SOLIGENIX, INC.
Form 10-K
March 27, 2017

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the Fiscal Year Ended **December 31, 2016**

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

For the transition period from _____ to _____

Commission File No. 000-16929

SOLIGENIX, INC.

(Exact name of registrant as specified in its charter)

Delaware	**41-1505029**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
29 EMMONS DRIVE, SUITE C-10	
PRINCETON, NJ	**08540**
(Address of principal executive offices)	(Zip Code)

(609) 538-8200

(Registrant's telephone number, including area code)

Securities registered under Section 12 (b) of the Exchange Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $.001 per share	**Nasdaq**
Common Stock Purchase Warrants	

Securities registered under Section 12(g) of the Exchange 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 þ

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 þ

Indicate by check mark whether the registrant (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 þ 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 (§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 þ 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 registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this 10-K or any amendments to this Form 10-K. þ

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company þ

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes No þ

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $18,585,798 (assuming, for this purpose, that executive officers, directors and holders of 10% or more of the common stock are affiliates), based on the closing price of the registrant’s common stock as reported on the Over-the-Counter Bulletin Board on June 30, 2016.

As of March 17, 2017, 5,472,532 shares of the registrant’s Common Stock, par value $0.001 per share, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: None.

SOLIGENIX, INC.

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ANNUAL REPORT ON FORM 10-K

For the Year Ended December 31, 2016

Table of Contents

PART I

Item 1. Business

This Annual Report on Form 10-K contains statements of a forward-looking nature relating to future events or our future financial performance. These statements are only predictions and actual events or results may differ materially. In evaluating such statements, you should carefully consider the various factors identified in this report that could cause actual results to differ materially from those indicated in any forward-looking statements, including those set forth in "Risk Factors" in this Annual Report on Form 10-K. See "Cautionary Note Regarding Forward Looking Statements."

Our Business Overview

We are a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense.

Our BioTherapeutics business segment is developing a novel photodynamic therapy (SGX301) utilizing topical synthetic hypericin activated with safe visible fluorescent light for the treatment of cutaneous T-cell lymphoma ("CTCL"), our first-in-class innate defense regulator technology, dusquetide (SGX942) for the treatment of oral mucositis in head and neck cancer, and proprietary formulations of oral beclomethasone 17,21-dipropionate ("BDP") for the prevention/treatment of gastrointestinal ("GI") disorders characterized by severe inflammation, including pediatric Crohn's disease (SGX203) and acute radiation enteritis (SGX201).

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine candidate, OrbeShield®, our GI acute radiation syndrome ("GI ARS") therapeutic candidate and SGX943, our melioidosis therapeutic candidate. The development of our vaccine programs currently is supported by our heat stabilization technology, known as ThermoVax®, under existing and on-going government contract funding. With the government contract from the National Institute of Allergy and Infectious Diseases ("NIAID"), we will attempt to advance the development of RiVax™ to protect against exposure to ricin toxin. We have advanced the development of OrbeShield® for the treatment of GI ARS with funds received under our awarded government contracts with the Biomedical Advanced Research and Development Authority ("BARDA") and grants from NIAID.

An outline of our business strategy follows:

Complete enrollment and report preliminary results in our pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL;
Obtain agreement from the United States Food and Drug Administration (the "FDA") on a pivotal Phase 3 protocol of SGX942 for the treatment of oral mucositis in head and neck cancer patients and initiate the trial;
Initiate a pivotal Phase 3 clinical trial of SGX203 for the treatment of pediatric Crohn's disease;
Continue development of RiVax™ in combination with our ThermoVax® technology, to develop new heat stable vaccines in biodefense with NIAID funding support;
Advance the preclinical and manufacturing development of OrbeShield® as a biodefense medical countermeasure for the treatment of GI ARS contingent upon government funding support;
Continue to apply for and secure additional government funding for each of our BioTherapeutics and Vaccines/BioDefense programs through grants, contracts and/or procurements;
Pursue business development opportunities for our pipeline programs, as well as explore merger/acquisition strategies; and
Acquire or in-license new clinical-stage compounds for development.

Corporate Information

We were incorporated in Delaware in 1987 under the name Biological Therapeutics, Inc. In 1987 we merged with Biological Therapeutics, Inc., a North Dakota corporation, pursuant to which we changed our name to "Immunotherapeutics, Inc." We changed our name to "Endorex Corp." in 1996, to "Endorex Corporation" in 1998, to "DOR BioPharma, Inc." in 2001, and finally to "Soligenix, Inc." in 2009. Our principal executive offices are located at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540 and our telephone number is (609) 538-8200.

Our Product Candidates in Development

The following tables summarize our product candidates under development:

BioTherapeutic Product Candidates

Soligenix Product Candidate	Therapeutic Indication	Stage of Development
SGX301	Cutaneous T-Cell Lymphoma	Phase 2 trial completed; demonstrated significantly higher response rate compared to placebo; Phase 3 clinical trial initiated in the second half of 2015, with data expected in the second half of 2017
SGX942	Oral Mucositis in Head and Neck Cancer	Phase 2 trial completed; demonstrated significant response compared to placebo with positive long-term (12 month) safety reported in 2016; seek to obtain FDA agreement on the Phase 3 protocol and initiate the trial in the first half of 2017, with data expected in the second half of 2018
SGX203**	Pediatric Crohn's disease	Phase 1/2 clinical trial completed June 2013, efficacy data, pharmacokinetic (PK)/pharmacodynamic (PD) profile and safety profile demonstrated; Phase 3 clinical trial planned for the second half of 2017, with data expected in the second half of 2019
SGX201**	Acute Radiation Enteritis	Phase 1/2 clinical trial complete; safety profile and preliminary efficacy demonstrated

Vaccine Thermostability Platform**

Indication	Stage of Development

Soligenix Product Candidate		
ThermoVax®	Thermostability of aluminum adjuvanted vaccines	Pre-clinical

BioDefense Products**

Soligenix Product Candidate	**Indication**	**Stage of Development**
RiVax™	Vaccine against	Phase 1b trial complete, safety and neutralizing antibodies for protection demonstrated;
	Ricin Toxin Poisoning	Phase 1/2 trial planned for the first half of 2018
OrbeShield®	Therapeutic against GI ARS	Pre-clinical
SGX943	Melioidosis	Pre-clinical

*** Contingent upon continued government contract/grant funding or other funding source.*

BioTherapeutics Overview

SGX301 – for Treating Cutaneous T-Cell Lymphoma

SGX301 is a novel photodynamic therapy that utilizes safe visible light for activation. The active ingredient in SGX301 is synthetic hypericin, a photosensitizer which is topically applied to skin lesions and then activated by fluorescent light 16 to 24 hours later. Hypericin is also found in several species of *Hypericum* plants, although the drug used in SGX301 is chemically synthesized by a proprietary manufacturing process and not extracted from plants. Importantly, hypericin is optimally activated with visible light thereby avoiding the negative consequences of ultraviolet light. Other light therapies using UVA light result in serious adverse effects including secondary skin cancers.

Combined with photoactivation, in clinical trials hypericin has demonstrated significant anti-proliferative effects on activated normal human lymphoid cells and inhibited growth of malignant T-cells isolated from CTCL patients. In both settings, it appears that the mode of action is an induction of cell death in a concentration as well as a light dose-dependent fashion. These effects appear to result, in part, from the generation of singlet oxygen during photoactivation of hypericin.

Hypericin is one of the most efficient known generators of singlet oxygen, the key component for phototherapy. The generation of singlet oxygen induces necrosis and apoptosis in adjacent cells. The use of topical hypericin coupled with directed visible light results in generation of singlet oxygen only at the treated site. We believe that the use of visible light (as opposed to cancer-causing ultraviolet light) is a major advance in photodynamic therapy. In a published Phase 2 clinical study in CTCL, after six weeks of twice weekly therapy, a majority of patients experienced a statistically significant ($p \leq 0.04$) improvement with topical hypericin treatment whereas the placebo was ineffective: 58.3% compared to 8.3%, respectively.

SGX301 has received orphan drug designation as well as Fast Track designation from the FDA. The Orphan Drug Act is intended to assist and encourage companies to develop safe and effective therapies for the treatment of rare diseases and disorders. In addition to providing a seven-year term of market exclusivity for SGX301 upon final FDA approval, orphan drug designation also positions us to be able to leverage a wide range of financial and regulatory benefits, including government grants for conducting clinical trials, waiver of FDA user fees for the potential submission of a New Drug Application ("NDA") for SGX301, and certain tax credits. In addition, Fast Track is a designation that the FDA reserves for a drug intended to treat a serious or life-threatening condition and one that demonstrates the potential to address an unmet medical need for the condition. Fast Track designation is designed to facilitate the development and expedite the review of new drugs. For instance, should events warrant, we will be eligible to submit a NDA for SGX301 on a rolling basis, permitting the FDA to review sections of the NDA prior to receiving the complete submission. Additionally, NDAs for Fast Track development programs ordinarily will be eligible for priority

review. SGX301 for the treatment of CTCL also was granted orphan drug designation from the European Medicines Agency ("EMA") Committee for Orphan Medical Products and Promising Innovative Medicine ("PIM") designation from the Medicines and Healthcare Products Regulatory Agency ("MHRA") in the United Kingdom ("UK").

We initiated our pivotal Phase 3 clinical study of SGX301 for the treatment of CTCL during December 2015 and are actively enrolling patients. The Phase 3 protocol is expected to be a highly powered, double-blind, randomized, placebo-controlled, multicenter trial and will seek to enroll approximately 120 evaluable subjects. The trial will consist of three treatment cycles, each of eight weeks duration. Treatments will be administered twice weekly for the first six weeks and treatment response will be determined at the end of the eighth week. In the first treatment cycle, approximately 80 subjects will receive SGX301 and 40 will receive placebo treatment of their index lesions. In the second cycle, all subjects will receive SGX301 treatment of their index lesions, and in the third cycle all subjects will receive SGX301 treatment of all of their lesions. Subjects will be followed for an additional six months after the completion of treatment. The primary efficacy endpoint will be assessed on the percentage of patients in each of the two treatment groups (i.e., SGX301 and placebo) achieving a partial or complete response of the treated lesions, defined as a ≥ 50% reduction in the total Composite Assessment of Index Lesion Disease Severity ("CAILS") score for three index lesions at the Cycle 1 evaluation visit (Week 8) compared to the total CAILS score at baseline. Other secondary measures will assess treatment response, including duration, degree of improvement, time to relapse and safety.

We estimate the potential worldwide market for SGX301 is in excess of $250 million for all applications, including the treatment of CTCL. This potential market information is a forward-looking statement. While we have determined this potential market size based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

Cutaneous T-Cell Lymphoma

CTCL is a class of non-Hodgkin's lymphoma ("NHL"), a type of cancer of the white blood cells that are an integral part of the immune system. Unlike most NHLs, which generally involve B-cell lymphocytes (involved in producing antibodies), CTCL is caused by an expansion of malignant T-cell lymphocytes (involved in cell-mediated immunity) normally programmed to migrate to the skin. These skin-trafficking malignant T-cells migrate to the skin, causing various lesions to appear that may change shape as the disease progresses, typically beginning as a rash and eventually forming plaques and tumors. Mycosis fungoides ("MF") is the most common form of CTCL. It generally presents with skin involvement only, manifested as scaly, erythematous patches. Advanced disease with diffuse lymph node and visceral organ involvement is usually associated with a poorer response rate to standard therapies. A relatively uncommon sub-group of CTCL patients present with extensive skin involvement and circulating malignant cerebriform T-cells, referred to as Sézary syndrome. These patients have substantially graver prognoses than those with MF.

CTCL mortality is related to stage of disease, with median survival generally ranging from about 12 years in the early stages to only 2.5 years when the disease has advanced. There is currently no FDA-approved drug for front-line treatment of early stage CTCL. Treatment of early-stage disease generally involves skin-directed therapies. One of the most common unapproved therapies used for early-stage disease is oral 5 or 8-methoxypsoralen ("Psoralen") given with ultraviolet A ("UVA") light, referred to as PUVA, which is approved for dermatological conditions such as disabling psoriasis not adequately responsive to other forms of therapy, idiopathic vitiligo and skin manifestations of CTCL in persons who have not been responsive to other forms of treatment. Psoralen is a mutagenic chemical that interferes with DNA causing mutations and other malignancies. Moreover, UVA is a carcinogenic light source that when combined with the Psoralen, results in serious adverse effects including secondary skin cancers; therefore, the FDA requires a Black Box warning for PUVA.

CTCL constitutes a rare group of NHLs, occurring in about 4% of the approximate 500,000 individuals living with NHL. We estimate, based upon review of historic published studies and reports and an interpolation of data on the incidence of CTCL, that it affects over 20,000 individuals in the U.S., with approximately 2,800 new cases seen annually.

Dusquetide

Dusquetide (research name: SGX94) is an innate defense regulator ("IDR") that regulates the innate immune system to simultaneously reduce inflammation, eliminate infection and enhance tissue healing.

Dusquetide is based on a new class of short, synthetic peptides known as IDRs that have a novel mechanism of action in that it is simultaneously anti-inflammatory and anti-infective. IDRs have no direct antibiotic activity but modulate host responses, increasing survival after infections with a broad range of bacterial Gram-negative and Gram-positive pathogens including both antibiotic sensitive and resistant strains, as well as accelerating resolution of tissue damage following exposure to a variety of agents including bacterial pathogens, trauma and chemo- or radiation-therapy. IDRs represent a novel approach to the control of infection and tissue damage via highly selective binding to an intracellular adaptor protein, sequestosome-1, also known as p62, which has a pivotal function in signal transduction during activation and control of the innate defense system. Preclinical data indicate that IDRs may be active in models of a wide range of therapeutic indications including life-threatening bacterial infections as well as the severe side-effects of chemo- and radiation-therapy.

Dusquetide has demonstrated efficacy in numerous animal disease models including mucositis, colitis, skin infection and other bacterial infections and has been evaluated in a double-blind, placebo-controlled Phase 1 clinical trial in 84 healthy volunteers with both single ascending dose and multiple ascending dose components. Dusquetide was shown to have a good safety profile and well-tolerated in all dose groups when administered by IV over 7 days and was consistent with safety results seen in pre-clinical studies. Dusquetide is the subject of an open Investigational New Drug ("IND") application which has been cleared by the FDA. We believe that market opportunities for dusquetide include mucositis, acute methicillin resistant *Staphylococcus aureus* (MRSA) bacterial infections, acinetobacter, melioidosis, and acute radiation syndrome.

SGX942 – for Treating Oral Mucositis in Head and Neck Cancer

SGX942 is our product candidate containing our IDR technology, dusquetide, targeting the treatment of oral mucositis in head and neck cancer patients. Oral mucositis in this patient population is an area of unmet medical need where there are currently no approved drug therapies. Accordingly, we received Fast Track designation for the treatment of oral mucositis as a result of radiation and/or chemotherapy treatment in head and neck cancer patients from the FDA. In addition, dusquetide has been granted PIM designation in the UK by the MHRA for the treatment of severe oral mucositis in head and neck cancer patients receiving chemoradiation therapy.

We initiated a Phase 2 clinical study of SGX942 for the treatment of oral mucositis in head and neck cancer patients in December of 2013. We completed enrollment in this trial in the second half of 2015 and in December 2015 released positive preliminary results. In this Phase 2 proof-of-concept clinical study that enrolled 111 patients, SGX942, at a dose of 1.5 mg/kg, successfully reduced the median duration of severe oral mucositis by 50%, from 18 days to 9 days ($p=0.099$) in all patients and by 67%, from 30 days to 10 days ($p=0.040$) in patients receiving the most aggressive chemoradiation therapy for treatment of their head and neck cancer. The p-values met the prospectively defined statistical threshold of $p<0.1$ in the study protocol. In addition to identifying the best dose of 1.5 mg/kg, this study achieved all objectives, including increased incidence of "complete response" of tumor at the one month follow up visit (47% in placebo vs. 63% in SGX942 at 1.5 mg/kg). Decreases in mortality and decreases in infection rate were also observed with SGX942 treatment, consistent with the preclinical results observed in animal models. SGX942 was found to be generally safe and well tolerated, consistent with the safety profile observed in the prior Phase 1 study conducted in 84 healthy volunteers. The long-term (12 month) follow-up data remains consistent with the preliminary positive safety and efficacy findings. While the placebo population experienced the expected 12-month survival rate of approximately 80%, as defined in the Surveillance, Epidemiology, and End Results statistics 1975-2012 from the National Cancer Institute, the SGX942 1.5 mg/kg treatment group reported a 12-month survival rate of 93% (7% mortality in the SGX942 1.5 mg/kg group compared to 19% in the placebo group). Similarly, tumor resolution (complete response) at 12 months was better in the SGX942 1.5 mg/kg treatment group relative to the placebo population (80% in the 1.5 mg/kg group compared to 74% in the placebo group). In addition to safety, evaluations of other secondary efficacy endpoints, such as the utilization of opioid pain medication, indicated that the SGX942 1.5mg/kg treatment group had a 40% decrease in the use of opioids at the later stage of the treatment phase of the trial, when oral mucositis is usually most severe and expected to increase paid medication use. This was in contrast to the placebo group, which demonstrated a 10% increase in use of opioids over this same period. Data from this Phase 2 trial was published online in the Journal of Biotechnology. The publication also delineates the supportive nonclinical

data in this indication, demonstrating consistency in the qualitative and quantitative biological response, including dose response, across the nonclinical and clinical data sets. The results are available at the following link: http://authors.elservier.com/sd/article/S01681656116315668.

On September 9, 2016, we and SciClone Pharmaceuticals, Inc. (“SciClone”) entered into an exclusive license agreement, pursuant to which we granted rights to SciClone to develop, promote, market, distribute and sell SGX942 in defined territories. Under the terms of the license agreement, SciClone will be responsible for all aspects of development, product registration and commercialization in the territories, having access to data generated by us. In exchange for exclusive rights, SciClone will pay us royalties on net sales, and we will supply commercial drug product to SciClone on a cost-plus basis, while maintaining worldwide manufacturing rights.

We are working with the FDA to obtain agreement on the design of a pivotal Phase 3 protocol for SGX942 in the treatment of oral mucositis in patients with head and neck cancer receiving chemoradiation therapy. Additionally, we have received positive Scientific Advice from the EMA for the development of SGX942 as a treatment for oral mucositis in patients with head and neck cancer. The Scientific Advice from the EMA indicates that a single, double-blind, placebo-controlled, multinational, Phase 3 pivotal study, if successful, in conjunction with the Phase 2 dose-ranging study, is generally considered sufficient to support a marketing authorization application ("MAA") to the EMA for potential licensure in Europe. The advice also provided several suggestions to strengthen the study design and data collection that will be integrated into the final protocol. Scientific Advice is offered by the EMA to stakeholders for clarification of questions arising during development of medicinal products. The scope of Scientific Advice is limited to scientific issues and focuses on development strategies rather than pre-evaluation of data to support an MAA. Scientific Advice is legally non-binding and is based on the current scientific knowledge which may be subject to future changes.

We estimate the potential worldwide market for SGX942 is in excess of $500 million for all applications, including the treatment of oral mucositis. This potential market information is a forward-looking statement. While we have determined this potential market size based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

Oral Mucositis

Mucositis is the clinical term for damage done to the mucosa by anticancer therapies. It can occur in any mucosal region, but is most commonly associated with the mouth, followed by the small intestine. We estimate, based upon our review of historic studies and reports, and an interpolation of data on the incidence of mucositis, that mucositis affects approximately 500,000 people in the U.S. per year and occurs in 40% of patients receiving chemotherapy. Mucositis can be severely debilitating and can lead to infection, sepsis, the need for parenteral nutrition and narcotic analgesia. The GI damage causes severe diarrhea. These symptoms can limit the doses and duration of cancer treatment, leading to sub-optimal treatment outcomes.

