities registered pursuant to Section 12(b) of the Act:	**Name of each exchange on which registered:**
Common Stock, $0.001 par value per share	**NYSE MKT, LLC**

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ¨ No x

Indicate by check mark whether the issuer: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of issuer's knowledge, in definitive proxy or information statements

incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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

Large Accelerated Filer ¨		Accelerated Filer	x
Non-accelerated Filer	¨ (Do not check if a smaller reporting company)	Smaller Reporting Company	¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ¨ No x

The aggregate market value of the registrant’s common stock held by non-affiliates of the registrant as of June 30, 2016, the last business day of the registrant’s recently completed second quarter, was approximately $141 million based on $1.80, the closing price of the registrant’s common stock as reported by the NYSE MKT on that date.

As of February 28, 2017, the registrant had 117,541,978 shares of common stock outstanding.

Documents incorporated by reference: **None**

SYNTHETIC BIOLOGICS, INC.

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PART I

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve substantial risks and uncertainties. The forward-looking statements are contained principally in Part I, Item 1. "Business," Part I, Item 1A. "Risk Factors," and Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations," but are also contained elsewhere in this Annual Report. In some cases you can identify forward-looking statements by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and simila These statements are based on our current beliefs, expectations, and assumptions and are subject to a number of risks and uncertainties, many of which are difficult to predict and generally beyond our control, that could cause actual results to differ materially from those expressed, projected or implied in or by the forward-looking statements.

You should refer to Item 1A. "Risk Factors" section of this Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We do not undertake any obligation to update any forward-looking statements.

Unless the context requires otherwise, references to "we," "us," "our," and "Synthetic Biologics," refer to Synthetic Biologic Inc. and its subsidiaries.

Item 1. ***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-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), and (2) 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), antibiotic-associated diarrhea (AAD) and the emergence of antimicrobial resistance (AMR). We are also developing preclinical stage monoclonal antibody therapies for the prevention and treatment of pertussis, and novel discovery stage biotherapeutics for the treatment of phenylketonuria (PKU).

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Our Product Pipeline

* Two Phase 2 studies completed. Planning a Phase 2b/3 pivotal trial

C- Cedars-Sinai Medical Center Collaboration

I-Intrexon Collaboration

T- The University of Texas at Austin Collaboration

Summary of Clinical and Preclinical Programs

Therapeutic Area	Product Candidate	Status
Treatment of IBS-C	SYN-010 (oral modified-release lovastatin lactone)	· Reported supportive topline data from two Phase 2 clinical trials (4Q 2015 & 1Q 2016) · Received Type C meeting responses from U.S. Food and Drug Administration (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 Digestive Disease Week Conference 2016 (DDW) (May 2016) · 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 the FDA (1Q 2017) · Plan to initiate first Phase 2b/3 adaptive pivotal clinical trial (2017) · Collaboration with Cedars-Sinai Medical Center

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Prevention of CDI and AAD (Degrade IV beta-lactam antibiotics)	SYN-004 (ribaxamase) (oral enzyme)	· Reported supportive Phase 1a/1b data (1Q 2015) · Initiated Phase 2b proof-of-concept clinical trial (3Q 2015) · Reported supportive topline data from first Phase 2a clinical trial (4Q 2015) · Reported supportive topline data from second Phase 2a clinical trial (2Q 2016) · 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 Centers for Disease Control and Prevention (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) · Plan to initiate Phase 3 clinical trial(s) (1H 2018)
Prevention of CDI and AAD (Degrade oral beta-lactam antibiotics)	SYN-007 (oral enzyme)	· Preclinical work ongoing to determine ability of SYN-007 to protect the gut microbiome and degrade oral beta-lactam antibiotics
Prevention and Treatment of pertussis	SYN-005 (monoclonal antibody therapies)	· 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) · Collaborations with Intrexon and UT Austin

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. In total, we hold approximately 140 U.S. and foreign patents and have over 55 U.S. and foreign patents pending.

Our Microbiome-Focused Pipeline

Our IBS-C and CDI/AAD programs are focused on protecting the healthy function of the gut microbiome, or gut flora, which is home to billions of microbial species and composed of 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.

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) stringent disease diagnosis criteria to ensure market relevance and a population most likely to receive a diagnosis and prescription drug treatment, 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 and other treatments include prescription and over-the-counter laxatives, which provide patients with temporary symptomatic relief and often cause diarrhea, but do not treat the underlying cause of pain, bloating and constipation associated with IBS-C. According to GlobalData, IBS — Global Drug Forecast and Market Analysis to 2023 (December 2014), the estimated global sales for IBS therapeutics for 2016 was $669.3 million, and global sales are expected to be greater than $1.5 billion in 2023.

Overview of our 2 Phase 2 Clinical Trials

In 2015 and 2016, we reported supportive data from our two SYN-010 Phase 2 trials, the first study was comprised of a randomized, double-blind, placebo-controlled, 4-week study comparing SYN-010 21 mg and 42 mg dose strengths to placebo (Study 1), followed by an open-label study in which eligible patients who completed Study 1 received SYN-010 42 mg for an additional 8 weeks (Study 2). The two Phase 2 SYN-010 clinical trials evaluated the change from baseline (Day 1 of Study 1) in breath methane, stool frequency and abdominal pain and bloating at the end of weeks 1, 4, 8 and 12 (Study 2 – Day 84) in patients diagnosed with IBS-C and with breath methane levels greater than 10 parts per million (ppm) at screening.

First Phase 2 Clinical Trial Results (4 Week Placebo-Controlled Acute Study)

In December 2015, we reported supportive topline results from our first Phase 2 placebo-controlled, randomized clinical trial of SYN-010, including lowered breath methane and improved stool frequency in patients with IBS-C. This first Phase 2 clinical trial was initiated in June 2015 and enrolled 63 patients who were randomized using a 1:1:1 ratio to one of three groups, including two different SYN-010 dose groups (21 mg and 42 mg) and a placebo group. Patients received single oral doses of SYN-010 or a placebo each day for 28 days. The primary objective of this clinical trial was to evaluate the change from baseline in the area under the curve (AUC) of breath methane, as determined by a lactulose breath test, in methane-positive patients with IBS-C after seven days of treatment with one of two dose levels of SYN-010 as compared with a placebo. The trial's secondary endpoints included improvement in the number of complete spontaneous bowel movements (CSBM) per week, and improvement in abdominal pain and bloating per standard scales required per FDA guidance. There were no serious adverse events observed.

In the first Phase 2 clinical trial of SYN-010, plasma trough levels of lovastatin species were low and variable, such that ≥50% of patients had undetectable plasma levels of each lovastatin analyte at days 7 and 28. In the few patients with detectable trough levels at day 28, concentrations of both lovastatin lactone and lovastatin beta-hydroxyacid were significantly lower than those reported in published studies of commercial lovastatin formulations. Modest reductions from baseline in mean cholesterol, LDL-C and triglycerides were observed after 7 days of SYN-010 treatment; however, changes were not different between SYN-010 and Placebo at Day 28 and were not evident after 12 weeks (Day 84). No significant changes in mean ALT or creatine kinase were observed in these patients. Changes in cholesterol, LDL-C, and triglycerides did not correlate with SYN-010 dose, or with changes in body weight, changes in breath methane, or plasma trough levels of either lovastatin lactone or lovastatin -hydroxyacid.

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Second Phase 2 Clinical Trial Results (8 Week Open-Label Extension Study)

In January 2016, we reported supportive topline data from our second Phase 2 clinical trial of SYN-010, which was initiated in October 2015. As the patients completed the first Phase 2 clinical trial, they were eligible to immediately rollover into the second Phase 2 clinical trial (multi-center, open-label) of SYN-010 that evaluated the sustainability of the effect of one dose strength of SYN-010 (42 mg) on breath methane production in 54 breath methane-positive patients with IBS-C, as well as key clinical outcomes, including frequency of CSBM, abdominal pain and bloating.

Patients in the second Phase 2 clinical trial reported compliance with the daily SYN-010 dosing regimen such that all patients in the second Phase 2 clinical trial received a minimum of 8 weeks treatment with SYN-010 42 mg. Patients who completed the second Phase 2 clinical trial demonstrated a statistically significant decrease in methane production ($p=0.002$) from the beginning of the first Phase 2 clinical trial (Baseline, Day 1, prior to any drug administration in the randomized study) to the end of the second Phase 2 clinical trial (12 weeks, Day 84), thus meeting the clinical trial's primary endpoint. Topline data from the second Phase 2 clinical trial also showed improvements in secondary efficacy endpoints, including: (1) a statistically significant reduction in the mean IBS Symptom Severity Score (IBS-SSS; $p<0.0001$), which includes abdominal pain, bloating, stool frequency and quality of life scores, for all patients from the first Phase 2 clinical trial baseline to the end of the second Phase 2 clinical trial, and (2) an increase in the percentage of patients identified as Monthly Responders, an FDA-defined composite measure incorporating improvements in CSBMs and abdominal pain.

Daily doses of SYN-010 were well-tolerated by IBS-C patients over the combined 12 weeks of the Phase 2a clinical trials (at least 8 weeks of SYN-010 42 mg). No serious adverse events were observed and there were no incidences of drug-related diarrhea.

DDW 2016 Presentation

In May 2016, we presented detailed data from two Phase 2 clinical trials of two dose strengths of SYN-010 at DDW2016.

Clinical data from the 57 patients who completed Study 1 and the 54 patients who completed Study 2 showed clinically meaningful improvements in measurable endpoints, including:

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Data from Study 1 demonstrating that three times as many patients in the placebo group took rescue medication compared to patients on either the 21 mg or 42 mg dose strength of SYN-010.

- Data from all patients who participated in both Study 1 and Study 2 and who were administered the 42 mg dose strength of SYN-010 for at least eight weeks demonstrated an inverse correlation (p=0.0259) between breath methane AUC and complete spontaneous bowel movements (CSBM). A similar inverse correlation (p=0.0028) was observed between breath methane AUC and spontaneous bowel movements (SBM).

- Data demonstrating the 42 mg dose strength of SYN-010 had a similar overall drug response rate to comparable FDA approved and clinical stage therapies for the treatment of IBS-C with a significantly lower rate of diarrhea in study participants.

- Data demonstrating clear improvements in abdominal pain, bloating and quality of life measures (IBS-SSS) in participants who were administered SYN-010.

Clinical Pharmacokinetic Study

In May 2016, we reported results from a separate completed randomized, open-label clinical study of healthy volunteers which evaluated the pharmacokinetic (PK) profile of the active ingredient of SYN-010. The PK data in healthy volunteers supported the modified-release profile of SYN-010, which is designed to avoid drug release in the stomach and deliver the antimethanogenic drug form, lovastatin lactone, into the lower small intestine and colon while reducing systemic exposure to the cholesterol-lowering lovastatin beta-hydroxyacid metabolite. Lovastatin lactone concentrations in stool samples from these healthy volunteers were equivalent to concentrations that caused 90% inhibition of methane production by stool samples from IBS-C patients in vitro. Consistent with the Phase 2a studies in IBS-C patients, data reported from this study demonstrated that the administration of SYN-010 21 mg and 42 mg did not result in adverse changes to the lipid profiles of study participants.

Phase 3 Planning

On July 20, 2016, we participated in an End of Phase 2 meeting with the FDA. Following a review of data from the two Phase 2 clinical trials of SYN-010 conducted by us, a collaborative and positive discussion ensued with the FDA to determine the optimal pathway to advance SYN-010 into Phase 3 development. On January 18, 2017, and in accordance with guidance from the FDA, we confirmed our plan to conduct a Phase 2b/3 adaptive design study for our first pivotal trial of SYN-010 which we plan to initiate during 2017.

In accordance with collaborative discussions with the FDA, key components of the SYN-010 Phase 2b/3 adaptive pivotal trial will include:

- A 12-week, multi-center, double-blind, placebo-controlled, adaptive design clinical trial
- A study population of approximately 840 adult subjects diagnosed with IBS-C
- Evaluation of efficacy and safety of two dose strengths of SYN-010 (21 mg and 42 mg) compared to placebo
- Conducted in approximately 150 clinical sites in North America
- Study subjects will be randomized in a 1:1:1 ratio, receiving either 21 mg of SYN-010, 42 mg of SYN-010, or placebo
- Enrollment will be open to all IBS-C patients; breath-methane will be measured at baseline to ensure a comparable ratio of high-to-low breath methane IBS-C patients in each treatment arm
- An interim futility analysis may be conducted when approximately 50% of patients in each dosing arm have completed treatment

Consistent with FDA written guidance, the primary objective for this study is to determine the efficacy of SYN-010, measured as an improvement from baseline in the percentage of overall weekly responders[1] during the 12-week treatment period for SYN-010 21 mg and 42 mg daily doses compared to placebo. Secondary efficacy endpoints for both dose strengths of SYN-010 will measure changes from baseline in abdominal pain, bloating, bowel movement frequency and stool consistency. Exploratory outcomes include adequate relief and quality of life measures using the well-validated EQ-5D-5L and PAC-SYM patient questionnaires.

Anticipated Regulatory Strategy

We believe that we will be able to utilize the regulatory approval pathway provided in Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the "FDCA") for SYN-010. A New Drug Application (NDA) submitted under Section 505(b)(2), referred to as a 505(b)(2) NDA, contains full safety and efficacy reports but allows at least some of the information required for NDA approval, such as safety and efficacy information on the active ingredient, to come from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. We believe we can rely in part on the FDA's previous findings of safety for Mevacor (lovastatin) in published clinical data. We expect to rely on published clinical trials using Mevacor to provide support of efficacy.

Intellectual Property

The SYN-010 intellectual property portfolio includes approximately 70 issued U.S. and foreign patents, and approximately 20 U.S. and foreign patents pending.

SYN-004 (ribaxamase) — Prevention of C. difficile infections (CDI) and antibiotic-associated diarrhea (AAD)

SYN-004 (ribaxamase) is an oral prophylactic therapy designed to degrade certain IV beta-lactam antibiotics within the GI tract and maintain the natural balance of the gut microbiome for the prevention of CDI, AAD and emergence of antibiotic-resistant organisms. Beta-lactam antibiotics are a mainstay in hospital infection management and include the commonly used penicillin and cephalosporin classes of antibiotics.

[1] An overall 12-week responder is defined as a subject with a weekly response in at least 50% of the weeks of treatment (6 of 12 weeks). Weekly Responder is defined as a patient who experiences a decrease in weekly average score for worst abdominal pain in the past 24 hours of at least 30% compared with Study 1 Baseline and a stool frequency increase of 1 or more CSBM per week compared with Study 1 Baseline.

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-Investigation New Drug (IND) package for P3A (which we now refer to as ribaxamase, formerly SYN-004), 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 call 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 our new product candidate, SYN-004 (ribaxamase). P1A was evaluated in four Phase 1 and one Phase 2 clinical trials conducted in Europe. In total, 112 patients and 143 healthy normal subjects participated in these studies.

Beta-lactamase enzymes have the ability to degrade beta-lactam antibiotics that may be excreted into the Gastro Intestinal tract (GI tract). P1A (the first generation candidate) showed acceptable safety and tolerability in a Phase 1 clinical trial. In addition, data from two Phase 2 clinical trials demonstrated that P1A had the ability to preserve GI microflora in hospitalized patients treated with IV ampicillin or the combination of piperacillin and tazobactam.

C. difficile

C. *difficile* is the leading type of hospital acquired infection and is frequently associated with IV beta-lactam antibiotic treatment. According to an article published in the New England Journal of Medicine (Leffler DA et al. N Engl J Med 2015; 372: 1539-1548), CDIs more than quadruple the cost of hospitalizations, increasing annual expenditures by approximately $1.5 billion in the U.S. CDI is a rising global hospital acquired infection (HAI) problem in which the toxins produced by *C. difficile* bacteria result in AAD, 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 4-7 days), underlying illness, and immune-compromising conditions including the administration of chemotherapy and advanced age. In addition, approximately 25% 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 a CDI each year. CDI has surpassed methicillin-resistant staphylococcus aureus (MRSA) as the most frequent hospital acquired infection. 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 CDI.

According to IMS Health Incorporated, each year 24 million unique patients are administered some form of IV antibiotic in the U.S. which may contribute to the onset of CDI*. Additional data that we requisitioned suggests SYN-004's (ribaxamase's) significant target market is represented by the 117 million average days SYN-004 (ribaxamase) could be administered with target IV beta-lactam antibiotics to the 16.7 million hospitalized patients each year, which at a price point of $100 per day indicates a potential market size of approximately $12.0 billion. This estimate is based upon data that we requisitioned and derived from the following report: Arlington Medical Resources (AMR), a Decision Resources Group Company, 2014 Audits of Acute Care Hospital Antibiotic Utilization. Currently there are no approved treatments designed to protect the gut microbiome from the damaging effects of IV antibiotics. We believe SYN-004's ability to degrade certain beta-lactam antibiotics will be consistent with, or more effective than results previously demonstrated by PIA, SYN-004's predecessor, in Phase 1 and Phase 2 studies conducted by IPSAT. In previously reported clinical studies, SYN-004 (ribaxamase) demonstrated greater efficacy in degrading certain cephalosporins (ceftriaxone) compared to its predecessor, PIA. The worldwide market for SYN-004 (ribaxamase) could represent a multi-billion dollar opportunity for us.

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

Phase 1a and 1b Clinical Trial Pharmacokinetic Data

In March 2015, we reported supportive pharmacokinetic data from our Phase 1a and 1b clinical trials, which suggests that SYN-004 (ribaxamase) may have no effect on the IV antibiotic in the bloodstream, allowing the antibiotic to fight the primary infection. In February 2015, we reported supportive topline results from our Phase 1b clinical trial of escalating doses of oral SYN-004 (ribaxamase), with no safety or tolerability issues reported at dose levels and dose regimens both meeting and exceeding those expected to be studied in upcoming clinical trials. The Phase 1a (40 participants) and 1b (24 participants) clinical trials of SYN-004 (ribaxamase) were initiated in December 2014.

First Phase 2a Clinical Trial Topline Results

In December 2015, we reported supportive topline results from our Phase 2a clinical trial of SYN-004 (ribaxamase), including data from ten ileostomized participants that demonstrated SYN-004 (ribaxamase) successfully degraded residual IV ceftriaxone in the chyme (digestive fluid in the small intestine) without affecting the intended level of ceftriaxone in the bloodstream. This Phase 2a clinical trial was initiated in March 2015 to evaluate the GI antibiotic-degrading effects and the safety of SYN-004 (ribaxamase).

Second Phase 2a Clinical Trial Topline Results

In June 2015, we initiated a second Phase 2a clinical trial of SYN-004 (ribaxamase) to evaluate the GI antibiotic-degrading ability and the safety of SYN-004 (ribaxamase), in the presence of the proton pump inhibitor (PPI), esomeprazole, in healthy participants with functioning ileostomies.

In May 2016, we reported supportive topline results from our second Phase 2a clinical trial of SYN-004 (ribaxamase), including data demonstrating the 150 mg dose of SYN-004 (ribaxamase), both alone and in the presence of the proton pump inhibiter (PPI), esomeprazole, degraded residual IV ceftriaxone to levels that were low or not detectable in the intestinal chyme (digestive fluid in the small intestine) of 14 healthy participants with functioning ileostomies. In addition, ceftriaxone plasma concentrations in study participants were very similar in the presence or absence of an oral PPI, suggesting limited drug-drug interactions with esomeprazole. The 150 mg dose strength of SYN-004 (ribaxamase) was well tolerated by all participants in this clinical trial.

Additional Studies

Data from an additional study conducted in humanized pigs demonstrated that when administered with ceftriaxone, SYN-004 (ribaxamase) prevented ceftriaxone-remediated changes in the pig fecal microflora, protecting the microbiome from antibiotic-mediated damage when compared to pigs who only received ceftriaxone.

CDC's Broad Agency Announcement

On October 6, 2016, we announced the award of a government contract by the CDC's Broad Agency Announcement (BAA) 2016-N-17812. The contract amount is up to $521,014. The award will support research conducted during our ongoing, randomized, placebo-controlled Phase 2b proof-of-concept clinical study of SYN-004 (ribaxamase) and the CDCs' efforts to assess how selective pressure from IV antibiotics may lead to the emergence of antibiotic resistance in the gut microbiome. The funding will also support research to evaluate SYN-004's (ribaxamase's) ability to reduce selective pressure associated with the emergence of antibiotic-resistant organisms in the gut microbiomes of patients enrolled in our Phase 2b clinical trial. We will examine DNA isolated from longitudinal samples obtained during the clinical trial and look for changes to the patient's gut resistome, specifically examining for alterations in the presence and/or abundance of antibiotic resistance genes.

Phase 2b Clinical Trial Design & Topline Results / Phase 3 Planning

In September 2015, we initiated a randomized placebo-controlled Phase 2b proof-of-concept clinical trial intended to evaluate the ability of SYN-004 (ribaxamase) to prevent CDI, *C. difficile* associated diarrhea (CDAD) and AAD in patients hospitalized for a lower respiratory tract infection and receiving IV ceftriaxone. A planned interim analysis was triggered and conducted following the enrollment of approximately 80% of the planned patients who also completed the follow-up period outlined in the study protocol. In September 2016, and following a closed session with the independent Interim Analysis Committee (IAC) in which we remained blinded to the study data, a recommendation was given by the IAC to continue the study per protocol without modification, indicating that the study was adequately powered and should continue as planned. No safety issues were identified by the IAC during the interim analysis. Based upon the recommendation by the IAC, we completed enrollment in this trial in September 2016 with 413 patients exceeding the desired sample size of 372 patients. Analysis of an exploratory endpoint from this trial designed to evaluate the ability of SYN-004 (ribaxamase) to limit disruption of the gut microbiome diversity, also known as dysbiosis, is ongoing.

On January 5, 2017, we announced positive topline data from our Phase 2b clinical trial demonstrating SYN-004 (ribaxamase) achieved its primary endpoint of significantly reducing CDI. Preliminary analysis of the data indicated seven confirmed cases of CDI in the placebo group compared to two cases in the ribaxamase treatment group. Patients receiving ribaxamase achieved a 71.4% relative risk reduction (p-value=0.045) in CDI rates compared to patients receiving placebo. Adverse events reported during this trial were comparable between treatment and placebo arms.

Preliminary analysis of the data demonstrated a significant reduction in new colonization by vancomycin-resistant enterococci (VRE) for patients receiving ribaxamase compared to placebo (p-value=0.0002). With agreement from the FDA, the study included a secondary endpoint to assess ribaxamase's capacity to decrease the incidence of antibiotic-associated diarrhea from all causes. Preliminary analysis of the data suggested a trend towards such a reduction (p-value=0.13), which was due, for the most part, to the reduction of CDI.

We are in the process of further analyzing data from this clinical trial and expect to share additional results from additional exploratory endpoints as they become available later this year, including results focused on ribaxamase's ability to prevent the emergence of antimicrobial resistance in the gut microbiome.

In 2017, we also plan to enter into strategic discussions with the CDC, hold an end of Phase 2 meeting with the FDA, and expect to initiate Phase 3 trial(s) towards the first half of 2018 or later.

SYN-007 — Prevention of CDI and AAD

Preclinical work is ongoing to determine the ability of SYN-007 to degrade oral beta-lactam antibiotics and protect the gut microbiome. SYN-007 comprises a reformulated version of SYN-004 for use with oral beta-lactam antibiotics versus IV beta-lactam antibiotics.

SYN-006 — Prevention of CDI and AAD

The development of SYN-006 is in the discovery stage. SYN-006 is intended to be an oral prophylactic therapy designed to degrade IV carbapenem antibiotics (a third class of beta-lactam antibiotics) within the GI tract and maintain the natural balance of the gut microbiome for the prevention of CDI and AAD. While SYN-004 (ribaxamase) is intended to degrade penicillin and certain cephalosporins in the GI tract, the SYN-006 discovery program has the potential to expand the activity to a broader spectrum of IV beta-lactam antibiotics in the GI tract to include carbapenem antibiotics.

C. difficile: Intellectual Property

The SYN-004 (ribaxamase) intellectual property portfolio includes approximately 60 issued U.S. and foreign patents, and approximately 35 U.S. and foreign patents pending.

Research Programs

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

SYN-005 — Pertussis (Whooping Cough)

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 World Health Organization (WHO), there are 50 million cases of whooping cough, and it is estimated that *B. pertussis* infection causes up to 300,000 deaths each year worldwide, primarily among unvaccinated infants.

Intrexon Collaboration and The University of Texas at Austin Agreement

In August 2012, we entered into a worldwide exclusive channel collaboration with Intrexon through which we intend to 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 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 April 2015, preclinical efficacy data that support advancing SYN-005 toward clinical trials were presented in two poster presentations at the European Congress of Clinical Microbiology and Infectious Diseases meeting (ECCMID) 2015 in Copenhagen, Denmark. The data suggest that SYN-005 has therapeutic potential to diminish morbidity, long-term complications and mortality from pertussis in critically ill infants. In addition, the data support a prophylactic approach for use in newborns that has the potential to save thousands of lives annually, particularly in the developing world where the unmet need is greatest.

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 evaluate the potential of our monoclonal antibody, 1B7, for the prevention of pertussis. This preclinical study is expected to provide support for the potential clinical application of 1B7.

Intellectual Property

We have three issued U.S. patents and ten patents pending on compositions and uses of SYN-005 and other pertussis mAbs from UT Austin.

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.

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). Published preclinical and clinical studies on IAP indicate that an oral IAP product may have efficacy in a broad range of significant therapeutic indications including celiac disease, inflammatory bowel disease, microbial dysbiosis and metabolic syndrome. We have identified cell systems in which IAP can be expressed are generating manufacturing cell lines and processes, and are initiating preclinical animal modeling for multiple novel indications.

Intellectual Property

All of our programs are supported by growing patent estates that we either own or exclusively license. Each potential product has issued patents that provide protection. In total, we have approximately 140 U.S. and foreign patents and over 55 U.S. and foreign patents pending. For instance, U.S. Patent No. 8,894,994, which has claims to compositions of matter and pharmaceutical compositions of beta-lactamases, including ribaxamase, carries a patent term to at least 2031. Further, U.S. Patent 9,301,995 and 9,301,996, which, will expire in 2031, cover various uses of beta-lactamases, including ribaxamase, in protecting the microbiome, and allowed U.S. Patent No.s 9,290,754, 9,376,673, 9,404,103 and 9,464,280, which, will expire in 2035, covers further beta-lactamase compositions of matter related to ribaxamase. Also, U.S. Patent No. 9,192,618, which expires in approximately 2023, includes claims that cover use of statins, including SYN-010, for the treatment of IBS-C. U.S. Patent No. 9,289,418, which expires in approximately 2033, includes claims that cover the use of a variety of compounds, including the active agent of SYN-010, to treat constipation in certain screened patients. Pending applications PCT /US2015/045140 and US 14/826,115, cover SYN-010 formulations and, if issued (after nationalization), are expected to have a term to at least 2035.

Our goal is to (i) obtain, maintain, and enforce patent protection for our products, formulations, processes, methods, and other proprietary technologies, ii) preserve our trade secrets, and (iii) operate without infringing on the proprietary rights of other parties, worldwide. We seek, where appropriate, the broadest intellectual property protection for product candidates, proprietary information, and proprietary technology through a combination of contractual arrangements and patents.

Our Collaborations

PKU Collaboration with Intrexon Corporation

On August 10, 2015, we expanded our relationship with Intrexon and entered into an Exclusive Channel Collaboration Agreement (the “PKU ECC”) arrangement in which we intend to use Intrexon’s technology relating to the development and commercialization of novel biotherapeutics (a “Collaboration Product”) for the treatment of patients with PKU. On September 2, 2015, in accordance with the terms of the Intrexon Stock Issuance Agreement that we entered into in connection with the Channel Agreement, we paid Intrexon a technology access fee by the issuance of 937,500 shares of common stock, having a value equal to $3 million as of August 7, 2015.

In addition, upon the achievement of certain milestones, we agreed to pay Intrexon milestone payments of up to $27 million for each product developed as follows: (i) $2 million upon first dosing of a patient in a Phase 1 clinical trial upon commencement of an IND, payable in stock or cash at our option; (ii) a payment 30 days after achievement of the first commercial sale of a Collaboration Product in the United States or approval of a New Drug Application and/or Biologics License Application for a Collaboration Product by the U.S. Food and Drug Administration; and (iii) a payment 30 days after achievement of the first commercial sale of a Collaboration Product in a nation subject to the authority of the European Medicines Agency (EMA) or approval of a Marketing Authorization Application for a Collaboration Product by the EMA. We will pay Intrexon royalties on annual net sales of Collaboration Products, calculated on a product-by-product basis, equal to a percentage of net sales (ranging from mid-single digits on the first $100 million of net sales to mid-teen digits on net sales in excess of $750 million). We have likewise agreed to pay Intrexon a percentage of quarterly revenue obtained from a sublicensor in the event of a sublicensing arrangement. Pursuant to the Second Amendment to Registration Rights Agreement, we filed a “resale” registration statement to register the shares issued under the Intrexon Stock Issuance Agreement, which was declared effective by the SEC on October 15, 2015.

Cedars-Sinai Medical Center License Agreement

On December 5, 2013, through our majority owned subsidiary, SYN Biomics, we entered into a worldwide exclusive license agreement (the “CSMC License Agreement”) for the right to develop, manufacture, use, and sell products for the human and veterinary therapeutic and prophylactic treatments for acute and chronic diseases. An investigational team lead by Dr. Mark Pimentel at CSMC has discovered that these products are intended to target certain pathogenic GI microorganisms that are perceived as an underlying cause of diseases such as IBS-C, obesity and type 2 diabetes. The portfolio of intellectual property licensed to SYN Biomics under the CSMC License Agreement included nine issued U.S. patents, 30 issued patents in various European countries, three issued Australian patents, one Canadian patent and one issued Japanese patent as well as several pending U.S. and international patent applications for most fields of use and modalities (subject to certain agreed-upon exceptions. On December 5, 2013, we also entered into an option agreement regarding IBS with CSMC, which expired unexercised on December 31, 2014.