The mechanisms of mucositis have been extensively studied and have been recently linked to the interaction of chemotherapy and/or radiation therapy with the innate defense system. Bacterial infection of the ulcerative lesions is regarded as a secondary consequence of dysregulated local inflammation triggered by therapy-induced cell death, rather than as the primary cause of the lesions.

We estimate, based upon our review of historic studies and reports, and an interpolation of data on the incidence of oral mucositis, that oral mucositis is a subpopulation of approximately 90,000 patients in the U.S., with a comparable number in Europe. Oral mucositis almost always occurs in patients with head and neck cancer treated with radiation therapy (greater than 80% incidence of severe mucositis) and is common in patients undergoing high dose

chemotherapy and hematopoietic cell transplantation, where the incidence and severity of oral mucositis depends greatly on the nature of the conditioning regimen used for myeloablation.

Oral BDP

Oral BDP (beclomethasone 17,21-dipropionate) represents a first-of-its-kind oral, locally acting therapy tailored to treat GI inflammation. BDP has been marketed in the U.S. and worldwide since the early 1970s as the active pharmaceutical ingredient in a nasal spray and in a metered-dose inhaler for the treatment of patients with allergic rhinitis and asthma. Oral BDP is specifically formulated for oral administration as a single product consisting of two tablets. One tablet is intended to release BDP in the upper sections of the GI tract and the other tablet is intended to release BDP in the lower sections of the GI tract.

Based on its pharmacological characteristics, oral BDP may have utility in treating other conditions of the gastrointestinal tract having an inflammatory component. We are planning to pursue development programs for the treatment of pediatric Crohn’s disease, acute radiation enteritis and GI ARS pending further grant funding. We are also exploring the possibility of testing oral BDP for local inflammation associated with ulcerative colitis, among other indications.

We are pursuing orphan drug designations for relevant indications as appropriate in both the U.S. and Europe. An orphan drug designation provides for seven years and ten years of market exclusivity upon approval in the U.S. and Europe, respectively.

SGX203 – for Treating Pediatric Crohn's Disease

SGX203 is a two tablet delivery system of BDP specifically designed for oral use that allows for administration of immediate and delayed release BDP throughout the small bowel and the colon. The FDA has given SGX203 orphan drug designation as well as Fast Track designation for the treatment of pediatric Crohn's disease.

We estimate the potential worldwide market for oral BDP is in excess of $500 million for all applications, including the treatment of pediatric Crohn's disease. This potential market information is a forward-looking statement. While we have determined this potential market size based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

Pediatric Crohn's Disease

Crohn's disease causes inflammation of the GI tract. Crohn's disease can affect any area of the GI tract, from the mouth to the anus, but it most commonly affects the lower part of the small intestine, called the ileum. The swelling caused by the disease extends deep into the lining of the affected organ. The swelling can induce pain and can make the intestines empty frequently, resulting in diarrhea. Because the symptoms of Crohn's disease are similar to other intestinal disorders, such as irritable bowel syndrome and ulcerative colitis, it can be difficult to diagnose. People of Ashkenazi Jewish heritage have an increased risk of developing Crohn's disease.

Crohn's disease can appear at any age, but it is most often diagnosed in adults in their 20s and 30s. However, approximately 30% of people with Crohn's disease develop symptoms before 20 years of age. We estimate, based upon our review of historic published studies and reports, and an interpolation of data on the incidence of pediatric Crohn's disease, that pediatric Crohn's disease is a subpopulation of approximately 80,000 patients in the U.S. with a comparable number in Europe. Crohn's disease tends to be both severe and extensive in the pediatric population and a relatively high proportion (approximately 40%) of pediatric Crohn's patients have involvement of their upper gastrointestinal tract.

Crohn's disease presents special challenges for children and teens. In addition to bothersome and often painful symptoms, the disease can stunt growth, delay puberty, and weaken bones. Crohn's disease symptoms may sometimes prevent a child from participating in enjoyable activities. The emotional and psychological issues of living with a chronic disease can be especially difficult for young people.

SGX201 – for Preventing Acute Radiation Enteritis

SGX201 is a delayed-release formulation of BDP specifically designed for oral use. In 2012, we completed a Phase 1/2 clinical trial testing SGX201 in prevention of acute radiation enteritis. Patients with rectal cancer scheduled to undergo concurrent radiation and chemotherapy prior to surgery were randomized to one of four dose groups. The objectives of the study were to evaluate the safety and maximal tolerated dose of escalating doses of SGX201, as well as the preliminary efficacy of SGX201 for prevention of signs and symptoms of acute radiation enteritis. The study demonstrated that oral administration of SGX201 was safe and well tolerated across all four dose groups. There was also evidence of a potential dose response with respect to diarrhea, nausea and vomiting and the assessment of enteritis according to National Cancer Institute Common Terminology Criteria for Adverse Events for selected gastrointestinal events. In addition, the incidence of diarrhea was lower than that seen in recent published historical control data in this patient population. This program was supported in part by a $500,000 two-year Small Business Innovation and Research (“SBIR”) grant awarded by the National Institutes of Health (“NIH”). We continue to work with our Radiation Enteritis medical advisors to identify additional funding opportunities to support the clinical development program.

We have received Fast Track designation from the FDA for SGX201 for acute radiation enteritis.

We estimate the potential worldwide market for oral BDP is in excess of $500 million for all applications, including the treatment of acute radiation enteritis. This potential market information is a forward-looking statement. While we have determined this potential market size based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

Acute Radiation Enteritis

External radiation therapy is used to treat most types of cancer, including cancer of the bladder, uterine, cervix, rectum, prostate, and vagina. During delivery of treatment, some level of radiation will also be delivered to healthy tissue, including the bowel, leading to acute and chronic toxicities. The large and small bowels are very sensitive to radiation and the larger the dose of radiation the greater the damage to normal bowel tissue. Radiation enteritis is a condition in which the lining of the bowel becomes swollen and inflamed during or after radiation therapy to the abdomen, pelvis, or rectum. Most tumors in the abdomen and pelvis need large doses, and almost all patients receiving radiation to the abdomen, pelvis, or rectum will show signs of acute enteritis.

Patients with acute enteritis may have nausea, vomiting, abdominal pain and bleeding, among other symptoms. Some patients may develop dehydration and require hospitalization. With diarrhea, the gastrointestinal tract does not function normally, and nutrients such as fat, lactose, bile salts, and vitamin B12 are not well absorbed.

Symptoms will usually resolve within two to six weeks after therapy has ceased. Radiation enteritis is often not a self-limited illness, as over 80% of patients who receive abdominal radiation therapy complain of a persistent change in bowel habits. Moreover, acute radiation injury increases the risk of development of chronic radiation enteropathy, and overall 5% to 15% of the patients who receive abdominal or pelvic irradiation will develop chronic radiation enteritis.

We estimate, based upon our review of historic published studies and reports, and an interpolation of data on the treatment courses and incidence of cancers occurring in the abdominal and pelvic regions, there to be over 100,000 patients annually in the U.S., with a comparable number in Europe, who receive abdominal or pelvic external beam radiation treatment for cancer, and these patients are at risk of developing acute and chronic radiation enteritis.

Vaccines/BioDefense Overview

ThermoVax® – Thermostability Technology

Our thermostability technology, ThermoVax®, is a novel method of rendering aluminum salt, (known colloquially as Alum), adjuvanted vaccines stable at elevated temperatures. Alum is the most widely employed adjuvant technology in the vaccine industry. The value of ThermoVax® lies in its potential ability to eliminate the need for cold chain production, transportation, and storage for Alum adjuvanted vaccines. This would relieve companies of the high costs

of producing and maintaining vaccines under refrigerated conditions. Based on historical reports from the World Health Organization and other scientific reports, we believe that a meaningful proportion of vaccine doses globally are wasted due to excursions from required cold chain temperature ranges. This is due to the fact that most Alum adjuvanted vaccines need to be maintained at between 2 and 8 degrees Celsius (“C”) and even brief excursions from this temperature range (especially below freezing) usually necessitates the destruction of the product or the initiation of costly stability programs specific for the vaccine lots in question. We believe that the savings realized from the elimination of cold chain costs and related product losses would significantly increase the profitability of vaccine products. We believe that elimination of the cold chain could further facilitate the use of these vaccines in the lesser developed parts of the world. ThermoVax® has the potential to facilitate easier storage and distribution of strategic national stockpile vaccines in emergency settings.

ThermoVax® development was supported pursuant to our $9.4 million NIAID grant enabling development of thermo-stable ricin (RiVax™) and anthrax (VeloThrax®) vaccines. Proof-of-concept preclinical studies with ThermoVax® indicate that it is able to produce stable vaccine formulations using adjuvants, protein immunogens, and other components that ordinarily would not withstand long temperature variations exceeding customary refrigerated storage conditions. These studies were conducted with our aluminum-adjuvanted ricin toxin vaccine, RiVax™ and our aluminum-adjuvanted anthrax vaccine, VeloThrax®. Each vaccine was manufactured under precise lyophilization conditions using excipients that aid in maintaining native protein structure of the key antigen. When RiVax™ was kept at 40 degrees C (104 degrees Fahrenheit) for up to one year, all of the animals vaccinated with the lyophilized RiVax™ vaccine developed potent and high titer neutralizing antibodies. In contrast, animals that were vaccinated with the liquid RiVax™ vaccine kept at 40 degrees C did not develop neutralizing antibodies and were not protected against ricin exposure. The ricin A chain is extremely sensitive to temperature and rapidly loses the ability to induce neutralizing antibodies when exposed to temperatures higher than 8 degrees C. When VeloThrax® was kept for up to 16 weeks at 70 degrees C, it was able to develop a potent antibody response, unlike the liquid formulation kept at the same temperature. Moreover, we also have demonstrated the compatibility of our thermostabilization technology with other secondary adjuvants such as TLR-4 agonists. Additionally, the University of Colorado conducted a study that demonstrated a heat stable vaccine formulation of a human papillomavirus ("HPV") vaccine. The work was conducted by Drs. Randolph and Garcea and demonstrated the successful conversion of a commercial virus-like-particle based vaccine requiring cold chain storage to a subunit, alum-adjuvanted, vaccine which is stable at ambient temperatures. This work, funded by a University of Colorado seed grant and the Specialized Program of Research Excellence in cervical cancer, is the first demonstration of the utility of ThermoVax® technology for the development of a subunit based commercial vaccine. The HPV vaccine formulation was found to be stable for at least 12 weeks at 50 degrees C. In the study, mice immunized with the ThermoVax®-stabilized HPV subunit vaccine were also found to achieve immune responses similar to the commercial HPV vaccine, Cervarix®, as measured by either total antibody levels or neutralizing antibody levels. Moreover, whereas the immune responses to Cervarix® were reduced after storage for 12 weeks at 50 degrees C, the ThermoVax® formulated vaccine retained its efficacy. The results were published online in the European Journal of Pharmaceutics and Biopharmaceutics see http://www.sciencedirect.com/science/article/pii/S0939641115002416).

We also entered into a collaboration agreement with Axel Lehrer, PhD of the Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine, University of Hawai i at Manoa and Hawaii Biotech, Inc. ("HBI") to develop a heat stable subunit Ebola vaccine. Dr. Lehrer, a co-inventor of the Ebola vaccine with HBI, has shown proof of concept efficacy with subunit Ebola vaccines in non-human primates. The most advanced Ebola vaccines involve the use of vesicular stomatitis virus and adenovirus vectors – live, viral vectors which complicate the manufacturing, stability and storage requirements. Dr. Lehrer's vaccine candidate is based on highly purified recombinant protein antigens, circumventing many of these manufacturing difficulties. Dr. Lehrer and HBI have developed a robust manufacturing process for the required proteins. Application of ThermoVax® may allow for a product that can avoid the need for cold chain distribution and storage, yielding a vaccine ideal for use in both the developed and developing world. Although this agreement has expired in accordance with its terms, we expect to extend the period of the agreement or enter into another agreement with Dr. Lehrer and HBI to replace this agreement.

We intend to seek out potential partnerships with companies marketing FDA/ex-U.S. health authority approved Alum adjuvanted vaccines and currently developing Alum adjuvanted vaccines that are interested in eliminating the need for cold chain for their products. We believe that ThermoVax® also will enable us to expand our vaccine development

expertise beyond biodefense into the infectious disease space and also has the potential to allow for the development of multivalent vaccines (e.g., combination ricin-anthrax vaccine).

RiVax™ – Ricin Toxin Vaccine

RiVax™ is our proprietary vaccine candidate being developed to protect against exposure to ricin toxin and if approved would be the first ricin vaccine. The immunogen in RiVax™ induces a protective immune response in animal models of ricin exposure and functionally active antibodies in humans. The immunogen consists of a genetically inactivated subunit ricin A chain that is enzymatically inactive and lacks residual toxicity of the holotoxin. RiVax™ has demonstrated statistically significant ($p<0.0001$) preclinical survival results in a lethal aerosol exposure non-human primate model (Roy et al, 2015, Thermostable ricin vaccine protects rhesus macaques against aerosolized ricin: Epitope-specific neutralizing antibodies correlate with protection, PNAS USA March 24, 2015), and has also been shown to be well tolerated and immunogenic in two Phase 1 clinical trials in healthy volunteers. Results of the first Phase 1 human trial of RiVax™ established that the immunogen was safe and induced antibodies that we believe may protect humans from ricin exposure. The antibodies generated from vaccination, concentrated and purified, were capable of conferring immunity passively to recipient animals, indicating that the vaccine was capable of inducing functionally active antibodies in humans. The outcome of this study was published in the Proceedings of the National Academy of Sciences (Vitetta et al., 2006, A Pilot Clinical Trial of a Recombinant Ricin Vaccine in Normal Humans, PNAS, 103:2268-2273). The second trial, which was completed in September 2012 and was sponsored by University of Texas Southwestern Medical Center (“UTSW”), evaluated a more potent formulation of RiVax™ that contained an aluminum adjuvant (Alum). The results of the Phase 1b study indicated that Alum adjuvanted RiVax™ was safe and well tolerated, and induced greater ricin neutralizing antibody levels in humans than adjuvant-free RiVax™. The outcomes of this second study were published in the *Clinical and Vaccine Immunology* (Vitetta et al., 2012, Recombinant Ricin Vaccine Phase 1b Clinical Trial, Clin. Vaccine Immunol. 10:1697-9). We have adapted the original manufacturing process for the immunogen contained in RiVax™ for thermostability and large scale manufacturing and are further establishing correlates of the human immune response in non-human primates. We have entered into a collaboration with IDT Biologika GmbH to scale-up the formulation/filling process and continue development and validation of analytical methods established at IDT to advance the program. We also have initiated a development agreement with Emergent BioSolutions, Inc. to implement a commercially viable, scalable production technology for the RiVax™ drug substance protein antigen.

The development of RiVax™ has been sponsored through a series of overlapping challenge grants, UC1, and cooperative grants, U01, from the NIH, granted to us and to UTSW where the vaccine originated. The second clinical trial was supported by a grant from the FDA's Office of Orphan Products to UTSW. To date, we and UTSW have collectively received approximately $25 million in grant funding from the NIH for the development of RiVax™. In September 2014, we entered into a contract with the NIH for the development of RiVax™ that would provide up to an additional $24.7 million of funding in the aggregate if options to extend the contract are exercised by the NIH. The development agreements with Emergent BioSolutions and IDT are specifically funded under this NIH contract.

RiVax™ has been granted orphan drug designation by the FDA for the prevention of ricin intoxication.

Assuming development efforts are successful for RiVax™, we believe potential government procurement contract(s) could reach $200 million. This potential procurement contract information is a forward-looking statement. While we have determined this potential procurement contract value based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

As a new chemical entity, an FDA approved RiVax™ vaccine has the potential to qualify for a biodefense Priority Review Voucher ("PRV"). Approved under the 21st Century Cures Act in late 2016, the biodefense PRV is awarded upon approval as a medical countermeasure when the active ingredient(s) have not been otherwise approved for use in any context. PRVs are transferable and can be sold, with sales in recent years varying from between $125 million to $350 million. When redeemed, PRVs entitle the user to an accelerated review period of six months, saving a median of seven months review time as calculated in 2009. However, FDA must be advised 90 days in advance of the use of the PRV and the use of a PRV is associated with an additional user fee ($2.7 million in 2017).

Ricin Toxin

Ricin toxin can be cheaply and easily produced, is stable over long periods of time, is toxic by several routes of exposure and thus has the potential to be used as a biological weapon against military and/or civilian targets. As a bioterrorism agent, ricin could be disseminated as an aerosol, by injection, or as a food supply contaminant. The potential use of ricin toxin as a biological weapon of mass destruction has been highlighted in a Federal Bureau of Investigation Bioterror report released in November 2007 titled *Terrorism 2002-2005*, which states that "Ricin and the bacterial agent anthrax are emerging as the most prevalent agents involved in WMD investigations" (http://www.fbi.gov/stats-services/publications/terrorism-2002-2005/terror02_05.pdf). In recent years, Al Qaeda in the Arabian Peninsula has threatened the use of ricin toxin to poison food and water supplies and in connection with explosive devices. Domestically, the threat from ricin remains a concern for security agencies. As recently as April 2013, letters addressed to the President of the United States, a U.S. Senator and a judge tested positive for ricin.

The Centers for Disease Control and Prevention has classified ricin toxin as a Category B biological agent. Ricin works by first binding to glycoproteins found on the exterior of a cell, and then entering the cell and inhibiting protein synthesis leading to cell death. Once exposed to ricin toxin, there is no effective therapy available to reverse the course of the toxin. The recent ricin threat to government officials has heightened the awareness of this toxic threat. Currently, there is no FDA approved vaccine to protect against the possibility of ricin toxin being used in a terrorist attack, or its use as a weapon on the battlefield nor is there a known antidote for ricin toxin exposure.

OrbeShield® – for Treating GI Acute Radiation Syndrome

OrbeShield® is an oral immediate and delayed release formulation of the topically active corticosteroid BDP and is being developed for the treatment of GI ARS. Corticosteroids are a widely used class of anti-inflammatory drugs. BDP is a corticosteroid with predominantly topical activity that is approved for use in asthma, psoriasis and allergic rhinitis.

OrbeShield® has demonstrated positive preclinical results in a canine GI ARS model which indicate that dogs treated with OrbeShield® demonstrated statistically significant (p=0.04) improvement in survival with dosing at either two hours or 24 hours after exposure to lethal doses of total body irradiation ("TBI") when compared to control dogs. OrbeShield® appears to significantly mitigate the damage to the GI epithelium caused by exposure to high doses of radiation using a well-established canine model of GI ARS.

The GI tract is highly sensitive to ionizing radiation and the destruction of epithelial tissue is one of the first effects of radiation exposure. The rapid loss of epithelial cells leads to inflammation and infection that are often the primary cause of death in acute radiation injury. This concept of GI damage also applies to the clinical setting of oncology, where high doses of radiation cannot be administered effectively to the abdomen because radiation is very toxic to the intestines. We are seeking to treat the same type of toxicity in our acute radiation enteritis clinical program with SGX201. As a result, we believe that OrbeShield® has the potential to be a "dual use" compound, a desirable characteristic which is a specific priority for ARS and other medical countermeasure indications. The FDA has cleared the IND application for OrbeShield® for the mitigation of morbidity and mortality associated with GI ARS.

In September 2013, we received two government contracts from BARDA and NIAID for the advanced preclinical and manufacturing development of OrbeShield® leading to FDA approval to treat GI ARS. The BARDA contract contains a two year base period with two contract options, exercisable by BARDA, for a total of five years and up to $26.3 million. The NIAID contract consists of a one year base period and two contract options, exercisable by NIAID, for a total of three years and up to $6.4 million. We received a combined approximate $18 million in contract funding from both BARDA and NIAID which includes combined supplemental funding of $634,000, extending the programs through the first quarter of 2017. The NIAID contract will be completed during the first quarter of 2017 along with the BARDA contract base period, with BARDA electing not to extend the current contract beyond the base period. We will continue to apply for additional government funding. Previously, development of OrbeShield® had been largely supported by a $1 million NIH grant to our academic partner, the Fred Hutchinson Cancer Research Center. In July 2012, we received an SBIR grant from NIAID of approximately $600,000 to support further preclinical development of OrbeShield® for the treatment of acute GI ARS. The FDA has given OrbeShield® orphan drug designation and Fast Track designation for the prevention of death following a potentially lethal dose of total body irradiation during or after a radiation disaster.

Assuming development efforts are successful for OrbeShield®, we believe potential government procurement contracts could reach as much as $450 million. This potential procurement contract information is a forward-looking statement. While we have determined this potential procurement contract value based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized.

GI Acute Radiation Syndrome

ARS occurs after toxic radiation exposure and involves several organ systems, notably the bone marrow, the GI tract and, later, the lungs. In the event of a nuclear disaster or terrorist detonation of a nuclear bomb, casualties exposed to greater than 2 grays (“Gy”) of absorbed radiation are at high risk for development of clinically significant ARS. Exposure to high doses of radiation exceeding 10-12 Gy causes acute GI injury which can result in death. The GI tract is highly sensitive due to the continuous need for crypt stem cells and production of mucosal epithelium. The extent of injury to the bone marrow and the GI tract are the principal determinants of survival after exposure to TBI. Although the hematopoietic syndrome can be rescued by bone marrow transplantation or growth factor administration, there is no established treatment or preventive measure for the GI damage that occurs after high-dose radiation. As a result, we believe there is an urgent medical need for specific medical counter measures against the lethal pathophysiological manifestations of radiation-induced GI injury.

SGX943 – for Treating Melioidosis

SGX943 uses the same active ingredient, dusquetide, as contained in SGX942. SGX943 is being developed in preclinical studies as a potential treatment for melioidosis. Because SGX943 directly targets the innate immune system (and does not attempt to kill the bacteria directly), we believe it is particularly relevant for antibiotic-resistant bacteria. The bacteria which causes melioidosis, *Burkholderia pseudomallei,* is known to be resistant to most antibiotics and to require prolonged treatment with the few antibiotics that do work. In February 2014, we were awarded a one-year NIAID SBIR award of approximately $300,000 to further evaluate SGX943 as a potential treatment for melioidosis. Preclinical results to date have demonstrated that SGX943 treatment, in combination with standard of care antibiotics such as doxycycline, can statistically significantly enhance survival in a lethal murine pneumonic melioidosis model ($p< 0.001$).

Melioidosis

Melioidosis is a potentially fatal infection caused by the Gram-negative bacillus, *Burkholderia pseudomallei* (“Bp”). Highly resistant to many antibiotics, Bp can cause an acute disease characterized by a fulminant pneumonia and a chronic condition that can recrudesce. There is no preventive vaccine or effective immunotherapy for melioidosis. We believe that there is an unmet medical need for improved prevention and therapy.

Bp infection (melioidosis) is a major public health concern in the endemic regions of Southeast Asia and Northern Australia. In Northeast Thailand, which has the highest incidence of melioidosis, the mortality rate associated with Bp infection is over 40 percent, making it the third most common cause of death from infectious disease in that region after HIV/AIDS and tuberculosis. Bp activity is seen in Southeast Asia, South America, Africa, the Middle East, India, and Australia. The highest pockets of disease activity occur in Northern Australia and Northeast Thailand with increasing recognition of disease activity in coastal regions of India.

Beyond its public health significance, Bp and the closely-related *Burkholderia mallei* (“Bm”) are considered possible biological warfare agents by the DHHS because of the potential for widespread dissemination through aerosol. Bp like its relative Bm, the cause of Glanders, was studied by the U.S. as a potential biological warfare agent, but was never weaponized. It has been reported that the Soviet Union was also experimenting with Bp as a biological warfare agent. Both Bp and Bm have been designated high priority threats by the DHHS in its PHEMCE Strategy released in 2012 and are classified as Category B Priority Pathogens by NIAID.

The Drug Approval Process

The FDA and comparable regulatory agencies in state, local and foreign jurisdictions impose substantial requirements on the clinical development, manufacture and marketing of new drug and biologic products. The FDA, through regulations that implement the Federal Food, Drug, and Cosmetic Act, as amended ("FDCA"), and other laws and comparable regulations for other agencies, regulate research and development activities and the testing, manufacture, labeling, storage, shipping, approval, recordkeeping, advertising, promotion, sale, export, import and distribution of such products. The regulatory approval process is generally lengthy, expensive and uncertain. Failure to comply with applicable FDA and other regulatory requirements can result in sanctions being imposed on us or the manufacturers of our products, including holds on clinical research, civil or criminal fines or other penalties, product recalls, or seizures, or total or partial suspension of production or injunctions, refusals to permit products to be imported into or exported out of the United States, refusals of the FDA to grant approval of drugs or to allow us to enter into government supply contracts, withdrawals of previously approved marketing applications and criminal prosecutions.

Before human clinical testing in the U.S. of a new drug compound or biological product can commence, an Investigational New Drug ("IND"), application is required to be submitted to the FDA. The IND application includes results of pre-clinical animal studies evaluating the safety and efficacy of the drug and a detailed description of the clinical investigations to be undertaken.

Clinical trials are normally done in three phases, although the phases may overlap. Phase 1 trials are smaller trials concerned primarily with metabolism and pharmacologic actions of the drug and with the safety of the product. Phase 2 trials are designed primarily to demonstrate effectiveness and safety in treating the disease or condition for which the product is indicated. These trials typically explore various doses and regimens. Phase 3 trials are expanded clinical trials intended to gather additional information on safety and effectiveness needed to clarify the product's benefit-risk relationship and generate information for proper labeling of the drug, among other things. The FDA receives reports on the progress of each phase of clinical testing and may require the modification, suspension or termination of clinical trials if an unwarranted risk is presented to patients. When data is required from long-term use of a drug following its approval and initial marketing, the FDA can require Phase 4, or post-marketing, studies to be conducted.

With certain exceptions, once successful clinical testing is completed, the sponsor can submit a New Drug Application ("NDA"), for approval of a drug, or a Biologic License Application ("BLA"), for biologics such as vaccines, which will be reviewed, and if successful, approved by the FDA, allowing the product to be marketed. The process of completing clinical trials for a new drug is likely to take a number of years and require the expenditure of substantial resources. Furthermore, the FDA or any foreign health authority may not grant an approval on a timely basis, if at all. The FDA may deny the approval of an NDA or BLA, in its sole discretion, if it determines that its regulatory criteria have not been satisfied or may require additional testing or information. Among the conditions for marketing approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to good manufacturing practice regulations. In complying with standards contained in these regulations, manufacturers must continue to expend time, money and effort in the area of production, quality control and quality assurance to ensure full technical compliance. Manufacturing facilities, both foreign and domestic, also are subject to inspections by, or under the authority of, the FDA and by other federal, state, local or foreign agencies.

Even after initial FDA or foreign health authority approval has been obtained, further studies, including Phase 4 post-marketing studies, may be required to provide additional data on safety and will be required to gain approval for the marketing of a product as a treatment for clinical indications other than those for which the product was initially tested. For certain drugs intended to treat serious, life-threatening conditions that show great promise in earlier testing, the FDA can also grant conditional approval. However, drug developers are required to study the drug further and verify clinical benefit as part of the conditional approval provision, and the FDA can revoke approval if later testing does not reproduce previous findings. The FDA may also condition approval of a product on the sponsor agreeing to certain mitigation strategies that can limit the unfettered marketing of a drug. Also, the FDA or foreign regulatory authority will require post-marketing reporting to monitor the side effects of the drug. Results of post-marketing programs may limit or expand the further marketing of the product. Further, if there are any modifications to the drug, including any change in indication, manufacturing process, labeling or manufacturing facility, an application seeking approval of such changes will likely be required to be submitted to the FDA or foreign regulatory authority.

In the U.S., the FDCA, the Public Health Service Act, the Federal Trade Commission Act, and other federal and state statutes and regulations govern, or influence the research, testing, manufacture, safety, labeling, storage, record keeping, approval, advertising and promotion of drug, biological, medical device and food products. Noncompliance with applicable requirements can result in, among other things, fines, recall or seizure of products, refusal to permit products to be imported into the U.S., refusal of the government to approve product approval applications or to allow the Company to enter into government supply contracts, withdrawal of previously approved applications and criminal prosecution. The FDA may also assess civil penalties for violations of the FDCA involving medical devices.

For biodefense development, such as with RiVax™ and OrbeShield®, the FDA has instituted policies that are expected to result in shorter pathways to market. This potentially includes approval for commercial use utilizing the results of animal efficacy trials, rather than efficacy trials in humans. However, the Company will still have to establish that the vaccine and countermeasures it is developing are safe in humans at doses that are correlated with the beneficial effect in animals. Such clinical trials will also have to be completed in distinct populations that are subject to the countermeasures; for instance, the very young and the very old, and in pregnant women, if the countermeasure is to be licensed for civilian use. Other agencies will have an influence over the benefit-risk scenarios for deploying the countermeasures and in establishing the number of doses utilized in the Strategic National Stockpile. We may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these correlates are difficult to establish and are often unclear. Invocation of the animal rule may raise issues of confidence in the model systems even if the models have been validated. For many of the biological threats, the animal models are not available and the Company may have to develop the animal models, a time-consuming research effort. There are few historical precedents, or recent precedents, for the development of new countermeasure for bioterrorism agents. Despite the animal rule, the FDA may require large clinical trials to establish safety and immunogenicity before licensure and it may require safety and immunogenicity trials in additional populations. Approval of biodefense products may be subject to post-marketing studies, and could be restricted in use in only certain populations.

Vaccines are approved under the BLA process that exists under the Public Health Service Act. In addition to the greater technical challenges associated with developing biologics, the potential for generic competition is lower for a BLA product than a small molecule product subject to an NDA under the Federal Food, Drug and Cosmetic Act. Under the Patient Protection and Affordable Care Act enacted in 2010, a “generic” version of a biologic is known as a biosimilar and the barriers to entry – whether legal, scientific, or logistical – for a biosimilar version of a biologic approved under a BLA are higher.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition – generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA or BLA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug or biologic for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the 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 NDA or BLA application user fee.

Fast Track Designation and Accelerated Approval

The FDA is required to facilitate the development, and expedite the review, of drugs or biologics that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug or biologic candidate may request that the FDA designate the candidate for a specific indication as a fast track drug or biologic concurrent with, or after, the filing of the IND for the candidate. The FDA must determine if the drug or biologic candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. Unique to a fast track product, the FDA may initiate review of sections of a fast track product's NDA or BLA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing an application does not begin until the last section of the NDA or BLA is submitted. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means the FDA may approve the product based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug or biologic candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug or biologic from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Pediatric Information

Under the Pediatric Research Equity Act (“PREA”), NDAs or BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

Early Access to Medicines Scheme

Launched in April 2014 in the United Kingdom by the MHRA, the Early Access to Medicines Scheme (“EAMS”) offers severely ill patients with life-threatening and seriously debilitating conditions the lifeline of trying ground-breaking new medicines earlier than they would normally be accessible. PIM designation is the first phase of EAMS and is awarded following an assessment of early nonclinical and clinical data by the MHRA. The criteria product candidates must meet to obtain PIM designation are:

Criterion 1 – The condition should be life-threatening or seriously debilitating with a high unmet medical need (i.e., there is no method of treatment, diagnosis or prevention available or existing methods have serious limitations).

Criterion 2 – The medicinal product is likely to offer major advantage over methods currently used in the UK.

Criterion 3 – The potential adverse effects of the medicinal product are likely to be outweighed by the benefits, allowing for the reasonable expectation of a positive benefit risk balance. A positive benefit risk balance should be based on preliminary scientific evidence that the safety profile of the medicinal product is likely to be manageable and acceptable in relation to the estimated benefits.

False Claims Laws

The federal False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the US government.

Anti-Kickback Laws

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other.

United States Healthcare Reform

Federal Physician Payments Sunshine Act and its implementing regulations require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The Health Insurance Portability and Accountability Act ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates" – independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Third-Party Suppliers and Manufacturers

Drug substance and drug product manufacturing is outsourced to qualified suppliers. We do not have manufacturing capabilities/infrastructure and do not intend to develop the capacity to manufacture drug products substances. We have agreements with third-party manufacturers to supply bulk drug substances for our product candidates and with third parties to formulate, package and distribute our product candidates. Our employees include professionals with expertise in pharmaceutical manufacturing development, quality assurance and third party supplier management who oversee work conducted by third-party companies. We believe that we have on hand or can easily obtain sufficient amounts of product candidates to complete our currently contemplated clinical trials. All of the drug substances used in our product candidates currently are manufactured by single suppliers. While we have not experienced any supply disruptions, the number of manufacturers of the drug substances is limited. In the event it is necessary or advisable to acquire supplies from alternative suppliers, assuming commercially reasonable terms could be reached, the challenge would be the efficient transfer of technology and know-how from current manufactures to the new supplier. Formulation and distribution of our finished product candidates also currently are conducted by single suppliers but we believe that alternative sources for these services are readily available on commercially reasonable terms, subject to the efficient transfer of technology and know-how from current suppliers to the new supplier.

All of the current agreements for the supply of bulk drug substances for our product candidates and for the formulation or distribution of our product candidates relate solely to the development (including preclinical and clinical) of our product candidates. Under these contracts, our product candidates are manufactured upon our order of a specific quantity. In the event that we obtain marketing approval for a product candidate, we will qualify secondary suppliers for all key manufacturing activities supporting the marketing application.

Marketing and Collaboration

We do not currently have any sales and marketing capability, other than to potentially market our biodefense vaccine products directly to government agencies. With respect to other commercialization efforts, we currently intend to seek distribution and other collaboration arrangements for the sales and marketing of any product candidate that is approved, while also evaluating the potential to commercialize on our own in orphan disease indications. From time to time, we have had and are having strategic discussions with potential collaboration partners for our biodefense vaccine product candidates, although no assurance can be given that we will be able to enter into one or more collaboration agreements for our product candidate on acceptable terms, if at all. We believe that both military and civilian health authorities of the U.S. and other countries will increase their stockpiling of therapeutics and vaccines to treat and prevent diseases and conditions that could ensue following a bioterrorism attack.

On December 20, 2012, we re-acquired the North American and European commercial rights to oral BDP through an amendment of our collaboration and supply agreement with Sigma-Tau Pharmaceuticals, Inc. (“Sigma-Tau”). The amendment requires us to make certain approval and commercialization milestone payments to Sigma-Tau which could reach up to $6 million. In addition, we have agreed to pay Sigma-Tau: (a) a royalty amount equal to 3% of all net sales of oral BDP made directly by us, and any third-party partner and/or their respective affiliates in the U.S., Canada, Mexico and in each country in the European Territory for the later to occur of: (i) a period of ten years from the first commercial sale of oral BDP in each country, or (ii) the expiration of our patents and patent applications relating to oral BDP in such country (the “Payment Period”); and (b) 15% of all up-front payments, milestone payments and any other consideration (exclusive of equity payments) received by us and/or a potential partner from us and/or potential partner’s licensees, distributors and agents for oral BDP in each relevant country in the territory, which amount will be paid on a product-by-product and a country-by-country basis for the Payment Period.

On August 25, 2013, we entered into an agreement with SciClone Pharmaceuticals, Inc. (“SciClone”), pursuant to which SciClone provided us with access to its oral mucositis clinical and regulatory data library in exchange for exclusive commercialization rights for SGX942 in the People’s Republic of China, including Hong Kong and Macau, subject to the negotiation of economic terms. SciClone’s data library was generated from two sequential Phase 2 clinical studies conducted in 2010 and 2012 evaluating SciClone’s compound, SCV-07, for the treatment of oral mucositis caused by chemoradiation therapy in head and neck cancer patients, before SciClone terminated its program. By analyzing data available from the placebo subjects in the SciClone trials, we acquired valuable insight into disease progression, along with quantitative understanding of its incidence and severity in the head and neck cancer patient population. This information assisted us with the design of the SGX942 Phase 2 clinical trial, in which positive preliminary results were announced in December 2015.

On September 9, 2016, we and SciClone entered into an exclusive license agreement, pursuant to which we granted rights to SciClone to develop, promote, market, distribute and sell SGX942 in the People’s Republic of China, including Hong Kong and Macau, as well as Taiwan, South Korea and Vietnam. Under the terms of the license agreement, SciClone will be responsible for all aspects of development, product registration and commercialization in

the territory, having access to data generated by us. In exchange for exclusive rights, SciClone will pay us royalties on net sales, and we will supply commercial drug product to SciClone on a cost-plus basis, while maintaining worldwide manufacturing rights.

We also entered into a common stock purchase agreement with SciClone pursuant to which we sold 352,942 shares of our common stock to SciClone for approximately $8.50 per share, for an aggregate price of $3,000,000. As part of the transaction, we granted SciClone certain demand registration rights, and SciClone agreed, subject to certain exceptions, not to pledge, sell or otherwise transfer or dispose of, or enter into any swap or other arrangement that transfers any of the economic consequences of ownership of, the shares purchased for at least one year from September 9, 2016.

Competition

Our competitors are pharmaceutical and biotechnology companies, most of whom have considerably greater financial, technical, and marketing resources than we do. Universities and other research institutions, including the U.S. Army Medical Research Institute of Infectious Diseases, also compete in the development of treatment technologies, and we face competition from other companies to acquire rights to those technologies.

SGX301 Competition

The FDA has approved several treatments for later stages (IIB-IV) of CTCL and/or in conditions that are unresponsive to prior treatment. Two are targeted therapies (Targretin®-caps and Ontak®), two are histone deacetylases inhibitors (Zolina® and Istodax®) and the remaining two are topical therapies (Valchor® and Targretin®-gel). There are currently no FDA approved therapies for the treatment of front-line, early stage (I-IIA) CTCL; however certain topical chemotherapies and topical, radiation, photo and other therapies which are approved for indications other than CTCL are prescribed off-label for the treatment of early stage CTCL. These include psoralen combined with ultraviolet A (UVA) light therapy ("PUVA"); however, PUVA treatments are usually limited to three times per week and 200 times in total due to the potentially carcinogenic side effect. There are other drugs currently in development that may have the potential to be used in early stage (I-IIA) CTCL – one in phase 2 (vorinostat) and others in phase 1. Vorinostat has been approved by the FDA to treat CTCL patients who have conditions that are unresponsive to other therapies. It currently is being studied in a phase 2 trial for the treatment of all stages of CTCL.

SGX94/942 Competition

Because SGX94 (dusquetide) uses a novel mechanism of action in combating bacterial infections, there are no direct competitors at this time. Bacterial infections are routinely treated with antibiotics and SGX94 treatment is anticipated to be utilized primarily where antibiotics are insufficient (e.g., due to antibiotic resistance) or contra-indicated (e.g., in situations where the development of antibiotic resistance is a significant concern). Many groups are working on the antibiotic resistance problem and research into the innate immune system is intensifying, making emerging competition likely (from companies such as Celtaxsys Inc., Innaxon Therapeutics and Innate Pharma SA).