Under the terms of the CSMC License Agreement we issued 334,911 unregistered shares of our common stock to CSMC, as payment of an initial license fee and patent reimbursement fees of $150,000 and $220,000, respectively. The parties also entered into a Stock Purchase Agreement with respect to such stock issuance and other issuances of unregistered shares of our common stock that may be issued to CSMC in lieu of cash, including license fees, milestone payments, expense reimbursements and option fees under the CSMC License Agreement. Commencing on the second anniversary of the CSMC License Agreement, SYN Biomics began paying an annual maintenance fee, which payment shall be creditable against annual royalty payments owed under the CSMC License Agreement. In addition to royalty payments which are a percentage of Net Sales (as defined in the CSMC License Agreement) of Licensed Products (as defined in the CSMC License Agreement) and Licensed Technology products (as defined in the CSMC License Agreement), SYN Biomics is obligated to pay CMSC a percentage of any non-royalty sublicense revenues, as well as additional consideration upon the achievement of the following milestones (the first two of which are payable in cash or unregistered shares of our stock at our option): (i) successful Phase 1 trial completion of the first Licensed Product or first Licensed Technology Product; (ii) successful Phase 2 trial completion of the first

Licensed Product or first Licensed Technology Product; (iii) initiation of Phase 3 dosing for each additional indication of a Licensed Product or Licensed Technology Product; (iv) successful Phase 3 trial completion for each Licensed Product and each Licensed Technology Product; (v) the FDA's acceptance of a New Drug Application for each Licensed Product and each Licensed Technology Product; (vi) regulatory approval for each Licensed Product and each Licensed Technology Product; and (vii) the first commercial sale of each Licensed Product and each Licensed Technology Product. The stock issuances are subject to prior approval of the NYSE MKT, LLC. During the year ended December 31, 2016, the Company paid Cedars-Sinai Medical Center $350,000 for milestone payments related this license agreement. There were no milestone payments made during year ended December 31, 2015.

Prior to the execution of the CSMC License Agreement, SYN Biomics issued shares of common stock of SYN Biomics to each of CSMC and Dr. Mark Pimentel (the primary inventor of the intellectual property), representing 11.5% and 8.5%, respectively, of the outstanding shares of SYN Biomics (the "SYN Biomics Shares"). The Stock Purchase Agreements for the SYN Biomics Shares provide for certain anti-dilution protection until such time as an aggregate of $3.0 million in proceeds from equity financings are received by SYN Biomics as well as a right, under certain circumstances in the event that the SYN Biomics Shares are not then freely tradeable, and subject to NYSE MKT, LLC approval, as of the 18 and 36 month anniversary date of the effective date of the Stock Purchase Agreements, for each of CSMC and the Dr. Pimentel to exchange up to 50% of their SYN Biomics Shares for unregistered shares of our common stock, with the rate of exchange based upon the relative contribution of the valuation of SYN Biomics to the public market valuation of us at the time of each exchange. The Stock Purchase Agreements also provide for tag-along rights in the event of the sale by us of our shares of SYN Biomics.

On August 29, 2015, we, SYN Biomics and Dr. Pimentel entered into the Pimentel Amendment to the Pimentel Stock Purchase Agreement entered into dated December 3, 2013, which accelerated the date upon which Dr. Pimentel can exchange his shares of common stock in SYN Biomics for shares of the our common stock. On August 29, 2015, Dr. Pimentel notified us of his intent to exchange all of the shares of common stock in SYN Biomics owned by him for 1,350,000 shares of our common stock in accordance with the terms of the Pimentel Stock Purchase Agreement, as amended and the exchange was effectuated on August 31, 2015. We filed a "resale" registration statement to register 200,000 of shares issued to Dr. Pimentel, which was declared effective by the SEC on October 15, 2015.

The CSMC License Agreement terminates: (i) automatically if SYN Biomics enters into a liquidating bankruptcy or other specified bankruptcy event or if the performance of any term, covenant, condition or provision of the CSMC License Agreement will jeopardize the licensure of CMSC, its participation in certain reimbursement programs, its full accreditation by the Joint Commission of Accreditation of Healthcare Organizations or any similar state organizations, its tax exempt status or is deemed illegal; (ii) upon 30 days' notice from CMSC if SYN Biomics fails to make a payment or use commercially reasonable efforts to exploit the patent rights; (iii) upon 60 days' notice from CMSC if SYN Biomics fails to cure any breach or default of any material obligations under the CSMC License Agreement; or (iv) upon 90 days' notice from SYN Biomics if CMCS fails to cure any breach or default of any material obligations under the CSMC License Agreement. SYN Biomics also has the right to terminate the License Agreement without cause upon 6 months' notice to CSMC; however, upon such termination, SYN Biomics is obligated to pay a termination fee with the amount of such fee reduced: (i) if such termination occurs after an IND submission to the FDA but prior to completion of a Phase 2 clinical trial, (ii) reduced further if such termination occurs after completion of Phase 2 clinical trial but prior to completion of a Phase 3 clinical trial; and (iii) reduced to zero if such termination occurs after completion of a Phase 3 clinical trial.

The University of Texas at Austin License Agreement and Sponsored Research Agreement

On December 19, 2012, we entered into a Patent License Agreement (the "Texas License Agreement") with The University of Texas at Austin (the "University") for the exclusive license of the right to use, develop, manufacture, market and commercialize certain research and patents related to pertussis antibodies developed in the lab of Dr. Jennifer A. Maynard, Associate Professor of Chemical Engineering. In accordance with the terms of the Texas License Agreement we made the following payments to the University: a payment of past patent expenses, an annual payment of $50,000 per year commencing on the effective date through December 31, 2014 and a $25,000 payment on December 31, 2015. The Texas License Agreement also provides that the University is entitled to milestone payments of $50,000 upon commencement of Phase 1 Clinical Trials, $100,000 upon commencement of Phase 3 Clinical Trials, $250,000 upon NDA submission in the United States, $100,000 upon European Medicines Agency approval and $100,000 upon regulatory approval in an Asian country. In addition, the University is entitled to a running royalty upon Net Product Sales and Net Service Sales (as defined in the Texas License Agreement). The License Agreement terminates upon the expiration of the patent rights (as defined in the Texas License Agreement); provided, however that the Texas License Agreement is subject to early termination by us in our discretion and by the University for a breach of the Texas License Agreement by us.

In connection with the Texas License Agreement, we also entered into a Sponsored Research Agreement (the "Sponsored Research Agreement") with the University pursuant to which the University will perform certain research work related to pertussis under the direction of Dr. Jennifer Maynard. All inventions conceived during such research shall be subject to the Texas License Agreement and we will obtain certain rights to patents and technology developed during the course of such research. We paid the University a fixed fee for the first year of $303,287 and the second and third years of $316,438 and $328,758, respectively. The Sponsored Research Agreement was amended on October 22, 2015, to extend its termination date to January 15, 2017 and again on September 2, 2016 to extend the agreement until January 15, 2018; provided, however, the Sponsored Research Agreement is subject to early termination upon the written agreement of the parties, a default in the material obligations under the Sponsored

Research Agreement which remain uncured for sixty days after receipt of notice, automatically upon our bankruptcy or insolvency and by us in our sole discretion at any time after the one year anniversary of the date of execution thereof upon no less than 90 days' notice. Upon a termination after December 31, 2014 or due to a breach by the University, we shall only be responsible for all reasonable expenses that do not exceed the fixed annual amount and that are incurred by the University prior to the termination date for services performed prior to the termination date.

We have an issued U.S. patent and patents pending on compositions and uses of SYN-005 that are co-owned UT and ourselves or licensed to us, and we have an issued U.S. patent and patent applications on other pertussis mAbs licensed from UT.

Oral Enzyme for C. difficile Program Acquisition Agreement

On November 8, 2012, we entered into an Asset Purchase Agreement (the "Prev Agreement") with Prev ABR LLC ("Prev"), and subsequently closed the transaction on November 28, 2012. Pursuant to the Prev Agreement we acquired the *C. difficile* program assets of Prev, including pre-IND package for P3A (SYN-004), Phase 1 and Phase 2 clinical data for P1A, manufacturing processes and data, and a portfolio of issued and pending U.S. and international patents intended to support an IND and BLA with the FDA. Pursuant to the Prev Agreement, we paid Prev an initial cash payment of $100,000 upon execution of the Prev Agreement and at closing paid an additional cash payment of $135,000 and issued 625,000 unregistered shares of our common stock to Prev. In addition, upon the achievement of the milestones set forth below, Prev may be entitled to receive additional consideration payable 50% in cash and 50% in our stock, subject to Prev's option to receive the entire payment in shares of our stock: (i) upon commencement of an IND; (ii) upon commencement of a Phase 1 clinical trial; (iii) upon commencement of a Phase 2 clinical trial; (iv) upon commencement of a Phase 3 clinical trial; (v) upon Biologic License Application (BLA) filing in the U.S. and for territories outside of the U.S. (as defined in the Prev Agreement); and (vi) upon BLA approval in the U.S. and upon approval in territories outside the U.S. As of December 31, 2015, the first three milestones have been met, and at Prev's option, Prev elected to receive 655,321 shares of the Company's common stock. The future stock issuances are subject to prior approval of the NYSE MKT, LLC. No royalties are payable to Prev under the Prev Agreement.

Infectious Disease Collaboration with Intrexon Corporation

On August 6, 2012, we expanded our relationship with Intrexon and entered into an Exclusive Channel Collaboration ("ECC") with Intrexon (the "Infectious Disease ECC") that governs a "channel collaboration" arrangement in which we intend to use Intrexon's technology relating to the identification, design and production of human antibodies and DNA vectors for the development and commercialization of a series of monoclonal antibody therapies for the treatment of pertussis (the "Field') . Such license is exclusive with respect to any clinical development, selling, offering for sale or other commercialization of our products within the Field ("Synthetic Products"), and otherwise is non-exclusive. We may not sublicense the rights described without Intrexon's written consent. Under the Infectious Disease ECC, and subject to certain exceptions, we are responsible for, among other things, the performance of the Program including the development, commercialization and manufacturing of products.

Subject to certain expense allocations and other offsets provided in the Infectious Disease ECC, we will pay Intrexon royalties on annual net sales of the Synthetic Products, calculated on a Synthetic Product-by-Synthetic Product basis. We have likewise agreed to pay Intrexon a percentage of quarterly revenue obtained from a sublicensor in the event of a sublicensing arrangement.

We may voluntarily terminate the Infectious Disease ECC upon 90 days written notice to Intrexon. Intrexon may also terminate the Infectious Disease ECC if we elect not to pursue the development of a Program identified by Intrexon that is a "Superior Therapy" as defined in the Infectious Disease ECC upon 60 days' notice unless we remedy the circumstances giving rise to the termination during such notice period. Each party has the right to terminate the agreement upon 60 days' notice if the other party commits a material breach of the Infectious Disease ECC, subject to certain cure periods.

Upon termination of the Infectious Disease ECC, we may continue to develop and commercialize any Synthetic Product that, at the time of termination satisfies one of the following:

·is being commercialized by us;

·has received regulatory approval;

·is a subject of an application for regulatory approval that is pending before the applicable regulatory authority;

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is a subject of at least a Phase 2 or Phase 3 clinical trial if such termination is by Intrexon due to a material breach by us of the Infectious Disease ECC or by us upon 60 days' notice after the first 18 months.

Our obligation to pay the royalties described above with respect to these "retained" products will survive termination of the Infectious Disease ECC.

On October 16, 2012, we issued 3,552,210 shares of our Common Stock as consideration in connection with the Infectious Disease ECC and the related Stock Issuance Agreement with Intrexon that we entered into on August 6, 2012 (the "Second Stock Issuance Agreement").

We also agreed upon the filing of an IND application with the FDA for a Synthetic Product, or alternatively the filing of the first equivalent regulatory filing with a foreign regulatory agency (both as applicable, the "IND Milestone Event"), to pay Intrexon either (i) $2.0 million in cash, or (ii) that number of shares of Common Stock (the "IND Milestone Shares") having a fair market value equaling $2.0 million where such fair market value is determined using published market data of the share price for Common Stock at the close of market on the business day immediately preceding the date of public announcement of attainment of the IND Milestone Event.

Upon the first to occur of either first commercial sale of a Synthetic Product in a country or the granting of the regulatory approval of that Synthetic Product (both as applicable, the "Approval Milestone Event"), we agreed to pay to Intrexon either (i) $3.0 million in cash, or (ii) that number of shares of Common Stock (the "Approval Milestone Shares") having a fair market value equaling $3.0 million where such fair market value is determined using published market data of the share price for Common Stock at the close of market on the business day immediately preceding the date of public announcement of attainment of the Approval Milestone Event.

In connection with the transactions contemplated by the Second Stock Issuance Agreement, and pursuant to the First Amendment to Registration Rights Agreement executed and delivered by the parties at the closing, we filed a "resale" registration statement registering the resale of certain of the shares issued under the Second Stock Issuance Agreement.

McLean Hospital Exclusive License Agreement and Meda AB Sublicense Agreement

In 2005, as amended in 2007 and 2010, we entered into an exclusive license agreement with the McLean Hospital, a Harvard University teaching hospital, relating to U.S. Patent No. 6,610,324 and its foreign equivalents, entitled "Flupirtine in the treatment of fibromyalgia and related conditions." Effective May 6, 2010, we entered into a Sublicense Agreement with Meda AB of Sweden. Pursuant to this agreement, Meda has been granted an exclusive sublicense to all of our patents covering the use of oral flupirtine for fibromyalgia. These patents have been issued in the U.S. and are pending in Canada and Japan. 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.

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The Regents of University of California License Agreement

On February 1, 2016, our subsidiary, Putney Drug, Inc. provided written notice to the Regents that we were terminating our (i) License Agreement and (ii) (collectively, the "CTA"). Pursuant to the terms of the License Agreement, Putney Drug, had licensed from the Regents certain U.S. patents for multiple sclerosis therapy related to our drug candidate Trimesta and Trimesta-combination therapies. Based upon the independent third party analysis of the investigator-sponsored Phase 2 clinical trial that evaluated Trimesta as a treatment for RRMS in women, it was determined that the License Agreement and the CTA should be terminated. In accordance with the termination provisions of the License Agreement and the CTA, the terminations were effective May 2, 2016.

Manufacturing

Our product candidates are biologics and small molecules that can be readily synthesized by processes that we have developed. We do not own or operate manufacturing facilities for the production of our product candidates for preclinical and clinical quantities. We rely on third-party contract manufacturers, and in most cases only one third-party, to manufacture critical raw materials, drug substance and final drug product for our research, preclinical development and clinical trial activities. Commercial quantities of any drugs we seek to develop will have to be manufactured in facilities and by processes that comply with the FDA and other regulations, and we plan to rely on third parties to manufacture commercial quantities of products we successfully develop.

Research and Development

During the years ended December 31, 2016, 2015 and 2014, we incurred approximately $29.1 million, $32.9 million and $14.5 million, respectively, in research and development expenses.

Government Regulation

In the U.S., the formulation, manufacturing, packaging, storing, labeling, promotion, advertising, distribution and sale of our products are subject to regulation by various governmental agencies, including primarily the FDA. Our proposed activities may also be regulated by various agencies of the states, localities and foreign countries in which our proposed products may be manufactured, distributed and sold. The FDA, in particular, regulates the formulation, manufacture and labeling of prescription drugs, such as those that we intend to distribute. FDA regulations require us and our suppliers to meet relevant cGMP regulations for the preparation, packing, labeling, and storage of all drugs.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing FDA regulation, including record-keeping requirements, reporting of adverse experiences, submitting periodic reports, drug sampling and distribution requirements, manufacturing or labeling changes, record-keeping requirements, and compliance with FDA promotion and advertising requirements. Drug manufacturers and their subcontractors are required to register their facilities with the FDA and state agencies, and are subject to periodic unannounced inspections for GMP compliance, imposing procedural and documentation requirements upon us and third-party manufacturers. Failure to comply with these regulations could result, among other things, in suspension of regulatory approval, recalls, suspension of production or injunctions, seizures, or civil or criminal sanctions. We cannot be certain that we or our present or future subcontractors will be able to comply with these regulations.

The FDA regulates prescription drug labeling and promotion activities. The FDA actively enforces regulations prohibiting the marketing of products for unapproved uses. The FDA permits the promotion of drugs for unapproved uses in certain circumstances, subject to stringent requirements. We and our product candidates are subject to a variety of state laws and regulations which may hinder our ability to market our products. Whether or not FDA approval has been obtained, approval by foreign regulatory authorities must be obtained prior to commencing clinical trials, and sales and marketing efforts in those countries. These approval procedures vary in complexity from country to country, and the processes may be longer or shorter than that required for FDA approval. We may incur significant costs to comply with these laws and regulations now or in the future.

The FDA, comparable foreign regulators and state and local pharmacy regulators impose substantial requirements upon clinical development, manufacture and marketing of pharmaceutical products. These and other entities regulate research and development and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising, and promotion of our products. The drug approval process required by the FDA under the Food, Drug, and Cosmetic Act generally involves:

·preclinical laboratory and animal tests;

·submission of an IND, prior to commencing human clinical trials;

·adequate and well-controlled human clinical trials to establish safety and efficacy for intended use;

·submission to the FDA of an NDA or BLA; and

·FDA review and approval of an NDA or BLA.

The testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approval will be granted on a timely basis, if at all.

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Preclinical tests include laboratory evaluation of the product candidate, its chemistry, formulation and stability, and animal studies to assess potential safety and efficacy. Certain preclinical tests must be conducted in compliance with good laboratory practice regulations. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring them to be replicated. In some cases, long-term preclinical studies are conducted concurrently with clinical studies.

We will submit the preclinical test results, together with manufacturing information and analytical data, to the FDA as part of an IND, which must become effective before we begin human clinical trials. The IND automatically becomes effective 30 days after filing, unless the FDA raises questions about conduct of the trials outlined in the IND and imposes a clinical hold, in which case, the IND sponsor and FDA must resolve the matters before clinical trials can begin. It is possible that our submission may not result in FDA authorization to commence clinical trials.

Clinical trials must be supervised by qualified investigators in accordance with good clinical practice (GCP) regulations, which include informed consent requirements. Each study must be approved and monitored by the appropriate Institutional Review Boards (IRBs) which are periodically informed of the study's progress, adverse events and changes in research. Annual updates are submitted to the FDA and more frequently if certain serious adverse events occur.

Human clinical trials of drug candidates typically have three sequential phases that may overlap:

Phase 1: The drug is initially tested in healthy human subjects or patients for safety, dosage tolerance, absorption, metabolism, distribution, and excretion.

Phase 2: The drug is studied in a limited patient population to identify possible adverse effects and safety risks, determine efficacy for specific diseases and establish dosage tolerance and optimal dosage.

Phase 3: When Phase 2 evaluations demonstrate that a dosage range is effective with an acceptable safety profile, Phase 3 trials to further evaluate dosage, clinical efficacy and safety, are undertaken in an expanded patient population, often at geographically dispersed sites.

We cannot be certain that we will successfully complete Phase 1, Phase 2, or Phase 3 testing of our product candidates within any specific time period, if at all. Furthermore, the FDA, an IRB or the IND sponsor may suspend clinical trials at any time on various grounds, including a finding that subjects or patients are exposed to unacceptable health risk.

Under the Pediatric Research Equity Act, we also must prepare, within 60 days of an End of Phase 2 meeting, a pediatric study plan or request for waiver or deferral of pediatric studies in the indication under development. Concurrent with these trials and studies, we also develop chemistry and physical characteristics data and finalize a manufacturing process in accordance with cGMP requirements. The manufacturing process must conform to consistency and quality standards, and we must develop methods for testing the quality, purity, and potency of the final products. Appropriate packaging is selected and tested, and chemistry stability studies are conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life. Results of the foregoing are submitted to the FDA as part of a NDA (or BLA in case of biologic products) for marketing and commercial shipment approval. The FDA reviews each NDA or BLA submitted and may request additional information. A sixty day period after the sponsor's submission of an NDA or BLA is used by the FDA to determine whether the application is sufficiently complete to permit substantive review, in which case the application is accepted for filing.

Once the FDA accepts the NDA or BLA for filing, it begins its in-depth review. The FDA has substantial discretion in the approval process and may disagree with our interpretation of the data submitted or identify new concerns. The process may be significantly extended by requests for new information or clarification of information already submitted. As part of this review, the FDA may refer the application to an advisory committee, typically a panel of clinicians. Manufacturing establishments often are inspected prior to NDA or BLA approval to assure compliance with GMPs and with manufacturing commitments made in the application.

Submission of an NDA or BLA with clinical data requires payment of a substantial fee. In return, the FDA assigns a goal for review and decision on the application, in which the FDA may approve or deny the NDA or BLA, or issue a complete response letter outlining information needed to support approval, including a potential need for additional clinical data. Even if these data are submitted, the FDA may ultimately decide the NDA or BLA does not satisfy approval criteria. If the FDA approves the NDA or BLA, the product becomes available for marketing. Product approval may be withdrawn if regulatory compliance is not maintained or safety problems occur. The FDA may require post-marketing studies, also known as Phase 4 studies, as a condition of approval, and Risk Evaluation and Mitigation Strategies (REMS) requires surveillance programs to monitor approved products that have been commercialized. The agency has the power to require changes in labeling or prohibit further marketing based on the results of post-marketing surveillance.

Satisfaction of these and other regulatory requirements typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures on our activities. We cannot be certain that the FDA or other regulatory agencies will approve any of our products on a timely basis, if at all. Success in preclinical or early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from preclinical and clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications or uses.

Even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain regulatory approvals would have a material adverse effect on our business.

The FDA's policies may change, and additional government regulations may be enacted which could prevent or delay regulatory approval of our potential products. Increased attention to the containment of health care costs worldwide could result in new government regulations materially adverse to our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

Section 505(b)(2) NDAs

NDAs for most new drug products generally are based on two full clinical studies which must contain substantial evidence of the safety and efficacy of the proposed new product. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the applicant to rely, in part, on the FDA's previous findings of safety and efficacy for the active moiety, or published literature, where such studies were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. We believe that we will be able to utilize the regulatory approval pathway provided in Section 505(b)(2) of the FDCA for SYN-010.

Orphan Drug Act

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the name of the sponsor, identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not shorten the duration of the regulatory review or approval process, but does provide certain advantages, such as a waiver of Prescription Drug User Fee Act, or PDUFA, fees, enhanced access to FDA staff and potential waiver of pediatric research requirements.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the application user fee. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Other Healthcare Laws and Compliance Requirements

In the United States, the research, manufacturing, distribution, sale and promotion of drug products and medical devices are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the U.S. Department of Justice, state Attorneys General, and other state and local government agencies. The federal Anti-Kickback Statute prohibits any person, including a prescription drug manufacturer (or a party acting on its behalf), from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce or reward either the referral of an individual, or the furnishing, recommending or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. The federal False Claims Act imposes liability on any person or entity that, among other things, knowingly presents or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In addition, various states have enacted anti-kickback statues and false claims laws analogous to the False Claims Act. Also, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) created several federal crimes, including healthcare fraud, and false statements relating to the delivery of or payments for healthcare benefits, items or services. HIPAA and its implementing regulations also established uniform federal standards for certain “covered entities” (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information.

Because of the breadth of these and other laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private "qui tam" actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Competitive Environment

The pharmaceutical and biotechnology industries 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 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. 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.

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.

Corporate History

Our predecessor, Sheffield Pharmaceuticals, Inc., was incorporated in 1986, and in 2006 engaged in a reverse merger with Pipex Therapeutics, Inc., a publicly-traded 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. On February 15, 2012, we changed our name to Synthetic Biologics, Inc.

Employees

As of February 28, 2017, we employed approximately 30 individuals, 28 of whom are full-time employees. A significant number of our management and professional employees have had prior experience with pharmaceutical, biotechnology or medical product companies. None of our employees are covered by collective bargaining agreements, and management considers relations with our employees to be good.

Properties

Our principal executive offices are located at 9605 Medical Center Drive, Suite 270, Rockville, Maryland 20850.

Available Information

Additional information about Synthetic Biologics is contained at our website, *www.syntheticbiologics.com.* Information contained on our website is not incorporated by reference into, and does not form any part of, this Annual Report on Form 10-K. We have included our website address as a factual reference and do not intend it to be an active link to our website. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act are available free of charge through the investor relations page of our internet website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The following Corporate Governance documents are also posted on our website: Code of Conduct, Code of Ethics for Financial Management and the Charters for the Audit Committee, Compensation Committee and Nominations Committee of the Board of Directors. Our phone number is (301) 417-4364 and our facsimile number is (301) 417-4367.

Item 1A. ***Risk Factors***

Investing in our securities involves a high degree of risk. In addition to the risks related to our business set forth in this Form 10-K and the other information included in this Form 10-K, you should carefully consider the risks described below before purchasing our securities. Additional risks, uncertainties and other factors not presently known to us or that we currently deem immaterial may also impair our business operations.

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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 year ended December 31, 2016, our operating activities used net cash of approximately $27.9 million and as of December 31, 2016 our cash and cash equivalents were $19.1 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 December 31, 2016, our accumulated deficit totaled approximately $172.0 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 ongoing 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 fees and grants.

We will need to raise additional capital to fund our operations and in order to 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 will not be sufficient to enable us to meet our near term expected plans. 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. If we do not succeed in raising additional funds in the next few months on acceptable terms, we will most likely be forced to delay the initiation of our planned clinical trials until such time as we obtain adequate financing. A failure otherwise to raise additional funds when needed in the future could result is 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. 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 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 independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.

Our consolidated financial statements as of December 31, 2016 have been prepared under the assumption that we will continue as a going concern for the next twelve months. 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, 2016 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-010 and SYN-004 (ribaxamase), 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-010 and SYN-004, which are our only two product candidates for which we have conducted clinical trials. Even though we are pursuing a registration pathway based on specific FDA input, there are many uncertainties known and unknown that may affect the outcome of the trial. 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 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 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 The University of Texas allows the University 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 and SYN 010, 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 and SYN-010. In addition, we have commenced manufacturing of SYN-004 and SYN-010 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 products and our other technologies. Should clinicians or regulatory authorities view alternative therapeutic regiments 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 only one manufacturer for each of our lead product candidates. Although, we believe additional manufacturers are available, if either 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. 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 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. Furthermore, 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. 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. 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. For example, 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.

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.

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 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 payers, 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 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 February 28, 2017, we employed approximately 30 individuals, 28 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 30 employees as of February 28, 2017. 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. Over the next several months we plan to add additional employees to assist us with our commercial programs. 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 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 COMMON STOCK AND WARRANTS

We expect to seek to raise additional capital in the future, which may be dilutive to stockholders or impose operational restrictions.

We expect to seek to raise additional capital in the future to help fund development of our proposed products. If we raise additional capital through the issuance of equity or of debt securities, the percentage ownership of our current stockholders will be reduced. We may also enter into strategic transactions, issue equity as part of license issue fees to our licensors, compensate consultants or settle outstanding payables using equity that may be dilutive. Our stockholders may experience additional dilution in net book value per share and any additional equity securities may have rights, preferences and privileges senior to those of the holders of our common stock.

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share paid by existing stockholders, thereby subjecting such stockholders to dilution. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by existing stockholders, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by existing stockholders.

Our principal stockholder has the ability to influence the vote on matters submitted to our stockholders and subsequent sales by such stockholder could adversely affect the market for our stock.

Through Intrexon and NRM VII Holdings I, LLC, Randal J. Kirk indirectly, beneficially owns approximately 13.2 million shares of our common stock as of December 31, 2016, or 11.3% of outstanding shares at such date. As a result, he will be able to exert influence over issues submitted to our stockholders, including the election of our Board of Directors and the vote on issues. The sale of a number of shares by our principal stockholder could have an adverse effect on the market for our stock and our share price.

Holders of our warrants issued in our October 2014 and November 2016 offering have no rights as common stockholders until they exercise their warrants and acquire our common stock and limited liquidity for the warrants.

Until the holders of the warrants we issued in our October 2014 and November 2016 offering acquire shares of our common stock by exercising their warrants, the holders have no rights as a stockholder with respect to the shares of common stock underlying their warrants. Upon exercise of the warrants, 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 warrants we issued, the liquidity of the warrants is limited. We do not expect a market to develop, nor do we intend to apply to list the warrants on any securities exchange. Upon exercise of the warrants, 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.

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

Whether the outstanding warrants will have any value will depend on the results of certain of our clinical trials as well as market conditions for our common stock generally, 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, holder of warrants will be unable to recover any of their investment in the warrants. 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 ability to repurchase the 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 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.

We cannot assure you that the common stock will be liquid or that it will remain listed on the NYSE MKT.

Our common stock is listed on the NYSE MKT. Although we currently meet the NYSE MKT's listing standards, which generally mandate that we meet certain requirements relating to stockholders' equity, 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 MKT. The NYSE MKT 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 fiscal years, as outlined in the NYSE MKT Exchange Company Guide. At December 31, 2016, we had stockholders' equity of $2.3 million. The NYSE MKT Exchange 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 the total value of our market capitalization exceeds $50.0 million and we have 1,100,000 shares publicly held, a market value of publicly held shares of at least $15.0 million and 400 round lot shareholders, there can be no assurance that the NYSE MKT will continue to list our common stock if we should 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 MKT. If we are delisted from the NYSE MKT 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. 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 MKT 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.

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 Although we currently do not have preferred shares outstanding, the Board of Directors could authorize the issuance of a 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 preferred stock, the rights of holders of common stock could be impaired thereby, including without limitation, with respect

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.

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

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

Resales of our common stock in the public market 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 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 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.

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties***

Our corporate headquarters are located in Rockville, Maryland, where we occupy approximately 10,363 square feet of office space under a lease agreement expiring July 31, 2022, with monthly rent of $23,820.

We do not own any real property. We believe that we have adequate space for our anticipated needs and that suitable additional space will be available at commercially reasonable prices as needed.

Item 3. ***Legal Proceedings***

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. ***Mine Safety Disclosures***

Not applicable.

PART II

Item 5. ***Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Our common stock has traded on the NYSE MKT, LLC 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 per share of our common stock as reported on the NYSE MKT, LLC for each of the calendar quarters during the years ended December 31, 2016 and December 31, 2015. The last price of our common stock as reported on the NYSE MKT, LLC on February 28, 2016 was $0.79 per share.

	High	Low
YEAR ENDED DECEMBER 31, 2016		
Fourth quarter	$1.77	$0.76
Third quarter	$1.91	$1.57
Second quarter	$2.73	$1.64
First quarter	$2.36	$1.01
YEAR ENDED DECEMBER 31, 2015		
Fourth quarter	$3.04	$2.08
Third quarter	$4.00	$2.07
Second quarter	$2.88	$1.84
First quarter	$3.00	$1.52

Dividend Policy

We have never paid or declared any cash dividends on our common stock to date, and do not anticipate paying such cash dividends in the foreseeable future. Whether we declare and pay dividends is determined by our Board of Directors at their discretion, subject to certain limitations imposed under Nevada corporate law. The timing, amount and form of dividends, if any, will depend on, among other things, our results of operations, financial condition, cash requirements and other factors deemed relevant by our Board of Directors.

Holders

As of February 28, 2017, we had approximately 344 stockholders of record of our common stock. This number does not include stockholders for whom shares are held in a "nominee" or "street" name.

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Stock Performance Graph

The following line graph and table compare changes in the cumulative total stockholder return for our common stock during the period from December 31, 2011 through December 31, 2016 in comparison to a major market index (the NASDAQ Composite Index) and a sub-index (the NASDAQ Biotechnology Index). The graph and table below assume (i) that $100 was invested at market close on December 31, 2011 in our common stock and in each of the NASDAQ Composite Index and the NASDAQ Biotechnology Index, and (ii) the reinvestment of dividends. The comparisons in the graph and table are required by the SEC and are not intended to be indicative of the possible future performance of our common stock.

ASSUMES $100 INVESTED ON DEC. 30, 2011

ASSUMES DIVIDENDS REINVESTED

FISCAL YEAR ENDING DEC. 31

	12/31/2011	12/31/2012	12/31/2013	12/31/2014	12/31/2015	12/31/2016
Synthetic Biologics, Inc.	100.00	139.68	121.43	115.87	181.75	60.52
NASDAQ Composite	100.00	116.41	165.47	188.69	200.32	216.54
NASDAQ Biotechnology	100.00	134.68	232.37	307.67	328.76	262.08

Equity Compensation Plan Information

See Item 12 under the heading “Equity Compensation Plan Information” of this Annual Report on Form 10-K for equity compensation plan information.

Recent Sales of Unregistered Securities

We did not sell any equity securities during the year ended December 31, 2016 in transactions that were not registered under the Securities Act, other than as previously disclosed in our filings with the Securities and Exchange Commission.

Issuer Purchases of Equity Securities

There were no issuer purchases of equity securities during the year ended December 31, 2016.

Item 6. ***Selected Financial Data***

The following table sets forth our selected consolidated financial data for the periods and as of the dates indicated. You should read the following selected consolidated financial data in conjunction with our audited consolidated financial statements and the related notes thereto included elsewhere in this Annual Report on Form 10-K and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this Annual Report on Form 10-K.

The consolidated statement of operations data for the years ended December 31, 2016, 2015 and 2014, and the consolidated balance sheet data as of December 31, 2016 2015, are derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Our audited consolidated financial statements have been prepared in U.S. dollars in accordance with U.S. GAAP.

Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our results for any interim period are not necessarily indicative of results to be expected for a full fiscal year.

	For the years ended December 31,				
	2016	2015	2014	2013	2012
	(in thousands, except per share)				
Consolidated Statement of Operations Data:					
Operating Costs and Expenses:					
General and administrative	$10,143	$8,074	$6,013	$5,832	$5,012

Research and development	29,109	32,906	14,489	6,507	12,287
Total Operating Costs and Expenses	39,252	40,980	20,502	12,339	17,299
Loss from Operations	(39,252)	(40,980)	(20,502)	(12,339)	(17,299)
Other Income (Expense):					
Change in fair value of warrant liability	11,412	(3,811)	620	—	—
Other income (expense)	—	—	95	(12)	(18)
Interest income	37	6	3	33	33
Total Other Income (Expense)	11,449	(3,805)	718	21	15
Loss from Continuing Operations	(27,803)	(44,785)	(19,784)	(12,318)	(17,284)
Loss from Discontinued Operations	—	—	—	—	216
Net Loss	(27,803)	(44,785)	(19,784)	(12,318)	(17,068)
Net Loss Attributable to Non-controlling Interest	(548)	(1,048)	—	(1)	—
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$(27,255)	$(43,737)	$(19,784)	$(12,317)	$(17,068)
Loss Per Share – Basic and Dilutive					
Continuing operations	$(0.29)	$(0.54)	$(0.32)	$(0.27)	$(0.50)
Discontinued operations	—	—	—	—	0.01
Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$(0.29)	$(0.54)	$(0.32)	$(0.27)	$(0.49)
Weighted average number of shares outstanding during the period – Basic and Dilutive	94,290,436	80,705,692	61,945,356	45,667,813	34,896,592

	As of December 31,				
	2016	2015	2014	2013	2012
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$19,055	$20,818	$17,525	$14,625	$9,954
Working capital	$1,814	$14,762	$9,485	$15,189	$12,068
Total assets	$22,498	$30,845	$19,144	$16,257	$13,423
Accumulated deficit	$(172,034)	$(144,779)	$(101,042)	$(81,258)	$(68,941)
Total stockholders equity	$2,250	$15,845	$9,556	$15,230	$13,028

Item 7. ***Management's Discussion and Analysis of Financial Condition and Results of Operations***

The following discussion of our financial condition and results of operations should be read in conjunction with our audited financial statements and notes thereto for the year ended December 31, 2016 included elsewhere in this Annual Report. In addition to historical information, the following discussion contains certain forward-looking statements that involve risks, uncertainties and assumptions. Where possible, we have tried to identify these forward looking statements by using words such as "anticipate," "believe," "intends," or similar expressions. Our actual results could differ materially from those expressed or implied by the forward-looking statements due to important factors and risks including, but not limited to, those set forth under "Risk Factors" in Part I, Item 1A of this Annual Report.

Overview

We are a late-stage clinical stage 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-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), and (2) 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), antibiotic-associated diarrhea (AAD) and the emergence of antimicrobial resistance (AMR). We are also developing preclinical stage monoclonal antibody therapies for the prevention and treatment of pertussis, and novel discovery stage biotherapeutics for the treatment of phenylketonuria (PKU).

Product Pipeline:

* Two Phase 2 studies completed. Planning a Phase 2b/3 pivotal trial

C- Cedars-Sinai Medical Center Collaboration

I-Intrexon Collaboration

T- The University of Texas at Austin Collaboration

Summary of Clinical and Preclinical Programs

Therapeutic Area	Product Candidate	Status
Treatment of IBS-C	SYN-010 (oral modified-release lovastatin lactone)	· Reported supportive topline data from two Phase 2 clinical trials (4Q 2015 & 1Q 2016) · Received Type C meeting responses from U.S. Food and Drug Administration (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 Digestive Disease Week Conference 2016 (DDW) (May 2016) · 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) · Plan to initiate first Phase 2b/3 pivotal adaptive clinical trial (2017) · Collaboration with Cedars-Sinai Medical Center
Prevention of CDI and AAD (Degrade IV beta-lactam antibiotics)	SYN-004 (ribaxamase) (oral enzyme)	· Reported supportive Phase 1a/1b data (1Q 2015) · Initiated Phase 2b proof-of-concept clinical trial (3Q 2015) · Reported supportive topline data from first Phase 2a clinical trial (4Q 2015) · Reported supportive topline data from second Phase 2a clinical trial (2Q 2016) · 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 Centers for Disease Control and Prevention (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) · Plan to initiate Phase 3 clinical trial(s) (1H 2018)
Prevention of CDI and AAD (Degrade oral beta-lactam antibiotics)	SYN-007 (oral enzyme)	· Preclinical work ongoing to determine ability of SYN-007 to protect the gut microbiome and degrade oral beta-lactam antibiotics
Prevention and Treatment of pertussis	SYN-005 (monoclonal antibody therapies)	· 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) · Collaborations with Intrexon and UT Austin

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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. In total, we hold approximately 100 U.S. and foreign patents and have over 55 U.S. and foreign patents pending.

Recent Developments

Clinical Developments

On January 18, 2017, and in accordance with guidance from the FDA, we confirmed our plan to conduct a Phase 2b/3 adaptive design study for our first pivotal trial of SYN-010 which we plan to initiate during 2017.

In accordance with collaborative discussions with the FDA, key components of the SYN-010 Phase 2b/3 adaptive pivotal trial will include:

- A 12-week, multi-center, double-blind, placebo-controlled, adaptive design clinical trial
- A study population of approximately 840 adult subjects diagnosed with IBS-C
- Evaluation of efficacy and safety of two dose strengths of SYN-010 (21 mg and 42 mg) compared to placebo
- Conducted in approximately 150 clinical sites in North America
- Study subjects will be randomized in a 1:1:1 ratio, receiving either 21 mg of SYN-010, 42 mg of SYN-010, or placebo
- Enrollment is open to all IBS-C patients; breath-methane will be measured at baseline to ensure a comparable ratio of high-to-low breath methane IBS-C patients in each treatment arm
- An interim futility analysis may be conducted when approximately 50% of patients in each dosing arm have completed treatment

Consistent with FDA written guidance, the primary objective for this study is to determine the efficacy of SYN-010, measured as an improvement from baseline in the percentage of overall weekly responders[2] during the 12-week treatment period for SYN-010 21 mg and 42 mg daily doses compared to placebo. Secondary efficacy endpoints for both dose strengths of SYN-010 will measure changes from baseline in abdominal pain, bloating, bowel movement frequency and stool consistency. Exploratory outcomes include adequate relief and quality of life measures using the well-validated EQ-5D-5L and PAC-SYM patient questionnaires.

On January 5, 2017, we announced positive topline data from our Phase 2b clinical trial which completed enrollment in September 2016. Data from this clinical trial demonstrated SYN-004 (ribaxamase) achieved its primary endpoint of significantly reducing CDI. Preliminary analysis of the data indicated seven confirmed cases of CDI in the placebo group compared to two cases in the ribaxamase treatment group. Patients receiving ribaxamase achieved a 71.4% relative risk reduction (p-value=0.045) in CDI rates compared to patients receiving placebo. Adverse events reported during this trial were comparable between treatment and placebo arms.

Preliminary analysis of the data demonstrated a significant reduction in new colonization by vancomycin-resistant enterococci (VRE) and for patients receiving ribaxamase compared to placebo (p-value=0.0002). With agreement from the FDA, the study included a secondary endpoint to assess ribaxamase's capacity to decrease the incidence of antibiotic-associated diarrhea from all causes. Preliminary analysis of the data suggested a trend towards such a reduction (p-value=0.13), which was due, for the most part, to the reduction of CDI.

We are in the process of further analyzing data from this clinical trial and expect to share additional results from additional exploratory endpoints as they become available later this year, including results focused on ribaxamase's ability to prevent the emergence of antimicrobial resistance in the gut microbiome.

[2] An overall 12-week responder is defined as a subject with a weekly response in at least 50% of the weeks of treatment (6 of 12 weeks). Weekly Responder is defined as a patient who experiences a decrease in weekly average score for worst abdominal pain in the past 24 hours of at least 30% compared with Study 1 Baseline and a stool frequency increase of 1 or more CSBM per week compared with Study 1 Baseline.

On October 6, 2016, we announced the award of a government contract by the CDC's Broad Agency Announcement (BAA) 2016-N-17812 . The contract amount is up to $521,014. The award will support research conducted during our ongoing, randomized, placebo-controlled Phase 2b proof-of-concept clinical study of SYN-004 (ribaxamase) and the CDCs' efforts to assess how selective pressure from IV antibiotics may lead to the emergence of antibiotic resistance in the gut microbiome. The funding will also support research to evaluate SYN-004's (ribaxamase's) ability to reduce selective pressure associated with the emergence of antibiotic-resistant organisms in the gut microbiomes of patients enrolled in our Phase 2b clinical trial. We will examine DNA isolated from longitudinal samples obtained during the clinical trial and look for changes to the patient's gut resistome, specifically examining for alterations in the presence and/or abundance of antibiotic resistance genes.

Financial Developments

On November 18, 2016, we completed a public offering of 25 million shares of common stock in combination with accompanying warrants to purchase an aggregate of 50,000,000 shares of the common stock. The stock and warrants were being sold in combination with two warrants for each share of common stock sold, a Series A warrant and a Series B warrant, each representing the right to purchase one share of common stock. The purchase price for each share of common stock and accompanying warrants was $1.00. The shares of common stock were immediately separable from the warrants and were issued separately. The initial per share exercise price of the Series A warrants is $1.43 and the per share exercise price of the Series B warrants is $1.72, each subject to adjustment as specified in the warrants. The Series A and Series B warrants may be exercised at any time on or after the date of issuance. The Series A warrants are exercisable until the four year anniversary of the issuance date. The Series B warrants are exercisable until December 31, 2017. Net proceeds, after deducting underwriting discounts and estimated expenses were approximately $23.3 million.

On August 5, 2016, the Company entered into the FBR Sales Agreement with FBR Capital Markets & Co., which enables the Company to offer and sell shares of the Company's common stock with an aggregate sales price of up to $40.0 million, from time to time through FBR Capital Markets & Co. as the Company's sales agent. Sales of common stock under the FBR Sales Agreement are made in sales deemed to be "at-the-market" equity offerings as defined in Rule 415 promulgated under the Securities Act, as amended. FBR Capital Markets & Co. is entitled to receive a commission rate of up 3.0% of gross sales in connection with the sale of the Company's common stock sold on the Company's behalf. From August 11, 2016 through December 31, 2016, the Company had sold through the FBR Sales Agreement an aggregate of 900,628 shares of the Company's common stock, and received gross proceeds of approximately $1,550,197, before deducting issuance expenses

Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements in accordance with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, net revenues and expenses, and related disclosures. We believe our estimates and assumptions are reasonable; however, actual results and the timing of the recognition of such amounts could differ from these estimates.

There are accounting policies that we believe are significant to the presentation of our consolidated financial statements. The most significant accounting policies relate to stock-based compensation, revenue recognition and accounts receivable.

Stock-Based Compensation

Calculating stock-based compensation expense requires the input of highly subjective assumptions. We apply the Black-Scholes option pricing model to determine the fair value of our stock options. Inherent in this model are assumptions related to expected stock-price volatility, option life, risk-free interest rate and dividend yield. We estimate the volatility of our common stock at the date of grant based on historical volatility. We estimate the expected life of our option using the contractual term of the option. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected life of the options. The dividend rate is based on our historical rate, which we anticipate to remain at zero. The assumptions used in calculating the fair value of stock options represent our best estimates, however these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the stock-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those stock options expected to vest over the service period.

Warrants

We have issued common stock warrants in connection with the execution of certain equity financings. The fair value of certain warrants, deemed to be derivative instruments, is recorded as a derivative liability under the provisions of FASB ASC 815 Derivatives and Hedging (“ASC 815”) upon issuance. Subsequently the liability is adjusted to fair value as of each reporting period and the changes in fair value of derivative liabilities are recorded in the consolidated statement of operations under the caption “Change in fair value of derivative liabilities.”

The fair value of warrants deemed to be derivative instruments is determined using the Monte Carlo Simulation option-pricing models using varying assumptions regarding volatility of our common share price, remaining life of the warrant, and risk-free interest rates at each period end. We thus use model-derived valuations where significant value drivers are unobservable to third parties to determine the fair value and accordingly classify such warrants in Level 3 per ASC 820.

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Revenue Recognition

We record revenue when all of the following have occurred: (1) persuasive evidence of an arrangement exists, (2) the service is completed without further obligation, (3) the sales price to the customer is fixed or determinable, and (4) collectability is reasonably assured. We recognize milestone payments or upfront payments that have no contingencies as revenue when payment is received.

License Revenues

Our licensing agreements may contain multiple elements, such as non-refundable up-front fees, payments related to the achievement of particular milestones and royalties. Fees associated with substantive at risk performance-based milestones are specified in the agreement. When we have substantive continuing performance obligations under an arrangement, revenue is recognized over the performance period of the obligations using a time-based proportional performance approach. Under the time-based method, revenue is recognized over the arrangement's estimated performance period based on the elapsed time compared to the total estimated performance period. Revenue recognized at any point in time is limited to the amount of non-contingent payments received or due. When we have no substantive continuing performance obligations under an arrangement, we recognize revenue as the related fees become due.

Revenues from royalties on third-party sales of licensed technologies are generally recognized in accordance with the contract terms when the royalties can be reliably determined and collectability is reasonably assured.

Research and Development Costs

We expense research and development costs associated with developmental products not yet approved by the FDA to research and development expense as incurred. Research and development costs consist primarily of license fees (including upfront payments), milestone payments, manufacturing costs, salaries, stock-based compensation and related employee costs, fees paid to consultants and outside service providers for laboratory development, legal expenses resulting from intellectual property prosecution and other expenses relating to the design, development, testing and enhancement of our product candidates. Research and development expenses include external contract research organization ("CRO") services. We make payments to the CROs based on agreed upon terms and may include payments in advance of a study services. We review and accrue CRO expenses based on services performed and rely on estimates of those costs applicable to the stage of completion of study as provided by the CRO. Accrued CRO costs are subject to revisions as such studies progress to completion. We have accrued CRO expenses of $1.1 million and $2.2 million that are included in accounts payable and accrued expenses at December 31, 2016 and 2015. We have

prepaid CRO costs of $1.7 million and $8.3 million as of December 31, 2016 and 2015.

Results of Operations

Year Ended December 31, 2016, 2015 and 2014

General and Administrative Expenses

General and administrative expenses increased to $10.1 million for the year ended December 31, 2016, from $8.1 million for the year ended December 31, 2015. This increase of 20% is primarily the result of bank and legal fees related to the November 2016 financing associated with the warrant liability, increased employee costs, costs associated with the transition of the administrative and financial office to our Maryland headquarters, and an increase in stock-based compensation. The charge relating to stock-based compensation expense was $2.4 million for the year ended December 31, 2016, compared to $2.1 million for the year ended December 31, 2015.

General and administrative expenses increased to $8.1 million for the year ended December 31, 2015, from $6.0 million for the year ended December 31, 2014. This increase of 34% is primarily the result of increased employee costs, audit fees related to the additional procedures required under the accelerated filer status, legal fees associated with SEC filings and collaborative agreements and stock-based compensation expense. The charge relating to stock-based compensation expense was $2.1 million for the year ended December 31, 2015, compared to $1.6 million for the year ended December 31, 2014.

Research and Development Expenses

Research and development expenses decreased to $29.1 million for the year ended December 31, 2016, from $32.9 million for the year ended December 31, 2015. This decrease of 13% is primarily the result of decreased program costs associated with clinical development programs and research activities within our pathogen-specific microbiome-focused pipeline, including our IBS-C and Pertussis programs offset by an increase in *C. difficile* program costs and an increase in manufacturing expenses. In 2015, we entered into an ECC with Intrexon Corporation for the development of a treatment for patients with PKU. Pursuant to the ECC, we issued 937,500 shares of our common stock in August 2015 to Intrexon Corporation as payment of the technology access fee that resulted in a non-cash charge of $3.0 million. Research and development expenses for 2015 also include a $1.0 million non-cash expense for achieving the third milestone as set forth in the Asset Purchase Agreement with Prev ABR LLC, dated November 28, 2012. Prev ABR LLC exercised its option to receive the milestone payment in shares of our common stock that were issued in April 2015. Research and development expenses also include a charge relating to non-cash stock-based compensation expense of $1.6 million for the year ended December 31, 2016, compared to $1.1 million for the year ended December 31, 2015.

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Research and development expenses increased to $32.9 million for the year ended December 31, 2015, from $14.5 million for the year ended December 31, 2014. This increase of 127% is primarily the result of increased program costs associated with expanded clinical development programs, manufacturing and research activities within our pathogen-specific microbiome-focused pipeline, including our *C. difficile,* IBS-C and pertussis programs. In August 2015, we entered into an ECC with Intrexon Corporation for the development of a treatment for patients with PKU. Pursuant to the ECC, we issued 937,500 shares of our common stock to Intrexon Corporation as payment of the technology access fee that resulted in a non-cash charge of $3.0 million. Research and development expenses also include a $1.0 million non-cash expense for achieving the third milestone as set forth in the Asset Purchase Agreement with Prev ABR LLC, dated November 28, 2012. Prev ABR LLC exercised its option to receive the milestone payment in shares of our common stock that were issued in April 2015. Research and development expenses also include a charge relating to non-cash stock-based compensation expense of $1.1 million for the year ended December 31, 2015, compared to $803,000 for the year ended December 31, 2014.

The following table sets forth our research and development expenses directly related to our therapeutic areas for the year ended December 31, 2016, 2015 and 2014. These direct expenses were external costs associated with preclinical studies and clinical trials. Indirect research and development costs related to employee costs, facilities, manufacturing, stock-based compensation and research and development support services are not directly allocated to specific drug candidates.

Therapeutic Areas	December 31, 2016	December 31, 2015	December 31, 2014
SYN-004	$ 11,840	$ 11,608	$ 6,946
SYN-010	4,762	7,917	749
SYN-005	79	883	1,743
Other therapeutic areas	99	527	791
Total direct costs	16,780	20,935	10,229
Total indirect costs	12,329	11,971	4,260
Total Research and development	$ 29,109	$ 32,906	$ 14,489

Other Income (Expense)

Other income was $11.4 million for the year ended December 31 2016, compared to other expense of $3.8 million for the year ended December 31, 2015. Other income for the year ended December 31, 2016 is primarily due to non-cash income of $11.4 million from the change in fair value of warrants. The decrease in the fair value of the warrants was due to the decrease in our stock price from the year ended December 31, 2015.

Other expense was $3.8 million for the year ended December 31 2015, compared to other income of $718,000 for the year ended December 31, 2014. Other expense for the year ended December 31, 2015 is primarily due to non-cash expense of $3.8 million from the change in fair value of warrants. The increase in the fair value of the warrants was

due to the increase in our stock price from the year ended December 31, 2014.

Net Loss

Our net loss for the year ended December 31, 2016, was $27.8 million, or $0.29 per common share, compared to $44.8 million, or $0.54 per common share for the year ended December 31, 2015.

Our net loss for the year ended December 31, 2015, was $44.8 million, or $0.54 per common share, compared to $19.8 million, or $0.32 per common share for the year ended December 31, 2014.

Liquidity and Capital Resources

With the exception of the three months ended June 30, 2010, we have experienced significant losses since inception and have a significant accumulated deficit. To date, we have financed our operations primarily through public and private sales of our common stock, and we expect to continue to seek to obtain the required capital in a similar manner. We have incurred an accumulated deficit of $172.0 million as of December 31, 2016 and expect to continue to incur losses in the future. With the exception of the quarter ended June 30, 2010, we have incurred negative cash flow from operations since our inception. We have spent, and expect to continue to spend, a substantial amount of funds in connection with implementing our business strategy, including our planned product development efforts, our clinical trials and our research and discovery efforts.

Based on our current plans, our cash and cash equivalents will not be sufficient to enable us to meet our near term expected plans. Our notes to financial statements contain an explanatory paragraph referring to our recurring and continuing losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. We cannot provide any assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding to achieve our current business plan, obtain the required regulatory approvals for our product candidates or complete additional corporate partnering or acquisition transactions in order to commercialize such product candidates once regulatory approval is received.

Our cash and cash equivalents totaled $19.1 million as of December 31, 2016, a decrease of $1.7 million from December 31, 2015. During the year ended December 31, 2016, the primary use of cash was for working capital requirements and operating activities which resulted in a net loss of $27.8 million for the year ended December 31, 2016.

Our continued operations as currently planned will primarily depend on our ability to raise additional capital from various sources, including equity (the FBR Sales Agreement as well as other equity sources) and debt financings, as well as, license fees from potential corporate partners, joint ventures and grant funding. Although we have been awarded a contract by the CDC's Broad Agency Announcement (BAA) 2016-N-17812, the amount of the award will not be sufficient to enable us to complete our clinical trials as planned and therefore we will be required to obtain additional capital. Such additional funds may not become available on acceptable terms or at all and there can be no assurance that any additional funding that we do obtain will be sufficient to meet our needs. We will continue to fund operations from cash on hand and through the similar sources of capital previously described. We can give no assurance that any additional capital that we are able to obtain will be sufficient to meet our needs.

Current and Future Financing Needs

Based on our current plans, our cash and cash equivalents will not be sufficient to enable us to meet our near term expected plans. Our notes to financial statements contain an explanatory paragraph referring to our recurring and continuing losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. We will be required to obtain additional funding in order to continue the development of our current product candidates as currently planned and to continue to fund operations at the current cash expenditure levels, although we do not currently have commitments from any third parties to provide us with capital. Potential sources of financing include strategic relationships, public or private sales of our equity (including through the FBR Sales Agreement that we entered into with FBR Capital Markets & Co. in August 2016) or debt and other sources. We cannot assure that we will meet the requirements for use of the FBR Sales Agreement or that additional funding will be available on favorable terms, or at all. If we fail to obtain additional funding in the next few months we will be forced to delay the initiation of our planned clinical trials until such time as we obtain adequate financing and if we fail to obtain additional funding otherwise in the future when needed, we may not be able to execute our business plan as planned and we may be forced to cease certain development activities until funding is received and our business will suffer, which would have a material adverse effect on our financial position, results of operations and cash flows.

The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

·the progress of our research activities;

· the number and scope of our research programs;

- the progress of our preclinical and clinical development activities;

- the progress of the development efforts of parties with whom we have entered into research and development agreements;

- our ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;

- our ability to achieve our milestones under licensing arrangements;

- the costs associated with manufacturing-related services to produce material for use in our clinical trials;

- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and

- the costs and timing of regulatory approvals.

We have based our estimate on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of our shares (including through the FBR Sales Agreement, if we meet the conditions for sale thereunder) or debt and other sources. Additionally, we may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we will be unable to carry out our business plan and we will be forced to delay the initiation of our planned clinical trials until such time as we obtain adequate financing. As a result, we may have to significantly limit our operations and our business, financial condition and results of operations would be materially harmed.

During the year ended December 31, 2016, our only source of funding was from the sale of our securities in our public offering and sales of common stock through the FBR Sales Agreement.

On August 5, 2016, we entered into the FBR Sales Agreement with FBR Capital Markets & Co.,. , which enables us to offer and sell shares of our common stock with an aggregate sales of up to $40.0 million, from time to time through FBR Capital Markets & Co. as our sales agent. Sales of common stock under the FBR Sales Agreement are made in sales deemed to be “at-the-market” equity offerings as defined in Rule 415 promulgated under the Securities Act. FBR

Capital Markets & Co. is entitled to receive a commission rate of up to 3.0% of gross sales in connection with the sale of our common stock sold on our behalf. From August 11, 2016 through December 31, 2016, we sold through the FBR Sales Agreement an aggregate of 900,628 shares of our common stock, and received gross proceeds of approximately $1,550,197, before deducting issuance expenses.

On November 18, 2016, we completed a public offering of 25 million shares of common stock in combination with accompanying warrants to purchase an aggregate of 50,000,000 shares of the common stock. The stock and warrants were being sold in combination with two warrants for each share of common stock sold, a Series A warrant and a Series B warrant, each representing the right to purchase one share of common stock. The purchase price for each share of common stock and accompanying warrants was $1.00. The shares of common stock were immediately separable from the warrants and were issued separately. The initial per share exercise price of the Series A warrants is $1.43 and the per share exercise price of the Series B warrants is $1.72, each subject to adjustment as specified in the warrants. The Series A and Series B warrants may be exercised at any time on or after the date of issuance. The Series A warrants are exercisable until the four year anniversary of the issuance date. The Series B warrants are exercisable until December 31, 2017. Net proceeds, after deducting underwriting discounts and estimated expenses were approximately $23.3 million.

License and Contractual Agreement Obligations

We have entered into several license and collaborative agreements for the right to use research, technology and patents. Some of these license and collaborative agreements may contain milestones. The specific timing of such milestones cannot be predicted and are dependent on future developments as well as regulatory actions which cannot be predicted with certainty (including actions which may never occur). Further, under the terms of certain licensing agreements, we may have the obligation to pay certain milestones contingent upon the achievement of specific levels of sales. Due to the long-range nature of such commercial milestone amounts, they are neither probable at this time nor predictable and consequently are not included in the table below.

Below is a table of our significant contractual obligations. Payments due by year have been presented based on payments due subsequent to December 31, 2016 *(in thousands)* .

Contractual Obligations

	2017	2018	2019	2020	2021	Total
Operating Lease	$204	$292	$300	$309	$321	$1,426
Total	$204	$292	$300	$309	$321	$1,426

Item 7A. ***Quantitative and Qualitative Disclosures About Market Risk***

The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. Our exposure to market risk is confined to our cash and cash equivalents. As of December 31, 2016, our cash and cash equivalents consisted primarily of money market securities. We do not engage in any hedging activities against changes in interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates or credit conditions on our securities portfolio. We may, however, require additional financing to fund future obligations and no assurance can be given that the terms of future sources of financing will not expose us to material market risk.

Item 8. ***Financial Statements and Supplementary Data***

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Synthetic Biologics, Inc.
Rockville, Maryland

We have audited the accompanying consolidated balance sheets of Synthetic Biologics, Inc. and Subsidiaries as of December 31, 2016 and 2015 and the related consolidated statements of operations, equity, and cash flows for each of the three years in the period ended December 31, 2016. These financial statements are the responsibility of Synthetic Biologics, Inc.'s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Synthetic Biologics, Inc. and Subsidiaries at December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and losses are expected to continue in the future. These factors raise substantial doubt about its ability to continue as a going concern. Management's plans in regards to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Synthetic Biologics, Inc. and Subsidiaries internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 2, 2017 expressed an unqualified

opinion thereon.