There is currently one drug approved for the treatment of oral mucositis in hematological cancer (palifermin). There are currently no approved drugs for treatment of oral mucositis in cancers with solid tumors (e.g., head and neck cancer). There are several drugs in clinical development for oral mucositis – one in Phase 3 (under development by Daewoong Pharmaceutical Co., Ltd.), four in Phase 2 (under development by Cellceutix Corporation, BioAlliance Pharma S.A., Onexeo S.A., and Alder Biopharmaceuticals Inc.) and one in Phase 1 (under development by ActoGenix N.V.). In addition, there are medical devices approved for the treatment of oral mucositis including MuGard, GelClair, Episil and Caphosol. These devices attempt to create a protective barrier around the oral ulceration with no biologic activity in treating the underlying disease.

Oral BDP Competition

There are a number of approved treatments for Crohn's disease and additional compounds are in late-stage development.

Remicade (infliximab) and Humira (adalimumab) are currently approved for the treatment of pediatric Crohn's disease; however, both carry significant Black Box warnings in their labeling for increased risk of serious infection and malignancy, and therefore are approved for treatment of moderate to severe patients. There is one other marketed biologic, Tysabri (natalizumab), in a Phase 2 study for pediatric Crohn's. Entocort (enteric-coated budesonide) also has completed Phase 3 trials in pediatric Crohn's disease.

ThermoVax® Competition

Multiple groups and companies are working to address the unmet need of vaccine thermostability using a variety of technologies. In addition, other organizations, such as the Bill and Melinda Gates Foundation and PATH, have programs designed to advance technologies to address this need.

Several stabilization technologies currently being developed involve mixing vaccine antigen +/- adjuvant with various proprietary excipients or co-factors that either serve to stabilize the vaccine or biological product in a liquid or dried (lyophilized) form. Examples of these approaches include the use of various plant-derived sugars and macromolecules being developed by companies such as Stabilitech Ltd. Variation Biotechnologies, Inc. ("VBI") is developing a lipid system (resembling liposomes) to stabilize viral antigens, including virus-like particles (VLPs), and for potential application to a conventional influenza vaccine among others.

Other approaches involve process variations to freeze-dry live virus vaccines. For example, PaxVax, Inc. is seeking to employ a spray drying technology in concert with enteric coating to achieve formulations for room temperature stability of live virus vaccines using adenovirus vectors. VBI is seeking to utilize their proprietary stabilization technology for a number of vaccines (as a co-development service, similar to the business model being developed by Stabilitech Ltd.), whereas PaxVax is applying the technology to their own proprietary vaccine development programs. Stabilitech uses combinations of excipients, which include glassifying sugars similar to the ThermoVax® technology, and variations in drying cycles during lyophilization, as does the ThermoVax® technology.

Additionally, companies like Pharmathene, Inc., Panacea Biotec Ltd., and Compass Biotech Inc. are developing proprietary vaccines with the application of some form of stabilization technology.

Vaccines/BioDefense Competition

We face competition in the area of biodefense product development from various public and private companies, universities and governmental agencies, such as the U.S. Army, some of whom may have their own proprietary technologies which may directly compete with our technologies.

The U.S. Army Medical Research Institute of Infectious Diseases, the DoD's lead laboratory for medical research to counter biological threats is also developing a ricin vaccine candidate, RVEc™. RVEc™ has been shown to be fully protective in mice exposed to lethal doses of ricin toxin by the aerosol route. Further studies, in both rabbits and nonhuman primates, were conducted to evaluate RVEc™'s safety as well as its immunogenicity, with positive results observed.

In the area of radiation-protective antidotes such as OrbeShield®, various companies, such as Cleveland Biolabs, Inc., Aeolus Pharmaceuticals, Inc., Boulder Biotechnology, Inc., RxBio, Inc., Avaxia Biologics, Inc., Exponential Biotherapies Inc., Osiris Therapeutics, Inc., ImmuneRegen BioSciences, Inc., Neumedicines, Inc., Cellerant Therapeutics, Inc., Onconova Therapeutics, Inc., Araim Pharmaceuticals, Inc., EVA Pharmaceuticals, Terapio Corporation, Cangene Corporation, Humanetics Corporation and the University of Arkansas Medical Sciences Center are developing biopharmaceutical products that may directly compete with OrbeShield®, even though their approaches to such treatment are different.

RxBio, Avaxia Biologics and the University of Arkansas have programs specifically for GI ARS. RxBio's Rx100 is a stem cell protectant designed as a single dose (oral or injection) which has shown promise in nonhuman primate studies. Avaxia is developing an orally delivered anti-TNF antibody as a treatment agent for exposure to radiation following a nuclear accident, attack or explosion. Pasireotide, a drug in development by Novartis for Cushing's

disease, is being developed at the University of Arkansas to protect the intestine by reducing pancreatic secretions that exacerbate intestinal inflammation.

Patents and Other Proprietary Rights

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the U.S. and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and elsewhere in the world.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors, none of which is patentable. To help protect our proprietary knowledge and experience that is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all employees, consultants, advisors and other contractors to enter into confidentiality agreements, which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

In 2014, we acquired a novel photodynamic therapy that utilizes safe visible light for activation, which we refer to as SGX301. The active ingredient in SGX301 is synthetic hypericin, a photosensitizer which is topically applied to skin lesions and then activated by fluorescent light 16 to 24 hours later. As part of the acquisition, we acquired a license agreement relating to the use of photo-activated hypericin, composition of matter patent for SGX301 (U.S. patent 8,629,302) and additional issued and pending applications, both in the US and abroad. U.S. patent 8,629,302 is expected to expire in June 2032. Our proprietary formulation of synthetic hypericin has been granted a European patent for the treatment of psoriasis, EP 2571507, and complements the method of treatment claims covered by the previously issued US patent 6001882, Photoactivated hypericin and the use thereof.

In addition to issued and pending patents, we also have “Orphan Drug” designations for SGX301 in the U.S. and the EU for CTCL, SGX203 in the U.S. for pediatric Crohn’s disease, and OrbeShield® in the U.S. for GI ARS, as well as for RiVax™ in the U.S. Our Orphan Drug designations provide for seven years of post-approval marketing exclusivity in the U.S. and ten years exclusivity in Europe. We have pending patent applications for this indication that, if granted, may extend our anticipated marketing exclusivity beyond the U.S. seven year or E.U. ten year post-approval exclusivity provided by Orphan Drug legislation.

In 2013, we expanded our patent portfolio to include innate defense regulation through the acquisition of the novel drug technology, known as SGX94. By binding to the pivotal regulatory protein p62, also known as sequestosome-1, SGX94 regulates the innate immune system to reduce inflammation, eliminate infection and enhance healing. As part of the acquisition, we acquired all rights, including composition of matter patents for SGX94 as well as other analogs and crystal structures of SGX94 with its protein target p62, including U.S. patent 8,124,721 and additional pending applications, both in the US and abroad. SGX94 was developed pursuant to discoveries made by Professors B. Brett Finlay and Robert Hancock of University of British Columbia (“UBC”). U.S. patent 8,124,721 is expected to expire in April 2028.

We have issued U.S. patents 8,263,582 and 6,096,731 that cover the use of oral BDP for treating inflammatory disorders of the gastrointestinal tract and the prevention and treatment of GI GVHD, respectively. U.S. patent numbers 8,263,582 and 6,096,731 are expected to expire in March 2022 and June 2018, respectively. We also have European patent EP 1392321 claiming the use of topically active corticosteroids in orally administered dosage forms that act concurrently to treat inflammation in the upper and lower gastrointestinal tract, as well as European patent EP 2242477 claiming the use of orally ingested BDP for treatment of interstitial lung disease. European patents EP 1392321 and EP 2242477 are expected to expire in March 2022 and January 2029.

The subject of U.S. patent application number 12/633,631 filed December 8, 2009 and corresponding European patent application number 09836727.9 is the use of topically active BDP in radiation and chemotherapeutics injury. Additionally, we have numerous patent filings currently issued or pending in foreign jurisdictions covering this subject matter, including Australia, Canada, China, Hong Kong, Israel, India, Japan, South Korea and New Zealand.

ThermoVax® is the subject of U.S. patent 8,444,991 issued on May 21, 2013 titled “Method of Preparing an Immunologically-Active Adjuvant-Bound Dried Vaccine Composition” and also U.S. patent application number 13/474,661 filed May 17, 2012 titled “Thermostable Vaccine Compositions and Methods of Preparing Same.” The patent application and the corresponding foreign filings for both patents are pending and licensed to us by the University of Colorado (“UC”) and they address the use of adjuvants in conjunction with vaccines that are formulated to resist thermal inactivation. The license agreement covers thermostable vaccines for biodefense as well as other potential vaccine indications. U.S. patent 8,444,991 is expected to expire in December 2031.

RiVax™ is the subject of three issued U.S. patent numbers 6,566,500, 6,960,652, and 7,829,668, all titled “Compositions and methods for modifying toxic effects of proteinaceous compounds.” This patent family includes composition of matter claims for the modified ricin toxin A chain which is the immunogen contained in RiVax™, and issued in 2003, 2005 and 2010 respectively. The initial filing date of these patents is March 2000 and they are expected to expire in March 2020. The issued patents contain claims that describe alteration of sequences within the ricin A chain that affect vascular leak, one of the deadly toxicities caused by ricin toxin. Another U.S. patent number 7,175,848 titled “Ricin A chain mutants lacking enzymatic activity as vaccines to protect against aerosolized ricin,” was filed in October of 2000 and is expected to expire in October 2020.

SGX301 License Agreement

In September 2014, we acquired a worldwide exclusive license agreement with New York University and Yeda Research and Development Company Ltd. for the rights to a novel photodynamic therapy that utilizes safe visible light for activation, which we refer to as SGX301. To maintain this license we are obligated to pay $25,000 in annual license fees. In addition, we will pay the licensors: (a) a royalty amount equal to 3% of all net sales of SGX301 made directly by us and/or any affiliates; (b) a royalty amount equal to 2.5% of all net sales of SGX301 made by our sublicensees, subject to stated maximums and (c) 20% of all payments, not based on net sales, received by us from our sublicensees. This license may be terminated by either party upon notice of a material breach by the other party that is not cured within the applicable cure period. The exclusive license includes rights to several issued US patents, including U.S. patent numbers 6,867,235 and 7,122,518, among other domestic and foreign patent applications. U.S. Patent numbers 6,867,235 and 7,122,518 are expected to expire in January 2020 and November 2023, respectively.

We acquired the license agreement for SGX301 and related intangible assets, including U.S. patent 8,629,302, properties and rights pursuant to an asset purchase agreement with Hy Biopharma Inc. (“Hy Biopharma”). As consideration for the assets acquired, we paid $275,000 in cash and issued 184,912 shares of common stock with a market value of $3,750,000. Provided all future success-orientated milestones are attained, we will be required to make payments of up to $10.0 million, if and when achieved, payable in common stock of the Company.

SGX94 License Agreements

On December 18, 2012, we announced the acquisition of a first in class drug technology, known as SGX94 (dusquetide), representing a novel approach to modulation of the innate immune system. SGX94 is an IDR that regulates the innate immune system to reduce inflammation, eliminate infection and enhance tissue healing by binding to the pivotal regulatory protein p62, also known as sequestosome-1. As part of the acquisition, we acquired all rights, including composition of matter patents, preclinical and Phase 1 clinical study datasets for SGX94. We also assumed a license agreement with UBC to advance the research and development of the SGX94 technology. The license agreement with UBC provides us with exclusive worldwide rights to manufacture, distribute, market sell and/or license or sublicense products derived or developed from this technology. Under the license agreement we are obligated to pay UBC (i) an annual license maintenance fee of CAN $1,000, and (ii) milestone payments which could reach up to CAN $1.2 million. This license agreement (a) will automatically terminate if we file, or become subject to an involuntary filing, for bankruptcy, and (b) may be terminated by UBC in the event of, among other things, our insolvency, dissolution, grant of a security interest in the technology licensed to us pursuant to the license agreement, or material breach of or failure to perform material obligations under the license agreement or other research agreements between us and UBC.

Oral BDP License Agreement

On November 24, 1998, the Company, known at the time as Enteron Pharmaceuticals, Inc. ("Enteron") and George B. McDonald ("Dr. McDonald") entered into an exclusive license agreement for the rights to intellectual property, including know-how, relating to oral BDP. The Company has an exclusive license to commercially exploit the covered products worldwide, subject to Dr. McDonald's right to make and use the technology for research purposes and the U.S. Government's right to use the technology for government purposes. Pursuant to the license agreement, as amended, the Company is required to (i) reimburse Dr. McDonald for certain out-of-pocket expenses incurred by Dr. McDonald in connection with the patent applications and issued patents, (ii) pay Dr. McDonald $300,000 upon approval by the FDA of the Company's first NDA incorporating oral BDP; (iii) pay Dr. McDonald royalty payments equal to 3% of net sales of the covered products and (iv) pay Dr. McDonald $400,000 in cash upon an approval of oral BDP by the European Medicines Agency.

Additionally, in the event that the Company sublicenses its rights under the license agreement, the Company will be required to pay Dr. McDonald 10% of any sublicense fees and royalty payments paid by the sublicense to the Company.

The term of the license agreement expires upon the expiration of the licensed patent applications or patents. Dr. McDonald has the right to terminate the license agreement in its entirety or to terminate exclusivity under the agreement if the Company or its sublicense has not commercialized or are not actively attempting to commercialize a covered product.

Additionally, the agreement terminates: (i) automatically upon the Company becoming insolvent; (ii) upon 30 days' notice, if the Company breaches any obligation under the agreement without curing such breach during the notice period; and (iii) upon 90 days' notice by the Company. After any termination, the Company will have the right to sell its inventory for a period not to exceed three months following the date of termination, subject to the payment of the amounts owed under the agreement.

ThermoVax® License Agreement

On December 21, 2010, we executed a worldwide exclusive license agreement with the UC for ThermoVax®, which is the subject of U.S. patent number 8,444,991 issued on May 21, 2013 titled "Method of Preparing an Immunologically-Active Adjuvant-Bound Dried Vaccine Composition." This patent and its corresponding foreign filings are licensed to us by the UC and they address the use of adjuvants in conjunction with vaccines that are formulated to resist thermal inactivation. U.S. Patent 8,444,991 is expected to expire in December 2031. The license agreement also covers thermostable vaccines for biodefense as well as other potential vaccine indications. In addition, we, in conjunction with UC, filed domestic and foreign patent applications claiming priority back to a provisional application filed on May 17, 2011 titled: "Thermostable Vaccine Compositions and Methods of Preparing Same." To maintain this license we are obligated to pay minimum annual license fees of $15,000 until the initiation of clinical trials, $20,000 following the initiation of a Phase 1 clinical trial, and $50,000 following the first commercial sale of a product incorporating ThermoVax®. Under the license agreement we are obligated to pay the UC (i) royalty payments equal to 2% of net sales of the covered products, (ii) 15% of all income from sublicenses and (iii) milestone payments which could reach up to $1.25 million.

RiVax™ License Agreement

In June 2003, we executed a worldwide exclusive option to license patent applications with UTSW for the nasal, pulmonary and oral uses of a non-toxic ricin vaccine. In June 2004, we entered into a license agreement with UTSW for the injectable rights to the ricin vaccine and, in October 2004, we negotiated the remaining oral rights to the ricin vaccine. To maintain this license we are obligated to pay $50,000 in annual license fees. Through this license, we have rights to the issued patent number 7,175,848 titled "Ricin A chain mutants lacking enzymatic activity as vaccines to protect against aerosolized ricin." This patent includes methods of use and composition claims for RiVax™.

Research and Development Expenditures

We spent approximately $4.3 million and $5.4 million in the years ended December 31, 2016 and 2015, respectively, on research and development. The amounts we spent on research and development per product during the years ended December 31, 2016, and 2015 are set forth in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this Annual Report on Form 10-K.

Employees

As of December 31, 2016, we had 19 full-time employees, 8 of whom are MDs/PhDs.

Available Investor Information

We file electronically with the Securities and Exchange Commission (“SEC”) our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) of 15(d) of the Securities Exchange Act of 1934, as amended. We make available through our website, free of charge, copies of these reports as soon as reasonably practicable after we electronically file or furnish them to the SEC. Our website is located at http://www.soligenix.com. You can also request copies of such documents by contacting the company at (609) 538-8200 or sending an email to info@soligenix.com.

Item 1A. Risk factors

An investment in our securities involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information about these risks contained in this Annual Report, as well as the other information contained in this Annual Report generally, before deciding to buy our securities. Any of the risks we describe below could adversely affect our business, financial condition, operating results or prospects. The market prices for our securities could decline if one or more of these risks and uncertainties develop into actual events and you could lose all or part of your investment. Additional risks and uncertainties that we do not yet know of, or that we currently think are immaterial, may also impair our business operations. You should also refer to the other information contained in this Annual Report, including our financial statements and the related notes.

Risks Related to our Business

We have had significant losses and anticipate future losses; if additional funding cannot be obtained, we may reduce or discontinue our product development and commercialization efforts.

We have experienced significant losses since inception and, at December 31, 2016, had an accumulated deficit of approximately $150 million. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of December 31, 2016, we had approximately $8.8 million in cash and cash equivalents available. Based on our projected budgetary needs, funding from existing contracts and grants over the next two years and sales to the purchasers under our existing equity line, we expect to be able to maintain the current level of our operations through at least March 31, 2018.

In September 2014, we entered into a contract with the NIH for the development of RiVax™ to protect against exposure to ricin toxin that would provide up to $24.7 million of funding in the aggregate if options to extend the contract are exercised by the NIH. In September 2013, we entered into contracts with NIAID and BARDA for the development of OrbeShield® that would provide up to $32.7 million of funding in the aggregate if options to extend the contracts are exercised by BARDA and the NIH. We have received approximately $18 million in combined BARDA and NIH contract funding for the development of OrbeShield®. We have completed the contract with NIAID and the BARDA contract base period, with BARDA electing not to extend the contract. In September 2009, we received a NIAID grant for approximately $9.4 million for the development of our biodefense programs. In July 2012, we received an additional SBIR grant from NIAID for $600,000 and in February 2014, we were awarded a one-year NIAID SBIR grant award of approximately $300,000 to further evaluate SGX943 as a treatment for melioidosis. Our biodefense grants have an overhead component that allows us an agency-approved percentage over our incurred costs. We estimate that the overhead component associated with our existing contracts and grants will fund some fixed costs for direct employees working on these contracts and grants as well as other administrative costs. We have approximately $17.3 million in awarded contract funding, assuming the NIAID options are exercised for the

development of RiVax™. BARDA has elected not to fund the additional options remaining under the contract.

Our product candidates are positioned for or are currently in clinical trials, and we have not yet generated any significant revenues from sales or licensing of these product candidates. From inception through December 2016, we have expended approximately $70.5 million developing our current product candidates for pre-clinical research and development and clinical trials, and we currently expect to spend approximately $10.7 million over the next 12 months in connection with the development of our therapeutic and vaccine products, licenses, employment agreements, and consulting agreements of which approximately $4.9 million will be reimbursed through our existing government contracts and grants.

We have no control over the resources and funding NIH, BARDA and NIAID may devote to our programs, which may be subject to periodic renewal and which generally may be terminated by the government at any time for convenience. Any significant reductions in the funding of U.S. government agencies or in the funding areas targeted by our business could materially and adversely affect our biodefense program and our results of operations and financial condition. If we fail to satisfy our obligations under the government contracts, the applicable Federal Acquisition Regulations allow the government to terminate the agreement in whole or in part, and we may be required to perform corrective actions, including but not limited to delivering to the government any incomplete work. If NIH, BARDA or NIAID do not exercise future funding options under the contracts or grants, terminate the funding or fail to perform their responsibilities under the agreements or grants, it could materially impact our biodefense program and our financial results.