/s/ BDO USA, LLP

Troy, Michigan

March 2, 2017

Synthetic Biologics, Inc. and Subsidiaries

Consolidated Balance Sheets

(In thousands except share amounts)

	December 31, 2016	December 31, 2015
Assets		
Current Assets		
Cash and cash equivalents	$ 19,055	$ 20,818
Prepaid expenses and other current assets	2,515	9,519
Total Current Assets	21,570	30,337
Property and equipment, net	905	494
Deposits and other assets	23	14
Total Assets	$ 22,498	$ 30,845
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,993	$ 4,413
Accrued expenses	2,627	297
Warrant liabilities	14,821	10,567
Accrued employee benefits	313	277
Deferred rent	3	21
Total Current Liabilities	19,757	15,575
Long term deferred rent	492	267
Total Liabilities	20,249	15,842
Commitments and Contingencies		
Stockholders' Equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, none issued and outstanding	-	-
Common stock, $0.001 par value; 250,000,000 shares authorized, 117,254,196 issued and 117,172,714 outstanding and 90,908,234 issued and 90,826,752 outstanding, respectively	117	91

Additional paid-in capital	175,762	160,739
Accumulated deficit	(172,034)	(144,779)
Total Synthetic Biologics, Inc. and Subsidiaries Equity	3,845	16,051
Non-controlling interest	(1,596)	(1,048)
Total Stockholders' Equity	2,249	15,003
Total Liabilities and Stockholders' Equity	$ 22,498	$ 30,845

See accompanying notes to consolidated financial statements

Synthetic Biologics, Inc. and Subsidiaries

Consolidated Statements of Operations

(In thousands, except share and per share amounts)

	For the years ended December 31,		
	2016	2015	2014
Operating Costs and Expenses:			
General and administrative	$10,143	$8,074	$6,013
Research and development	29,109	32,906	14,489
Total Operating Costs and Expenses	39,252	40,980	20,502
Loss from Operations	(39,252)	(40,980)	(20,502)
Other Income (Expense):			
Change in fair value of warrant liability	11,412	(3,811)	620
Other income	-	-	95
Interest income	37	6	3
Total Other Income (Expense)	11,449	(3,805)	718
Net Loss	(27,803)	(44,785)	(19,784)
Net Loss Attributable to Non-controlling Interest	(548)	(1,048)	-
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$(27,255)	$(43,737)	$(19,784)
Loss Per Share - Basic and Dilutive	$(0.29)	$(0.54)	$(0.32)
Weighted average number of shares outstanding during the period - Basic and Dilutive	94,290,436	80,705,692	61,945,356

See accompanying notes to consolidated financial statements

Synthetic Biologics, Inc. and Subsidiaries

Consolidated Statements of Equity

(In thousands, except share amounts)

	Common Stock $0.001 Par Value					
	Shares	Amount	APIC	Accumulated Deficit	Non-Controlling Interest	Total Stockholders' Equity
Balance at December 31, 2013	58,214,326	$ 58	$96,430	$ (81,258)	$ -	$ 15,230
Stock-based compensation	-	-	2,459	-	-	2,459
Issuance of common stock, net of issuance costs of $1,645	14,059,616	14	11,633	-	-	11,647
Stock issued for exercise of stock options	6,583	-	4	-	-	4
Stock issued for cashless exercise of warrants	232,619	-	-	-	-	-
Net Loss	-	-	-	(19,784)	-	(19,784)
Balance at December 31, 2014	72,513,144	72	110,526	(101,042)	-	9,556
Stock-based compensation		-	3,198	-	-	3,198
Issuance of common stock, net of issuance costs	15,333,333	16	42,627	-	-	42,643
Stock issued for milestone payments	2,005,321	2	1,348	-	-	1,350
Stock issued for exclusive channel collaboration agreement	937,500	1	2,999	-	-	3,000
Stock issued for exercise of stock options	35,006	-	41	-	-	41
Stock issued for cashless exercise of warrants	2,446	-	-	-	-	-
Net Loss	-	-	-	(43,737)	-	(43,737)
Non-controlling interest	-	-	-	-	(1,048)	(1,048)
Balance at December 31, 2015	90,826,752	91	160,739	(144,779)	(1,048)	15,003
Stock-based compensation		-	4,009	-	-	4,009
Issuance of common stock, net of issuance costs	25,000,000	25	24,359	-	-	24,384

Fair Value of warrants issued with common stock	-		(15,667)	-	-	(15,667)
Stock issued under "at the market" offering	900,628	1	1,508	-	-	1,509
Stock issued for exercise of stock options	445,334	-	814	-	-	814
Net Loss	-	-	-	(27,255)	-	(27,255)
Non-controlling interest	-	-	-	-	(548)	(548)
Balance at December 31, 2016	117,172,714	$ 117	$175,762	$ (172,034)	$ (1,596)	$ 2,249

See accompanying notes to consolidated financial statements

Synthetic Biologics, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

(In thousands)

	For the years ended December 31,		
	2016	2015	2014
Cash Flows From Operating Activities:			
Net Loss	$ (27,803)	$ (44,785)	$ (19,784)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	4,009	3,198	2,459
Stock issued for milestone payments	-	1,350	-
Stock issued for exclusive channel collaboration agreement	-	3,000	-
Change in fair value of warrant liabilities	(11,412)	3,811	(620)
Depreciation	157	72	20
Changes in operating assets and liabilities:			-
Prepaid expenses and other current assets	7,004	(7,971)	43
Deposits and other assets	(9)	(8)	(2)
Accounts payable	(2,420)	3,417	854
Accrued expenses	2,330	(1,001)	416
Accrued employee benefits	36	(261)	535
Deferred rent	207	288	-
Net Cash Used In Operating Activities	(27,901)	(38,890)	(16,079)
Cash Flows From Investing Activities:			
Purchases of property and equipment	(569)	(501)	(48)
Net Cash Used In Investing Activities	(569)	(501)	(48)
Cash Flows From Financing Activities:			
Proceeds from issuance of common stock	25,000	46,000	20,668
Cash paid as direct offering costs	(616)	(3,357)	(1,645)
Proceeds from issuance of common stock for stock option exercises	814	41	4
Proceeds from "at the market" stock issuance	1,509	-	-
Net Cash Provided By Financing Activities	26,707	42,684	19,027
Net (decrease) increase in cash	(1,763)	3,293	2,900
Cash at beginning of period	20,818	17,525	14,625
Cash at end of period	$ 19,055	$ 20,818	$ 17,525

Supplemental disclosures of cash flow information:			
Cash paid for interest	$ -	$ -	$ -
Cash paid for taxes	$ -	$ -	$ -

See accompanying notes to consolidated financial statements

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

1. Organization and Nature of Operations and Basis of Presentation

Description of Business

Synthetic Biologics, Inc. (the "Company" or "Synthetic Biologics") is a late-stage clinical company developing therapeutics designed to preserve the microbiome to protect and restore the health of patients. The Company's lead candidates poised for Phase 3 development are: (1) 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), and (2) SYN-004 which is designed to protect the gut microbiome (gastrointestinal (GI) microflora) from the effects of certain commonly used intravenous (IV) antibiotics for the prevention of *C. difficile* infection (CDI) and antibiotic-associated diarrhea (AAD). In collaboration with Intrexon Corporation (NYSE: XON), the Company is also developing preclinical stage monoclonal antibody therapies for the prevention and treatment of pertussis, and novel discovery stage biotherapeutics for the treatment of phenylketonuria (PKU).

Basis of Presentation and Corporate Structure

As of December 31, 2016, the Company had eight subsidiaries, Pipex Therapeutics, Inc. ("Pipex Therapeutics"), Effective Pharmaceuticals, Inc. ("EPI"), Solovax, Inc. ("Solovax"), CD4 Biosciences, Inc. ("CD4"), Epitope Pharmaceuticals, Inc. ("Epitope"), Healthmine, Inc. ("Healthmine"), Putney Drug Corp. ("Putney") and Synthetic Biomics, Inc. ("SYN Biomics"). Pipex Therapeutics, EPI, Healthmine and Putney are wholly owned, and Solovax, CD4, Epitope and SYN Biomics are majority-owned.

For financial reporting purposes, the outstanding common stock of the Company is that of Synthetic Biologics, Inc. All statements of operations, equity and cash flows for each of the entities are presented as consolidated. All subsidiaries were formed under the laws of the State of Delaware on January 8, 2001, except for EPI, which was incorporated in Delaware on December 12, 2000, Epitope which was incorporated in Delaware in January of 2002, Putney which was incorporated in Delaware in November of 2006, Healthmine which was incorporated in Delaware in December of 2007 and SYN Biomics which was incorporated in Nevada in December of 2013.

2. Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company has recurring losses and as of December 31, 2016, the Company had an accumulated deficit of approximately $172.0 million. Since inception, the Company has financed its activities principally from the proceeds from the issuance of equity securities.

The Company’s ability to continue as a going concern is dependent upon the Company’s ability to raise additional debt and equity capital. There can be no assurance that such capital will be available in sufficient amounts or on terms acceptable to the Company. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability of the recorded assets or the classification of liabilities that may be necessary should the Company be unable to continue as a going concern.

The Company does not have sufficient capital to fund our plan of operations over the next twelve months. In order to address our capital needs, including our planned Phase 2b/3 clinical trials, and the Company is actively pursuing additional equity or debt financing, in the form of either a private placement or a public offering. The Company has been in ongoing discussions with strategic institutional investors and investment banks with respect to such possible offerings. Such additional financing opportunities might not be available to the Company, when and if needed, on acceptable terms or at all. If the Company is unable to obtain additional financing in sufficient amounts or on acceptable terms under such circumstances, the Company’s operating results and prospects will be adversely affected.

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

3. Summary of Significant Accounting Policies

Principles of Consolidation

All inter-company transactions and accounts have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Such estimates and assumptions impact, among others, the following: the estimated useful lives for property and equipment, fair value of warrants and stock options granted for services or compensation, respectively, estimates of the probability and potential magnitude of contingent liabilities, and the valuation allowance for deferred tax assets due to continuing and expected future operating losses.

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of consolidated financial statements, which management considered in formulating its estimate could change in the near term due to one or more future confirming events. Accordingly, actual results could differ from those estimates.

Non-controlling Interest

The Company’s non-controlling interest represents the minority shareholder’s ownership interest related to the Company’s subsidiary, SYN Biomics. The Company reports its non-controlling interest in subsidiaries as a separate

component of equity in the Consolidated Balance Sheets and reports both net loss attributable to the non-controlling interest and net loss attributable to the Company's common shareholders on the face of the Consolidated Statements of Operations. The Company's equity interest in SYN Biomics is 88.5% and the non-controlling stockholder's interest is 11.5%. This is reflected in the Consolidated Statements of Equity.

Revenue Recognition

The Company records revenue when all of the following have occurred: (1) persuasive evidence of an arrangement exists, (2) the service is completed without further obligation, (3) the sales price to the customer is fixed or determinable, and (4) collectability is reasonably assured. The Company recognizes milestone payments or upfront payments that have no contingencies as revenue when payment is received. For the years ended December 31, 2016, 2015 and 2014 the Company did not report any revenues.

License Revenues

The Company's licensing agreements may contain multiple elements, such as non-refundable up-front fees, payments related to the achievement of particular milestones and royalties. Fees associated with substantive at risk performance-based milestones are recognized as revenue upon completion of the scientific or regulatory event specified in the agreement. When the Company has substantive continuing performance obligations under an arrangement, revenue is recognized over the performance period of the obligations using a time-based proportional performance approach. Under the time-based method, revenue is recognized over the arrangement's estimated performance period based on the elapsed time compared to the total estimated performance period. Revenue recognized at any point in time is limited to the amount of non-contingent payments received or due. When the Company has no substantive continuing performance obligations under an arrangement, it recognizes revenue as the related fees become due.

Revenues from royalties on third-party sales of licensed technologies are generally recognized in accordance with the contract terms when the royalties can be reliably determined and collectability is reasonably assured. To date, the Company has not received any royalty revenues.

Risks and Uncertainties

The Company's operations could be subject to significant risks and uncertainties including financial, operational and regulatory risks and the potential risk of business failure. The global economic crisis has caused a general tightening in the credit markets, lower levels of liquidity, increases in the rates of default and bankruptcy, and extreme volatility in credit, equity and fixed income markets. These conditions may not only limit the Company's access to capital, but also make it difficult for its customers, its vendors and its ability to accurately forecast and plan future business

activities.

Cash and Cash Equivalents

Cash and cash equivalents include cash and highly liquid short-term investments with original maturities of three months or less.

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

3. Summary of Significant Accounting Policies – (continued)

Property and Equipment

Property and equipment is recorded at cost and depreciated or amortized using the straight-line method over the estimated useful life of the asset or the underlying lease term for leasehold improvements, whichever is shorter. The estimated useful life by asset description is noted in the following table.

Asset Description	**Estimated Useful Life**
Office equipment and furniture	3 – 5 years
Manufacturing equipment	10 years
Leasehold improvements and fixtures	Lesser of estimated useful life or lease term

Depreciation and amortization expense was approximately $157,000, $72,000 and $20,000 for the years ended December 31, 2016, 2015 and 2014, respectively. When assets are disposed of, the cost and accumulated depreciation are removed from the accounts. Repairs and maintenance are charged to expense as incurred.

The Company reviews property and equipment for impairment to determine if assets are impaired due to obsolescence. As a result of this review, there was no impairment recognized for the years ended December 31, 2016, 2015 and 2014.

Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If such an event or change in circumstances occurs and potential impairment is indicated because the carrying values exceed the estimated future undiscounted cash flows of

the asset, the Company will measure the impairment loss as the amount by which the carrying value of the asset exceeds its fair value.

Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding. Diluted net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding including the effect of common share equivalents. Diluted net loss per share assumes the issuance of potential dilutive common shares outstanding for the period and adjusts for any changes in income and the repurchase of common shares that would have occurred from the assumed issuance, unless such effect is anti-dilutive. The number of options and warrants for the purchase of common stock that were excluded from the computations of net loss per common share for the year ended December 31, 2016 were 11,636,227 and 57,341,642, respectively, for the year ended December 31, 2015 were 8,941,930 and 7,908,899, respectively, and for the year ended December 31, 2014 were 5,981,106 and 7,974,794, respectively.

Research and Development Costs

The Company expenses research and development costs associated with developmental products not yet approved by the FDA to research and development expense as incurred. Research and development costs consist primarily of license fees (including upfront payments), milestone payments, manufacturing costs, salaries, stock-based compensation and related employee costs, fees paid to consultants and outside service providers for laboratory development, legal expenses resulting from intellectual property prosecution and other expenses relating to the design, development, testing and enhancement of our product candidates. Research and development expenses include external contract research organization (“CRO”) services. The Company makes payments to the CROs based on agreed upon terms and may include payments in advance of study services. The Company reviews and accrues CRO expenses based on services performed and rely on estimates of those costs applicable to the stage of completion of a study as provided by the CRO. Accrued CRO costs are subject to revisions as such studies progress to completion. The Company has accrued CRO expenses of $1.1 million and $2.2 million that are included in accounts payable and accrued expenses at December 31, 2016 and 2015. The Company has prepaid CRO costs of $1.7 million and $8.3 at December 31, 2016 and 2015.

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

3. Summary of Significant Accounting Policies – (continued)

Fair Value of Financial Instruments

The fair value accounting standards define fair value as the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is determined based upon assumptions that market participants would use in pricing an asset or liability. Fair value measurements are rated on a three-tier hierarchy as follows:

- Level 1 inputs: Quoted prices (unadjusted) for identical assets or liabilities in active markets;
- Level 2 inputs: Inputs, other than quoted prices, included in Level 1 that are observable either directly or indirectly; and
- Level 3 inputs: Unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions.

In many cases, a valuation technique used to measure fair value includes inputs from multiple levels of the fair value hierarchy described above. The lowest level of significant input determines the placement of the entire fair value measurement in the hierarchy.

The carrying amounts of the Company’s short-term financial instruments, including cash and cash equivalents, other current assets, accounts payable and accrued liabilities approximate fair value due to the relatively short period to maturity for these instruments.

Cash and cash equivalents include money market accounts of $1.7 million and $5.3 million as of December 31, 2016 and December 31, 2015, respectively, that are measured using Level 1 inputs.

The warrants issued in conjunction with the registered direct offering in October 2014 include a provision, that if the Company were to enter into a certain transaction, as defined in the agreement, the warrants would be purchased from the holder at a premium. The warrants issued in conjunction with the public offering of the Company's securities in November 2016 include a provision, that if the Company were to enter into a certain transaction, as defined in the warrant agreement, the warrants would be purchased from the holder for cash. Accordingly, the Company recorded the warrants as liabilities at their fair value upon issuance and re-measures the fair value at each period end with the change in fair value recorded in the Statement of Operations. The Company uses the Monte Carlo simulation options pricing model to estimate the fair value of the warrants. In using this model, the fair value is determined by applying Level 3 inputs for which there is little or no observable market data, requiring the Company to develop its own assumptions. The assumptions used in calculating the estimated fair value of the warrants represent the Company's best estimates; however, these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the warrant liability and the change in estimated fair value could be materially different.

Stock-Based Payment Arrangements

Generally, all forms of stock-based payments, including stock option grants, warrants, restricted stock grants and stock appreciation rights are measured at their fair value on the awards' grant date typically using a Black-Scholes pricing model, based on the estimated number of awards that are ultimately expected to vest. Stock-based compensation awards issued to non-employees for services rendered are recorded at either the fair value of the services rendered or the fair value of the stock-based payment, whichever is more readily determinable and are re-measured over the corresponding vesting period. The expense resulting from stock-based payments is recorded in research and development expense or general and administrative expense in the Consolidated Statement of Operations, depending on the nature of the services provided.

Derivative Instruments

The warrants issued in conjunction with the registered direct offering in October 2014 include a provision, that if the Company were to enter into a certain transaction, as defined in the agreement, the warrants would be purchased from the holder at a premium. The warrants issued in conjunction with the public offering of the Company's securities in November 2016 include a provision, that if the Company were to enter into a certain transaction, as defined in the warrant agreement, the warrants would be purchased from the holder for cash. The provisions of these warrants preclude equity accounting treatment under ASC 815. Accordingly, the Company is required to record the warrants as liabilities at their fair value upon issuance and re-measure the fair value at each period end with the change in fair value recorded in the Statement of Operations. When the warrants are exercised or cancelled, they are reclassified to equity. The Company uses the Monte Carlo simulation options pricing model to estimate the fair value of the warrants.

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Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

3. Summary of Significant Accounting Policies – (continued)

Income Taxes

The Company recognizes deferred tax liabilities and assets based on the differences between the financial statement carrying amounts and the tax bases of assets and liabilities, using enacted tax rates in effect in the years the differences are expected to reverse. Deferred income tax benefit (expense) results from the change in net deferred tax assets or deferred tax liabilities. A valuation allowance is recorded when it is more likely than not that some or all deferred tax assets will not be realized.

Management assesses the need to accrue or disclose uncertain tax positions for proposed potential adjustments from various federal and state authorities who regularly audit the Company in the normal course of business. In making these assessments, management must often analyze complex tax laws of multiple jurisdictions. The Company records the related interest expense and penalties, if any, as tax expense in the tax provision. At December 31, 2016 and 2015, respectively, the Company did not record any liabilities for uncertain tax positions.

Recent Accounting Pronouncements and Developments

In August 2016, the FASB issued ASU 2016-15 to clarify whether the following items should be categorized as operating, investing or financing in the statement of cash flows: (i) debt prepayments and extinguishment costs, (ii) settlement of zero-coupon debt, (iii) settlement of contingent consideration, (iv) insurance proceeds, (v) settlement of corporate-owned life insurance (COLI) and bank-owned life insurance (BOLI) policies, (vi) distributions from equity method investees, (vii) beneficial interests in securitization transactions, and (viii) receipts and payments with aspects of more than one class of cash flows. Accordingly, ASU No. 2016-015 is effective for public business entities for fiscal years beginning after December 15, 2017, with early adoption permitted. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In March 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2016-09, *Compensation - Stock Compensation (Topic 718)*, which is part of the FASB's Simplification Initiative. The updated guidance simplifies the accounting for share-based payment transactions. The amended guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016, with early adoption permitted. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* , which establishes a new lease accounting model for lessees. The updated guidance requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases, along with additional qualitative and quantitative disclosures. The amended guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* , to provide guidance on revenue recognition. ASU No. 2014-09 requires a company to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under today’s guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date* , which provided for the adoption of the new standard for fiscal years beginning after December 15, 2017. Accordingly, ASU No. 2014-09 is effective for the Company in the first quarter of 2018. Early adoption up to the first quarter of 2017 is permitted. Upon adoption, ASU No. 2014-09 can be applied retrospectively to all periods presented or only to the most current period presented with the cumulative effect of changes reflected in the opening balance of retained earnings in the most current period presented. The FASB has also issued the following standards which clarify ASU No. 2014-09 and have the same effective date as the original standard:

- ASU No. 2016-10, *Identifying Performance Obligations and Licensing (Topic 606);*

- ASU No. 2016-11, *Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting;* and

- ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*.

- ASU No. 2016-20, *Technical Correction and Improvements.*

- ASU No. 2016-20, *Technical correction and improvements to Topic 606, Revenue form Contracts with Customers*.

The adoption of ASU 2014-09 may have a material effect on the recognition of future revenues. ASU 2014-09 differs from the current accounting standard in many respects, such as in the accounting for variable consideration, including milestone payments. Accordingly, we expect that our evaluation of the accounting for collaboration agreements under the new revenue standard could identify material changes from the current accounting treatment. The new accounting standard will require entities to determine an appropriate attribution method using either output or input methods and does not include a presumption that entities would default to a ratable attribution approach for upfront non-refundable fees. These factors could materially impact the amount and timing of our revenue recognition from our license and collaboration agreements under the new revenue standard. The Company will need to evaluate the impact of adoption ASU No. 2014-09 on its results of operations, cash flows and financial position.

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

4. Selected Balance Sheet Information

Prepaid expenses and other current assets (in thousands):

	December 31, 2016	December 31, 2015
Prepaid clinical research organizations	$ 1,677	$ 8,329
Prepaid insurances	358	339
Other prepaid expenses	295	208
Other receivables	185	-
Intrexon prepaid research and development expenses	-	643
Total	$ 2,515	$ 9,519

The Intrexon prepaid research and development expenses were classified as a current asset at December 31, 2015. As of December 31, 2016, the Company had applied all of the Intrexon prepaid research and development expenses to research and development expenses.

Prepaid clinical research organization expense is classified as a current asset. The Company makes payments to the clinical research organizations based on agreed upon terms that includes payments in advance of study services. The Company anticipates that the majority of the prepaid clinical research organization expenses will be applied to research and development expenses during 2017.

Property and equipment (in thousands):

	December 31, 2016	December 31, 2015
Computer and office equipment	$ 641	$ 346
Software	11	11
Leasehold improvements	439	242
	1,091	599
Less accumulated depreciation and amortization	(186)	(105)
Total	$ 905	$ 494

Accrued expenses (in thousands):

	December 31, 2016	December 31, 2015
Accrued manufacturing costs	$ 14	$ -
Accrued vendor payments	400	133
Accrued clinical consulting services	2,211	164
Other accrued expenses	2	-
Total	$ 2,627	$ 297

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

5. Stock-Based Compensation

Stock Incentive Plan

During 2001, the Company's Board of Directors and stockholders adopted the 2001 Stock Incentive Plan (the "2001 Stock Plan"). The total number of shares of stock with respect to which stock options and stock appreciation rights may be granted to any one employee of the Company or a subsidiary during any one-year period under the 2001 Stock Plan shall not exceed 250,000. All awards pursuant to the 2001 Stock Plan shall terminate upon the termination of the grantee's employment for any reason. Awards include options, restricted shares, stock appreciation rights, performance shares and cash-based awards (the "Awards"). The 2001 Stock Plan contains certain anti-dilution provisions in the event of a stock split, stock dividend or other capital adjustment, as defined in the plan. The 2001 Stock Plan provides for a Committee of the Board to grant awards and to determine the exercise price, vesting term, expiration date and all other terms and conditions of the awards, including acceleration of the vesting of an award at any time. As of December 31, 2016, there were 228,773 options issued and outstanding under the 2001 Stock Plan.

On March 20, 2007, the Company's Board of Directors approved the 2007 Stock Incentive Plan (the "2007 Stock Plan") for the issuance of up to 2,500,000 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. This plan was approved by stockholders on November 2, 2007. The exercise price of stock options under the 2007 Stock Plan is determined by the compensation committee of the Board of Directors, and may be equal to or greater than the fair market value of the Company's common stock on the date the option is granted. The total number of shares of stock with respect to which stock options and stock appreciation rights may be granted to any one employee of the Company or a subsidiary during any one-year period under the 2007 plan shall not exceed 250,000. Options become exercisable over various periods from the date of grant, and generally expire ten years after the grant date. As of December 31, 2016, there were 659,988 options issued and outstanding under the 2007 Stock Plan.

On November 2, 2010, the Board of Directors and stockholders adopted the 2010 Stock Incentive Plan ("2010 Stock Plan") for the issuance of up to 3,000,000 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its

subsidiaries. On October 22, 2013, the stockholders approved and adopted an amendment to the Company's 2010 Incentive Stock Plan to increase the number of shares of Company's common stock reserved for issuance under the Plan from 3,000,000 to 6,000,000. On May 15, 2015, the stockholders approved and adopted an amendment to the Company's 2010 Incentive Stock Plan to increase the number of shares of the Company's common stock reserved for issuance under the Plan from 6,000,000 to 8,000,000. On August 25, 2016, the stockholders approved and adopted an amendment to the 2010 Stock Plan to increase the number of shares of the Company's common stock reserved for issuance under the 2010 Stock Plan from 8,000,000 to 14,000,000. The exercise price of stock options under the 2010 Stock Plan is determined by the compensation committee of the Board of Directors, and may be equal to or greater than the fair market value of the Company's common stock on the date the option is granted. Options become exercisable over various period from the date of grant, and expire between five and ten years after the grant date. As of December 31, 2016, there were 10,747,466 options issued and outstanding under the 2010 Stock Plan.

In the event of an employee's termination, the Company will cease to recognize compensation expense for that employee. There is no deferred compensation recorded upon initial grant date, instead, the fair value of the stock-based payment is recognized ratably over the stated vesting period.

The Company has applied fair value accounting for all share based payment awards since inception. The fair value of each option or warrant granted is estimated on the date of grant using the Black-Scholes option pricing model. The Black-Scholes assumptions used in the years ended December 31, 2016, 2015 and 2014 are as follows:

	Year ended December 31,		
	2016	**2015**	**2014**
Exercise price	$0.80 – $2.66	$1.54 – $2.76	$1.46 – $2.91
Expected dividends	0%	0%	0%
Expected volatility	96% – 123%	88% – 131%	101% – 150%
Risk free interest rate	1.40% – 2.13%	1.32% – 2.19%	1.57% – 2.73%
Expected life of option	7 years	5 years – 10 years	5 years – 10 years

The Company records stock-based compensation based upon the stated vested provisions in the related agreements. The vesting provisions for these agreements have various terms as follows:

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

5. Stock-Based Compensation – (continued)

- immediate vesting,
- half vesting immediately and remaining over three years,
- quarterly over three years,
- annually over three years,
- one-third immediate vesting and remaining annually over two years,
- one-half immediate vesting and remaining over nine months,
- one-quarter immediate vesting and remaining over three years,
- one-quarter immediate vesting and remaining over 33 months; and
- monthly over three years.

During the years ended December 31, 2016, 2015 and 2014 the Company granted 3,861,425, 3,781,666 and 2,382,500 options to employees and directors having an approximate fair value of $3.1 million, $8.0 million and $5.0 million based upon the Black-Scholes options pricing model, respectively.

Stock-based compensation expense included in general and administrative expenses and research and development expenses relating to stock options issued to employees for the years ended December 31, 2016, 2015 and 2014 was $3.4 million, $2.3 million and $2.1 million, respectively. Stock-based compensation expense included in general and administrative expenses and research and development expenses relating to stock options issued to consultants for the years ended December 31, 2016, 2015 and 2014 were $603,000, $888,000 and $380,000, respectively.

A summary of stock option activities for the years ended December 31, 2016, 2015 and 2014, is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Balance - December 31, 2013	3,909,580	$ 1.78	5.59 years	$785,000
Granted	2,382,500	$ 2.36		
Exercised	(6,583)	$ 0.58		$8,000
Forfeited	(304,391)	$ 1.93		
Balance - December 31, 2014	5,981,106	$ 2.01	5.80 years	$685,000
Granted	3,781,666	$ 2.37		
Exercised	(35,008)	$ 1.16		$44,000
Expired	(483,332)	$ 2.48		
Forfeited	(302,502)	$ 1.91		
Balance - December 31, 2015	8,941,930	$ 2.14	5.67 years	$2,900,000
Granted	3,861,425	$ 0.98		
Exercised	(445,334)	$ 1.83		$137,488
Expired	(338,529)	$ 1.96		
Forfeited	(383,265)	$ 2.26		
Balance - December 31, 2016 - outstanding	11,636,227	$ 1.77	5.49 years	$194,355
Balance - December 31, 2016 - exercisable	6,193,649	$ 2.02	4.49 years	$194,355
Grant date fair value of options granted - December 31, 2016		$ 3,091,000		
Weighted average grant date fair value - December 31, 2016		$ 0.80		
Grant date fair value of options granted - December 31, 2015		$ 7,974,000		
Weighted average grant date fair value - December 31, 2015		$ 2.12		

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Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

5. Stock-Based Compensation – (continued)

The options outstanding and exercisable at December 31, 2016 are as follows:

Options Outstanding				**Options Exercisable**		
Range of Exercise Price	**Options**	**Weighted Average Exercise Price**	**Weighted Average Remaining Contractual Life**	**Options**	**Weighted Average Exercise Price**	**Weighted Average Remaining Contractual Life**
$0.09 – $2.00	5,769,987	$ 1.00	5.37 years	2,324,504	$ 1.19	3.17 years
$2.01 – $3.00	5,820,416	2.50	5.64 years	3,823,321	2.49	5.33 years
$3.01 – $6.00	45,824	5.24	.62 years	45,824	5.24	.62 years
$0.09 – $6.00	11,636,227	$ 1.77	5.49 years	6,193,649	$ 2.02	4.49 years

The options outstanding and exercisable at December 31, 2015 are as follows:

Options Outstanding				Options Exercisable		
Range of Exercise Price	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
$0.09 – $2.00	3,029,938	$ 1.40	4.12 years	2,363,683	$ 1.34	3.38 years
$2.01 – $3.00	5,866,168	2.50	6.50 years	2,348,247	2.44	5.76 years
$3.01 – $6.00	45,824	5.24	1.62 years	45,824	5.24	1.62 years
$0.09 – $6.00	8,941,930	$ 2.14	5.67 years	4,757,754	$ 1.92	4.54 years

The options outstanding and exercisable at December 31, 2014 are as follows:

Options Outstanding				Options Exercisable		
Range of Exercise Price	Options	**Weighted Average Exercise Price**	**Weighted Average Remaining Contractual Life**	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
$0.09 – $2.00	2,703,280	$ 1.37	4.33 years	2,018,074	$ 1.28	3.73 years
$2.01 – $3.00	3,232,002	2.49	7.08 years	1,829,298	2.40	6.73 years
$3.01 – $6.00	45,824	5.24	2.62 years	45,824	5.24	2.62 years
$0.09 – $6.00	5,981,106	$ 2.01	5.80 years	3,893,196	$ 1.85	5.12 years

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

5. Stock-Based Compensation – (continued)

The following is a summary of the Company's non-vested stock options at December 31, 2016:

	Unvested Stock Options	Weighted Average Grant Date Fair Value
Balance - December 31, 2013	756,043	$ 2.17
Granted	2,382,500	$ 2.09
Vested/Exercised	(1,050,633)	$ 2.35
Forfeited/Cancelled	-	$ -
Balance - December 31, 2014	2,087,910	$ 2.30
Granted	3,781,666	$ 2.12
Vested/Exercised	(1,382,898)	$ 2.02
Forfeited/Cancelled	(302,502)	$ 1.92
Balance - December 31, 2015	4,184,176	$ 1.97
Granted	3,861,425	$ 0.80
Vested/Exercised	(2,219,758)	$ 1.87
Forfeited/Cancelled	(383,265)	$ 2.26
Non-vested - December 31, 2016	5,442,578	$ 1.18
Weighted average remaining period for vesting	1.99	

As of December 31, 2016, total unrecognized stock-based compensation expense related to stock options was $6.4 million, which is expected to be expensed through January 2019.

FASB's guidance for stock-based payments requires cash flows from excess tax benefits to be classified as a part of cash flows from financing activities. Excess tax benefits are realized tax benefits from tax deductions for exercised options in excess of the deferred tax asset attributable to stock compensation costs for such options. The Company did not record any excess tax benefits in 2016, 2015 or 2014. Cash received from option exercises under the Company's stock-based compensation plans for the years ended December 31, 2016, 2015 and 2014 was $814,000, $41,000 and $4,000, respectively.

Stock Warrants

On November 18, 2016, the Company completed a public offering of 25 million shares of common stock in combination with accompanying warrants to purchase an aggregate of 50,000,000 shares of the common stock. The stock and warrants were sold in combination, with two warrants for each share of common stock sold, a Series A warrant and a Series B warrant, each representing the right to purchase one share of common stock. The purchase price for each share of common stock and accompanying warrants was $1.00. The shares of common stock were immediately separable from the warrants and will be issued separately. The initial per share exercise price of the Series A warrants is $1.43 and the per share exercise price of the Series B warrants is $1.72, each subject to adjustment as specified in the Warrants. The Series A and Series B warrants may be exercised at any time on or after the date of issuance. The Series A warrants are exercisable until the four year anniversary of the issuance date. The Series B warrants are exercisable until December 31, 2017. The warrants include a provision, that if the Company were to enter into a certain transaction, as defined in the agreement, the warrants would be purchased from the holder for cash. Accordingly, the Company recorded the warrants as a liability at their estimated fair value on the issuance date, which was $15.7 million, and changes in estimated fair value will be recorded as non-cash income or expense in the Company's Statement of Operations at each subsequent period. At December 31, 2016, the fair value of the warrant liability was $12.7 million, which resulted in non-cash income of $3.0 million in 2016. In accordance with authoritative accounting guidance, the warrants were valued on the date of grant using the Monte Carlo Simulation valuation model. The assumptions used by the Company are summarized in the following table:

	Series A		Series B	
	Issuance Date	December 31, 2016	Issuance Date	December 31, 2016
Closing stock price	$0.89	$0.76	$0.89	$0.76
Expected dividends	0 %	0 %	0 %	0 %
Expected volatility	85.0 %	85.0 %	85.0 %	90.0 %
Risk free interest rate	1.58 %	1.67 %	0.81 %	0.85 %
Expected life of warrant	4 years	3.9 years	1.1 years	1 years

On October 10, 2014, the Company raised net proceeds of $19.1 million through the sale of 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 the Company's common stock and a warrant to purchase 0.5 shares of common stock. The warrants, exercisable for an aggregate of 7,029,808 shares of common stock, have an exercise price of $1.75 per share and a life of five years. The warrants vested immediately and expire October 10, 2019.

The warrants issued in conjunction with the registered direct offering in October 2014 include a provision, that if the Company were to enter into a certain transaction, as defined in the agreement, the warrants would be purchased from the holder at a premium. Accordingly, the Company recorded the warrants as a liability at their estimated fair value on the issuance date, which was $7.4 million, and changes in estimated fair value will be recorded as non-cash income or expense in the Company's statement of operations at each subsequent period. At December 31, 2016, the fair value of the warrant liability was $2.1 million, which resulted in non-cash income of $8.5 million in 2016. At December 31, 2015, the fair value of the warrant liability was $10.6 million, which resulted in non-cash income of $3.8 million in 2015. In accordance with authoritative accounting guidance, the warrants were valued on the date of grant using the Black-Scholes valuation model which approximates the value derived using the Monte Carlo Simulation valuation model. The assumptions used by the Company are summarized in the following table:

	Issuance Date		**December 31, 2016**	
Closing stock price	$ 1.75		$ 0.76	
Expected dividends	0	%	0	%
Expected volatility	95	%	95	%
Risk free interest rate	1.39	%	1.41	%
Expected life of warrant	5 years		2.79 years	

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

5. Stock-Based Compensation – (continued)

The following table summarizes the estimated fair value of the warrant liability *(in thousands)* :

Balance at December 31, 2014	$6,756
Change in fair value of warrant liability	3,811
Balance at December 31, 2015	10,567
Warrants Liability	15,667
Change in fair value of warrant liability	(11,412)
Balance at December 31, 2016	$14,821

As of December 31, 2016, all of the warrants remained outstanding.

On October 25, 2012, the Company entered into a Common Stock Purchase Agreement with certain accredited investors. As part of this agreement, the Company issued warrants to purchase 635,855 shares of common stock to the placement agent, or its permitted assigns. The warrants have an exercise price of $1.60 and a life of five years. The warrants vested immediately and expire October 25, 2017. Since these warrants were granted as part of an equity raise, the Company has treated them as a direct offering cost. The result of the transaction has no affect to equity. As of December 31, 2016, 311,834 of these warrants remained outstanding.

A summary of warrant activity for the Company for the years ended December 31, 2016 and 2015 is as follows:

	Number of Warrants	Weighted Average Exercise Price
Balance at December 31, 2014	7,974,794	$ 1.80

Granted	-	$ -
Exercised	(2,446)	$ 1.60
Forfeited	(63,449)	$ 1.79
Balance at December 31, 2015	7,908,899	$ 1.79
Granted	50,000,000	$ 1.58
Exercised	-	$ -
Forfeited	(567,257)	$ 2.35
Balance at December 31, 2016	57,341,642	$ 1.60

There was no stock-based compensation expense included in general and administrative expenses relating to warrants issued to consultants for the years ended December 31, 2016, 2015 and 2014.

A summary of all outstanding and exercisable warrants as of December 31, 2016 is as follows:

Exercise Price	Warrants Outstanding	Warrants Exercisable	Weighted Average Remaining Contractual Life
$ 1.60	311,834	311,834	0.82 years
$ 1.43	25,000,000	25,000,000	3.88 years
$ 1.72	25,000,000	25,000,000	1.00 years
$ 1.75	7,029,808	7,029,808	2.78 years
$ 1.77	57,341,642	57,341,642	2.47 years

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

6. Stockholders' Equity

Year Ended December 31, 2016

On November 18, 2016, the Company completed a public offering of 25 million shares of common stock in combination with accompanying warrants to purchase an aggregate of 50,000,000 shares of the common stock. The stock and warrants were sold in combination, with two warrants for each share of common stock sold, a Series A warrant and a Series B warrant, each representing the right to purchase one share of common stock. The purchase price for each share of common stock and accompanying warrants was $1.00. The shares of common stock are immediately separable from the warrants and were issued separately. The initial per share exercise price of the Series A warrants was $1.43 and the per share exercise price of the Series B warrants was $1.72, each subject to adjustment as specified in the warrants. The Series A and Series B warrants may be exercised at any time on or after the date of issuance. The Series A warrants are exercisable until the four year anniversary of the issuance date. The Series B warrants are exercisable until December 31, 2017. Net proceeds, after deducting underwriting discounts and estimated expenses were approximately $23.3 million.

On August 5, 2016, the Company entered into the FBR Sales Agreement with FBR Capital Markets & Co., which enables the Company to offer and sell shares of the Company's common stock with an aggregate sales price of up to $40.0 million, from time to time through FBR Capital Markets & Co. as the Company's sales agent. Sales of common stock under the FBR Sales Agreement are made in sales deemed to be "at-the-market" equity offerings as defined in Rule 415 promulgated under the Securities Act, as amended. FBR Capital Markets & Co. is entitled to receive a commission rate of up 3.0% of gross sales in connection with the sale of the Company's common stock sold on the Company's behalf. From August 11, 2016 through December 31, 2016, the Company had sold through the FBR Sales Agreement an aggregate of 900,628 shares of the Company's common stock, and received gross proceeds of approximately $1,550,197, before deducting issuance expenses.

Also, during the year ended December 31, 2016, the Company issued 445,334 shares of common stock, in connection with the exercise of stock options and warrants, for proceeds of approximately $814,000.

Year Ended December 31, 2015

On August 29, 2015, the Company, SYN Biomics, a majority-owned subsidiary, and Mark Pimentel, M.D. entered into an amendment to the Stock Purchase Agreement dated December 3, 2013, which accelerated the date upon which Dr. Pimentel could exchange his shares of common stock in SYN Biomics for shares of the Company's common stock. On August 29, 2015, Dr. Pimentel notified the Company of his intent to exchange all of the shares of common stock in SYN Biomics owned by him for 1,350,000 shares of the Company's common stock in accordance with the terms of the Stock Purchase Agreement, as amended. On August 31, 2015, the Company issued 1,350,000 shares of the Company's common stock to Dr. Pimentel in exchange for all of the shares of common stock of SYN Biomics held by Dr. Pimentel.

On August 10, 2015, the Company expanded its relationship with Intrexon Corporation ("Intrexon") and entered into an Exclusive Channel Collaboration Agreement with Intrexon that governs a "channel collaboration" arrangement in which the Company will use Intrexon's technology relating to the development and commercialization of novel biotherapeutics for the treatment of patients with PKU. The Company paid Intrexon a technology access fee by the issuance of 937,500 shares of common stock, having a value equal to $3.0 million, which has been recorded as research and development expense.

In July 2015, the Company completed a public offering of 15,333,333 shares of common stock, including the fully exercised over-allotment option by the underwriters covering 2.0 million shares, at an offering price of $3.00 per share. The total gross proceeds of the offering, including the exercise in full of the over-allotment option, were approximately $46.0 million. Net proceeds to the Company, after deducting the underwriters' discount and other estimated expenses, were approximately $42.6 million. The Company paid direct offering costs of $3.4 million.

In addition, during the year ended December 31, 2015, the Company issued 655,321 shares of common stock to Prev ABR LLC, with a fair value of $1,350,000, that was recorded as research and development expense, in consideration for achieving the first three milestones as set forth in the Asset Purchase Agreement dated November 28, 2012. In lieu of receiving any cash payment for achieving the first three milestones, Prev ABR LLC exercised its option to receive the milestone payments in shares of the Company's common stock. The number of shares of common stock issued upon achievement of each milestone was based upon the average of the opening and closing prices of the Company's stock on the date each milestone was achieved as specified in the Asset Purchase Agreement.

Also, during the year ended December 31, 2015, the Company issued 35,006 shares of common stock, in connection with the exercise of stock options and warrants, for proceeds of approximately $41,000.

Year Ended December 31, 2014

On October 10, 2014, the Company completed a registered direct offering of 14,059,616 units, with each unit consisting of one share of the Company's common stock at a closing price of $1.47 for gross proceeds of $20.7 million and net proceeds of $19.1 million. The Company paid direct offering costs of $1.6 million.

During the year ended December 31, 2014, the Company issued 6,583 shares of common stock, in connection with the exercise of stock options, for proceeds of approximately $4,000. The Company also issued 232,619 shares of common stock, in connection with cashless warrant exercises for the year ended December 31, 2014.

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

7. Non-controlling Interest

On August 29, 2015, the Company, SYN Biomics and Mark Pimentel, M.D. entered into an amendment to the Pimentel Stock Purchase Agreement dated December 3, 2013, which accelerated the date upon which Dr. Pimentel could exchange his shares of common stock in SYN Biomics for shares of the Company's common stock. On August 29, 2015, Dr. Pimentel notified the Company of his intent to exchange all of the shares of common stock in SYN Biomics, 8.5%, owned by him for 1,350,000 shares of the Company's common stock in accordance with the terms of the Stock Purchase Agreement, as amended. On August 31, 2015, the Company issued 1,350,000 shares of the Company's common stock to Dr. Pimentel in exchange for all of the shares of common stock of SYN Biomics held by Dr. Pimentel.

The Company's non-controlling interest is accounted for under ASC 810, *Consolidation* ("ASC 810") and represents the minority shareholder's ownership interest related to the Company's subsidiary, SYN Biomics. In accordance with ASC 810, the Company reports its non-controlling interest in subsidiaries as a separate component of equity in the Condensed Consolidated Balance Sheets and reports both net loss attributable to the non-controlling interest and net loss attributable to the Company's common shareholders on the face of the Consolidated Statements of Operations. After Dr. Pimentel's transaction, the Company's equity interest in SYN Biomics is 88.5% and the non-controlling stockholder's interest is 11.5%. As of December 31, 2016, the accumulated net loss attributable to the non-controlling interest is $1.6 million that includes $1 million of prior year losses attributable to minority stockholders includingthe reversal of Dr. Pimentel's 2015 losses of $505,000 associated with the exchange of his shares of common stock in SYN Biomics for shares of the Company's common stock, and current year losses of $548,000 attributable to minority stockholders. Management considers the amounts which should have been recorded in prior years to be immaterial.

8. License, Collaborative and Employment Agreements and Commitments

License and Collaborative Agreements

As described below, the Company has entered into several license and collaborative agreements for the right to use research, technology and patents. Some of these license and collaborative agreements may contain milestones. The

specific timing of such milestones cannot be predicted and are dependent on future developments as well as regulatory actions which cannot be predicted with certainty (including actions which may never occur). Further, under the terms of certain licensing agreements, the Company may have the obligation to pay certain milestones contingent upon the achievement of specific levels of sales. Due to the long-range nature of such commercial milestone amounts, they are neither probable at this time nor predictable and consequently are not included in this disclosure.

Cedars-Sinai Medical Center ("CSMC") Agreement

On December 5, 2013, the Company, through its newly formed, majority owned subsidiary, SYN Biomics entered into a worldwide exclusive License Agreement with CSMC for the development of new treatment approaches to target non-bacterial intestinal microorganism life forms known as archaea that are associated with intestinal methane production and chronic diseases such as irritable bowel syndrome (IBS), obesity and type 2 diabetes. As part of the terms of the License Agreement the Company issued 334,911 unregistered shares of Company common stock to CSMC, paid $150,000 for the initial license fee and $220,000 for patent reimbursement fees. The License Agreement also provides that commencing on the second anniversary of the License Agreement, SYN Biomics will pay an annual maintenance fee, which payment shall be creditable against annual royalty payments owed under the License Agreement. In addition to royalty payments which are a percentage of Net Sales of licensed and technology products, SYN Biomics is obligated to pay CMSC a percentage of any non-royalty sublicense revenues, as well as additional consideration upon the achievement of milestones (the first two of which are payable in cash or unregistered shares of Company stock at the Company's option). On December 5, 2013, the Company also entered into an option agreement with CSMC, which expired unexercised on December 31, 2014.

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

8. License, Collaborative and Employment Agreements and Commitments – (continued)

The License Agreement terminates: (i) automatically if SYN Biomics enters into a liquidating bankruptcy or other specified bankruptcy event or if the performance of any term, covenant, condition or provision of the License Agreement will jeopardize the licensure of CMSC, its participation in certain reimbursement programs, its full accreditation by the Joint Commission of Accreditation of Healthcare Organizations or any similar state organizations, its tax exempt status or is deemed illegal; (ii) upon 30 days notice from CMSC if SYN Biomics fails to make a payment or use commercially reasonable efforts to exploit the patent rights; (iii) upon 60 days notice from CMSC if SYN Biomics fails to cure any breach or default of any material obligations under the License Agreement; or (iv) upon 90 days notice from SYN Biomics if CMCS fails to cure any breach or default of any material obligations under the License Agreement. SYN Biomics also has the right to terminate the License Agreement without cause upon six months notice to CSMC; however, upon such termination, SYN Biomics is obligated to pay a termination fee with the amount of such fee reduced: (i) if such termination occurs after an Investigational New Drug submission to the FDA but prior to completion of a Phase 2 clinical trial, (ii) reduced further if such termination occurs after completion of Phase 2 clinical trial but prior to completion of a Phase 3 clinical trial; and (iii) reduced to zero if such termination occurs after completion of a Phase 3 clinical trial.

Prior to the execution of the CSMC License Agreement, SYN Biomics issued shares of common stock of SYN Biomics to each of CSMC and Mark Pimentel, M.D. (the primary inventor of the intellectual property), representing 11.5% and 8.5%, respectively, of the outstanding shares of SYN Biomics (the “SYN Biomics Shares”). The Stock Purchase Agreements for the SYN Biomics Shares provide for certain anti-dilution protection until such time as an aggregate of $3.0 million in proceeds from equity financings are received by SYN Biomics as well as a right, under certain circumstances in the event that the SYN Biomics Shares are not then freely tradable, and subject to NYSE MKT, LLC approval, as of the 18 and 36 month anniversary date of the effective date of the Stock Purchase Agreements, for each of CSMC and the Dr. Pimentel to exchange up to 50% of their SYN Biomics shares for unregistered share of the Company’s common stock, with the rate of exchange based upon the relative contribution of the valuation of SYN Biomics to the public market valuation of us at the time of each exchange. The Stock Purchase Agreements also provide for tag-along rights in the event of the sale by the Company of its shares of SYN Biomics.

On August 29, 2015, the Company, SYN Biomics and Mark Pimentel, M.D. entered into an amendment to the Pimentel Stock Purchase Agreement, which accelerated the date upon which Dr. Pimentel can exchange his shares of common stock in SYN Biomics for shares of the Company’s common stock. On August 29, 2015, Dr. Pimentel notified the Company of his intent to exchange all of the shares of common stock in SYN Biomics owned by him for

1,350,000 shares of the Company's common stock in accordance with the terms of the Pimentel Stock Purchase Agreement, as amended. On August 31, 2015, the Company issued 1,350,000 shares of the Company's common stock to Dr. Pimentel in exchange for all of the shares of common stock of SYN Biomics held by Dr. Pimentel.

University of Texas Austin Agreement

On December 19, 2012, the Company entered into a License Agreement with The University of Texas at Austin (the "University") for the exclusive license of the right to use, develop, manufacture, market and commercialize certain research and patents related to pertussis antibodies. The License Agreement provides that the University is entitled to payment of past patent expenses, an annual payment of $50,000 per year commencing on the effective date through December 31, 2014 and a $25,000 payment on December 31, 2015 and milestone payments of $50,000 upon commencement of Phase 1 clinical trials, $100,000 upon commencement of Phase 3 clinical trials, $250,000 upon NDA submission in the U.S., $100,000 upon European Medicines Agency approval and $100,000 upon regulatory approval in an Asian country. In addition, the University is entitled to a running royalty upon net sales. The License Agreement terminates upon the expiration of the patent rights; provided, however that the License Agreement is subject to early termination by the Company in its discretion and by the University for a breach of the License Agreement by the Company.

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

8. License, Collaborative and Employment Agreements and Commitments – (continued)

In connection with the License Agreement, the Company and the University also entered into a Sponsored Research Agreement pursuant to which the University will perform certain research work related to pertussis. The Sponsored Research Agreement may be renewed annually, in the sole discretion of the Company, after the first year for two additional one year terms with a fixed fee for the first year of $303,287. The Sponsored Research Agreement was renewed for the second and third years for a fixed fee of $316,438 and $328,758 respectively, all payable in quarterly installments. The Sponsored Research Agreement was to expire on December 31, 2015; provided, however, the Sponsored Research Agreement is subject to early termination upon the written agreement of the parties, a default in the material obligations under the Research Agreement which remain uncured for sixty days after receipt of notice, automatically upon the Company's bankruptcy or insolvency and by the Company in its sole discretion at any time after the one year anniversary of the date of execution thereof upon no less than 90 days notice.

On October 22, 2015, the Company and the University amended the Sponsored Research Agreement to extend the termination date to January 15, 2017 and again on September 2, 2016 to extend the agreement until January 15, 2018. All other terms and conditions of the Sponsored Research Agreement remain unchanged. No further or additional payments will be made to the University as a result of this amendment.

Prev ABR LLC ("Prev") Agreement

On November 28, 2012, the Company entered into an agreement ("Prev Agreement") to acquire the C. diff program assets of Prev, including pre-Investigational New Drug (IND) package, Phase 1 and Phase 2 clinical data, manufacturing process data and all issued and pending U.S. and international patents. Upon execution and closing of the Prev Agreement, the Company paid Prev cash payments of $235,000 and issued 625,000 unregistered shares of its common stock to Prev. As set forth in the Prev Agreement, Prev may be entitled to receive additional consideration upon the achievement of certain milestones including: (i) commencement of an IND; (ii) commencement of a Phase 1 clinical trial; (iii) commencement of a Phase 2 clinical trial; (iv) commencement of a Phase 3 clinical trial; (v) filing a Biologic License Application (BLA) in the U.S. and for territories outside of the U.S. (as defined in the Prev Agreement); and (vi) approval of a BLA in the U.S. and for territories outside the-U.S. With exception of the first milestone payment, the remaining milestones are payable 50% in cash and 50% in our stock, however, at Prev's option the entire milestone may be payable in shares of our stock. Under the Prev Agreement, the Company may be required

to the return all of assets acquired from Prev if on or prior to the Prev Agreement execution date (i) the Company has not initiated toxicology studies in non-rodent models within 30 months, or (ii) within 36 months the Company has not filed a C. Diff program IND and such failure is not due to action or inaction of Prev or breach of its representations or warranties or covenants or if there is a change of control as defined in the Prev Agreement and after such change of control the assets are not further developed; provided however that such 30 and 36 month periods can be extended by the Company for an additional 12 months upon payment of a cash milestone payment. As of December 31, 2015, the first three milestones have been met, and at Prev's option, Prev elected to receive 655,321 shares of the Company's common stock. No milestones were achieved or such payments were made during the year ended December 31, 2016.

Intrexon Exclusive Channel Collaboration

On August 6, 2012, the Company expanded its relationship with Intrexon and entered into an Exclusive Channel Collaboration ("ECC") ("Infectious Disease ECC") with Intrexon that governs an "exclusive channel collaboration" arrangement in which the Company will use Intrexon's technology relating to the identification, design and production of human antibodies and DNA vectors for the development and commercialization of a series of monoclonal antibody therapies for the treatment of certain serious infectious diseases. Pursuant to the terms of the Second Stock Issuance Agreement with Intrexon, which was approved by the Company's stockholders on October 5, 2012, the Company issued 3,552,210 shares of its common stock, $0.001 par value, which issuance is also deemed paid in consideration for the execution and delivery of the Infectious Disease ECC, dated August 6, 2012, between the Company and Intrexon. The fair value of this transaction was $7.8 million and was charged to research and development expense for the year ended December 31, 2012, in accordance with the Company's accounting policy. In connection with the transactions contemplated by the Second Stock Issuance Agreement, and pursuant to the First Amendment to Registration Rights Agreement (the "First Amendment to Registration Rights Agreement") executed and delivered by the parties at the closing, which was declared effective on May 5, 2013. The Company filed a "resale" registration statement registering the resale of the shares issued under the Second Stock Issuance Agreement.

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

8. License, Collaborative and Employment Agreements and Commitments – (continued)

Subject to certain expense allocations and other offsets provided in the Infectious Disease ECC, the Company will pay Intrexon royalties on annual net sales of the Synthetic Products, calculated on a Synthetic Product-by-Synthetic Product basis. The Company has likewise agreed to pay Intrexon a percentage of quarterly revenue obtained from a sublicensor in the event of a sublicensing arrangement. No such payments were made during the year ended December 31, 2016.

The Company also agreed upon the filing of an IND application with the FDA for a Synthetic Product, or alternatively the filing of the first equivalent regulatory filing with a foreign regulatory agency (both as applicable, the "IND Milestone Event"), to pay Intrexon either (i) $2.0 million in cash, or (ii) that number of shares of Common Stock (the "IND Milestone Shares") having a fair market value equaling $2.0 million where such fair market value is determined using published market data of the share price for Common Stock at the close of market on the business day immediately preceding the date of public announcement of attainment of the IND Milestone Event.

Upon the first to occur of either first commercial sale of a Synthetic Product in a country or the granting of the regulatory approval of that Synthetic Product (both as applicable, the "Approval Milestone Event"), the Company agreed to pay to Intrexon either (i) $3.0 million in cash, or (ii) that number of shares of Common Stock (the "Approval Milestone Shares") having a fair market value equaling $3.0 million where such fair market value is determined using published market data of the share price for Common Stock at the close of market on the business day immediately preceding the date of public announcement of attainment of the Approval Milestone Event.

The Company also agreed that it will pay an optional and varying fee whereby the Company remits a payment, in cash or equity at our sole discretion, to Intrexon calculated as a multiple of the number of targets in excess of three total that the Company desires to elect (the "Field Expansion Fee"). The Field Expansion Fee must be paid completely in either Common Stock or cash, and will comprise either (i) $2.0 million in cash for each target in excess of three total that the Company elects, or (ii) that number of shares of Common Stock (the "Field Expansion Fee Shares") having a fair market value equaling $2.0 million for each such target that the Company elects in excess of three where such fair market value is determined using published market data establishing the volume-weighted average price for a share of Common Stock over the 30 day period immediately preceding the date of the Field Expansion Fee Closing. No milestones were achieved or such payments were made during the year ended December 31, 2016.

On August 10, 2015, the Company expanded our relationship with Intrexon and entered into an Exclusive Channel Collaboration Agreement (the “Channel Agreement”) with Intrexon that governs a “channel collaboration” arrangement in which the Company will use Intrexon’s technology relating to the development and commercialization of novel biotherapeutics (a “Collaboration Product”) for the treatment of patients with PKU. On September 2, 2015, in accordance with the terms of the Intrexon Stock Issuance Agreement that that the Company entered into in connection with the Channel Agreement, the Company paid Intrexon a technology access fee by the issuance of 937,500 shares of common stock, having a value equal to $3 million as of August 7, 2015.

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

8. License, Collaborative and Employment Agreements and Commitments – (continued)

In addition, upon the achievement of certain milestones, the Company agreed to pay Intrexon milestone payments of up to $27 million for each product developed as follows: (i) $2 million upon first dosing of a patient in a Phase 1 clinical trial upon commencement of an IND, payable in stock or cash at our option; (ii) a payment 30 days after achievement of the first commercial sale of a Collaboration Product in the United States or approval of a New Drug Application and/or Biologics License Application for a Collaboration Product by the U.S. Food and Drug Administration; and (iii) a payment 30 days after achievement of the first commercial sale of a Collaboration Product in a nation subject to the authority of the European Medicines Agency (EMA) or approval of a Marketing Authorization Application for a Collaboration Product by the EMA. The Company will pay Intrexon royalties on annual net sales of Collaboration Products, calculated on a product-by-product basis, equal to a percent of net sales (ranging from mid-single digits on the first $100 million of net sales to mid-teen digits on net sales in excess of $750 million). The Company likewise agreed to pay Intrexon a percentage of quarterly revenue obtained from a sublicensor in the event of a sublicensing arrangement. Pursuant to the Second Amendment to Registration Rights Agreement, the Company filed a “resale” registration statement to register the shares issued under the Intrexon Stock Issuance Agreement, which was declared effective by the SEC on October 15, 2015.

During December 2012, the Company paid Intrexon a prepayment of research and development expenses of $2.5 million for research and development goods and services to be provided in the future and has been recorded on the Company’s consolidated balance sheets in prepaid expenses and other current assets. Related research and development expenses of $643,000, $424,000 and $293,000 were recorded against this prepayment for the years ended December 31, 2016, 2015 and 2014, respectively. At December 31, 2016, there is no remaining balance of the Intrexon prepayment of research and development expenses.

Employment Agreements

Effective February 3, 2012, Jeffrey Riley was appointed to serve as the Company’s Chief Executive Officer and President. In connection with his appointment, Mr. Riley entered into a three-year employment agreement with the Company (the “Original Riley Agreement”). Pursuant to the Original Riley Employment Agreement, Mr. Riley was entitled to an annual base salary of $348,000 and was eligible for discretionary performance and transactional bonus payments. Additionally, Mr. Riley was granted options to purchase 750,000 shares of the Company’s common stock

with an exercise price equal to the per share market price on the date of issue. These options will vest pro rata, on a monthly basis, over 36 months. The Company measured the fair value of the stock options at approximately $1.7 million using a Black-Scholes valuation model.

Effective March 18, 2015, the Company entered into a new two-year employment agreement with Mr. Riley (the "Riley Employment Agreement"). Pursuant to the new Riley Employment Agreement Mr. Riley's annual base salary remained at $385,000. Beginning in 2015 and for each full calendar year thereafter, Mr. Riley is eligible for an annual performance bonus of up to seventy-five percent (75%) of his base salary. The annual bonus will be based upon the Board's assessment of Mr. Riley's performance. The Employment Agreement also includes confidentiality obligations, inventions assignments by Mr. Riley as well as change in control, non-solicitation and non-competition provisions.

Effective December 4, 2015, the Company entered into an amendment to the Riley Employment Agreement dated March 18, 2015, to increase Mr. Riley's annual base salary to $550,000.

On April 28, 2015, the Company entered into a two-year employment agreement with Steven A. Shallcross (the "Shallcross Employment Agreement"), who was appointed to serve as the Company's Chief Financial Officer, Treasurer and Secretary, effective June 1, 2015. Pursuant to the Employment agreement, Mr. Shallcross is entitled to an annual base salary of $315,000. Additionally, Mr. Shallcross was granted options to purchase 900,000 shares of the Company's common stock with an exercise price equal to the per share market price on the date of issue. These options vest pro rata, on a monthly basis, over 36 months. The Company measured the fair value of the stock options at approximately $1.9 million using a Black-Scholes valuation model. In 2015 and for each full calendar year thereafter, Mr. Shallcross will be eligible for an annual performance bonus of up to seventy-five percent (75%) of his base salary. The annual bonus is to be based upon the Board's assessment of Mr. Shallcross' performance. The Employment Agreement also includes confidentiality obligations and inventions assignments by Mr. Shallcross and non-solicitation and non-competition provisions.

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

8. License, Collaborative and Employment Agreements and Commitments – (continued)

Effective November 30, 2016, the Company entered into an amendment to Shallcross Employment Agreement dated April 28, 2015, to increase Mr. Shallcross' annual base salary to $346,500.

The Riley Employment Agreement and the Shallcross Employment Agreement each have a stated term of two years but may be terminated earlier pursuant to their terms. If either Mr. Riley's or Mr. Shallcross' (each an "Executive") employment is terminated for any reason, he or his estate as the case may be, will be entitled to receive the accrued base salary, vacation pay, expense reimbursement and any other entitlements accrued by him to the extent not previously paid (the "Accrued Obligations"); provided , however , that if his employment is terminated (1) by the Company without Cause or by the Executive for Good Reason (as each is defined below) then in addition to paying the Accrued Obligations, (x) the Company will continue to pay his then current base salary and continue to provide benefits at least equal to those which were provided at the time of termination for a period of twelve (12) months and (y) he shall have the right to exercise any vested equity awards until the earlier of six (6) months after termination or the remaining term of the awards, or (2) by reason of his death or Disability (as defined in the Riley Employment Agreement and the Shallcross Employment Agreement), then in addition to paying the Accrued Obligations, he would have the right to exercise any vested options until the earlier of six (6) months after termination or the remaining term of the awards. In such event, if the Executive commenced employment with another employer and becomes eligible to receive medical or other welfare benefits under another employer-provided plan, the medical and other welfare benefits to be provided by The Company as described herein will terminate.

The Riley Employment Agreement and the Shallcross Employment Agreement each provide that upon the closing of a "Change in Control" (as defined below), the time period that the Executive will have to exercise all vested stock options and other awards that the Executive may have will be equal to the shorter of: (i) six (6) months after termination, or (ii) the remaining term of the award(s). Upon the closing of a Change in Control, all of Mr. Shallcross' unvested options shall immediately vest. If within one year after the occurrence of a Change in Control, the Executive terminates his employment for "Good Reason" or the Company terminates the Executive's employment for any reason other than death, Disability or Cause, the Executive will be entitled to receive: (i) the portion of his base salary for periods prior to the effective date of termination accrued but unpaid (if any); (ii) all unreimbursed expenses (if any); (iii) an aggregate amount (the "Change in Control Severance Amount") equal to two times the sum of the base salary plus an amount equal to the bonus that would be payable if the "target" level performance were achieved under the Company's annual bonus plan (if any) in respect of the fiscal year during which the termination occurs (or the prior fiscal year if bonus levels have not yet been established for the year of termination); and (iv) the payment or provision

of any other benefits. The Change in Control Severance Amount is to be paid in a lump sum, if the Change in Control event constitutes a “change in the ownership” or a “change in the effective control” of the Company or a “change in the ownership of a substantial portion of a corporation’s assets” (each within the meaning of Section 409A of the Internal Revenue Code), or in 48 substantially equal payments, if the Change in Control event does not so comply with Section 409A. Upon the termination of employment for Good Reason by the Executive or upon the involuntary termination of employment of Executive for any reason other than death, Disability or Cause, in either case within two years commencing after the occurrence of a Change in Control, the Executive will be entitled to receive for a period of two years commencing on the date of such termination medical, dental, life and disability coverage for himself and his family members which is not less favorable than the coverage carried by the Company at the time of termination.