Unless and until we are able to generate sales or licensing revenue from one of our product candidates, we will require additional funding to meet these commitments, sustain our research and development efforts, provide for future clinical trials, and continue our operations. There can be no assurance we can raise such funds. If additional funds are raised through the issuance of equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the common stock. If additional funds are raised by the issuance of debt, we may be subject to limitations on our operations. If we cannot raise such additional funds, we may have to delay or stop some or all of our drug development programs.

If we are unable to develop our product candidates, our ability to generate revenues and viability as a company will be significantly impaired.

In order to generate revenues and profits, our organization must, along with corporate partners and collaborators, positively research, develop and commercialize our technologies or product candidates. Our current product candidates are in various stages of early clinical and pre-clinical development and will require significant further funding, research, development, pre-clinical and/or clinical testing, regulatory approval and commercialization, and are subject to the risks of failure inherent in the development of products based on innovative or novel technologies. Specifically, each of the following is possible with respect to any of our product candidates:

- we may not be able to maintain our current research and development schedules;
- we may be unable to secure procurement contracts on beneficial economic terms or at all from the U.S. government or others for our biodefense products;
- we may encounter problems in clinical trials; or
- the technology or product may be found to be ineffective or unsafe, or may fail to obtain marketing approval.

If any of the risks set forth above occur, or if we are unable to obtain the necessary regulatory approvals as discussed below, we may be unable to develop our technologies and product candidates and our business will be seriously harmed. Furthermore, for reasons including those set forth below, we may be unable to commercialize or receive royalties from the sale of any other technology we develop, even if it is shown to be effective, if:

- it is not economical or the market for the product does not develop or diminishes;
- we are not able to enter into arrangements or collaborations to manufacture and/or market the product;
- the product is not eligible for third-party reimbursement from government or private insurers;
- others hold proprietary rights that preclude us from commercializing the product;
- we are not able to manufacture the product reliably;
- others have brought to market similar or superior products; or
- the product has undesirable or unintended side effects that prevent or limit its commercial use.

24

We expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

We are a late-stage biopharmaceutical company. Our operations to date have been primarily limited to developing our technology and undertaking pre-clinical studies and clinical trials of our product candidates in our two active business segments, BioTherapeutics and Vaccines/BioDefense. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had commercialized products. Our financial condition has varied significantly in the past and will continue to fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include other factors described elsewhere in this Annual Report and also include:

our ability to obtain additional funding to develop our product candidates;
delays in the commencement, enrollment and timing of clinical trials;
the success of our product candidates through all phases of clinical development;
any delays in regulatory review and approval of product candidates in clinical development;
our ability to obtain and maintain regulatory approval for our product candidates in the United States and foreign jurisdictions;
potential side effects of our product candidates that could delay or prevent commercialization, limit the indications for any approved drug, require the establishment of risk evaluation and mitigation strategies, or cause an approved drug to be taken off the market;
our dependence on third-party contract manufacturing organizations to supply or manufacture our products;
our dependence on contract research organizations to conduct our clinical trials;
our ability to establish or maintain collaborations, licensing or other arrangements;
market acceptance of our product candidates;
our ability to establish and maintain an effective sales and marketing infrastructure, either through the creation of a commercial infrastructure or through strategic collaborations;
competition from existing products or new products that may emerge;
the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our products;
our ability to discover and develop additional product candidates;
our ability and our licensors' abilities to successfully obtain, maintain, defend and enforce intellectual property rights important to our business;
our ability to attract and retain key personnel to manage our business effectively;
our ability to build our finance infrastructure and improve our accounting systems and controls;
potential product liability claims;
potential liabilities associated with hazardous materials; and
our ability to obtain and maintain adequate insurance policies.

Accordingly, the results of any quarterly or annual periods should not be relied upon as indications of future operating performance.

We have no approved products on the market and therefore do not expect to generate any revenues from product sales in the foreseeable future, if at all.

To date, we have no approved product on the market and have not generated any significant product revenues. We have funded our operations primarily from sales of our securities and from government grants. We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our product candidates. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with commercial potential or successfully obtain government procurement or stockpiling agreements. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

Our business is subject to extensive governmental regulation, which can be costly, time consuming and subjects us to unanticipated delays.

Our business is subject to very stringent federal, foreign, state and local government laws and regulations, including the Federal Food, Drug and Cosmetic Act, the Environmental Protection Act, the Occupational Safety and Health Act, and state and local counterparts to these acts. These laws and regulations may be amended, additional laws and regulations may be enacted, and the policies of the FDA and other regulatory agencies may change.

The regulatory process applicable to our products requires pre-clinical and clinical testing of any product to establish its safety and efficacy. This testing can take many years, is uncertain as to outcome, and requires the expenditure of substantial capital and other resources. We estimate that the clinical trials of our product candidates that we have planned will 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. Favorable results in early studies or trials, if any, 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, Phase 1 and Phase 2 clinical trials does not ensure that later Phase 2 or Phase 3 clinical trials will be successful. In addition, we, the FDA or other regulatory authorities may suspend clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or the FDA or other regulatory authorities find deficiencies in our submissions or conduct of our trials.

We may not be able to obtain, or we may experience difficulties and delays in obtaining, necessary domestic and foreign governmental clearances and approvals to market a product. Also, even if regulatory approval of a product is granted, that approval may entail limitations on the indicated uses for which the product may be marketed.

Following any regulatory approval, a marketed product and its manufacturer are subject to continual regulatory review. Later discovery of problems with a product or manufacturer may result in restrictions on such product or manufacturer. These restrictions may include product recalls and suspension or withdrawal of the marketing approval for the product. Furthermore, the advertising, promotion and export, among other things, of a product are subject to extensive regulation by governmental authorities in the U.S. and other countries. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and/or criminal prosecution.

There may be unforeseen challenges in developing our biodefense products.

For development of biodefense vaccines and therapeutics, the FDA has instituted policies that are expected to result in accelerated approval. This includes approval for commercial use using the results of animal efficacy trials, rather than efficacy trials in humans, referred to as the Animal Rule. However, we will still have to establish that the vaccines we are developing are safe in humans at doses that are correlated with the beneficial effect in animals. Such clinical trials will also have to be completed in distinct populations that are subject to the countermeasures; for instance, the very young and the very old, and in pregnant women, if the countermeasure is to be licensed for civilian use. Other agencies will have an influence over the risk benefit scenarios for deploying the countermeasures and in establishing the number of doses utilized in the Strategic National Stockpile. We may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these correlates are difficult to establish and are often unclear. Invocation of the Animal Rule may raise issues of confidence in the model systems even if the models have been validated. For many of the biological threats, the animal models are not available and we may have to develop the animal models, a time-consuming research effort. There are few historical precedents, or recent precedents, for the development of new countermeasure for bioterrorism agents. Despite the Animal Rule, the FDA may require large

clinical trials to establish safety and immunogenicity before licensure and it may require safety and immunogenicity trials in additional populations. Approval of biodefense products may be subject to post-marketing studies, and could be restricted in use in only certain populations. The government's biodefense priorities can change, which could adversely affect the commercial opportunity for the products we are developing. Further, other countries have not, at this time, established criteria for review and approval of these types of products outside their normal review process, i.e., there is no Animal Rule equivalent, and consequently there can be no assurance that we will be able to make a submission for marketing approval in foreign countries based on such animal data.

Additionally, few facilities in the United States and internationally have the capability to test animals with anthrax or ricin, or otherwise assist us in qualifying the requisite animal models. We have to compete with other biodefense companies for access to this limited pool of highly specialized resources. We therefore may not be able to secure contracts to conduct the testing in a predictable timeframe or at all.

We are dependent on government funding, which is inherently uncertain, for the success of our biodefense operations.

We are subject to risks specifically associated with operating in the biodefense industry, which is a new and unproven business area. We do not anticipate that a significant commercial market will develop for our biodefense products. Because we anticipate that the principal potential purchasers of these products, as well as potential sources of research and development funds, will be the U.S. government and governmental agencies, the success of our biodefense division will be dependent in large part upon government spending decisions. The funding of government programs is dependent on budgetary limitations, congressional appropriations and administrative allotment of funds, all of which are inherently uncertain and may be affected by changes in U.S. government policies resulting from various political and military developments. Our receipt of government funding is also dependent on our ability to adhere to the terms and provisions of the original grant documents and other regulations. We can provide no assurance that we will receive or continue to receive funding for grants we have been awarded. The loss of government funds could have a material adverse effect on our ability to progress our biodefense business.

If the parties we depend on for supplying our drug substance raw materials and certain manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to develop, manufacture and market our products. We do not have or anticipate having internal manufacturing capabilities.

We rely on suppliers for our drug substance raw materials and third parties for certain manufacturing-related services to produce material that meets appropriate content, quality and stability standards, which material will be used in clinical trials of our products and, after approval, for commercial distribution. To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We and our suppliers and vendors may not be able to (i) produce our drug substance or drug product 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 be able to develop, produce, secure regulatory approval of 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 develop our own manufacturing capabilities 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.

We rely on third parties for pre-clinical and clinical trials of our product candidates and, in some cases, to maintain regulatory files for our product candidates. If we are not able to maintain or secure agreements with such third parties on acceptable terms, if these third parties do not perform their services as required, or if these third parties fail to timely transfer any regulatory information held by them to us, we may not be able to obtain regulatory approval for, or commercialize, our product candidates.

We rely on academic institutions, hospitals, clinics and other third-party collaborators for preclinical and clinical trials of our product candidates. Although we monitor, support, and/or oversee our pre-clinical and clinical trials, because we do not conduct these trials ourselves, we have less control over the timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials wholly by ourselves. If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated, we may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate. In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by a contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our product candidates. If these third parties fail to meet expected deadlines, fail to timely transfer to us any regulatory information, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then preclinical and/or clinical trials of our product candidates may be extended, delayed or terminated, or our data may be rejected by the FDA or regulatory agencies.

The manufacturing of our products is a highly exacting process, and if we or one of our materials suppliers encounter problems manufacturing our products, our business could suffer.

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with current Good Manufacturing Practice ("cGMP") or similar requirements that the FDA or foreign regulators establish. We, or our materials suppliers, may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the supplier may not be able to maintain compliance with the FDA's cGMP requirements, or those of foreign regulators, necessary to continue manufacturing our drug substance. Any failure to comply with cGMP requirements or other FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products.

We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and human resources, we are currently focusing on the regulatory approval of certain product candidates. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on existing and future product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic alliance, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in an area in which it would have been more advantageous to enter into a partnering arrangement.

Even if approved, our products will be subject to extensive post-approval regulation.

Once a product is approved, numerous post-approval requirements apply. Among other things, the holder of an approved New Drug Application ("NDA") is subject to periodic and other FDA monitoring and reporting obligations, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the NDA. Application holders must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials.

Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw product approval.

Even if we obtain regulatory approval to market our product candidates, our product candidates may not be accepted by the market.

Even if the FDA approves one or more of our product candidates, physicians and patients may not accept it or use it. Even if physicians and patients would like to use our products, our products may not gain market acceptance among healthcare payors such as managed care formularies, insurance companies or government programs such as Medicare or Medicaid. Acceptance and use of our products will depend upon a number of factors including: perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drug or device product; cost-effectiveness of our product relative to competing products; availability of reimbursement for our product from government or other healthcare payers; and effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The degree of market acceptance of any product that we develop will depend on a number of factors, including:

cost-effectiveness;
the safety and effectiveness of our products, including any significant potential side effects, as compared to alternative products or treatment methods;
the timing of market entry as compared to competitive products;
the rate of adoption of our products by doctors and nurses;
product labeling or product insert required by the FDA for each of our products;
reimbursement policies of government and third-party payors;
effectiveness of our sales, marketing and distribution capabilities and the effectiveness of such capabilities of our collaborative partners, if any; and
unfavorable publicity concerning our products or any similar products.

Our product candidates, if successfully developed, will compete with a number of products manufactured and marketed by major pharmaceutical companies, biotechnology companies and manufacturers of generic drugs. Our products may also compete with new products currently under development by others. Physicians, patients, third-party payors and the medical community may not accept and utilize any of our product candidates. If our products do not achieve market acceptance, we will not be able to generate significant revenues or become profitable.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of these products to find market acceptance would harm our business and could require us to seek additional financing.

We do not have extensive sales and marketing experience and our lack of experience may restrict our success in commercializing some of our product candidates.

We do not have extensive experience in marketing or selling pharmaceutical products whether in the U.S. or internationally. To obtain the expertise necessary to successfully market and sell any of our products, the development of our own commercial infrastructure and/or collaborative commercial arrangements and partnerships will be required. Our ability to make that investment and also execute our current operating plan is dependent on numerous factors, including, the performance of third party collaborators with whom we may contract.

Our products, if approved, may not be commercially viable due to change in health care practice and third party reimbursement limitations.

Recent initiatives to reduce the federal deficit and to change health care delivery are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative benefits, controls on health care spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, price controls on pharmaceuticals, and other fundamental changes to the health care delivery system. Any changes of this type could negatively impact the commercial viability of our products, if approved. Our ability to successfully commercialize our product candidates, if they are approved, will depend in part on the extent to which appropriate reimbursement codes and authorized cost reimbursement levels of these products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations. In the absence of national Medicare coverage determination, local contractors that administer the Medicare program may make their own coverage decisions. Any of our product candidates, if approved and when commercially available, may not be included within the then current Medicare coverage determination or the coverage determination of state Medicaid programs, private insurance companies or other health care providers. In addition, third-party payers are increasingly challenging the necessity and prices charged for medical products, treatments and services.

Our product candidates may cause serious adverse events or undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Serious adverse events or undesirable side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. The results of future clinical trials may show that our product candidates cause serious adverse events or undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities.

If any of our product candidates cause serious adverse events or undesirable side effects:

regulatory authorities may impose a clinical hold which could result in substantial delays and adversely impact our ability to continue development of the product;
regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
we may be required to implement a risk minimization action plan, which could result in substantial cost increases and have a negative impact on our ability to commercialize the product;
we may be required to limit the patients who can receive the product;
we may be subject to limitations on how we promote the product;
sales of the product may decrease significantly;
regulatory authorities may require us to take our approved product off the market;
we may be subject to litigation or product liability claims; and
our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products.

If we fail to obtain or maintain orphan drug exclusivity for our product candidates, our competitors may sell products to treat the same conditions and our revenue will be reduced.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the European Medicines Agency's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Even though we have orphan drug designation for SGX301 in the United States and Europe, and SGX203, RiVax™ and OrbeShield® in the United States, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing drugs or biologic products. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Absent patent or other intellectual property protection, even after an orphan drug is approved, the FDA or European Medicines Agency may subsequently approve the same drug with the same active moiety for the same condition if the FDA or European Medicines Agency concludes that the later drug is safer, more effective, or makes a major contribution to patient care.

Federal and/or state health care reform initiatives could negatively affect our business.

The availability of reimbursement by governmental and other third-party payers affects the market for any pharmaceutical product. These third-party payers continually attempt to contain or reduce the costs of healthcare. There have been a number of legislative and regulatory proposals to change the healthcare system and further proposals are likely. Medicare's policies may decrease the market for our products. Significant uncertainty exists with respect to the reimbursement status of newly approved healthcare products.

In addition, third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services. Once approved, we might not be able to sell our products profitably or recoup the value of our investment in product development if reimbursement is unavailable or limited in scope, particularly for product candidates addressing small patient populations. On July 15, 2008, the Medicare Improvements for Patients and Providers Act of 2008 became law with a number of Medicare and Medicaid reforms to establish a bundled Medicare payment rate that includes services and drug/labs that were separately billed at that time. Bundling initiatives that have been implemented in other healthcare settings have occasionally resulted in lower utilization of services that had not previously been a part of the bundled payment.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. We expect that there will continue to be a number of U.S. federal and state proposals to implement governmental pricing controls. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

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

We currently rely on license agreements from New York University, Yeda Research and Development Company Ltd., the University of Texas Southwestern Medical Center, the University of British Columbia, Harvard University, the University of Colorado, and George B. McDonald, MD for the rights to commercialize key product candidates. We may not be able to retain the rights granted under these agreements or negotiate additional agreements on reasonable terms, if at all. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our drug candidates. See “Business - Patents and Other Proprietary Rights” for a description of our license agreements.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business, and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including but not limited to:

the scope of rights granted under the license agreement and other interpretation-related issues;
the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
the sublicensing of patent and other rights;
our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

Additionally, the research resulting in certain of our licensed patent rights and technology was funded by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

Furthermore, we currently have very limited product development capabilities and no manufacturing, marketing or sales capabilities. For us to research, develop and test our product candidates, we need to contract or partner with outside researchers, in most cases with or through those parties that did the original research and from whom we have licensed the technologies. If products are successfully developed and approved for commercialization, then we will need to enter into additional collaboration and other agreements with third parties to manufacture and market our products. We may not be able to induce the third parties to enter into these agreements, and, even if we are able to do so, the terms of these agreements may not be favorable to us. Our inability to enter into these agreements could delay or preclude the development, manufacture and/or marketing of some of our product candidates or could significantly increase the costs of doing so. In the future, we may grant to our development partners rights to license and commercialize pharmaceutical and related products developed under the agreements with them, and these rights may limit our flexibility in considering alternatives for the commercialization of these products. Furthermore, third-party manufacturers or suppliers may not be able to meet our needs with respect to timing, quantity and quality for the products.

Additionally, if we do not enter into relationships with additional third parties for the marketing of our products, if and when they are approved and ready for commercialization, we would have to build our own sales force or enter into commercialization agreements with other companies. Development of an effective sales force in any part of the world would require significant financial resources, time and expertise. We may not be able to obtain the financing necessary to establish a sales force in a timely or cost effective manner, if at all, and any sales force we are able to establish may not be capable of generating demand for our product candidates, if they are approved.

We may suffer product and other liability claims; we maintain only limited product liability insurance, which may not be sufficient.

The clinical testing, manufacture and sale of our products involves an inherent risk that human subjects in clinical testing or consumers of our products may suffer serious bodily injury or death due to side effects, allergic reactions or other unintended negative reactions to our products. As a result, product and other liability claims may be brought against us. We currently have clinical trial and product liability insurance with limits of liability of $10 million, which may not be sufficient to cover our potential liabilities. Because liability insurance is expensive and difficult to obtain, we may not be able to maintain existing insurance or obtain additional liability insurance on acceptable terms or with adequate coverage against potential liabilities. Furthermore, if any claims are brought against us, even if we are fully covered by insurance, we may suffer harm such as adverse publicity.

We may use hazardous chemicals in our business. Potential claims relating to improper handling, storage or disposal of these chemicals could affect us and be time consuming and costly.

Our research and development processes and/or those of our third party contractors involve the controlled use of hazardous materials and chemicals. These hazardous chemicals are reagents and solvents typically found in a chemistry laboratory. Our operations also may produce hazardous waste products. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. While we attempt to comply with all environmental laws and regulations, including those relating to the outsourcing of the disposal of all hazardous chemicals and waste products, we cannot eliminate the risk of contamination from or discharge of hazardous materials and any resultant injury. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations.

Compliance with environmental laws and regulations may be expensive. Current or future environmental regulations may impair our research, development or production efforts. We might have to pay civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. We are not insured against these environmental risks.

We may agree to indemnify our collaborators in some circumstances against damages and other liabilities arising out of development activities or products produced in connection with these collaborations.