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

8. License, Collaborative and Employment Agreements and Commitments – (continued)

For the purposes of the Riley Employment Agreement and the Shallcross Employment Agreement "Change in Control" is defined as: (i) any person or entity becoming the beneficial owner, directly or indirectly, of our securities representing fifty (50%) percent of the total voting power of all its then outstanding voting securities; (ii) a merger or consolidation of us in which our voting securities immediately prior to the merger or consolidation do not represent, or are not converted into securities that represent, a majority of the voting power of all voting securities of the surviving entity immediately after the merger or consolidation; or (iii) a sale of substantially all of our assets or our liquidation or dissolution.

For purpose of the Riley Employment Agreement and the Shallcross Employment Agreement, "Good Reason" is defined as the occurrence of any of the following events without the respective Executive's consent: (i) a material reduction in the Executive's base salary (other than an across-the-board decrease in base salary applicable to all executive officers of the Company); (ii) a material breach of the employment agreement by the Company; (iii) a material reduction in the Executive's duties, authority and responsibilities relative to the Executive's duties, authority, and responsibilities in effect immediately prior to such reduction; or (iv) the relocation of the Executive's principal place of employment, without the Executive's consent, in a manner that lengthens his one-way commute distance by fifty (50) or more miles from his then-current principal place of employment immediately prior to such relocation.

For purposes of the Riley Employment Agreement and the Shallcross Employment Agreement, "Cause" is defined as that the Executive shall have engaged in any of the following acts or that any of the following events shall have occurred, all as determined by the Board of Directors of the Company in its sole and absolute discretion: (i) gross insubordination, acts of embezzlement or misappropriation of funds, fraud, dereliction of fiduciary obligations; (ii) conviction of a felony or other crime involving moral turpitude, dishonesty or theft (including entry of a ***nolo contendere*** plea); (iii) willful unauthorized disclosure of confidential information belonging to the Company or entrusted to the Company by a client; (iv) material violation of any provision of the Executive's employment agreement, of any Company policy, and/or of a confidentiality agreement, which, to the extent it is curable by the Executive, is not cured by the Executive within thirty (30) days of receiving written notice of such violation by the Company; (v) being under the influence of drugs (other than prescription medicine or other medically related drugs to the extent that they are taken in accordance with their directions) during the performance of the Executive's duties; (vi) engaging in behavior that would constitute grounds for liability for harassment (as proscribed by the U.S. Equal Employment Opportunity Commission Guidelines or any other applicable state or local regulatory body) or other egregious conduct that violates laws governing the workplace; or (vii) willful failure to perform his written assigned

tasks, where such failure is attributable to the fault of the Executive which, to the extent it is curable by the Executive, is not cured by Executive within thirty (30) days of receiving written notice of such violation by the Company.

Operating Lease

During 2012, the Company entered into a twelve month operating lease for office space in Ann Arbor, Michigan. In September 2015, this lease was amended to extend the term of the lease to December 31, 2016, for annual lease payments of $40,000. This lease was not renewed. In August 2015, the Company also entered into a sixty-six month operating lease that may be renewed for one additional term of five years, for office space in Rockville, Maryland, for annual lease payments of $142,172. The Company's lease provides for fixed monthly rent for the term of the lease, with monthly rent increasing every 12 months subsequent to the first 12 months of the lease. In March 2016, the Company amended the Rockville, Maryland lease to increase the leased space and extend the lease term of the August 2015 lease conterminous with the lease amendment to sixty-nine months for annual lease payments of $285,843.

During the years ended December 31, 2016, 2015 and 2014, the Company recognized rent expense of $145,000, $108,000 and $77,000, respectively. The following table summarizes the Company's future minimum lease payments as of December 31, 2016 *(in thousands)*:

	2017	**2018**	**2019**	**2020**	**2021**	**Total**
Operating Lease	$204	$292	$300	$309	$321	$1,426
Total	$204	$292	$300	$309	$321	$1,426

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

9. Income Taxes

There was no income tax expense for the years ended December 31, 2016 and 2015 due to the Company's net losses. The Company's tax expense differs from the "expected" tax expense for the years ended December 31, 2016 and 2015 (computed by applying the Federal Corporate tax rate of 34% to loss before taxes and 3.96% for blended state income tax rate, the blended rate used was 37.96%), as follows (*in thousands*):

	2016	2015
Computed "expected" tax-benefit – Federal	$(9,453)	$(14,870)
Computed "expected" tax-benefit – State	(1,101)	(1,732)
Adjustment of "expected" tax-benefit to actual	(431)	199
Meals, entertainment and other	10	8
Non-deductible stock-based compensation	574	877
Fair Market Value Adjustment – Warrants	(4,332)	1,447
Change in valuation allowance	14,733	14,071
	$—	$—

The effects of temporary differences that gave rise to significant portions of deferred tax assets at December 31, 2016 and 2015 are as follows (*in thousands*):

	2016	2015
Deferred tax assets:		
Stock issued for services	$1,861	$922
Accrued compensation	119	105
Stock issued for acquisition of program	1,576	1,337
Stock issued for license agreement	3,147	2,308
Stock issued for milestone payment	478	-
Amortizable License Fee	9	-
Net operating loss carry-forward	50,517	38,302
Total gross deferred tax assets	57,707	42,974
Less: valuation allowance	(57,707)	(42,974)

Total net deferred tax assets	$—	$—

At December 31, 2016, the Company has a net operating loss carry-forward of approximately $133.3 million available to offset future taxable income expiring through 2035. However, utilization of these net operating losses may be limited due to potential ownership changes under Section 382 of the Internal Revenue Code.

The valuation allowance at December 31, 2015 was approximately $42.9 million. The net change in valuation allowance during the year ended December 31, 2016 was an increase of approximately $14.7 million. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The ultimate realization of deferred income tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred income tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based on consideration of these items, management has determined that enough uncertainty exists relative to the realization of the deferred income tax asset balances to warrant the application of a full valuation allowance as of December 31, 2016.

ASC 740-10 “ *Accounting for Uncertain Tax Positions* ” prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return and also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition.

As of December 31, 2016 and 2015, the Company had no unrecognized tax benefits and no adjustments to liabilities or operations were required under ASC 740-10. The Company’s practice was and continues to be to recognize interest and penalty expenses related to uncertain tax positions in income tax expense, which was zero for the years ended December 31, 2016 and 2015. The Company files United States federal and various state income tax returns.

The Company does not anticipate that it is reasonably possible that unrecognized tax benefits as of December 31, 2016 will significantly change within the next 12 months.

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

10. Related Party Transactions

In August 2015, the Company expanded its relationship with Intrexon and entered into an Exclusive Channel Collaboration Agreement with Intrexon. In connection with the Channel Agreement, the Company paid Intrexon a technology access fee by the issuance of 937,500 shares of common stock, having a value equal to $3 million as of August 7, 2015. In August 2012, the Company entered into an Infectious Disease ECC with Intrexon and issued 3,552,210 shares of common stock as consideration, having a fair value of $7.8 million ($2.20 per share), based on the quoted closing trading price on October 5, 2012. In November 2011, the Company entered into its initial ECC with Intrexon and issued 3,123,558 shares of common stock as consideration, having a fair value of $1.7 million ($0.54 per share), based on the quoted closing trading price. In connection with the November 2011 and August 2012 ECCs, the Company paid Intrexon approximately $2.9 million during 2012, including a prepayment of research and development expenses of $2.5 million for research and development goods and services to be provided in the future which has been recorded on the Company's balance sheet in prepaid expenses and other current assets as described in Note 4. In October 2012, the Company consummated its October 2012 Private Placement and entered into a stock purchase agreement with several investors, including NRM VII Holdings I, LLC, an entity affiliated with Intrexon. Randal J. Kirk, directly and through certain affiliates, has voting and dispositive power over a majority of the outstanding capital of Intrexon Corporation, and controls NRM VII Holdings I, LLC. Mr. Kirk disclaims beneficial ownership of the shares held by Intrexon Corporation and NRM VII Holdings I, LLC, except to the extent of any pecuniary interest therein.

In December 2013, through the Company's subsidiary, Synthetic Biomics, Inc., the Company 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. The Company 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. During the year ended December 31, 2016, the Company paid Cedars-Sinai Medical Center $350,000 for milestone payments related this license agreement. There were no milestone payments made during year ended December 31, 2015.

On November 18, 2016, Scott Tarriff acquired 300,000 shares of the Company's common stock together with a Series A warrant to purchase 300,000 shares of the Company's common stock at an exercise price of $1.43 and a Series B warrant to purchase 300,000 shares of the Company's common stock at an exercise price of $1.72 for an aggregate

purchase price of $300,000. The shares of stock and warrants were acquired in the Company's public offering that was consummated on November 18, 2016. The Series A warrant may be exercised until the four year anniversary of the date of its issuance and the Series B warrant may be exercised until December 31, 2017.

11. Selected Quarterly Financial Data (Unaudited) ***(In thousands, except per share amounts)***

	Quarter Ended			
	March 31, 2016	June 30, 2016	September 30, 2016	December 31, 2016
Loss from operations	$(10,581)	$(9,311)	$(9,156)	$(10,204)
Net loss	$(11,078)	$(5,764)	$(8,489)	$(2,472)
Net loss per share – basic	$(0.12)	$(0.06)	$(0.09)	$(0.02)
Net loss per share – dilutive	$(0.12)	$(0.10)	$(0.09)	$(0.02)
Weighted average common share – basic	90,826,752	91,015,733	91,441,687	103,804,308
Weighted average common share – dilutive	90,826,752	93,930,540	91,441,687	103,804,308

	Quarter Ended			
	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
Loss from operations	$(8,207)	$(9,730)	$(11,650)	$(11,393)
Net loss	$(12,359)	$(13,623)	$(7,507)	$(11,296)
Net loss per share – basic	$(0.17)	$(0.19)	$(0.08)	$(0.12)
Net loss per share – dilutive	$(0.17)	$(0.19)	$(0.12)	$(0.12)
Weighted average common share – basic	72,673,959	72,736,829	85,974,751	90,810,629
Weighted average common share – dilutive	72,673,959	72,736,829	87,585,103	90,810,629

12. Subsequent Events

On January 17, 2017, the Company entered into a two-year employment agreement with Dr. Joseph Sliman (the "Sliman Employment Agreement"), who was promoted at the Company from the position of Senior Vice President–Clinical & Regulatory Affairs to the position of Chief Medical Officer. The terms of the Employment Agreement are set forth below. Pursuant to the terms of the Employment Agreement, Dr. Sliman is entitled to an annual base salary of $385,000 and an annual performance bonus of up to seventy five percent (75%) of his annual base salary. The annual bonus will be based upon the assessment of the Company's Board of Directors (the "Board") of Dr. Sliman's performance. Dr. Sliman was also granted a seven (7) year incentive stock option to purchase at an exercise price equal to the per share market price on the date of issue, one hundred and eighty-eight thousand nine hundred and twenty-seven (188,927) shares of the Company's common stock, vesting pro rata on a monthly basis over

a three (3) year period. The Employment Agreement also includes confidentiality obligations and inventions assignments by Dr. Sliman and non-solicitation and non-competition provisions.

Effective February 27, 2017, the Company entered into a new two-year employment agreement with Mr. Riley (the "Riley Employment Agreement"), which replaced the prior two -year employment agreement that the Company had entered into on March 18, 2015 with Mr. Riley which was due to expire on March 17, 2017. Pursuant to the Riley Employment Agreement, Mr. Riley's annual base salary remained at $550,000. Beginning in 2017 and for each full calendar year thereafter, Mr. Riley is eligible for an annual performance bonus of up to seventy-five percent (75%) of his base salary. The annual bonus will be based upon the Board's assessment of Mr. Riley's performance. The Riley Employment Agreement also includes confidentiality obligations, inventions assignments by Mr. Riley as well as change in control, non-solicitation and non-competition provisions.

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

Not applicable.

Item 9A. ***Controls and Procedures***

Disclosure Controls and Procedures

The Company has adopted and maintains disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Annual Report on Form 10-K, is collected, recorded, processed, summarized and reported within the time periods specified in the rules of the SEC. The Company's disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to management to allow timely decisions regarding required disclosure. As required under Exchange Act Rule 13a-15, the Company's management, including the Chief Executive Officer and Chief Financial Officer, after evaluating the effectiveness of disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Annual Report on Form 10-K have concluded that based on such evaluation, the Company's disclosure controls and procedures were effective to ensure that information required to be disclosed by the Company in the reports that the Company files or submits under the Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control Over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15. Internal control over financial reporting is defined in Rule 13a-15(f) and 15(d)-15(f) under the Exchange Act as a process designed to provide reasonable assurance to the Company's management and Board of Directors regarding the preparation and fair presentation of published financial statements. Management conducted an assessment of the Company's internal control over financial reporting as of December 31, 2016 based on the framework and criteria established by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013). Based on the assessment, management concluded that, as of December 31, 2016, the Company's internal control over financial reporting was effective based on those criteria.

The Company's management, including its Chief Executive Officer and Chief Financial Officer, does not expect that the Company's disclosure controls and procedures and its internal control processes will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of error or fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that the breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

BDO USA LLP, the independent registered public accounting firm that audited the Company's financial statements included elsewhere in this Annual Report on Form 10-K for the fiscal year ended December 31, 2016, has issued an attestation report on the effectiveness of the Company's internal control over financial reporting as of December 31, 2016. Such report appears below in this Item 9A under the adding "Report of Independent Registered Public Accounting Firm."

Changes in Internal Control

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during our fiscal quarter ended December 31, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

Synthetic Biologics, Inc.

Rockville, Maryland

We have audited Synthetic Biologics, Inc.'s internal control over financial reporting as of December 31, 2016, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Synthetic Biologics, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become

inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion Synthetic Biologics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Synthetic Biologics, Inc. as of December 31, 2016 and 2015, and the related consolidated statements of operations, equity, and cash flows for each of the three years in the period ended December 31, 2016, and our report dated March 2, 2017 expressed an unqualified opinion thereon that included an explanatory paragraph regarding Synthetic Biologic, Inc.'s ability to continue as a going concern.

/s/ BDO USA, LLP

Troy, Michigan

March 2, 2017

Item 9B. ***Other Information***

Effective February 27, 2017, we entered into a new two-year employment agreement with Mr. Riley (the "2017 Riley Employment Agreement"), which replaced the prior two -year employment agreement that we had entered into on March 18, 2015 with Mr. Riley which was due to expire on March 17, 2017. Pursuant to the 2017 Riley Employment Agreement, Mr. Riley's annual base salary remained at $550,000. Beginning in 2017 and for each full calendar year thereafter, Mr. Riley is eligible for an annual performance bonus of up to seventy-five percent (75%) of his base salary. The annual bonus will be based upon the Board's assessment of Mr. Riley's performance. See Item 11 Executive Compensation-Employment Agreements for a more detailed description of the terms of the 2017 Riley Employment Agreement.

PART III

Item 10.*Directors, Executive Officers and Corporate Governance*

Below is certain information regarding our directors and executive officers.

Name	Age	Position
Jeffrey Riley	54	Chief Executive Officer, President and Director
Steven A. Shallcross	55	Chief Financial Officer, Treasurer and Secretary
Joseph A Sliman	44	Chief Medical Officer
Jeffrey J. Kraws	52	Chairman
Scott L. Tarriff	57	Director
Jeffrey Wolf, J.D.	53	Director

Jeffrey Riley. Mr. Riley, a member of the Company's Board of Directors since March 2010 and Chairman of the Board from November 2011 to May 2012, was appointed as the Company's President and Chief Executive Officer in February 2012. He has more than 20 years of experience in the biotechnology and pharmaceutical industries during which he negotiated numerous worldwide strategic corporate alliances, established joint ventures, and assisted in obtaining venture financings to support product development. From November 2009 until January 2012, Mr. Riley served as Managing Director of 526 Ventures, a life science-focused venture consulting firm with a commercial and traditional focus. Prior to this, he was a venture partner with QIC Bioventures Fund, the life science-focused venture component of the $70 billion Australian-based Queensland Investment Corporation (QIC). Over his career, Mr. Riley held senior positions within the mergers & acquisitions and in country management groups at both SmithKline Beecham and Pfizer. Additionally, he served as CFO and VP Corporate Development for Nichols Institute Diagnostics, later acquired by Corning and spun out to Quest Diagnostics, Inc. (NYSE: DGX). Mr. Riley holds a Bachelor of Science degree from Boise State University, completed coursework at UCSF/Berkeley in drug discovery/development and participated in a dual-degree graduate program (MBA/MIM) sponsored by Arizona State University and the Thunderbird School of Global Management.

Mr. Riley brings to the Board extensive knowledge of the pharmaceutical industry. Having served in senior corporate positions in biotech and pharmaceutical companies he has a vast knowledge of the industry. His business experience provides him with a broad understanding of the operational, financial and strategic issues facing public companies.

Steven A. Shallcross. Mr. Shallcross joined the Company in June 2015 as Chief Financial Officer, Treasurer and Secretary. Mr. Shallcross brings to Synthetic Biologics operational, financial and international biotech industry experience, as well as an established track record at leading the financial development and strategy for several publicly traded biotech companies. From May 2013 through May 2015, Mr. Shallcross served as Executive Vice

President and Chief Financial Officer of Nuo Therapeutics, Inc. (formerly Cytomedix, Inc.). In January 2016, Nuo Therapeutics, Inc. filed a voluntary petition for relief under Chapter 11 of the U.S. Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware and on April 25, 2016, the Bankruptcy Court entered an order granting approval of Nuo's plan of reorganization. From July 2012 to May 2013, Mr. Shallcross held the offices of Executive Vice President, Chief Financial Officer and Treasurer of Empire Petroleum Partners, LLC, a motor fuel distribution company. From July 2011 to March 2012, Mr. Shallcross was Acting Chief Financial Officer of Senseonics, a privately-held medical device company located in Germantown, MD. From January 2009 to March 2011, he served as Executive Vice President and Chief Financial Officer of Innocoll AG (formerly privately held Innocoll Holdings, Inc.), a global, commercial-stage biopharmaceutical company specializing in the development and commercialization of collagen based products. He also served for four years as the Chief Financial Officer and Treasurer of Vanda Pharmaceuticals, Inc., leading the company through its successful IPO and follow-on offering and previously served as the Senior Vice President and Chief Financial Officer of Middlebrook Pharmaceuticals, Inc. (formerly Advancis Pharmaceutical Corporation). In addition Mr. Shallcross also served as the Chief Financial Officer of Bering Truck Corporation. He holds an MBA from the University of Chicago's Booth School of Business, a Bachelor of Science degree in Accounting from the University of Illinois, Chicago, and is a Certified Public Accountant in the State of Illinois.

Joseph A. Sliman. Mr. Sliman was appointed as the Company's Chief Medical Officer, effective January 17, 2017. From January 13, 2014 until January 17, 2017, Dr. Sliman served as the Company's Senior Vice President-Clinical & Regulatory Affairs. Dr. Sliman has more than 18 years of experience in clinical and public health research, including 10 years directing clinical projects and product development, in therapeutic areas such as infectious diseases and vaccines. From September 2012 until January 2014, Dr. Sliman served as Senior Medical Director and Head of Patient Safety and Pharmacovigilance at Vanda Pharmaceuticals Inc., where he directed efforts for a New Drug Application for HETLIOZ (tasimelteon), which is indicated for the treatment of Non-24 Hour Disorder in totally blind adults. From December 2008 until August 2012, Dr. Sliman served as Medical Director in Vaccines and Infectious Diseases at MedImmune, Inc., where he was a member of successful Biologics Licensure Application teams. Prior to joining MedImmune, Inc., he served as Associate Medical Director at Dynport Vaccine Company, where he was the clinical director for seasonal and pandemic influenza vaccine trials as well as its Defense Vaccines development program (partnered with Department of Defense Joint Vaccines Acquisition Program). During his service in the United States Navy, Dr. Sliman led the U. S. Pacific Fleet disease surveillance programs, including influenza surveillance, preparedness, and prevention, as well as communicable disease and injury surveillance and prevention and health policy development. Dr. Sliman earned an M.D. from the Uniformed Services University, a Master's Degree in Public Health from the Johns Hopkins University School of Public Health, and a B.S. in Molecular and Cell Biology, with Honors in Biology, from Pennsylvania State University.

Jeffrey J. Kraws. Mr. Kraws has been a member of the Company's Board of Directors since January of 2006, and was appointed independent, non-executive Chairman of the Board in May 2012. Since 2003, Mr. Kraws has served as Chief Executive Officer and co-founder of Crystal Research Associates and CRA Advisors, and since February 2012, he has served as partner and co-founder of TopHat Capital, LLC. Since August 2016, Mr. Kraws has served as the President of Ra Medical Systems Inc., a private medical device company. Mr. Kraws is a Registered Representative at Terranova Capital Partners, Inc. since October 2014, a partner at Grannus Securities Pty Ltd. (an Australian based private equity fund) since November 2015 and a partner at Phoenix Holdings since November 2015. Well known and respected on Wall Street, Mr. Kraws has received some of the most prestigious awards in the industry. Among other awards, he was given a "5-Star Rating" in 2001 by Zacks and was ranked the number one analyst among all pharmaceutical analysts for stock performance in 2001 by Starmine.com. Prior to founding Crystal Research Associates, Mr. Kraws served as co-president of The Investor Relations Group (IRG), a firm representing primarily under-followed, small-capitalization companies. Previously, Mr. Kraws served as a managing director of healthcare research for Ryan Beck & Co. and as director of research/senior pharmaceutical analyst and managing director at Gruntal & Co., LLC (prior to its merger with Ryan Beck & Company). Mr. Kraws served as managing director of the healthcare research group and senior pharmaceutical analyst at First Union Securities (formerly EVEREN Securities); as senior U.S. pharmaceutical analyst for the Swedish-Swiss conglomerate Asea Brown Boveri; and as managing director and president of the Brokerage/Investment Banking operation of ABB Aros Securities, Inc. He also served as senior pharmaceutical analyst at Nationsbanc Montgomery Securities, BT Alex Brown & Sons, and Buckingham Research. Mr. Kraws also has industry experience, having been responsible for competitive analysis within the treasury group at Bristol-Myers-Squibb Company. During 2006 through February of 2007, Mr. Kraws served as our Vice President of Business Development, on a part-time basis. Since December 2013, Mr. Kraws serves on the board of directors of Saleen Automotive, Inc. (OTC: SLNN). He holds an M.B.A. from Cornell University and a B.S. degree from State University of New York — Buffalo. Mr. Kraws brings a strong business background to Synthetic Biologics, having worked as a pharmaceutical analyst for over 22 years.

Mr. Kraws brings to the Board significant strategic, business and financial experience related to the business and financial issues facing pharmaceutical companies. Mr. Kraws has a broad understanding of the operational, financial and strategic issues facing pharmaceutical companies. Through his services as the Company's Vice President of Business Development during 2006 and a part of 2007, he developed extensive knowledge of Synthetic Biologics' business.

Scott L. Tarriff. Mr. Tarriff has been a member of the Company's Board of Directors since February 3, 2012. Since January 2007 he has served as a director and Chief Executive Officer of Eagle Pharmaceuticals, Inc., a publicly traded, hospital specialty company. Eagle Pharmaceuticals, Inc. (NASDAQ: EGRX) is focused on developing branded parenteral products through the application of various in-licensed drug delivery technologies. Prior to joining Eagle, Mr. Tariff held various executive positions at Par Pharmaceutical Companies, Inc., a publicly-traded developer, manufacturer and marketer of specialty pharmaceuticals, including as president and chief executive officer from September 2003 to September 2006, after joining Par in 1998. Mr. Tarriff also served on Par's board of directors from 2002 to September 2006. Prior to that, Mr. Tarriff held various positions with Bristol-Meyers Squibb, a publicly-traded biopharmaceutical company, including senior director marketing. Mr. Tarriff currently serves on the board of directors of ZIOPHARM Oncology, Inc., a publicly traded company biopharmaceutical company and previously served on the board of directors of Clinical Data, Inc., a publicly-traded pharmaceutical company, from September 2009 to April 2011 when Clinical Data was acquired by Forest Laboratories, Inc. Mr. Tarriff holds a B.S.

in marketing from Pennsylvania State University and an M.B.A. from Rider College.

Mr. Tarriff brings to our Board of Directors significant knowledge of and experience in the pharmaceutical and medical industries. He has extensive business, managerial, executive and leadership experience that further qualify him to serve as a member of the Board and a valuable understanding of the role played by the Board of Directors acquired through service on the boards of many companies. He has had a long and successful career in top executive leadership positions with leading, publicly traded pharmaceutical companies including Eagle Pharmaceuticals, Inc., Par Pharmaceuticals Companies, Inc. and Bristol-Myers Squibb.

Jeffrey Wolf, J.D. Mr. Wolf, who has been a member of the Company's Board of Directors since 2006, has substantial experience in creating, financing, nurturing and growing new ventures based upon breakthrough research and technology. In August 2008, Mr. Wolf founded Heat Biologics, Inc. (NASDAQ: HTBX), a publicly traded company engaged in research and development of drugs focused on combating cancer and other diseases. Since April 2010, Mr. Wolf has served as the Chief Executive Officer and Chairman of the Board of Heat Biologics, Inc. Prior to founding Heat Biologics, Inc., from June 1997 to March 2011, Mr. Wolf has served as managing director at Seed-One Ventures, LLC a venture firm focused on launching and growing exceptional healthcare companies from the ground up. Since founding Seed-One, Mr. Wolf has founded and run several medical companies. Mr. Wolf's start-ups include Avigen, a San Francisco-based gene therapy company where he was a co-founder and director; TyRx Pharma, a Princeton-based company focused on the development of bio-compatible polymers where he was a co-founder and Chairman; EluSys Therapeutics, a New Jersey company focused on the development of novel technology to remove blood-borne pathogens where he was a cofounder, Chairman and Chief Executive Officer; and GenerationOne, a Miami-based company focused on mobile-based collaborative care, where he was the founder, Chairman and Chief Executive Officer. Mr. Wolf received his M.B.A. from Stanford Business School, his J.D. from New York University School of Law and his B.A. from the University of Chicago, where he graduated with honors in Economics. Mr. Wolf serves as a director of several Seed-One portfolio companies.

Mr. Wolf has extensive knowledge of the industry and in particular research and development. His legal and business background provide him with a broad understanding of the legal, operational, financial and strategic issues facing Synthetic Biologics. Having served as a board member on other public company boards, Mr. Wolf has an extensive understanding of the operational, financial and strategic issues facing public companies.

Directors' Term of Office

Directors will hold office until the next annual meeting of stockholders and the election and qualification of their successors. Officers are elected annually by our Board of Directors and serve at the discretion of the Board of Directors.

Audit Committee

The Audit Committee is comprised of Mr. Wolf (Chairman), Mr. Kraws and Mr. Tarriff. The Audit Committee is responsible for recommending our independent public accounting firm and reviewing management's actions in matters relating to audit functions. The Committee reviews with our independent public accountants the scope and results of the audit engagement and the system of internal controls and procedures. The Committee also reviews the effectiveness of procedures intended to prevent violations of laws. The Committee also reviews, prior to publication, our reports on Form 10-K and Form 10-Q. Our Board has determined that all audit committee members are independent under applicable SEC regulations and NYSE MKT rules. Our Board of Directors has determined that each of Mr. Wolf, Mr. Kraws and Mr. Tarriff qualify as "audit committee financial experts" as that term is used in Section 407 of Regulation S-K. Our Audit Committee charter is located on our website *www.syntheticbiologics.com*.

Compensation Committee

Our Compensation Committee consists of Mr. Kraws (Chairman), Mr. Tarriff and Mr. Wolf. This committee performs several functions, including reviewing all forms of compensation provided to our executive officers, directors, consultants and employees, including stock compensation. Our Board has determined that all compensation committee members are independent under applicable SEC regulations and NYSE MKT rules. Our Compensation Committee charter is located on our website *www.syntheticbiologics.com*.

Nominations Committee

Our Nominations Committee consists of Mr. Tarriff (Chairman), Mr. Kraws and Mr. Wolf. This committee performs several functions, including identifying qualified individuals to become members of the Board and recommending appointments to the Board and appointment of executive officers. The committee seeks individuals who have an inquisitive and objective perspective, practical wisdom and mature judgment, and the talent and expertise to understand, and provide sound and prudent guidance with respect to, our activities, operations and interests. Candidates must also be individuals who have the highest personal and professional integrity, who have demonstrated exceptional ability and judgment, and who are likely to be the most effective, in conjunction with the other members of the Board, in collectively serving the long-term interests of stockholders. Our Board has determined that all nominations committee members are independent under applicable SEC regulations and NYSE MKT rules. Our Nominations Committee charter is located on our website *www.syntheticbiologics.com*.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our executive officers, directors and persons who beneficially own more than 10 percent of a registered class of the Synthetic Biologics' equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock. Such officers, directors and persons are required by SEC regulation to furnish us with copies of all Section 16(a) forms that they file with the SEC.

Based solely on a review of the copies of such forms that were received by us, or written representations from certain reporting persons that no Forms 5 were required for those persons, we are not aware of any failures to file reports or report transactions in a timely manner during the year ended December 31, 2016.

Code of Ethics

We have long maintained a Code of Conduct which is applicable to all of our directors, officers and employees. In addition, we have adopted a Code of Ethics for Financial Management which applies to our Chief Executive Officer, Chief Financial Officer, Treasurer and Controller. Each of these codes is posted on our website at *www.syntheticbiologics.com*.

Item 11. ***Executive Compensation***

COMPENSATION DISCUSSION AND ANALYSIS

Overview of Our Compensation Program

A. Philosophy and Objectives

The Compensation Committee seeks to attract and retain executive talent by offering competitive base salaries, bonuses and long-term incentives. The Compensation Committee's philosophy is to provide a compensation package that attracts and retains superior executive talent and delivers higher rewards for superior performance and consequences for underperformance. It is also the Compensation Committee's practice to provide a balanced mix of cash and equity-based compensation that aligns both the short and long-term interests of our executives with that of our stockholders. Our executive compensation program is based on the following philosophies and objectives:

- *Compensation Should Align with Stockholders' Interests* — The Compensation Committee believes that executives' interests should be aligned with those of the stockholders. Executives are granted stock options so that their total compensation is tied directly to the same value realized by our stockholders. Executive bonuses are tied directly to the value that we gain from an executive's contribution to our success as a whole.

- *Compensation is Competitive* — The Compensation Committee seeks to provide a total compensation package that attracts, motivates and retains the executive talent that we need in order to maximize its return to stockholders. To accomplish this objective, executive compensation is reviewed annually to ensure that compensation levels are competitive and reasonable given our level of performance and other comparable companies with which we competes for talent.

- *Compensation Motivates and Rewards the Achievement of Goals* — Our executive compensation program is designed to appropriately reward both individual and collective performance that meets and exceeds our annual, long-term and strategic goals. To accomplish this objective, a substantial percentage of total compensation is variable, "at risk", both through annual incentive compensation and the granting of long-term incentive awards.

B. Compensation Administration

Role of the Compensation Committee

Pursuant to the terms of its charter, the Compensation Committee is responsible for the review of all aspects of our executive compensation program and makes decisions regarding the compensation of Named Executive Officers. The Compensation Committee's responsibilities include but are not limited to the following:

- Establishing on an annual basis the performance goals and objectives for purposes of determining the compensation of our Chief Executive Officer and other senior executive officers.

- Evaluating the Chief Executive Officer's and other Named Executive Officer's performance at least annually in light of those goals and objectives, and based upon these evaluations setting the compensation level for those officers.

- Reviewing the competitive position of, and making recommendations to the Board of Directors with respect to the cash-based and equity-based compensation plans and our programs relating to compensation and benefits.

- Overseeing administration of our stock option plan and incentive compensation plans, making recommendations to the Board of Directors regarding the granting of options and incentives and otherwise assisting the Board of Directors in administering awards under these plans.

- Reviewing the financial performance and operations of our major benefit plans.

Additional information regarding the Compensation Committee's responsibilities is set forth in its charter, which is posted on our website at *www.syntheticbiologics.com*.

Role of the Chief Executive Officer

Our Chief Executive Officer, Jeffery Riley, makes recommendations to the Compensation Committee regarding the compensation of our other Named Executive Officers. Mr. Riley does not participate in any discussions or processes concerning his own compensation, and participates in a non-voting capacity in discussions or processes concerning the compensation of our Chief Financial Officer and other members of management.

C. Program Design

The Compensation Committee uses a simple and straightforward approach in compensating our Named Executive Officers in which base salary, annual incentives and stock options are the principal components. In addition, executives generally participate in the same benefit programs as other full-time employees.

Our executive compensation program is designed to provide executives with a reasonable level of fixed compensation through base salary and benefits, and an opportunity to earn incentive compensation through the annual and long-term incentive programs based on a mix of individual and corporate performance and increases in the value of our stock. Our target pay mix places a significant emphasis on performance based variable compensation. The incentive plans are designed to pay well when performance meets or exceeds expectations and pay little or no incentive if performance is below expectations.

As an executive's level of responsibility increases, the Compensation Committee generally targets a greater portion of the executive's compensation to be contingent upon performance. For example, our Chief Executive Officer and Chief Financial Officer have a higher percentage of compensation at risk (and thus greater upside and downside potential) relative to our other employees. The Compensation Committee believes this is appropriate because the Chief Executive Officer and Chief Financial Officer have the greatest influence on our performance. During 2016, salaries for our Chief Executive Officer and Chief Financial Officer was 31% and 35% of their compensation packages and performance based variable compensation comprised 65% and 61% of the compensation packages. Of the performance based variable compensation there was a heavier emphasis on equity incentive performance based compensation.

D. Compensation Review Process

The Compensation Committee annually reviews compensation for our Named Executive Officers. The Compensation Committee considers the executive's role and responsibilities, corporate and individual performance, and industry-wide compensation practices and trends for other companies of similar size. This approach is used to set base salaries, bonuses, stock option award levels and the mix of compensation elements.

When making compensation decisions, the Compensation Committee compares the compensation for our Named Executive Officers with the compensation at several comparable companies. To that end, in 2016 the Compensation Committee utilized a number of resources which included a compensation survey prepared by Top 5 Data Services, Inc. Our Compensation Committee values the opinion of our stockholders. At our 2016 Annual Meeting of Stockholders approximately 67% of the votes were cast in favor of our say-on-pay proposal adopting a resolution approving the compensation paid to our Named Executive Officers as disclosed in our proxy statement for our 2016 Annual Meeting of Stockholders. In addition, at our 2016 Annual Meeting of Stockholders approximately the greatest number of votes were cast in favor of a three (3) year frequency for holding an advisory vote on executive compensation.

E. Components of Compensation

We provide four compensation components to Named Executive Officers:

- base salary;
- bonuses based on the achievement of specified goals and objectives;
- long-term incentives; and
- benefits.

1. Base Salaries

We provide our Named Executive Officers a base salary commensurate with their position, responsibilities and experience. In setting the base salary, the Compensation Committee considers the scope and accountability associated with each Named Executive Officer's position and such factors as performance and experience of each Named Executive Officer. We design base pay to provide the essential reward for an employee's work, and are required to be competitive in attracting talent. Once base pay levels are initially determined, increases in base pay may be provided to recognize an employee's specific performance achievements. The base salaries are targeted to be competitive with other similar biotechnology companies. Base salaries for the Named Executive Officers are set by their respective employment contracts and are reviewed annually by the Compensation Committee. Our Chief Executive Officer, Chief Financial Officer and Chief Medical Officer typically make performance assessments of our other employees throughout the year, and provide ongoing feedback to employees, provide resources and maximize individual and team performance levels. Based on the analysis, surveys and other comparative research performed by the Committee, the Committee was able to compare the overall compensation package for the Chief Executive Officer and Chief Financial Officer, including base salary, long-term incentives and bonuses. It was determined that our Chief Executive's Officer's salary was at the 50th percentile of the compensation of Chief Executive Officers for companies in the survey with similar size market cap and therefore his salary remained the same as in the prior year. It was determined that the Chief Financial Officer base salary that had remained at $315,000 since April 2015 would be below the 50th percentile for companies in the survey with similar size market cap after taking into account cost of living adjustments since the date of the survey. Therefore the base salary for our Chief Financial Officer was increased by ten percent (10%) to $346,500 in December 2016, to keep the salaries competitive with those of similarly situated executives in companies with similar size market caps.

Named Executive Officer	**Base Salary**
Jeffrey Riley, Chief Executive Officer and President	$ 550,000
Steven A. Shallcross, Chief Financial Officer, Treasurer and Secretary	$ 346,500

2. Bonuses

The Compensation Committee also makes recommendations to the full Board of Directors for determining bonuses. The Compensation Committee also used information from the report and analysis discussed above in determining bonuses as well as its own research of peer company compensation. For the year ended December 31, 2016, the Compensation Committee approved a $412,000 cash bonus and an option grant exercisable for 1,129,000 shares of our common stock for Mr. Riley, a $236,250 cash bonus and an option grant exercisable for 500,000 shares of our common stock for Mr. Shallcross.

The employment agreement with each of Mr. Riley and Mr. Shallcross that was in effect during 2016 provided that each was eligible for a bonus of up to seventy five percent (75%) of his base salary in cash or equity and each of Mr. Riley and Mr. Shallcross received cash bonuses with a value equal to seventy five percent (75%) of their base salary. The employment agreement that was entered into with Riley on February 27, 2017 to replace his prior employment agreement, also provides that Mr. Riley is eligible for a bonus of up to seventy five percent (75%) of his base salary in cash or equity. The bonuses are to be rewarded based on whether, in the discretion of the Compensation Committee and the Board of Directors, our company and the Named Executive Officer met certain objectives established by the Compensation Committee or the Board of Directors. The Compensation Committee believes that the granting of a bonus is appropriate to motivate the Named Executive Officers. The Compensation Committee focuses on individual performance, which enables the Compensation Committee to differentiate among executives and emphasize the link between personal performance and compensation. Although the Compensation Committee does not use any fixed formula in determining bonuses, it does link them to financial objectives of importance to it. The following factors were among the reviewed in determining the bonus: successful execution of a financing raising substantial capital in November 2016; advancement of the clinical development program (reporting topline data from the SYN-010 Phase 2 clinical trial, holding an end of Phase 2 meeting with FDA for the SYN-010 Phase 2 clinical trial, reporting topline data form the second Phase 2a clinical trial for SYN-004 and completing enrollment of the Phase 2b proof of concept study for SYN-004) and expansion of existing preclinical programs. Actual levels of achievement were not assigned to any one factor and the performance objectives were looked at in totality.

3. Long-Term Incentives

The Compensation Committee believes that a substantial portion of the Named Executive Officer’s compensation should be awarded in equity-based compensation since equity-based compensation is directly linked to the interests of stockholders. The Compensation Committee has elected to grant stock options to the Named Executive Officers and other key employees as the primary long-term incentive vehicle. In making this determination, the Compensation Committee considered a number of factors including: the accounting impact, potential value of stock option grants versus other equity instruments and cash incentives, and the alignment of equity participants with stockholders. The Compensation Committee determined to grant stock options to:

- enhance the link between the creation of stockholder value and executive compensation;
- provide an opportunity for equity ownership;
- act as a retention tool; and
- provide competitive levels of total compensation.

Each of Mr. Riley and Mr. Shallcross were granted options exercisable for 750,000 and 900,000 shares of common stock, respectively, upon hire. Mr. Riley's bonus for the years ended December 31, 2013, 2014 and 2015 included a grant of options exercisable for 500,000, 350,000 and 500,000 shares of common stock, respectively. Mr. Shallcross' bonus for the years ended December 31, 2015 included a grant of options exercisable for 100,000 shares of common stock. In addition, Mr. Riley's and Mr. Shallcross' 2016 bonus included a grant of options exercisable for 1,129,000 and 500,000 shares of common stock, respectively. The stock options granted vest in equal monthly installments over a three year term and are subject to the recipient's continued employment, therefore acting as a significant retention incentive.

The Compensation Committee reviews the performance, potential burn rates and dilution levels to create an option pool that may be awarded to employee participants. Grants to the Named Executive Officers were determined by the Compensation Committee after reviewing market data, including the reports and analysis discussed above and after considering each executive's performance, role and responsibilities.

The Compensation Committee does not seek to time equity grants to take advantage of information, either positive or negative, about our company that has not been publicly disclosed. Option grants are effective on the date the award determination is made by the Compensation Committee and the exercise price of options is the closing market price of our common stock on the business day of the grant or, if the grant is made on a weekend or holiday, on the prior business day.

4. Benefits

Named Executive Officers are eligible to participate in our standard medical, dental, vision, disability insurance, life insurance plans and other health and welfare plans provided to other full time employees.

Each of our Named Executive Officers are entitled to participate in our 401(k) program.

Pension Benefits

We do not currently provide pension arrangements or post-retirement health coverage for our employees, although we may consider such benefits in the future.

Retirement Benefits

Each of our Named Executive Officers are eligible to participate in our 401(k) contributory defined contribution plan. Pursuant to our 401(k) plan, all eligible employees, including our Named Executive Officers, are provided with a means of saving for their retirement.

Nonqualified Deferred Compensation

We do not provide any nonqualified deferred compensation plans to our employees, although we may consider such benefits in the future.

Conclusion

Attracting and retaining talented and motivated management and key employees is essential to creating long-term stockholder value. Offering a competitive, performance-based compensation program with a substantial equity component helps to achieve this objective by aligning the interests of the executive officers and other key employees with those of stockholders. We believe that our compensation program met these objectives and that our 2016 compensation program was appropriate in light of the challenges we and our employees face.

Risk Analysis of Our Compensation Program

Our Compensation Committee has reviewed our compensation policies as generally applicable to our employees and believes that our policies do not encourage excessive or inappropriate risk taking and that the level of risk that they do encourage is not reasonably likely to have a material adverse effect on us. As part of its assessment, the Compensation Committee considered, among other factors, the allocation of compensation among base salary and short- and long-term compensation, our approach to establishing company-wide and individual financial, operational and other performance goals.

REPORT OF THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS

The Compensation Committee has reviewed and discussed with management the Compensation Discussion and Analysis for 2016. Based on the review and the discussions, the Compensation Committee recommended to the Board of Directors (and the Board of Directors approved), that the Compensation Discussion and Analysis be included in our Annual Report on Form 10-K for the year ended December 31, 2016.

This report is submitted by the Compensation Committee.

Jeffrey Kraws (Chairman)

Scott L. Tarriff

Jeffrey Wolf

Summary Compensation Table

The following table summarizes all compensation awarded to, earned by or paid to Jeffrey Riley and Steven A. Shallcross and, our Named Executive Officers, during the fiscal years presented below.

Name and Principal Position	Year	Salary ($)	Bonus ($)	**Options Awards ($)[1]**	**All Other Compensation ($)[2]**	Total ($)
Jeffrey Riley	2016	$550,000	$412,500	$722,560	$ 66,703	$1,751,763
President and Chief Executive Officer[3] [5]	2015	$396,875	$288,750	$1,767,490	$ 97,986	$2,551,101
	2014	$374,068	$275,000	$1,186,500	20,006	$1,855,574
Steven Shallcross[4]	2016	$315,000	$236,250	$320,003	$ 49,929	$921,182
Chief Financial Officer	2015	$183,750	$137,813	$2,119,855	$ 11,657	$2,453,075

(1) Amount reflects the grant date fair value of the Named Executive Officer's stock options, calculated in accordance with FASB ASC Topic 718. For a discussion of the assumptions used in calculating these values, see Note 4 to our consolidated financial statements. In November 2016 Mr. Riley was issued an option to purchase 1,129,000 shares of common stock and Mr. Shallcross was issued an option to purchase 500,000 shares of common stock; both awards vest monthly over 36 months.

(2) The all other compensation column is comprised of vacation accrual paid, and the portion of medical, dental and vision premiums paid by us on behalf of our Named Executive Officer. These benefits are offered to all Synthetic Biologics' employees who work at least 17.5 hours per week

(3) Mr. Riley was appointed as our President and Chief Executive Officer on February 3, 2012. Mr. Riley's salary was increased in December 2015 to $550,000.

(4) Mr. Shallcross was appointed as our Chief Financial Officer on June 1, 2015. Mr. Shallcross' annual salary is $346,500 commencing December 1, 2016.

(5) These bonuses were earned in 2014 and paid in 2015.

Outstanding Equity Awards at Fiscal Year End

The table below reflects all outstanding equity awards made to each of the Named Executive Officers that are outstanding at December 31, 2016. We currently grant stock-based awards pursuant to our 2010 Stock Incentive Plan (the "2010 Stock Plan") and have outstanding awards under our 2001 Stock Incentive Plan (the "2001 Stock Plan") and 2007 Stock Incentive Plan (the "2007 Stock Plan").

Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price ($)	Option Expiration Date
Jeffrey Riley	11/30/16[1]	31,000	1,098,000	$ 0.80	11/30/23
	12/04/15[1]	167,000	333,000	$ 2.76	12/04/22
	01/08/15[1]	204,000	146,000	$ 1.54	01/08/25
	04/17/14[1]	444,000	56,000	$ 2.52	04/17/24
	02/03/12[1]	750,000	-	$ 2.30	02/03/22
	11/17/11[2]	100,000	-	$ 0.49	11/17/18
	01/05/11[3]	25,000	-	$ 1.50	01/05/18
	12/01/10[3]	8,333	-	$ 0.74	12/01/20
	03/03/10[3]	25,000	-	$ 0.87	03/03/20
Steven Shallcross	11/30/16[1]	14,000	486,000	$ 0.80	11/30/23
	12/04/15[1]	33,000	67,000	$ 2.76	12/04/22
	06/01/15[1]	450,000	450,000	$ 2.16	06/01/25

(1) Options will vest pro rata, on a monthly basis, over 36 months.

(2) 12,500 options vested immediately on the date of grant; the balance of options vested quarterly.

(3) Options vested immediately on the date of grant.

Grants of Plan-Based Awards for Fiscal 2016

The following table sets forth information regarding grants of compensation in the form of plan-based awards made during 2016 to our Named Executive Officers. The equity awards granted in 2016 identified in the table below are also reported in the table above entitled “Outstanding Equity Awards at Fiscal Year End”:

Name	Grant Date	All Other Stock Awards: Number of Shares of Stock or Units (#)	All Other Stock Awards: Number of Securities Underlying Options[1]	Exercise or Base Price of Option Awards ($/Sh)	Grant Date Fair Value of Stock and Option Awards[2]
Jeffrey Riley	N/A	-	-	$ -	$ -
	11/30/16	-	1,129,000	$ 0.80	$ 723,000
Steven Shallcross	N/A	-	-	$ -	$ -
	11/30/16	-	500,000	$ 0.80	$ 320,000

(1) Each stock option was granted with an exercise price equal to the fair market value of our common stock on the grant date.

(2) Amount reflects the grant date fair value of the Named Executive Officer's stock options, calculated in accordance with FASB ASC Topic 718. For a discussion of the assumptions used in calculating these values, see Note 4 to our consolidated financial statements. . In November 2016 Mr. Riley was issued an option to purchase 1,129,000 shares of common stock and Mr. Shallcross was issued an option to purchase 500,000 shares of common stock; both awards vest monthly over 36 months commencing on the first month following the applicable grant date.

Option Exercises and Stock Vested in 2016

There were no options exercised by the Named Executive Officers in 2016. There were no stock awards held by our Named Executive Officers that vested in 2016.

Employment Agreements

Jeffrey Riley, Chief Executive Officer and President

Effective February 3, 2012, Jeffrey Riley was appointed to serve as our Chief Executive Officer and President. In connection with his appointment, Mr. Riley entered into a three-year employment agreement (the "Original Riley Agreement"). Pursuant to the Original Riley Agreement, Mr. Riley was entitled to an annual base salary of $348,000 and was eligible for discretionary performance and transactional bonus payments. Additionally, Mr. Riley was granted options to purchase 750,000 shares of our common stock with an exercise price equal to the per share market price on the date of issue. These options will vest pro rata, on a monthly basis, over 36 months. Effective April 17, 2014, the Original Riley Agreement was amended to increase his base salary to $385,000.

Effective March 18, 2015, we entered into a new two-year employment agreement with Mr. Riley (the "2015 Riley Employment Agreement"). Pursuant to the 2015 Riley Employment Agreement, Mr. Riley's annual base salary remained at $385,000 until it was amended effective December 4, 2015 to an annual base salary of $550,000. Beginning in 2015 and for each full calendar year thereafter, Mr. Riley was eligible for an annual performance bonus of up to seventy-five percent (75%) of his base salary. The annual bonus was to be based upon the Board's assessment of Mr. Riley's performance. The 2015 Riley Employment Agreement also included confidentiality obligations, inventions assignments by Mr. Riley as well as change in control, non-solicitation and non-competition provisions.

Effective February 27, 2017, we entered into a new two-year employment agreement with Mr. Riley, which replaced the 2015 Riley Employment Agreement that was due to expire on March 17, 2017. Pursuant to the 2017 Riley Employment Agreement, Mr. Riley's annual base salary remained at $550,000. Pursuant to the terms of the 2017 Riley Employment Agreement, beginning in 2017 and for each full calendar year thereafter, Mr. Riley is eligible for an annual performance bonus of up to seventy-five percent (75%) of his base salary. The annual bonus will be based upon the Board's assessment of Mr. Riley's performance. Mr. Riley also signed a standard agreement that includes confidentiality obligations, inventions assignments by Mr. Riley, non-solicitation and non-competition provisions.

Steven A. Shallcross, Chief Financial Officer, Treasurer and Secretary

On April 28, 2015, we entered into a two-year employment agreement with Steven A. Shallcross (the "Shallcross Employment Agreement"), who was appointed to serve as the Company's Chief Financial Officer, Treasurer and Secretary, effective June 1, 2015. Pursuant to the Shallcross Employment Agreement, Mr. Shallcross is entitled to an annual base salary of $315,000. Additionally, Mr. Shallcross was granted options to purchase 900,000 shares of the Company's common stock with an exercise price equal to the per share market price on the date of issue. These options vest pro rata, on a monthly basis, over 36 months. In 2015 and for each full calendar year thereafter, Mr. Shallcross will be eligible for an annual performance bonus of up to seventy- five percent (75%) of his base salary. The annual bonus is to be based upon the Board's assessment of Mr. Shallcross' performance. Mr. Shallcross also signed a standard agreement that includes confidentiality obligations, inventions assignments by Mr. Shallcross, non-solicitation and non-competition provisions.

The 2017 Riley Employment Agreement and the Shallcross Employment Agreement each have a stated term of two years but may be terminated earlier pursuant to their terms. If either Mr. Riley's or Mr. Shallcross' (each an "Executive") employment is terminated for any reason, he or his estate as the case may be, will be entitled to receive the accrued base salary, vacation pay, expense reimbursement and any other entitlements accrued by him to the extent not previously paid (the "Accrued Obligations"); provided , however , that if his employment is terminated (1) by us without Cause or by the Executive for Good Reason (as each is defined below) then in addition to paying the Accrued Obligations, (x) we will continue to pay his then current base salary and continue to provide benefits at least equal to those which were provided at the time of termination for a period of twelve (12) months and (y) he shall have the right to exercise any vested equity awards until the earlier of six (6) months after termination or the remaining term of the awards, or (2) by reason of his death or Disability (as defined in the 2017 Riley Employment Agreement and the Shallcross Employment Agreement), then in addition to paying the Accrued Obligations, he would have the right to exercise any vested options until the earlier of six (6) months after termination or the remaining term of the awards. In such event, if the Executive commenced employment with another employer and becomes eligible to receive medical or other welfare benefits under another employer-provided plan, the medical and other welfare benefits to be provided by us as described herein will terminate.

The 2017 Riley Employment Agreement and the Shallcross Employment Agreement each provide that upon the closing of a "Change in Control" (as defined below), the time period that the Executive will have to exercise all vested stock options and other awards that the Executive may have will be equal to the shorter of: (i) six (6) months after termination, or (ii) the remaining term of the award(s). Upon the closing of a Change in Control, all of Mr. Riley's and Mr. Shallcross' unvested options shall immediately vest. If within one year after the occurrence of a Change in Control, the Executive terminates his employment for "Good Reason" or the Company terminates the Executive's employment for any reason other than death, Disability or Cause, the Executive will be entitled to receive: (i) the portion of his base salary for periods prior to the effective date of termination accrued but unpaid (if any); (ii) all unreimbursed expenses (if any); (iii) an aggregate amount (the "Change in Control Severance Amount") equal to two times the sum of the base salary plus an amount equal to the bonus that would be payable if the "target" level performance were achieved under the Company's annual bonus plan (if any) in respect of the fiscal year during which the termination occurs (or the prior fiscal year if bonus levels have not yet been established for the year of termination); and (iv) the payment or provision of any other benefits. The Change in Control Severance Amount is to be paid in a lump sum, if the Change in Control event constitutes a "change in the ownership" or a "change in the effective control" of us or a "change in the ownership of a substantial portion of a corporation's assets" (each within the meaning of Section 409A of the Internal Revenue Code), or in 48 substantially equal payments, if the Change in Control event does not so comply with Section 409A. Upon the termination of employment for Good Reason by the Executive or upon the involuntary termination of employment of Executive for any reason other than death, Disability or Cause, in either case within two years commencing after the occurrence of a Change in Control, the Executive will be entitled to receive for a period of two years commencing on the date of such termination medical, dental, life and disability coverage for himself and his family members which is not less favorable than the coverage carried by us at the time of termination.

For the purposes of the 2017 Riley Employment Agreement and the Shallcross Employment Agreement "Change in Control" is defined as: (i) any person or entity becoming the beneficial owner, directly or indirectly, of our securities representing fifty (50%) percent of the total voting power of all its then outstanding voting securities; (ii) a merger or consolidation of us in which our voting securities immediately prior to the merger or consolidation do not represent, or are not converted into securities that represent, a majority of the voting power of all voting securities of the surviving entity immediately after the merger or consolidation; or (iii) a sale of substantially all of our assets or our liquidation or dissolution.

For purpose of the 2017 Riley Employment Agreement and the Shallcross Employment Agreement, "Good Reason" is defined as the occurrence of any of the following events without the respective Executive's consent: (i) a material reduction in the Executive's base salary (other than an across-the-board decrease in base salary applicable to all of our executive officers); (ii) a material breach of the employment agreement by us; (iii) a material reduction in the Executive's duties, authority and responsibilities relative to the Executive's duties, authority, and responsibilities in effect immediately prior to such reduction; or (iv) the relocation of the Executive's principal place of employment, without the Executive's consent, in a manner that lengthens his one-way commute distance by fifty (50) or more miles from his then-current principal place of employment immediately prior to such relocation.

For purposes of the 2017 Riley Employment Agreement and the Shallcross Employment Agreement, “Cause” is defined as that the Executive shall have engaged in any of the following acts or that any of the following events shall have occurred, all as determined by the Board of Directors in its sole and absolute discretion: (i) gross insubordination, acts of embezzlement or misappropriation of funds, fraud, dereliction of fiduciary obligations; (ii) conviction of a felony or other crime involving moral turpitude, dishonesty or theft (including entry of a ***nolo contendere*** plea); (iii) willful unauthorized disclosure of confidential information belonging to the us or entrusted to us by a client; (iv) material violation of any provision of the Executive’s employment agreement, of any of our policies, and/or of a confidentiality agreement, which, to the extent it is curable by the Executive, is not cured by the Executive within thirty (30) days of receiving written notice of such violation by us; (v) being under the influence of drugs (other than prescription medicine or other medically related drugs to the extent that they are taken in accordance with their directions) during the performance of the Executive’s duties; (vi) engaging in behavior that would constitute grounds for liability for harassment (as proscribed by the U.S. Equal Employment Opportunity Commission Guidelines or any other applicable state or local regulatory body) or other egregious conduct that violates laws governing the workplace; or (vii) willful failure to perform his written assigned tasks, where such failure is attributable to the fault of the Executive which, to the extent it is curable by the Executive, is not cured by Executive within thirty (30) days of receiving written notice of such violation by us.

Dr. Joseph Sliman, Chief Medical Officer

On January 17, 2017, we entered into a two-year employment agreement with Dr. Joseph Sliman, who was promoted from the position of Senior Vice President–Clinical & Regulatory Affairs to the position of Chief Medical Officer. Pursuant to the terms of Dr. Sliman's employment agreement, he will receive an annual base salary of $385,000. In connection with his appointment, Dr. Sliman was granted options exercisable for 188,927 shares of common stock upon his appointment as Chief Medical Officer.

The terms of the Sliman Employment Agreement are set forth below.

Pursuant to the terms of the Sliman Employment Agreement, Dr. Sliman is entitled to an annual base salary of $385,000 and an annual performance bonus of up to seventy five percent (75%) of his annual base salary. The annual bonus will be based upon the assessment of the Board of Dr. Sliman's performance. Dr. Sliman was also granted a seven (7) year incentive stock option to purchase at an exercise price of $0.83 per share one hundred and eighty-eight thousand nine hundred and twenty-seven (188,927) shares of our common stock, vesting pro rata on a monthly basis over a three (3) year period. Dr. Sliman also signed a standard agreement that also includes confidentiality obligations and inventions assignments by Dr. Sliman and non-solicitation and non-competition provisions.

The Sliman Employment Agreement has a stated term of two years but may be terminated earlier pursuant to its terms. If Dr. Sliman's employment is terminated for any reason, he or his estate as the case may be, will be entitled to receive the accrued base salary, vacation pay, expense reimbursement and any other entitlements accrued by him to the extent not previously paid (the "Sliman Accrued Obligations"); provided, however, that if his employment is terminated (i) by the Company without Cause or by Dr. Sliman for Good Reason (as each is defined in the Sliman Employment Agreement) then in addition to paying the Sliman Accrued Obligations, (a) the Company will continue to pay his then current base salary and continue to provide benefits at least equal to those that were provided at the time of termination for a period of twelve (12) months and (b) he shall have the right to exercise any vested equity awards until the earlier of six (6) months after termination or the remaining term of the awards; or (ii) by reason of his death or Disability (as defined in the Sliman Employment Agreement), then in addition to paying the Sliman Accrued Obligations, Dr. Sliman would have the right to exercise any vested options until the earlier of six (6) months after termination or the remaining term of the awards. In such event, if Dr. Sliman commenced employment with another employer and becomes eligible to receive medical or other welfare benefits under another employer-provided plan, the medical and other welfare benefits to be provided by the Company as described herein would terminate.

The Sliman Employment Agreement provides that upon the closing of a "Change in Control" (as defined in the Sliman Employment Agreement), all unvested options shall immediately vest and the time period that Dr. Sliman will have to exercise all vested stock options and other awards that Dr. Sliman may have will be equal to the shorter of: (i) six (6) months after termination, or (ii) the remaining term of the award(s). If within one (1) year after the occurrence of a

Change in Control, Dr. Sliman terminates his employment for "Good Reason" or the Company terminates Dr. Sliman's employment for any reason other than death, disability or Cause, Dr. Sliman will be entitled to receive: (i) the portion of his base salary for periods prior to the effective date of termination accrued but unpaid (if any); (ii) all unreimbursed expenses (if any); (iii) an aggregate amount (the "Change in Control Severance Amount") equal to two (2) times the sum of his base salary plus an amount equal to the bonus that would be payable if the "target" level performance were achieved under the Company's annual bonus plan (if any) in respect of the fiscal year during which the termination occurs (or the prior fiscal year if bonus levels have not yet been established for the year of termination); and (iv) the payment or provision of any other benefits. If within two (2) years after the occurrence of a Change in Control, Dr. Sliman terminates his employment for "Good Reason" or the Company terminates Dr. Sliman's employment for any reason other than death, disability or Cause, Dr. Sliman will be entitled to also receive for the period of two (2) consecutive years commencing on the date of such termination of his employment, medical, dental, life and disability insurance coverage for him and the members of his family that are not less favorable to him than the group medical, dental, life and disability insurance coverage carried by the Company for him. The Change in Control Severance Amount is to be paid in a lump sum if the Change in Control event constitutes a "change in the ownership" or a "change in the effective control" of the Company or a "change in the ownership of a substantial portion of a corporation's assets" (each within the meaning of Section 409A of the Internal Revenue Code ("Rule 409A")), or in 48 substantially equal payments, if the Change in Control event does not so comply with Section 409A.

The following table shows the estimated, incremental amounts that would have been payable to the Named Executive Officers upon the occurrence of the indicated event, had the applicable event occurred on December 31, 2016. These amounts would be incremental to the compensation and benefit entitlements described above that are not contingent upon a termination or change in control. The amounts attributable to the vesting of stock options are based upon the fair market value of our common stock on December 31, 2016, which was $0.76 per share. The actual compensation and benefits the Named Executive Officer would receive at any subsequent date would likely vary from the amounts set forth below as a result of certain factors, such as a change in the price of our common stock and any additional benefits the Named Executive Officer may have accrued as of that time under the applicable employment agreement.