In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

We may not be able to compete with our larger and better financed competitors in the biotechnology industry.

The biotechnology industry is intensely competitive, subject to rapid change and sensitive to new product introductions or enhancements. Most of our existing competitors have greater financial resources, larger technical staffs, and larger research budgets than we have, as well as greater experience in developing products and conducting clinical trials. Our competition is particularly intense in the gastroenterology and transplant areas and is also intense in the therapeutic area of inflammatory bowel diseases. We face intense competition in the biodefense area from various public and private companies and universities as well as governmental agencies, such as the U.S. Army, which may have their own proprietary technologies that may directly compete with our technologies. In addition, there may be other companies that are currently developing competitive technologies and products or that may in the future develop technologies and products that are comparable or superior to our technologies and products. We may not be able to

compete with our existing and future competitors, which could lead to the failure of our business.

Additionally, if a competitor receives FDA approval before we do for a drug that is similar to one of our product candidates, FDA approval for our product candidate may be precluded or delayed due to periods of non-patent exclusivity and/or the listing with the FDA by the competitor of patents covering its newly-approved drug product. Periods of non-patent exclusivity for new versions of existing drugs such as our current product candidates can extend up to three and one-half years. See “Business - The Drug Approval Process.”

These competitive factors could require us to conduct substantial new research and development activities to establish new product targets, which would be costly and time consuming. These activities would adversely affect our ability to commercialize products and achieve revenue and profits.

Competition and technological change may make our product candidates and technologies less attractive or obsolete.

We compete with established pharmaceutical and biotechnology companies that are pursuing other forms of treatment for the same indications we are pursuing and that have greater financial and other resources. Other companies may succeed in developing products earlier than us, obtaining FDA approval for products more rapidly, or developing products that are more effective than our product candidates. Research and development by others may render our technology or product candidates obsolete or noncompetitive, or result in treatments or cures superior to any therapy we develop. We face competition from companies that internally develop competing technology or acquire competing technology from universities and other research institutions. As these companies develop their technologies, they may develop competitive positions that may prevent, make futile, or limit our product commercialization efforts, which would result in a decrease in the revenue we would be able to derive from the sale of any products.

There can be no assurance that any of our product candidates will be accepted by the marketplace as readily as these or other competing treatments. Furthermore, if our competitors' products are approved before ours, it could be more difficult for us to obtain approval from the FDA. Even if our products are successfully developed and approved for use by all governing regulatory bodies, there can be no assurance that physicians and patients will accept our product(s) as a treatment of choice.

Furthermore, the pharmaceutical research industry is diverse, complex, and rapidly changing. By its nature, the business risks associated therewith are numerous and significant. The effects of competition, intellectual property disputes, market acceptance, and FDA regulations preclude us from forecasting revenues or income with certainty or even confidence.

Our business could be harmed if we fail to retain our current personnel or if they are unable to effectively run our business.

We currently have 19 employees and we depend upon these employees, in particular Dr. Christopher Schaber, our President and Chief Executive Officer, to manage the day-to-day activities of our business. Because we have such limited personnel, the loss of any of them or our inability to attract and retain other qualified employees in a timely manner would likely have a negative impact on our operations. We may be unable to effectively manage and operate our business, and our business may suffer, if we lose the services of our employees.

Instability and volatility in the financial markets could have a negative impact on our business, financial condition, results of operations, and cash flows.

During recent years, there has been substantial volatility in financial markets due at least in part to the uncertainty with regard to the global economic environment. In addition, there has been substantial uncertainty in the capital markets and access to additional financing is uncertain. Moreover, customer spending habits may be adversely affected by current and future economic conditions. These conditions could have an adverse effect on our industry and business, including our financial condition, results of operations, and cash flows.

To the extent that we do not generate sufficient cash from operations, we may need to issue stock or incur indebtedness to finance our plans for growth. Recent turmoil in the credit markets and the potential impact on the liquidity of major financial institutions may have an adverse effect on our ability to fund our business strategy through borrowings, under either existing or newly created instruments in the public or private markets on terms we believe to be reasonable, if at all.

We may not be able to utilize all of our net operating loss carryforwards.

The State of New Jersey's Technology Business Tax Certificate Program allows certain high technology and biotechnology companies to sell unused net operating loss ("NOL") carryforwards to other New Jersey-based corporate taxpayers. In accordance with this program, during the year ended December 31, 2016, we sold New Jersey NOL carryforwards, resulting in the recognition of $530,143 of income tax benefit. If there is an unfavorable change in the State of New Jersey's Technology Business Tax Certificate Program (whether as a result of a change in law, policy or otherwise) that terminates the program or eliminates or reduces our ability to use or sell our NOL carryforwards, our cash taxes may increase which may have an adverse effect on our financial condition.

Risks Related to our Intellectual Property

We may be unable to commercialize our products if we are unable to protect our proprietary rights, and we may be liable for significant costs and damages if we face a claim of intellectual property infringement by a third party.

Our near and long term prospects depend in part on our ability to obtain and maintain patents, protect trade secrets and operate without infringing upon the proprietary rights of others. In the absence of patent and trade secret protection, competitors may adversely affect our business by independently developing and marketing substantially equivalent or superior products and technology, possibly at lower prices. We could also incur substantial costs in litigation and suffer diversion of attention of technical and management personnel if we are required to defend ourselves in intellectual property infringement suits brought by third parties, with or without merit, or if we are required to initiate litigation against others to protect or assert our intellectual property rights. Moreover, any such litigation may not be resolved in our favor.

Although we and our licensors have filed various patent applications covering the uses of our product candidates, patents may not be issued from the patent applications already filed or from applications that we might file in the future. Moreover, the patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions, and recently has been the subject of much litigation. Any patents we own or license, now or in the future, may be challenged, invalidated or circumvented. To date, no consistent policy has been developed in the U.S. Patent and Trademark Office (the “PTO”) regarding the breadth of claims allowed in biotechnology patents.

In addition, because patent applications in the U.S. are maintained in secrecy until patent applications publish or patents issue, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we and our licensors are the first creators of inventions covered by any licensed patent applications or patents or that we or they are the first to file. The PTO may commence interference proceedings involving patents or patent applications, in which the question of first inventorship is contested. Accordingly, the patents owned or licensed to us may not be valid or may not afford us protection against competitors with similar technology, and the patent applications licensed to us may not result in the issuance of patents.

It is also possible that our owned and licensed technologies may infringe on patents or other rights owned by others, and licenses to which may not be available to us. We may be unable to obtain a license under such patent on terms favorable to us, if at all. We may have to alter our products or processes, pay licensing fees or cease activities altogether because of patent rights of third parties.

In addition to the products for which we have patents or have filed patent applications, we rely upon unpatented proprietary technology and may not be able to meaningfully protect our rights with regard to that unpatented proprietary technology. Furthermore, to the extent that consultants, key employees or other third parties apply technological information developed by them or by others to any of our proposed projects, disputes may arise as to the proprietary rights to this information, which may not be resolved in our favor.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive and time consuming.

The pharmaceutical industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We may become subject to infringement claims or litigation arising out of patents and pending applications of our competitors, or additional interference proceedings declared by the PTO to determine the priority of inventions. The defense and prosecution of intellectual property suits, PTO proceedings, and related legal and administrative proceedings are costly and time-consuming to pursue, and their outcome is uncertain. Litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how, or to determine the enforceability, scope, and validity of the proprietary rights of others. An adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities, require us to obtain licenses from third parties, or restrict or prevent us from selling our products in certain markets. Although patent and intellectual property disputes might be settled through licensing or similar arrangements, the costs associated with such arrangements may be substantial and could include our paying large fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all.

Competitors may infringe our patents, and we may file infringement claims to counter infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly.

Also, a third party may assert that our patents are invalid and/or unenforceable. There are no unresolved communications, allegations, complaints or threats of litigation related to the possibility that our patents are invalid or unenforceable. Any litigation or claims against us, whether or not merited, may result in substantial costs, place a significant strain on our financial resources, divert the attention of management and harm our reputation. An adverse decision in litigation could result in inadequate protection for our product candidates and/or reduce the value of any license agreements we have with third parties.

Interference proceedings brought before the PTO may be necessary to determine priority of invention with respect to our patents or patent applications. During an interference proceeding, it may be determined that we do not have priority of invention for one or more aspects in our patents or patent applications and could result in the invalidation in part or whole of a patent or could put a patent application at risk of not issuing. Even if successful, an interference proceeding may result in substantial costs and distraction to our management.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or interference proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the price of our common stock could be adversely affected.

If we infringe the rights of third parties we could be prevented from selling products, forced to pay damages, and defend against litigation.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to: obtain licenses, which may not be available on commercially reasonable terms, if at all; abandon an infringing product candidate; redesign our products or processes to avoid infringement; stop using the subject matter claimed in the patents held by others; pay damages; and/or defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

Risks Related to our Securities

The price of our common stock and warrants may be highly volatile.

The market price of our securities, like that of many other research and development public pharmaceutical and biotechnology companies, has been highly volatile and the price of our common stock and warrants may be volatile in the future due to a wide variety of factors, including:

announcements by us or others of results of pre-clinical testing and clinical trials;
announcements of technological innovations, more important bio-threats or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;
our quarterly operating results and performance;
developments or disputes concerning patents or other proprietary rights;
acquisitions;
litigation and government proceedings;
adverse legislation;
changes in government regulations;
our available working capital;
economic and other external factors; and
general market conditions.

Since January 1, 2016, the closing stock price (split adjusted) of our common stock has fluctuated between a high of $11.92 per share to a low of $1.98 per share. On March 17, 2017, the last quoted sale price of our common stock as reported on Nasdaq Capital Market was $2.70 per share. Since December 13, 2016, the date of the initial listing of our common stock warrants, the closing price of our common stock warrant has fluctuated between a high of $0.82 per warrant to a low of $0.32 per warrant. The fluctuation in the price of our common stock and warrants has sometimes been unrelated or disproportionate to our operating performance. In addition, potential dilutive effects of future sales of shares of common stock and warrants by the Company, as well as potential sale of common stock by the holders of warrants and options, could have an adverse effect on the market price of our shares.

The warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the warrants may exercise their right to acquire the common stock and pay an exercise price of $3.95 per share, prior to five years from the date of issuance, after which date any unexercised warrants will expire and have no further value.

The warrants may not have any value.

Each warrant has an exercise price of $3.95 per share and will expire on the fifth anniversary of December 13, 2016. In the event our common stock price does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value.

Shareholders may suffer substantial dilution related to issued stock warrants and options.

As of December 31, 2016, we had a number of agreements or obligations that may result in dilution to investors. These include:

warrants to purchase a total of approximately 2,853,575 shares of our common stock at a current weighted average exercise price of approximately $4.13; and
options to purchase approximately 330,605 shares of our common stock at a current weighted average exercise price of approximately $17.07.

We also have an incentive compensation plan for our management, employees and consultants. We have granted, and expect to grant in the future, options to purchase shares of our common stock to our directors, employees and consultants. To the extent that warrants or options are exercised, our stockholders will experience dilution and our

stock price may decrease.

Additionally, the sale, or even the possibility of the sale, of the shares of common stock underlying these warrants and options could have an adverse effect on the market price for our securities or on our ability to obtain future financing.

Anti-takeover provisions in our stockholder rights plan and under Delaware law could make a third party acquisition of the Company difficult.

Our stockholder rights plan contains provisions that could make it more difficult for a third party to acquire us, even if doing so might be deemed beneficial by our stockholders. These provisions could limit the price that investors might be willing to pay in the future for shares of our common stock. We are also subject to certain provisions of Delaware law that could delay, deter or prevent a change in control of the Company. The rights issued pursuant to our stockholder rights plan will become exercisable the tenth day after a person or group announces acquisition of 15% or more of our common stock or commences, or announces an intention to make, a tender or exchange offer the consummation of which would result in ownership by the person or group of 15% or more of our common stock. If the rights become exercisable, the holders of the rights (other than the person acquiring 15% or more of our common stock) will be entitled to acquire, in exchange for the rights' exercise price, shares of our common stock or shares of any company in which we are merged, with a value equal to twice the rights' exercise price.

Our shares of common stock and warrants are thinly traded, so stockholders may be unable to sell at or near ask prices or at all if they need to sell shares or warrants to raise money or otherwise desire to liquidate their shares.

Our common stock and warrants have from time to time been "thinly-traded," meaning that the number of persons interested in purchasing our common stock or warrants at or near ask prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company that is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we become more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give stockholders any assurance that a broader or more active public trading market for our common shares and warrants will develop or be sustained, or that current trading levels will be sustained.

We do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock.

We have never declared or paid cash dividends on our common stock and do not anticipate paying any cash dividends to holders of our common stock in the foreseeable future. Consequently, our stockholders must rely on sales of their common stock and warrants after price appreciation, which may never occur, as the only way to realize any future gains on their investments. There is no guarantee that shares of our common stock or warrants will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

Upon dissolution of the Company, our stockholders may not recoup all or any portion of their investment.

In the event of a liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the proceeds and/or assets of the Company remaining after giving effect to such transaction, and the payment of all of our debts and liabilities will be distributed to the holders of common stock on a pro rata basis. There can be no assurance that we will have available assets to pay to the holders of common stock, or any amounts, upon such a liquidation, dissolution or winding-up of the Company. In this event, our stockholders could lose some or all of their investment.

The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

On March 22, 2016, we entered into a purchase agreement (the "2016 Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the 2016 Purchase Agreement, Lincoln Park has committed to purchase up to $12 million of our common stock, of which $10.3 million worth of our common stock remains issuable as of the date of this filing. Concurrently with the execution of the 2016 Purchase Agreement, we issued 10,000 shares of our common stock to Lincoln Park as a partial fee for its commitment to purchase shares of our common stock under the 2016 Purchase Agreement. From March 22, 2016 through the date of this filing, we sold 260,000 shares to Lincoln Park and issued 7,135 additional shares to Lincoln Park as additional commitment shares under the 2016 Purchase Agreement and received proceeds of $1,712,320. The shares that may be sold pursuant to the 2016 Purchase Agreement may be sold by us to Lincoln Park at our sole discretion from time to time over the remaining term of approximately 24 months from the date of the filing of this report, provided the registration statement registering the resale of shares sold to Lincoln Park under the 2016 Purchase Agreement remains effective. The purchase price for the shares that we may sell to Lincoln Park under the 2016 Purchase Agreement will fluctuate based on the price of our common stock. We have the right to control the timing and amount of any sales of our shares to Lincoln Park, except that, pursuant to the terms of our agreements with Lincoln Park, we would be unable to sell shares to Lincoln Park that would cause Lincoln Park to beneficially own more than 4.99% of our issued and outstanding common stock.

Depending on market liquidity at the time, sales of shares under the 2016 Purchase Agreement may cause the trading price of our common stock to fall. Additionally, further sales of our common stock, if any, to Lincoln Park under the 2016 Purchase Agreement will depend upon market conditions and other factors to be determined by us. Lincoln Park may ultimately purchase all, some or none of the shares of our common stock that may be sold pursuant to the 2016 Purchase Agreement and, after it has acquired shares, Lincoln Park may sell all, some or none of those shares. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

The issuance of our common stock pursuant to the terms of the asset purchase agreement with Hy Biopharma Inc. may cause dilution and the issuance of such shares of common stock, or the perception that such issuances may occur, could cause the price of our common stock to fall.

On April 1, 2014, we entered into an option agreement pursuant to which Hy Biopharma Inc. granted us an option to purchase certain assets, properties and rights (the “Hypericin Assets”) related to the development of Hy Biopharma’s synthetic hypericin product candidate for the treatment of CTCL, which we refer to as SGX301, from Hy Biopharma. In exchange for the option, we paid $50,000 in cash and issued 4,307 shares of common stock in the aggregate to Hy Biopharma and its assignees. We subsequently exercised the option, and on September 3, 2014, we entered into an asset purchase agreement with Hy Biopharma, pursuant to which we purchased the Hypericin Assets. Pursuant to the purchase agreement, we paid $275,000 in cash and issued 184,912 shares of common stock in the aggregate to Hy Biopharma and its assignees, and the licensors of the license agreement acquired from Hy Biopharma, and may issue up to an aggregate of $10 million worth of our common stock (subject to a cap equal to 19.99% of our issued and outstanding common stock) in the aggregate upon attainment of specified milestones. The next milestone payment will be payable if the Phase 3 clinical trial of SGX301 is successful in demonstrating efficacy and safety in the CTCL patient population. Also on September 3, 2014, we entered into the Registration Rights Agreement with Hy Biopharma, pursuant to which we have filed a registration statement with the SEC.

The number of shares that we may issue under the purchase agreement will fluctuate based on the market price of our common stock. Depending on market liquidity at the time, the issuance of such shares may cause the trading price of our common stock to fall.

We may ultimately issue all, some or none of the additional shares of our common stock that may be issued pursuant to the purchase agreement. We are required to register any shares issued pursuant to the purchase agreement for resale under the Securities Act of 1993, as amended. After any such shares are registered, the holders will be able to sell all, some or none of those shares. Therefore, issuances by us under the purchase agreement could result in substantial dilution to the interests of other holders of our common stock. Additionally, the issuance of a substantial number of shares of our common stock pursuant to the purchase agreement, or the anticipation of such issuances, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might

otherwise wish to effect sales.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We currently lease approximately 5,200 square feet of office space at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540. This office space currently serves as our corporate headquarters. In December 2014, we entered into a lease agreement through May 31, 2018 for existing and expanded office space. The rent for the first 12 months was approximately $12,300 per month, or approximately $20.85 per square foot. The rent increased to approximately $12,375 per month, or approximately $20.95 per square foot, for the next 12 months, and thereafter increased to approximately $12,460 per month, or approximately $21.13 per square foot for the remainder of the lease. Our office space is sufficient to satisfy our current needs.

Item 3. Legal Proceedings

From time to time, we are a party to claims and legal proceedings arising in the ordinary course of business. Our management evaluates our exposure to these claims and proceedings individually and in the aggregate and allocates additional monies for potential losses on such litigation if it is possible to estimate the amount of loss and if the amount of the loss is probable.

PART II

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

Our common stock is quoted on the Nasdaq under the symbol "SNGX." The following table sets forth, as adjusted for the reverse stock split of one-for-ten effective October 7, 2016, for the periods indicated, the high and low sales prices per share of our common stock as reported by the OTCQB through December 12, 2016 and the Nasdaq Capital Market, beginning with our uplisting to Nasdaq and trading on December 13, 2016.

	Price Range	
Period	High	Low
Year Ended December 31, 2015:		
First Quarter	$23.00	$9.80
Second Quarter	$29.50	$13.60
Third Quarter	$24.80	$9.10
Fourth Quarter	$14.40	$4.40
Year Ended December 31, 2016:		
First Quarter	$12.50	$6.20
Second Quarter	$9.00	$6.20
Third Quarter	$8.50	$5.60
Fourth Quarter	$8.11	$2.05
Year Ending December 31, 2017:		
First Quarter (through March 17, 2017)	$3.10	$1.90

On March 17, 2017, the last reported price of our common stock quoted on the Nasdaq was $2.70 per share. The Nasdaq prices set forth above represent inter-dealer quotations, without adjustment for retail mark-up, mark-down or commission, and may not represent the prices of actual transactions. Our stock is listed on the Nasdaq capital market under the under the symbol "SNGX." On December 13, 2016, our common stock warrants began trading on the Nasdaq Capital Market under the symbol "SNGXW". For the period December 13, 2016 through the fourth quarter ended December 31, 2016, the high and low sales price per warrant as reported by Nasdaq were $0.56 and $0.26, respectively. On March 17, 2017, the last reported price of our common stock warrant on Nasdaq was $0.50 per warrant.