Name	Event	Salary & Other Continuing Payments ($)		Extension of Post-Termination Exercise Period ($)[3]	Total ($)
Jeffrey Riley	Termination without Cause or resignation for Good Reason	$ 989,527	(1)	$ 37,000	$ 1,026,527
	Upon Death or Disability	$ -		$ 37,000	$ 37,000
	Termination without Cause or resignation for Good Reason following a Change of Control	$ 1,539,527	(2)	$ 37,000	$ 1,576,527
Steven A. Shallcross	Termination without Cause or resignation for Good Reason	$ 632,264	(1)	$ -	$ 632,264
	Upon Death or Disability	$ -		$ -	$ -
	Termination without Cause or resignation for Good Reason following a Change of Control	$ 978,764	(2)	$ -	$ 978,764
	Change of Control	$ -		$ -	$ -

(1) Base salary and COBRA premiums, and, where provided under the applicable employment agreement, pro-rated bonus. Pro-rated bonus amounts assume annual bonus at 100% of target performance (75% of base salary).

(2) Two times base salary and COBRA premiums, and, where provided under the applicable employment agreement, pro-rated bonus. Pro-rated bonus amounts assume annual bonus at 100% of target performance (75% of base salary).

(3) Reflects the increase in value of the spread, or in-the-money value, as of the end of the extended exercise period provided under the applicable employment agreement, as compared to the value of the spread at December 31, 2016, of options to purchase our common stock which were vested as of, or which would vest upon the occurrence of, the specified event, where provided under the applicable employment agreement, as assuming that the price of our common stock was the closing price on December 31, 2016, $0.76 per share. Does not include the value of out-of-the-money options. Please refer to the Outstanding Equity Awards at Fiscal Year End table above for listing of the vested and unvested stock options held by the Named Executive Officers as of December 31, 2016.

Compensation of Directors

The following table sets forth information for the fiscal year ended December 31, 2016 regarding the compensation of our directors who at December 31, 2016 were not also our Named Executive Officers.

Name	Fees Earned or Paid in Cash	Option Awards[1][3]	Other Compensation	Total
Jeffrey J. Kraws[2]	$ 169,000	$ 109,000	$ -	$ 278,000
Scott Tarriff	$ 48,000	$ 109,000	$ -	$ 157,000
Jeffrey Wolf	$ 54,000	$ 109,000	$ -	$ 163,000

(1) The amounts in the "Option Awards" column reflect the dollar amounts of the grant date fair value for the financial statement reporting purposes for stock options for the fiscal year ended December 31, 2016 in accordance with ASC 718. The fair value of the options was determined using the Black-Scholes model. For a discussion of the assumptions used in computing this valuation, see "Management's Discussion and Analysis of Financial Conditions and Results of Operations" and Note 4 of the Notes to Consolidated Financial Statements in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

(2) Mr. Kraws was appointed as our independent, non-executive Chairman of the Board of Directors in May 2012. Pursuant to his agreement he receives an annual retainer of $150,000 for serving as our Chairman.

(3) As of December 31, 2016, the following are the outstanding aggregate number of option awards held by each of our directors who were not also Named Executive Officers:

Name	Option Awards (#)
Jeffrey J. Kraws	810,855
Scott Tarriff	473,750
Jeffrey Wolf	521,240

During 2016, the compensation of non-employee members of the Board of Directors remained the same as the compensation for 2015. During 2016, each non-employee member of the Board of Directors received an annual cash retainer of $43,000, our independent, non-executive Chairman of the Board of Directors receives an annual cash retainer of $150,000, all non-employee directors receive an annual cash fee of $7,500, $5,000 and $3,250 for service on the Audit, Compensation and Nominations Committees, respectively, and the Chairman of the Audit, Compensation and Nominations Committees receive an additional annual cash fee of $13,500, $10,000 and $6,000, respectively. In addition, each non-employee member of the Board of Directors was issued an option exercisable for 168,750 shares of our common stock, for a term of seven years, vesting annually on a pro rata basis over a three year period, with one-third of the grant vesting on the date of grant and one-third vesting on each of the next two yearly anniversaries.

Compensation Committee Interlocks

During the last fiscal year ended December 31, 2016, none of our executive officers served on the Board of Directors or Compensation Committee of any other entity whose officers served either on our Board of Directors or Compensation Committee.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The following table sets forth information, as of March 2, 2017, or as otherwise set forth below, with respect to the beneficial ownership of our common stock (i) all persons know to us to be the beneficial owners of more than 5% of the outstanding shares of our common stock; (ii) each of our directors and our named executive officers named in the Summary Compensation Table; and (iii) all of our directors and our executive officer as a group.

Name and Address of Beneficial Ownership[2]	**Shares Owned[1]**		
	Number of Share Owned	**Percentages of Shares[3]**	
Randal J. Kirk and affiliated entities[4]	13,238,268	11.3	%
Intrexon[4]	9,613,268	8.2	%
Anand Parekh and Alyeska affiliated entities[5]	12,495,671	9.99	%
Jeffrey J. Kraws[6]	656,125	*	
Jeff Riley[7]	2,060,260	*	
Steven Shallcross[8]	688,888	*	
Scott L. Tarriff[9]	1,219,020	*	
Jeffrey Wolf[10]	366,510	*	
All officers and directors as a group (5 persons)	4,990,803	4.1	%

* represents less than 1% of our common stock

(1) The address for each beneficial owner except Intrexon Corporation, Alyseka Investment Group, L.P., Alyseka Fund GP, LLC, Alyeska Fund 2 GP, LLC, Anand Parekh, and Randal J. Kirk is 9605 Medical Center, Suite 270, Rockville, Maryland 20850. The address for Intrexon Corporation is 20358 Seneca Meadows Pkwy, Germantown, Maryland 20876. The address for Alyseka Investment Group, L.P., Alyseka Fund GP, LLC, Alyeska Fund 2 GP, LLC and Anand Parekh is 77 West Wacher Drive, 7th Floor Chicago, Illinois 60601. The address for Mr. Kirk is The Governor Tyler, 1881 Grove Avenue, Radford, Virginia 24141.

(2) Beneficial ownership is determined in accordance with SEC rules and generally includes voting or investment power with respect to securities. Except as indicated in the footnotes to the table, to the knowledge of the Company, the persons named in the table have sole voting and investment power with respect to all shares of common stock, options and/or warrants shown as beneficially owned by them, subject to community property laws, where applicable. Pursuant to the rules of the SEC, the number of shares of our common stock deemed outstanding includes shares issuable pursuant to options held by the respective person or group that are currently exercisable or may be exercised within 60 days of March 2, 2017.

(3) As of March 2, 2017, the Company had 117,541,978 shares of common stock outstanding.

(4) Share ownership information is based on information contained in a Schedule 13D/A filed with the SEC on September 2, 2015 by Randal J. Kirk, Third Security, LLC., NRM VII Holdings I, LLC, and Intrexon Corporation. Intrexon Corporation owns 9,613,268 shares of common stock and NRM VII Holdings I, LLC owns 3,625,000 shares of Common Stock. NRM VII Holdings I, LLC is managed by an affiliate that is managed by Third Security, LLC and Third Security, LLC is managed by Mr. Kirk. Mr. Kirk could be deemed to have indirect beneficial ownership of the shares of common stock directly owned by Intrexon Corporation and NRM VII Holdings I, LLC.

(5) Includes 4,586,592 shares of Common Stock and warrants to purchase up to 7,851,235 shares of Common Stock. Anand Parekh is the indirect beneficial owner of warrants to purchase 10,000,000 shares of Common Stock; however, the warrants contain a provision limiting their exercise to such number of shares of Common Stock that would constitute 9.99% of our total outstanding number of shares of Common Stock when aggregated with all other shares of Common Stock owned by Alyeska entities. Anand Parekh is the Chief Executive Officer and control person of Alyeska Investment Group, L.P., which is the investment advisor to Alyseka Fund GP, LLC and Alyeska Fund 2 GP, LLC. Alyeska Fund GP, LLC is the general partner of Alyeska Master Fund, L.P. and Alyeska Fund 2 GP, LLC is the general partner of Alyseska Master Fund 2, L.P.s , and therefore is deemed to indirectly beneficially own The foregoing information is based on information contained in Schedule 13G filed on February 14, 2017 by Alyseka Investment Group, L.P., Alyseka Fund GP, LLC, Alyeska Fund 2 GP, LLC and Anand Parekh reporting beneficial ownership of such shares and warrants.

(6) Includes 656,125 shares issuable upon exercise of options held by Mr. Kraws that are exercisable within the 60-day period following March 2, 2017. Does not include an additional 154,730 shares issuable upon exercise of options held by Mr. Kraws that are not exercisable within the 60-day period following March 2, 2017.

(7) Includes 2,049,860 shares issuable upon exercise of options held by Mr. Riley that are exercisable within the 60-day period following March 2, 2017. Does not include an additional 1,337,473 shares issuable upon exercise of options held by Mr. Riley that are not exercisable within the 60-day period following March 2, 2017.

(8) Includes 688,888 shares issuable upon exercise of options held by Mr. Shallcross that are exercisable within the 60-day period following March 2, 2017. Does not include an additional 811,112 shares issuable upon exercise of options held by Mr. Shallcross that are not exercisable within the 60-day period following March 2, 2017.

(9) Includes (i) 300,000 shares purchased from us in our November 2016 offering, (ii) 319,020 shares issuable upon exercise of options held by Mr. Tarriff that are exercisable within the 60-day period following March 2, 2017, and (iii) warrants to purchase 600,000 shares of our common stock, which warrants were acquired in our November 2016 offering. Does not include an additional 154,730 shares issuable upon exercise of options held by Mr. Tarriff that are not exercisable within the 60-day period following March 2, 2017.

(10) Includes 366,510 shares issuable upon exercise of options held by Mr. Wolf that are exercisable within the 60-day period following March 2, 2017. Does not include an additional 154,730 shares issuable upon exercise of options held by Mr. Wolf that are not exercisable within the 60-day period following March 2, 2017.

Equity Compensation Plan Information

The following table sets forth information about the securities authorized for issuance under our equity compensation plans for the fiscal year ended December 31, 2016.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options	Weighted-Average Exercise Price of Outstanding Options	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans
Equity compensation plans approved by stockholders:			
2001 Stock Incentive Plan	228,773	$ 0.09	—
2007 Stock Incentive Plan	659,988	$ 1.81	310,103
2010 Stock Incentive Plan	10,747,466	$ 1.80	3,222,398
Equity compensation plans not approved by stockholder	N/A	N/A	N/A
Total	11,636,227	1.77	3,532,501

Item 13. ***Certain Relationships and Related Transactions, and Director Independence***

Pursuant to our charter, our Audit Committee shall review on an on-going basis for potential conflicts of interest, and approve if appropriate, all our “Related Party Transactions” as required by Section 120 of the NYSE MKT Company Guide. For purposes of the Audit Committee Charter, “Related Party Transactions” shall mean those transactions required to be disclosed pursuant to SEC Regulation S-K, Item 404.

The Board of Directors has determined that Mr. Kraws, Mr. Tarriff and Mr. Wolf are independent directors.

On November 18, 2016, Scott Tarriff acquired 300,000 shares of our common stock together with a Series A warrant to purchase 300,000 shares of our common stock at an exercise price of $1.43 and a Series B warrant to purchase 300,000 shares of our common stock at an exercise price of $1.72 for an aggregate purchase price of $300,000. The shares of stock and warrants were acquired in our public offering that was consummated on November 18, 2016. The Series A warrant may be exercised until the four year anniversary of the date of its issuance and the Series B warrant may be exercised until December 31, 2017.

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Item 14. ***Principal Accountant Fees and Services***

Independent Registered Public Accounting Firm Fees and Services

The following table sets forth the aggregate fees including expenses billed to us for the years ended December 31, 2016 and 2015 by BDO USA, LLP.

	December 31,	
	2016	**2015**
Audit Fees and Expenses (1)	$334,000	$297,000
	$334,000	$297,000

(1) Audit fees and expenses were for professional services rendered for the audit and reviews of the consolidated financial statements of the Company, professional services rendered for issuance of consents and assistance with review of documents filed with the SEC.

Audit Committee Pre-Approval Policy

The Audit Committee has adopted procedures for pre-approving all audit and non-audit services provided by the independent registered public accounting firm, including the fees and terms of such services. These procedures include reviewing detailed back-up documentation for audit and permitted non-audit services. The documentation includes a description of, and a budgeted amount for, particular categories of non-audit services that are recurring in nature and therefore anticipated at the time that the budget is submitted. Audit Committee approval is required to exceed the pre-approved amount for a particular category of non-audit services and to engage the independent registered public accounting firm for any non-audit services not included in those pre-approved amounts. For both types of pre-approval, the Audit Committee considers whether such services are consistent with the rules on auditor independence promulgated by the SEC and the Public Company Accounting Oversight Board (PCAOB). The Audit Committee also considers whether the independent registered public accounting firm is best positioned to provide the most effective and efficient service, based on such reasons as the auditor's familiarity with our business, people, culture, accounting systems, risk profile, and whether the services enhance our ability to manage or control risks and improve audit quality. The Audit Committee may form and delegate pre-approval authority to subcommittees consisting of one or more members of the Audit Committee, and such subcommittees must report any pre-approval decisions to the Audit Committee at its next scheduled meeting. All of the services provided by the independent registered public accounting firm were pre-approved by the Audit Committee.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a)(1) The following financial statements are included in this Annual Report on Form 10-K for the fiscal years ended December 31, 2016, 2015, and 2014.

1. Independent Registered Public Accounting Firm

2. Consolidated Balance Sheets as of December 31, 2016 and 2015

3. Consolidated Statements of Operations for the years ended December 31, 2016, 2015 and 2014

4. Consolidated Statements of changes in Stockholders' Equity for the years ended December 31, 2016, 2015 and 2014

5. Consolidated Statements of Cash Flows for the years ended December 31, 2016, 2015 and 2014

6. Notes to Consolidated Financial Statements

(a)(2) All financial statement schedules have been omitted as the required information is either inapplicable or included in the Consolidated Financial Statements or related notes.

(a)(3) The following exhibits are either filed as part of this report or are incorporated herein by reference:

1.1	Underwriting Agreement, dated July 16, 2015. (Incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed on July 17, 2015, File No. 001-12584.)
1.2	At Market Issuance Agreement dated August 5, 2016 between Synthetic Biologics, Inc. and FBR Capital Markets & Co. (Incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K filed August 5, 2016, File No. 001-12584.)
1.3	Underwriting Agreement, dated November 15, 2016 between Synthetic Biologics, Inc. and Cantor Fitzgerald & Co. (Incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K filed November 15, 2016, File No. 001-12584.)
3.1	Certificate of Incorporation, as amended (Incorporated by reference to (i) Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 16, 2008, File No. 001-12584, (ii) Exhibit 3.1 of the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2001 filed August 14, 2001, File No. 001-12584; and (iii) Exhibits 3.1, 4.1 and 4.2 of the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 1998 filed August 14, 1998, File No. 001-12584.)
3.2	Articles of Merger (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 19, 2009, File No. 001-12584.)
3.3	Certificate of Merger filed with the Secretary of State of Delaware (Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed October 19, 2009, File No. 001-12584.)
3.4	Articles of Incorporation filed with the Nevada Secretary of State (Incorporated by reference to Exhibit 3.3 of the Registrant's Current Report on Form 8-K filed October 19, 2009, File No. 001-12584.)
3.5	By-Laws (Incorporated by reference to (i) Exhibit 3.4 of the Registrant's Current Report on Form 8-K filed October 19, 2009, File No. 001-12584, and (ii) Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed June 3, 2010, File No. 001-12584.)
3.6	Amended and Restated Bylaws Adopted and Effective October 31, 2011 (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed November 2, 2011, File No. 001-12584.)
3.7	Certificate of Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed February 16, 2012, File No. 001-12584.)
3.8	Certificate of Amendment to Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed May 18, 2015, File No. 001-12584.)
4.1	Form of Warrant Certificate (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed December 1, 2006, File No. 001-12584.)
*4.2	2001 Stock Incentive Plan (Incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-8 filed January 18, 2008, File No. 333-148764.)

*4.3	2007 Stock Incentive Plan (Incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-8 filed January 18, 2008, File No. 333-148764.)
*4.4	2010 Stock Incentive Plan (Incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-8 filed November 29, 2010, File No. 333-170858.)
4.5	Form of Warrant Certificate issued to Enclave Capital LLC (Incorporated by reference to Exhibit 4.1 of the Registrant's Form 8-K filed July 6, 2010, File No. 001-12584.)
4.6	Form of Warrant to Purchase Common Stock issued January 2011 (Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed February 2, 2011, File No. 001-12584.)
4.7	Form of Warrant to Purchase Common Stock issued April 2011 (Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed April 6, 2011, File No. 001-12584.)
4.8	Form of Exchange Warrant to Purchase Common Stock issued in exchange of the Warrant issued April 2011 (Incorporated by reference to Exhibit 4.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011 filed August 15, 2011, File No. 001-12584.)
4.9	Form of Exchange Warrant to Purchase Common Stock issued in exchange of the Warrant issued February 2011 (Incorporated by reference to Exhibit 4.2 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011 filed August 15, 2011, File No. 001-12584.)
4.10	Form of Warrant to Purchase Common Stock issued February 2012 (Incorporated by reference to Exhibit 4.10 of the Registrant's Annual Report on Form 10-K for the year ended December 3, 2011 filed March 30, 2012, File No. 001-12584.)

4.11	Form of Warrant to Purchase Common Stock issued to Griffin Securities, Inc. on October 30, 2012 (Incorporated by reference to Exhibit 10.4 of the Registrant's Current Report on Form 8-K filed October 31, 2012, File No. 001-12584.)
4.12	Specimen Stock Certificate (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-3 filed on July 3, 2013, File No. 333-189794.)
4.13	Amended and Restated 2010 Stock Incentive Plan (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 filed on November 15, 2013, File No. 333-192355.)
4.14	Form of Warrant for Purchasers of Units (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on October 10, 2014, File No. 001-12584.)
*4.15	Synthetic Biologics, Inc. 2010 Stock Incentive Plan, as amended and restated on May 15, 2015. (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 filed on August 10, 2015, File No. 333-206268.)
4.16	Synthetic Biologics, Inc. 2010 Stock Incentive Plan, as amended and restated on May 15, 2015. (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 filed on August 31, 2016, File No. 333-206268.)
4.17	Form of Series A Warrant to Purchase Common Stock issued November 18, 2016 (Incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on November 15, 2016, File No. 001-12584.)
4.18	Form of Series B Warrant to Purchase Common Stock issued November 18, 2016 (Incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K filed on November 15, 2016, File No. 001-12584.)
4.19	Form of Warrant Agreement, dated November 18, 2016 between Synthetic Biologics, Inc. and Corporate Stock Transfer, Inc. (Incorporated by reference to Exhibit 4.3 of the Registrant's Current Report on Form 8-K filed on November 15, 2016, File No. 001-12584.)
10.1	Unit Purchase Agreement (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed December 1, 2006, File No. 001-12584.)
10.2	License Agreement between The Regents of the University of California and Epitope Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.22 of the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2008 filed August 14, 2008, File No. 001-12584.)
*10.3	Form of Director/Officer Indemnification Agreement (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed January 6, 2009, File No. 001-12584.)
10.4	Agreement and Plan of Reincorporation Merger (Incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K filed October 19, 2009, File No. 001-12584.)
10.5	Sublicense Agreement between Meda AB, Adeona Pharamaceuticals, Inc. and Pipex Therapeutics, Inc. (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed May 11, 2010,

File No. 001-12584.)

10.6	Non-Disturbance Agreement among Pipex Therapeutics, Inc., Mclean Hospital Corp and Meda AB (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed May 11, 2010, File No. 001-12584.)
10.7	McLean Hospital Corporation Exclusive License Agreement (Incorporated by reference to Exhibit 10.21 of the Registrant's Annual Report on Form 10-K filed March 31, 2011, File No. 001-12584.)

10.8	Agreement with Chardan Capital Markets, LLC (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed April 6, 2011, File No. 001-12584.)
10.9	Exchange Agreement with respect to Warrant issued April 2011(Incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011 filed August 15, 2011, File No. 001-12584.)
10.10	Exchange Agreement with respect to Warrant issued February 2011(Incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011 filed August 15, 2011, File No. 001-12584.)
10.11	Stock Purchase Agreement with Intrexon Corporation (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed November 21, 2011, File No. 001-12584.)
10.12	Registration Rights Agreement with Intrexon Corporation (Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed November 21, 2011, File No. 001-12584.)
*10.13	Employment Agreement with Jeffrey Riley (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed February 6, 2012, File No. 001-12584.)
10.14	Membership Interest Purchase Agreement by and among Synthetic Biologics, Inc., Hartlab LLC, and Adeona Clinical Laboratory, LLC, dated as of March 7, 2012 (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed March 12, 2012, File No. 001-12584.)
10.15	Pledge and Security Agreement between Synthetic Biologics, Inc. and Hartlab, LLC dated as of March 7, 2012 (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed March 12, 2012, File No. 001-12584.)
10.16	Non-Recourse Promissory Note between Synthetic Biologics, Inc. and Hartlab, LLC dated as of March 7, 2012 (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed March 12, 2012, File No. 001-12584.)
10.17	Exclusive Channel Collaboration Agreement with Intrexon Corporation (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed August 9, 2012, File No. 001-12584.)
10.18	Stock Purchase Agreement with Intrexon Corporation (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed August 9, 2012, File No. 001-12584.)
10.19	First Amendment to Registration Rights Agreement between Synthetic Biologics, Inc. and Intrexon Corporation (Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed August 9, 2012, File No. 001-12584.)
10.20	Stock Purchase Agreement dated October 25, 2012 with investors (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed October 31, 2012, File No. 001-12584.)
10.21	

	Registration Rights Agreement dated October 25, 2012 with investors (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed October 31, 2012, File No. 001-12584.)
10.22	Joinder Agreement by and among Synthetic Biologics, Inc., NRM VII Holdings I, LLC and Intrexon Corporation (Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed October 31, 2012, File No. 001-12584.)
10.23	Asset Purchase Agreement dated November 8, 2012 between Synthetic Biologics, Inc. and Prev ABR LLC (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed November 13, 2012, File No. 001-12584.)
*10.24	Amendment to Employment Agreement dated October 1, 2012 with Steve H. Kanzer (Incorporated by reference to Exhibit 10.42 of the Registrant's Registration Statement on Form S-1 filed December 13, 2012, File No. 333-185457.)
10.25	Patent License Agreement dated December 19, 2012 between Synthetic Biologics, Inc. and The University of Texas at Austin (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed December 21, 2012, File No. 001-12584.)
10.26	Sponsored Research Agreement dated December 19, 2012 between Synthetic Biologics, Inc. and The University of Texas at Austin (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed December 21, 2012, File No. 001-12584.)

10.27	Exclusive License Agreement with The Regents of The University of California (Incorporated by reference to Exhibit 10.45 of the Registrant's Annual Report on Form 10-K filed April 16, 2013, File No. 001-12584.)
10.28	First Amendment to Exclusive License Agreement with The Regents of The University of California (Incorporated by reference to Exhibit 10.46 of the Registrant's Annual Report on Form 10-K filed April 16, 2013, File No. 001-12584.)
10.29	Second Amendment to Exclusive License Agreement with The Regents of The University of California (Incorporated by reference to Exhibit 10.47 of the Registrant's Annual Report on Form 10-K filed April 16, 2013, File No. 001-12584.)
10.30	Third Amendment to Exclusive License Agreement with The Regents of The University of California (Incorporated by reference to Exhibit 10.48 of the Registrant's Annual Report on Form 10-K filed April 16, 2013, File No. 001-12584.)
10.31	Fourth Amendment to Exclusive License Agreement with The Regents of The University of California (Incorporated by reference to Exhibit 10.49 of the Registrant's Annual Report on Form 10-K filed April 16, 2013, File No. 001-12584.)
10.32	Exclusive License Agreement between Synthetic Biologics, Inc., Synthetic Biomics, Inc. and Cedars-Sinai Medical Center dated December 5, 2013 (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 10, 2013, File No. 001-12584.)
10.33	Exclusive Option Agreement between Synthetic Biologics, Inc., Synthetic Biomics, Inc. and Cedars-Sinai Medical Center dated December 5, 2013 (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on December 10, 2013, File No. 001-12584.)
10.34	Stock Purchase Agreement between Synthetic Biologics, Inc., Synthetic Biomics, Inc. and Cedars-Sinai Medical Center dated December 5, 2013(Incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on December 10, 2013, File No. 001-12584.)
10.35	Stock Purchase Agreement between Synthetic Biologics, Inc., Synthetic Biomics, Inc. and Mark Pimentel dated December 5, 2013 (Incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on December 10, 2013, File No. 001-12584.)
10.36	Stock Purchase Agreement between Synthetic Biologics, Inc., Synthetic Biomics, Inc. and Cedars-Sinai Medical Center dated December 5, 2013(Incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed on December 10, 2013, File No. 001-12584.)
10.37	First Amendment to Exclusive License Agreement. (Incorporated by reference to Exhibit 10.49 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013 filed March 31, 2014, File No. 001-12584.)
10.38	Form of Subscription Agreement dated as of October 10, 2014 (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on October 10, 2014, File No. 001-12584.)
10.39	

	Placement Agency Agreement dated October 10, 2014 between Synthetic Biologics, Inc. and William Blair & Company, L.L.C. (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on October 10, 2014, File No. 001-12584.)
*10.40	Employment Agreement, dated March 18, 2015, by and between Jeffrey Riley and the Company. (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on March 19, 2015, File No. 001-12584.)
*10.41	Employment Agreement, dated March 18, 2015, by and between C. Evan Ballantyne and the Company. (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on March 19, 2015, File No. 001-12584.)
10.42	Amended and Restated 2010 Stock Incentive Plan. (Incorporated by reference to Exhibit B to the Definitive Proxy Statement filed with the Securities and Exchange Commission on April 13, 2015, File No. 001-12584.)
*10.43	Employment Agreement, dated April 28, 2015, by and between Stephen A. Shallcross and the Company. (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on May 4, 2015, File No. 001-12584.)
*10.44	Severance Agreement, dated April 29, 2015, by and between C. Evan Ballantyne and the Company. (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on May 4, 2015, File No. 001-12584.)
10.45	Fifth Amendment to the Exclusive License Agreement with The Regents of The University of California, dated July 25, 2014. (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on July 9, 2015, File No. 001-12584.)
10.46	Sixth Amendment to the Exclusive License Agreement with The Regents of The University of California, dated July 8, 2015. (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on July 9, 2015, File No. 001-12584.)

10.47	Clinical Trial Agreement between Putney Drug Corp. and The Regents of The University of California, dated April 29, 2010. (Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on July 9, 2015, File No. 001-12584.)
10.48	Amendment to the Clinical Trial Agreement between Putney Drug Corp. and The Regents of The University of California, dated July 8, 2015. (Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on July 9, 2015, File No. 001-12584.)
10.49	Exclusive Channel Collaboration Agreement by and between Synthetic Biologics, Inc. and Intrexon Corporation dated as of August 10, 2015**. (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on August 10, 2015, File No. 001-12584.)
10.50	Stock Issuance Agreement by and between Synthetic Biologics, Inc., and Intrexon Corporation, dated August 10, 2015. (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on August 10, 2015, File No. 001-12584.)
10.51	Second Amendment to the Registration Rights Agreement by and between Synthetic Biologics, Inc. and Intrexon Corporation, dated as of August 10, 2015. (Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed August 10, 2015, File No. 001-12584.)
10.52	Amendment, dated August 29, 2015, to the Stock Purchase Agreement, dated December 3, 2013, by and among Synthetic Biologics, Inc., Synthetic Biomics, Inc. and Mark Pimentel, M.D. (Incorporated by reference to Exhibit 10.5 of the Registrant's Current Report on Form 8-K filed September 3, 2015, File No. 001-12584.)
10.53	Third Amendment to the License Agreement between Synthetic Biologics, Inc., Synthetic Biomics, Inc. and Cedar-Sinai Medical Center, dated September 4, 2015. (Incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015 filed November 5, 2015, File No. 001-12584.)
*10.54	Amendment to Employment Agreement by and between Synthetic Biologics, Inc. and Jeffrey Riley, dated as of December 4, 2015. (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed December 10, 2015, File No. 001-12584.)
*10.55	Form of Stock Option Agreement. (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed December 10, 2015, File No. 001-12584.)
*10.56	Amendment to Employment Agreement by and between Synthetic Biologics, Inc. and Steven A. Shallcross, dated as of December 1, 2016. (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed December 2, 2016, File No. 001-12584.)
*10.57	Employment Agreement by and between Synthetic Biologics, Inc. and Joseph Sliman dated as of January 17, 2017 (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed January 19, 2017, File No. 001-12584.)
*10.58	Employment Agreement by and between Synthetic Biologics, Inc. and Jeffrey Riley dated as of February 27, 2017. (1)

21	List of Subsidiaries [(1)]
23.1	Consent of Independent Registered Public Accounting Firm (BDO USA, LLP) [(1)]
31.1	Certification of Jeffrey Riley, Chief Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a) [(1)]
31.2	Certification of Steven A. Shallcross, Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) [(1)]
32.1	Certification of Jeffrey Riley, Chief Executive Officer pursuant to Section 1350 of the Sarbanes-Oxley Act of 2002 [(1)]
32.2	Certification of Steven A. Shallcross, Chief Financial Officer pursuant to Section 1350 of the Sarbanes-Oxley Act of 2002 [(1)]
101.INS	XBRL Instance Document [(1)]
101.SCH	XBRL Taxonomy Extension Schema Document [(1)]
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document [(1)]
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document [(1)]
101.LAB	XBRL Taxonomy Extension Label Linkbase Document [(1)]
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document [(1)]

(1) Filed herewith.

*** Management contract or compensatory plan or arrangement required to be identified pursuant to Item 15(a)(3) of this report.**

**** Confidential treatment has been requested as to certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

Item 16. ***Form 10-K Summary***

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned.

SYNTHETIC BIOLOGICS, INC.

By: /s/ Jeffrey Riley

Jeffrey Riley
Chief Executive Officer and Director
(Principal Executive Officer)
Date: March 2, 2017

By: /s/ Steven A. Shallcross

Steven A. Shallcross
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)
Date: March 2, 2017

Pursuant to the requirements of the Securities Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Date: March 2, 2017 By: /s/ Jeffrey Riley
Jeffrey Riley
Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 2, 2017 By: /s/ Jeffrey J. Kraws
Jeffrey J. Kraws
Chairman

Date: March 2, 2017 By: /s/ Scott L. Tarriff
Scott L. Tarriff
Director

Date: March 2, 2017 By: /s/ Jeffrey Wolf
Jeffrey Wolf

Director

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