Transfer Agent

The transfer agent and registrar for our common stock and warrants is American Stock Transfer & Trust Company, LLC. The address is 6201 15th Avenue, Brooklyn, NY 11219 and the telephone number is (718) 921-8200.

Holders of Common Stock

As of March 17, 2017, there were 336 holders of record of our common stock. As of such date, 5,472,532 shares of our common stock were issued and outstanding.

Dividends

We have never declared nor paid any cash dividends, and currently intend to retain all our cash and any earnings for use in our business and, therefore, do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of the Board of Directors and will be dependent upon our consolidated financial condition, results of operations, capital requirements and such other factors as the Board of Directors deems relevant.

Item 6. Selected Financial Data

Not applicable.

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

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements that reflect our current expectations about our future results, performance, prospects and opportunities. These forward-looking statements are subject to significant risks, uncertainties, and other factors, including those identified in "Risk Factors" above, which may cause actual results to differ materially from those expressed in, or implied by, any forward-looking statements. The forward-looking statements within this Form 10-K may be identified by words such as "believes," "anticipates," "expects," "intends," "may," "would," "will" and other similar expressions. However, these words are not the exclusive means of identifying these statements. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Except as expressly required by the federal securities laws, we undertake no obligation to publicly update or revise any forward-looking statements to reflect events or circumstances occurring subsequent to the filing of this Form 10-K with the SEC or for any other reason. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the SEC that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

Our Business Overview

We are a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense.

Our BioTherapeutics business segment is developing a novel photodynamic therapy (SGX301) utilizing topical synthetic hypericin activated with safe visible fluorescent light for the treatment of cutaneous T-cell lymphoma ("CTCL"), our first-in-class innate defense regulator technology, dusquetide (SGX942) for the treatment of oral mucositis in head and neck cancer, and proprietary formulations of oral beclomethasone 17,21-dipropionate ("BDP") for the prevention/treatment of gastrointestinal ("GI") disorders characterized by severe inflammation, including pediatric Crohn's disease (SGX203) and acute radiation enteritis (SGX201).

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine candidate, OrbeShield®, our GI acute radiation syndrome ("GI ARS") therapeutic candidate and SGX943, our melioidosis therapeutic candidate. The development of our vaccine programs currently is supported by our heat stabilization technology, known as ThermoVax®, under existing and on-going government contract funding. With the government contract from the National Institute of Allergy and Infectious Diseases ("NIAID"), we will attempt to

advance the development of RiVax™ to protect against exposure to ricin toxin. We have advanced the development of OrbeShield® for the treatment of GI ARS with funds received under our awarded government contracts with the Biomedical Advanced Research and Development Authority ("BARDA") and grants from NIAID.

An outline of our business strategy follows:

Complete enrollment and report preliminary results in our pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL;
Obtain agreement from the United States Food and Drug Administration (the "FDA") on a pivotal Phase 3 protocol of SGX942 for the treatment of oral mucositis in head and neck cancer patients and initiate the trial;
Initiate a pivotal Phase 3 clinical trial of SGX203 for the treatment of pediatric Crohn's disease;
Continue development of RiVax™ in combination with our ThermoVax® technology to develop new heat stable vaccines in biodefense with NIAID funding support;
Advance the preclinical and manufacturing development of OrbeShield® as a biodefense medical countermeasure for the treatment of GI ARS contingent upon government funding support;
Continue to apply for and secure additional government funding for each of our BioTherapeutics and Vaccines/BioDefense programs through grants, contracts and/or procurements;
Pursue business development opportunities for our pipeline programs, as well as explore merger/acquisition strategies; and
Acquire or in-license new clinical-stage compounds for development.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosure of contingent assets and liabilities. We evaluate these estimates and judgments on an on-going basis.

Intangible Assets

One of the most significant estimates or judgments that we make is whether to capitalize or expense patent and license costs. We make this judgment based on whether the technology has alternative future uses, as defined in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 730, *Research and Development*. Based on this consideration, we capitalized payments made to legal firms that are engaged in filing and protecting rights to intellectual property and rights for our current product candidates in both the domestic and international markets. We believe that patent rights are one of our most valuable assets. Patents and patent applications are a key component of intellectual property, especially in the early stage of product development, as their purchase and maintenance gives us access to key product development rights from our academic and industry partners. These rights can also be sold or sub-licensed as part of our strategy to partner our product candidates at each stage of development as the intangible assets have alternative future use. The legal costs incurred for these patents consist of work associated with filing new patents designed to protect, preserve and maintain our rights, and perhaps extend the lives of the patents. We capitalize such costs and amortize intangibles on a straight-line basis over their expected useful life – generally a period of 11 to 16 years.

These intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable or if the underlying program is no longer being pursued. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and carrying value of the related asset or group of assets.

Fair Value of Financial Instruments

FASB ASC 820 — *Fair Value Measurements and Disclosures,* defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. FASB ASC 820 requires disclosures about the fair value of all financial instruments, whether or not recognized, for financial statement purposes. Disclosures about the fair value of financial instruments are based on pertinent

information available to us on December 31, 2016. Accordingly, the estimates presented in the financial statements are not necessarily indicative of the amounts that could be realized on disposition of the financial instruments.

FASB ASC 820 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

The three levels of the fair value hierarchy are as follows:

Level 1 — Quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.

Level 2 — Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 includes financial instruments that are valued using models or other valuation methodologies. These models consider various assumptions, including volatility factors, current market prices and contractual prices for the underlying financial instruments. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.
Level 3 — Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable.

The carrying amounts reported in the consolidated balance sheet for cash and cash equivalents, contracts and grants receivable, accounts payable, accrued expenses, notes payable and accrued compensation approximate their fair value based on the short-term maturity of these instruments. We recognize all derivative financial instruments as assets or liabilities in the financial statements and measure them at fair value with changes in fair value reflected as current period income or loss unless the derivatives qualify as hedges. As a result, certain warrants issued in connection with our June 2013 registered public offering were accounted for as derivatives.

Revenue Recognition

Our revenues are primarily generated from government contracts and grants. The revenue from government contracts and grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the contracts and grants, plus a facilities and administrative rate that provides funding for overhead expenses and management fees. These revenues are recognized when expenses have been incurred by subcontractors or when we incur reimbursable internal expenses that are related to the government contracts and grants.

Research and Development Costs

Research and development costs are charged to expense when incurred in accordance with FASB ASC 730, *Research and Development*. Research and development includes costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies and materials, salaries, share-based compensation, employee benefits, equipment depreciation and allocation of various corporate costs. Purchased in-process research and development expense represents the value assigned or paid for acquired research and development for which there is no alternative future use as of the date of acquisition.

Accounting for Warrants

We considered FASB ASC 815, *Evaluating Whether an Instrument is Considered Indexed to an Entity's Own Stock*, which provides guidance for determining whether an equity-linked financial instrument (or embedded feature) issued by an entity is indexed to the entity's stock and, therefore, qualifying for the first part of the scope exception in paragraph 815-10-15. We evaluated the provisions and determined that warrants issued in connection with our June 2013 registered public offering contain provisions that protect holders from a decline in the issue price of our common stock (or "down-round" provisions) and contain net settlement provisions. Consequently, these warrants were recognized as liabilities at their fair value on the date of grant and remeasured at fair value on each reporting date. During November 2016, we entered into amendments with the holders of these warrants pursuant to which we agreed to reduce the exercise price (after giving effect to the one-for-ten reverse stock split effective October 7, 2016) from $5.10 per share to $0.80 per share and permit those warrants to be exercised on a "cashless exercise" basis, and we eliminated the "down-round" provision of those warrants not immediately exercised. As a result of the amendments, the fair value of the warrant liability was remeasured as of the date of the modification and the change in fair value was recognized in the statement of operations. The warrant liability was then reclassified to equity as the amended terms of the warrants qualified them to be accounted for as equity instruments. All other warrants that have been issued by us were indexed to our own stock and therefore are accounted for as equity instruments for 2016 and 2015.

Share-Based Compensation

Stock options are issued with an exercise price equal to the market price on the date of grant. Stock options issued to directors upon re-election vest quarterly for a period of one year (new director issuances are fully vested upon issuance). Stock options issued to employees generally vest 25% on the grant date, then 25% each subsequent year for a period of three years. Stock options vest over each three-month period from the date of issuance to the end of the three year period. These options have a ten year life for as long as the individuals remain employees or directors. In general, when an employee or director terminates their position the options will expire within three months, unless otherwise extended by the Board.

From time to time, we issue restricted shares of common stock to vendors and consultants as compensation for services performed. Typically these instruments vest upon issuance and therefore the entire share-based compensation expense is recognized upon issuance to the vendors and/or consultants.

Share-based compensation expense for options, warrants and shares of common stock granted to non-employees has been determined in accordance with FASB ASC 505-50, *Equity-Based Payments to Non-Employees*, and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employees is amortized as the options vest. The fair value is remeasured each reporting period until performance is complete.

The fair value of each option grant made during 2016 and 2015 was estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option vesting periods, which approximates the service period.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including the Company’s current and past performance, the market environment in which the Company operates, the utilization of past tax credits, and the length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. No current or deferred income taxes have been provided through December 31, 2016 due to the net operating losses incurred by the Company since its inception. The Company recognizes accrued interest and penalties associated

with uncertain tax positions, if any, as part of income tax expense. There were no tax related interest and penalties recorded for 2016 and 2015. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at December 31, 2016 and 2015.

Earnings Per Share

Basic earnings per share ("EPS") excludes dilution and is computed by dividing income (loss) available to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that shared in the earnings of the entity. Since there is a significant number of options and warrants outstanding, fluctuations in the actual market price can have a variety of results for each period presented.

Use of Estimates and Assumptions

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions such as the fair value of warrants and stock options and recovery of the useful life of intangibles that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ from those estimates.

Material Changes in Results of Operations

Year Ended December 31, 2016 Compared to 2015

For the year ended December 31, 2016, we had a net loss of $3,245,383 as compared to a net loss of $7,831,230 for the prior year, representing a decreased loss of $4,585,847 or 59%. Included in the net loss for December 31, 2016 and 2015 is the change in the fair value of the warrant liability related to warrants issued in connection with our June 2013 registered public financing of $1,541,241 of other income and $1,201,870 of other expense, respectively. During the year ended December 31, 2016, the price protection provision of the warrants was eliminated through an amendment and the warrant liability was reclassified to equity as the amended terms of the warrants qualified them to be accounted for as equity instruments.

For the year ended December 31, 2016 and 2015, revenues and associated costs related to government contracts and grants awarded in support of our development of OrbeShield® for the treatment of GI ARS and RiVax™. and other development programs. For the year ended December 31, 2016, we had revenues of $10,448,794 as compared to $8,768,390 for the prior year, representing an increase of $1,680,404 or 19%. The increase in revenues was a result of increased activities performed under our government contracts associated with RiVax™

We incurred costs related to contract and grant revenues in the year ended December 31, 2016 and 2015 of $8,433,671 and $6,882,204, respectively, representing an increase of $1,551,467 or 23%. The costs primarily relate to the increased development activity in these programs and the resulting payments made to subcontractors and the allocated employee costs in connection with research performed pursuant to the contracts and grants.

Our gross profit for the year ended December 31, 2016 was $2,015,123 or 19%, as compared to $1,886,186 or 22% for the prior year, representing an increase of $128,937 or 7%. This increase in gross profit is due primarily to the increased activity in our RiVax™ development contracts. The decrease in gross profit percentage is attributable to the management fee associated with certain contracts payable upon the achievement of development milestones.

Research and development expenses decreased by $1,103,972 or 20%, to $4,295,867 for the year ended December 31, 2016 as compared to $5,399,839 for the prior year. This decrease is primarily related to the manufacturing expenditures for the pediatric Crohn’s development program incurred during 2015, as well as the completion of patient enrollment in the Phase 2 trial of SGX942 for the treatment of oral mucositis in head and neck cancer in late 2015.

General and administrative expenses decreased by $167,785 or 5%, to $3,428,838 for the year ended December 31, 2016, as compared to $3,596,623 for the prior year. This decrease is primarily related to a decrease in professional fees.

Other income (expense) for the year ended December 31, 2016 was $1,934,056 as compared to $(1,209,887) for the prior year, reflecting a change of $3,143,943 or 260%. The change is primarily due to the change in the fair value of the warrant liability resulting in $(1,201,870) of other expense in 2015 compared to $1,541,241 of other income in 2016. In addition, $390,599 is included in other income in 2016 related to an amount that had previously been accrued. We were notified that the amount was no longer considered outstanding by the counterparty and therefore reversed the amount accrued, resulting in other income.

The State of New Jersey’s Technology Business Tax Certificate Program allows certain high technology and biotechnology companies to sell unused net operating loss (“NOL”) carryforwards to other New Jersey-based corporate taxpayers. In accordance with this program, during the year ended December 31, 2016, we sold New Jersey NOL carryforwards, resulting in the recognition of $530,143 of income tax benefit as compared to $488,933 for the year ended December 31, 2015. There can be no assurance as to the continuation or magnitude of this program in future years.

Business Segments

We maintain two active business segments for the years ended December 31, 2016 and December 31, 2015: Vaccines/BioDefense and BioTherapeutics.

Revenues for the Vaccines/BioDefense business segment for the year ended December 31, 2016 were $10,448,794 as compared to $8,754,418 for the year ended December 31, 2015, representing an increase of $1,694,376 or 19%. This increase in revenues was a result of the increased development activity under our RiVax™ contracts. Revenues for the BioTherapeutics business segment for the year ended December 31, 2016 were $0 as compared to $13,972 for the year ended December 31, 2015. The revenue for the year ended December 31, 2015 is related to work performed under our oral mucositis grant which expired in early 2015.

Income from operations for the Vaccines/BioDefense business segment for the year ended December 31, 2016 was $1,563,884 as compared to $1,263,709 for the year ended December 31, 2015. Income from operations is primarily attributable to our gross margins related to our government contracts. Loss from operations for the BioTherapeutics business segment for the year ended December 31, 2016 was $3,399,933 as compared to $4,487,988 for the year ended December 31, 2015, representing a decrease of $1,088,055 or 24%. This decreased loss is due primarily to the completion of patient enrollment in the Phase 2 clinical trial of SGX942 in patients suffering from oral mucositis associated with their CRT for head and neck cancer and offset by expenses incurred in the initiation of the pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL.

Amortization and depreciation expense for the Vaccines/BioDefense business segment for the year ended December 31, 2016 was $40,186 as compared to $39,925 for the year ended December 31, 2015. Amortization and depreciation expense for the BioTherapeutics business segment for the year ended December 31, 2016 was $41,395 as compared to $199,661 for the year ended December 31, 2015. The $158,266 decrease in amortization and depreciation expense for the BioTherapeutics segment was the result of a license agreement becoming fully amortized during the year ended December 31, 2015 and accordingly, there was no amortization expense recognized during the year ended December 31, 2016 for the license agreement.

Financial Condition and Liquidity

Cash and Working Capital

As of December 31, 2016, we had cash and cash equivalents of $8,772,567 as compared to $4,921,545 as of December 31, 2015, representing an increase of $3,851,022 or 78%. The increase in cash was primarily the result of net proceeds received from financing activities in 2016 of $8,840,602, primarily from a public offering of our stock and our stock purchase agreement with SciClone Pharmaceuticals, Inc. This was partially offset by cash used in operations of $4,982,421. As of December 31, 2016, we had working capital of $7,243,918 as compared to working capital of $2,179,694, which excludes a non-cash warrant liability of $2,434,101, as of December 31, 2015, representing an increase of $5,064,224 or 232%. The increase in working capital was primarily the result of the cash received from our financing activities.

Based on our current rate of cash outflows, cash on hand, proceeds from government contract and grant programs, proceeds available from the equity line with Lincoln Park, LLC (“Lincoln Park”) and proceeds from the State of New Jersey Technology Business Tax Certificate Transfer Program, management believes that its current cash will be sufficient to meet the anticipated cash needs for working capital and capital expenditures through at least March 31, 2018, and therefore no uncertainties exist regarding the Company’s ability to continue its operations as a going concern.

Our plans with respect to our liquidity management include, but are not limited to, the following:

We have up to $17.3 million in active contract funding still available to support our associated research programs in 2017 and beyond, provided the federal agencies exercise all options and do not elect to terminate the contracts for convenience. We plan to submit additional contract and grant applications for further support of these programs with various funding agencies;
We have continued to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners and expect to continue to do so for the foreseeable future;

We will pursue NOL sales in the State of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of $530,143 in proceeds from the sale of NJ NOL in 2016, we expect to participate in the program during 2017 and beyond as the program is available;
We plan to pursue potential partnership for our pipeline programs. However, there can be no assurances that we can consummate such transactions;
We have $10.3 million available from an equity facility expiring in March 2019; and
We may seek additional capital in the private and/or public equity markets to continue our operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. We are currently evaluating additional equity/debt financing opportunities on an ongoing basis and may execute them when appropriate. However, there can be no assurances that we can consummate such a transaction, or consummate a transaction at favorable pricing.

Expenditures

Under our budget and based upon our existing product development agreements and license agreements pursuant to letters of intent and option agreements, we expect our total research and development expenditures for the next 12 months to be approximately $10.7 million before any contract or grant reimbursements, of which $5.8 million relates to the BioTherapeutics business and $4.9 million relates to the Vaccines/BioDefense business. We anticipate contract reimbursements in the next 12 months of approximately $4.9 million to offset research and development expenses in the Vaccines/BioDefense business segment.

The table below details our costs for research and development by program and amounts reimbursed for the years ended December 31, 2016 and 2015:

	2016	2015
Research & Development Expenses		
Oral BDP	$184,192	$74,543
RiVax™ & ThermoVax® Vaccines	447,993	622,908
Dusquetide (SGX942)	1,325,796	2,216,632
SGX943	1,643	10,671
SGX301	1,836,974	2,141,175
Other	499,269	333,910
Total	$4,295,867	$5,399,839
Reimbursed under Government Contracts and Grants		
OrbeShield®	$3,797,178	$5,240,377
RiVax™ & ThermoVax® Vaccines	4,636,493	1,557,082
Other	-	84,745
Total	$8,433,671	$6,882,204
Grand Total	$12,729,538	$12,282,043

Contractual Obligations

We have commitments of approximately $500,000 at December 31, 2016 for several licensing agreements with consultants and universities. Additionally, we have collaboration and license agreements, which upon clinical or commercialization success, may require the payment of milestones of up to $7.9 million and/or royalties up to 6% of net sales of covered products, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

In December 2014, we entered into a lease agreement through May 31, 2018 for existing and expanded office space. The rent for the first 12 months was approximately $12,300 per month, or approximately $20.85 per square foot. This rent increased to approximately $12,375 per month, or approximately $20.95 per square foot, for the next 12 months, and thereafter increased to approximately $12,460 per month, or approximately $21.13 per square foot for the remainder of the lease.

On September 3, 2014, we entered into an asset purchase agreement with Hy Biopharma, Inc. ("Hy Biopharma") pursuant to which we acquired certain intangible assets, properties and rights of Hy Biopharma related to the development of Hy BioPharma's synthetic hypericin product. As consideration for the assets acquired, we paid $275,000 in cash and issued 184,912 shares of common stock with a fair value based on our stock price on the date of grant of $3,750,000. These amounts were charged to research and development expense during the third quarter of 2014 as the assets will be used in our research and development activities and do not have alternative future use pursuant to generally accepted accounting principles in the United States. Provided all future success-oriented milestones are attained, we will be required to make payments of up to $10.0 million, if and when achieved. Payments will be payable in restricted securities; not to exceed 19.9% ownership of our outstanding stock.

In February 2007, our Board of Directors authorized the issuance of 5,000 shares of our common stock to Dr. Schaber immediately prior to the completion of a transaction, or series or a combination of related transactions negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of our assets are transferred from us and/or our stockholders to a third party. Dr. Schaber's amended employment agreement includes our obligation to issue such shares if such event occurs.

As a result of the above agreements, we have future contractual obligations over the next five years as follows:

Year	Research and Development	**Property and Other Leases**	**Total**
2017	$ 100,000	$151,000	$251,000
2018	100,000	52,000	152,000
2019	100,000	-	100,000
2020	100,000	-	100,000
2021	100,000	-	100,000
Total	$ 500,000	$203,000	$703,000

Item 8. Financial Statements and Supplementary Data

The information required by this Item 8 is contained on pages F-1 through F-24 of this Annual Report on Form 10-K and is incorporated herein by reference.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are the Company's controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the possible controls and procedures.

Our management has evaluated, with the participation of our principal executive officer and principal financial officer, the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this report. Based upon that evaluation, our management, including our principal executive officer and principal financial officer, has concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Company management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by the Company's Board of Directors, management and other personnel 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 and includes those policies and procedures that:

pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
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
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 inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2016. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in *Internal Control-Integrated Framework, 2013*.

Based on our assessment, management has concluded that, as of December 31, 2016, the Company's internal control over financial reporting is effective.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting identified in connection with the evaluation of such internal control that occurred during the Company's last fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The table below contains information regarding the current members of the Board of Directors and executive officers. The ages of individuals are provided as of March 17, 2017:

Name	Age	Position
Christopher J. Schaber, PhD	50	Chairman of the Board, Chief Executive Officer and President
Keith L. Brownlie, CPA	64	Director
Marco M. Brughera, DVM	61	Director
Gregg A. Lapointe, CPA	58	Director
Robert J. Rubin, MD	71	Director
Jerome B. Zeldis, MD, PhD	66	Director
Oreola Donini, PhD	45	Chief Scientific Officer and Senior Vice President
Karen Krumeich	63	Chief Financial Officer, Senior Vice President and Corporate Secretary
Richard Straube, MD	65	Chief Medical Officer and Senior Vice President

Christopher J. Schaber, PhD has over 27 years of experience in the pharmaceutical and biotechnology industry. Dr. Schaber has been our President and Chief Executive Officer and a director since August 2006. He was appointed Chairman of the Board on October 8, 2009. He also serves on the board of directors of the Biotechnology Council of New Jersey ("BioNJ") since January 2009 and the Alliance for Biosecurity since October 2014, and has been a member of the corporate councils of both the National Organization for Rare Diseases ("NORD") and the American Society for Blood and Marrow Transplantation ("ASBMT") since October 2009 and July 2009, respectively. Prior to joining Soligenix, Dr. Schaber served from 1998 to 2006 as Executive Vice President and Chief Operating Officer of Discovery Laboratories, Inc., where he was responsible for overall pipeline development and key areas of commercial operations, including regulatory affairs, quality control and assurance, manufacturing and distribution, pre-clinical and clinical research, and medical affairs, as well as coordination of commercial launch preparation activities. From 1996 to 1998, Dr. Schaber was a co-founder of Acute Therapeutics, Inc., and served as its Vice President of Regulatory Compliance and Drug Development. From 1994 to 1996, Dr. Schaber was employed by Ohmeda PPD, Inc., as Worldwide Director of Regulatory Affairs and Operations. From 1989 to 1994, Dr. Schaber held a variety of regulatory, development and operations positions with The Liposome Company, Inc., and Elkins-Sinn Inc., a division of Wyeth-Ayerst Laboratories. Dr. Schaber received his BA degree from Western Maryland College, his MS degree in Pharmaceutics from Temple University School of Pharmacy and his PhD degree in Pharmaceutical Sciences from the Union Graduate School. Dr. Schaber was selected to serve as a member of our Board of Directors because of his extensive experience in drug development and pharmaceutical operations, including his experience as an executive senior officer with our Company and Discovery Laboratories, Inc., and as a member of the board of directors of BioNJ; because of his proven ability to raise funds and provide access to capital; and because of his advanced degrees in science and business.

Keith L. Brownlie, CPA has been a director since June 2011. Mr. Brownlie currently serves on the Board of Directors of Rxi Pharmaceuticals Corporation, a publicly traded biotechnology company involved in the research and development of RNAi products for the diagnosis, prevention and treatment of human diseases, a position he has held since June 2012. From July 2013 until December 2014, Mr. Brownlie served on the Board of Directors of Cancer Genetics, Inc., a publicly traded, early stage diagnostics company. Mr. Brownlie served as a member of the Board of Directors of Epicept Corporation, a publicly traded, specialty pharmaceutical company focused on the clinical development and commercialization of pharmaceutical products for the treatment of cancer and pain, from April 2011 to August 2013 when Epicept Corporation merged with Immune Pharmaceuticals, Inc. From 1974 to 2010, Mr. Brownlie worked with the accounting firm of Ernst & Young LLP where he served as audit partner for numerous public companies and was the Life Sciences Industry Leader for the New York metro area. Mr. Brownlie received a BS in Accounting from Lehigh University and is a Certified Public Accountant in the state of New Jersey. Mr. Brownlie co-founded the New Jersey Entrepreneur of the Year Program and was Vice President and Trustee of the New Jersey Society of CPAs. In addition, he served as accounting advisor to the board of the Biotechnology Council of New Jersey. Mr. Brownlie was selected to serve as a member of our Board of Directors because of his vast experience as an audit partner for numerous public companies and as a director of publicly traded specialty pharmaceutical and biotechnology companies.

Marco M. Brughera, DVM joined the Board of Directors in October 2013. He is the Global Head Rare Disease of the Leadiant Group, a position he has held since October 2012. Dr. Brughera serves as CEO on the board of directors of Leadiant Biosciences SpA and as director on the board of directors of Leadiant Biosciences Ltd, Leadiant Biosciences, Inc., Fennec Pharmaceuticals, Inc. and Lee's Pharmaceutical Holdings Ltd. From December 2011 through January 2014, Dr. Brughera served on the Board of Directors of Gentium S.p.A., a publicly traded biopharmaceutical company. From January 2011 through October 2012, Dr. Brughera held several other positions with the Sigma-Tau Group, including Corporate Research and Development Managing Director of Sigma-Tau I ndustrie Farmaceutiche Riuntite S.p.A., President of Sigma-Tau Research Switzerland S.A. and board member of Sigma-Tau Pharmaceuticals, Inc., and of Sigma-Tau Rare Diseases S.A. and Sigma-Tau Pharma Ltd. From 2004 to 2010, Dr. Brughera served as the Vice President of Preclinical Development at Nerviano Medical Sciences S.r.l. ("NMS Group"), a pharmaceutical oncology-focused integrated discovery and development company. He also served as the Managing Director at Accelera, S.r.l., an independent contract research organization affiliated with the NMS Group. From 1999 to 2004, Dr. Brughera held several senior level positions in the areas of discovery and development toxicology with Pharmacia Corporation and Pfizer, Inc. Prior to 1999, he held various positions at Pharmacia & Upjohn Company, Inc., and Farmitalia Carlo Erba S.p.A., an Italian pharmaceutical company. Dr. Brughera earned his degree in veterinary medicine from the University of Milan and is a European Registered Toxicologist. Dr. Brughera was selected to serve as a member our Board of Directors because of his background in the areas of drug discovery and development and his experience as an executive officer and a director in the pharmaceutical industry.

Gregg A. Lapointe, CPA, MBA has been a director since March 2009. Mr. Lapointe is currently CEO of Cerium Pharmaceuticals, Inc. and serves on the Board of Directors of SciClone Pharmaceuticals, Inc., Raptor Pharmaceuticals, Inc., ImmunoCellular Therapeutics Ltd. and the Board of Trustees of the Keck Graduate Institute of Applied Life Sciences. He has previously served on the Board of Directors of the Pharmaceuticals Research and Manufacturers of America (PhRMA) and Questcor Pharmaceuticals, Inc. He previously served in varying roles for Sigma-Tau Pharmaceuticals, Inc., a private biopharmaceutical company, from September 2001 through February 2012, including Chief Operating Officer from November 2003 to April 2008 and Chief Executive Officer from April 2008 to February 2012. From May, 1996 to August 2001, he served as Vice President of Operations and Vice President, Controller of AstenJohnson, Inc. (formerly JWI Inc.). Prior to that, Mr. Lapointe spent several years in the Canadian medical products industry in both distribution and manufacturing. Mr. Lapointe began his career at Price Waterhouse. Mr. Lapointe received his B.A. degree in Commerce from Concordia University in Montreal, Canada, a graduate diploma in Accountancy from McGill University and his M.B.A. degree from Duke University. He is a C.P.A. in the state of Illinois. Mr. Lapointe was selected to serve as a member of our Board of Directors because of his significant experience in the areas of global strategic planning and implementation, business development, corporate finance, and acquisitions, and his experience as an executive officer and board member in the pharmaceutical and medical products industries.

Robert J. Rubin, MD has been a director since October 2009. Dr. Rubin was a clinical professor of medicine at Georgetown University from 1995 until 2012 when he was appointed a Distinguished Professor of Medicine. From 1987 to 2001, he was president of the Lewin Group (purchased by Quintiles Transnational Corp. in 1996), an international health policy and management consulting firm. From 1994 to 1996, Dr. Rubin served as Medical Director of ValueRx, a pharmaceutical benefits company. From 1992 to 1996, Dr. Rubin served as President of Lewin-VHI, a health care consulting company. From 1987 to 1992, he served as President of Lewin-ICF, a health care consulting company. From 1984 to 1987, Dr. Rubin served as a principal of ICF, Inc., a health care consulting

company. From 1981 to 1984, Dr. Rubin served as the Assistant Secretary for Planning and Evaluation at the Department of Health and Human Services and as an Assistant Surgeon General in the United States Public Health Service. Dr. Rubin has served on the Board of BioTelemetry, Inc. (formerly known as CardioNet, Inc.) since 2007. He is a board certified nephrologist and internist. Dr. Rubin received an undergraduate degree in Political Science from Williams College and his medical degree from Cornell University Medical College. Dr. Rubin was selected to serve as a member of our Board of Directors because of his vast experience in the health care industry, including his experience as a nephrologist, internist, clinical professor of medicine and Assistant Surgeon General, and his business experience in the pharmaceutical industry.

Jerome B. Zeldis, MD, PhD has been a director since June 2011. Dr. Zeldis is currently Chief Medical Officer and President of Clinical Development of Sorrento Therapeutics, Inc. Previously, Dr. Zeldis was Chief Executive Officer of Celgene Global Health and Chief Medical Officer of Celgene Corporation, a publicly traded, fully integrated biopharmaceutical company. He was employed by Celegene from 1997 to 2016. From September 1994 to February 1997, Dr. Zeldis worked at Sandoz Research Institute and the Janssen Research Institute in both clinical research and medical development. He has been a board member of several biotechnology companies and is currently on the boards of the NJ Chapter of the Arthritis Foundation, the Castleman's Disease Organization and PTC Therapeutics, Inc. and Alliqua, Inc. Additionally, he has served as Assistant Professor of Medicine at the Harvard Medical School (from July 1987 to September 1988), Associate Professor of Medicine at University of California, Davis from (September 1988 to September 1994), Clinical Associate Professor of Medicine at Cornell Medical School (January 1995 to December 2003) and Professor of Clinical Medicine at the Robert Wood Johnson Medical School (July 1998 to June 2010). Dr. Zeldis received a BA and an MS from Brown University, and an MD, and a PhD in Molecular Biophysics and Biochemistry from Yale University. Dr. Zeldis trained in Internal Medicine at the UCLA Center for the Health Sciences and in Gastroenterology at the Massachusetts General Hospital and Harvard Medical School. Dr. Zeldis was selected to serve as a member of our Board of Directors because of his experience as an executive officer of a publicly traded biopharmaceutical company and in clinical research and medical development, and his experience in the health care industry, including his experience as an internist, gastroenterologist and professor of medicine.

Oreola Donini, PhD, has been with our company since August 15, 2013 and is currently our Chief Scientific Officer and Senior Vice President, a position she has held since December 5, 2014. Dr. Donini served as our Vice President of Preclinical Research and Development from August 15, 2013 until December 4, 2014. She has more than 15 years' experience in drug discovery and preclinical development with start-up biotechnology companies. From 2012 to 2013, Dr. Donini worked with ESSA Pharma Inc. as Vice President Research and Development. From 2004 to 2013, Dr. Donini worked with Inimex Pharmaceuticals Inc., ("Inimex"), lastly as Senior Director of Preclinical R&D from 2007-2013. Prior to joining Inimex, she worked with Kinetek Pharmaceuticals Inc., developing therapies for infectious disease, cancer and cancer supportive care. Dr. Donini is a co-inventor and leader of the Company's SGX94 innate defense regulator technology, developed by Inimex and subsequently acquired by the Company. She was responsible for overseeing the manufacturing and preclinical testing of SGX94, which demonstrated efficacy in combating bacterial infections and mitigating the effects of tissue damage due to trauma, infection, radiation and/or chemotherapy treatment. These preclinical studies resulted in a successful Phase 1 clinical study and clearance of Phase 2 protocols for oral mucositis in head and neck cancer and acute bacterial skin and skin structure infections. While with ESSA Pharma Inc. as the Vice President of Research and Development, Dr. Donini led the preclinical testing of a novel N-terminal domain inhibitor of the androgen receptor for the treatment of prostate cancer. While with Kinetek Pharmaceuticals Inc., her work related to the discovery of novel kinase and phosphatase inhibitors for the treatment of cancer. Dr. Donini received her PhD from Queen's University in Kinston, Ontario, Canada and completed her post-doctoral work at the University of California, San Francisco. Her research has spanned drug discovery, preclinical development, manufacturing and clinical development in infectious disease, cancer and cancer supportive care.

Karen Krumeich has been with our company since June 2016 and is currently our Senior Vice President and Chief Financial Officer. Ms. Krumeich has served as Chief Financial Officer and Vice President of Finance for public and private emerging-growth, start-up and national companies in various sectors of healthcare, including pharmaceuticals, medical devices and healthcare service companies. She has expertise in equity financings, both private and public,

Sarbanes-Oxley compliance, acquisitions and integrations, strategic business development and operations analysis. Most recently Ms. Krumeich was the Vice President of Finance for Cerecor Inc., a clinical stage neuroscience company. At Cerecor she was involved in the company's equity financings and was responsible for all finance and administrative functions. Prior to joining Cerecor she was a CFO Partner with Tatum, LLC, a national consulting firm, and a member of the firm's National Healthcare Group. As a Partner with Tatum, she served as Interim Chief Financial Officer for drug development and medical device companies. Prior to joining Tatum in 2006, she was the Vice President of Finance and Chief Financial Officer of Strata Skin Sciences, Inc. (formerly Mela Sciences, Inc.), a publicly traded development-stage medical device company. At Mela Sciences, she played a key role in the company's initial public offering and was responsible for all functional areas of finance and accounting, administration, and investor relations. As Vice President of Finance of Gran Care Pharmacy, Inc., she was responsible for the financial leadership of the pharmacy division and directed an aggressive acquisition program. Ms. Krumeich began her career with a B.S. in Pharmacy from the University of Toledo, subsequently completed an accounting major and transitioned into finance after completing the CPA exam.

Richard Straube, MD has been with our company since January 2014 and is currently our Senior Vice President and Chief Medical Officer. Dr. Straube is a board-certified pediatrician with 35 years' experience in both academia and industry, including clinical research experience in host-response modulation. From 2009 until joining our company, he was Chief Medical Officer of Stealth Peptides Incorporated, a privately-held, clinical stage, biopharmaceutical company. Prior to joining the Company, Dr. Straube served from 1988 to 1993 in various capacities, including most recently as Senior Director, Infectious Diseases and Immunology, Clinical Research, for Centocor, Inc., a privately-held biopharmaceutical company focused on developing monoclonal antibody-based diagnostics. While at Centocor, Inc., Dr. Straube was responsible for the initial anti-cytokine and anti-endotoxin programs targeted at ameliorating inappropriate host responses to infectious and immunologic challenges. Programs that he managed at Centocor, Inc. include assessments of immunomodulation using monoclonal removal of inciting molecular triggers, removal of internal immune-messengers, augmentation of normal host defenses, and maintenance of normal sub-cellular function in the face of injury. From 1993 to 1995, Dr. Straube was Director of Medical Affairs at T-cell Sciences, Inc., a privately-held biotechnology company. From 1995 to 1997, he was Director of Clinical Investigations of the Pharmaceutical Products Division of Ohmeda Corp., a privately-held biopharmaceutical company. He served from 1998 to 2007 as Executive Vice President of Research and Development and Chief Scientific Officer at INO Therapeutics LLC, a privately-held biotherapeutics company, where he was responsible for the clinical trials and subsequent approval of inhaled nitric oxide for the treatment of persistent pulmonary hypertension of the newborn. From 2007 to 2009, Dr. Straube was the Chief Medical Officer at Critical Biologics Corporation, a privately-held biotechnology company. Dr. Straube received his medical degree and residency training at the University of Chicago, completed a joint adult and pediatrician infectious diseases fellowship at the University of California, San Diego ("UCSD"), and as a Milbank Scholar completed training in clinical trial design at the London School of Hygiene and Tropical Medicine. While on the faculty at the UCSD Medical Center, his research focused on interventional studies for serious viral infections.

Board Leadership Structure

Our Board of Directors believes that Dr. Schaber's service as both the Chairman of our Board of Directors and our Chief Executive Officer is in the best interest of our Company and our stockholders. Dr. Schaber possesses detailed and in-depth knowledge of the issues, opportunities and challenges facing our Company and our business and, therefore, is best positioned to develop agendas that ensure that the Board of Directors' time and attention are focused on the most important matters. His combined role enables decisive leadership, ensures clear accountability, and enhances our ability to communicate our message and strategy clearly and consistently to our stockholders, employees, and collaborative partners.

Messrs. Brownlie and Lapointe, Dr. Brughera, Dr. Rubin, and Dr. Zeldis are independent and the Board of Directors believes that the independent directors provide effective oversight of management. Moreover, in addition to feedback provided during the course of meetings of the Board of Directors, the independent directors hold executive sessions. Following an executive session of independent directors, the independent directors' report back to the full Board of Directors regarding any specific feedback or issues, provide the Chairman with input regarding agenda items for Board of Directors and Committee meetings, and coordinate with the Chairman regarding information to be provided to the independent directors in performing their duties. The Board of Directors believes that this approach

appropriately and effectively complements the combined Chairman/Chief Executive Officer structure.

Although the Company believes that the combination of the Chairman and Chief Executive Officer roles is appropriate under the current circumstances, our corporate governance guidelines do not establish this approach as a policy, and the Board of Directors may determine that it is more appropriate to separate the roles in the future.

Section 16(a) Beneficial Ownership Reporting Compliance

We are required to identify each person who was an officer, director or beneficial owner of more than 10% of our registered equity securities during our most recent fiscal year and who failed to file on a timely basis reports required by Section 16(a) of the Exchange Act.

To our knowledge, based solely on review of these filings and written representations from the certain reporting persons, we believe that during the year ended December 31, 2016, our officers, directors and significant stockholders have timely filed the appropriate form under Section 16(a) of the Exchange Act.

Committees of the Board of Directors

Our Board of Directors has the following three committees: (1) Compensation, (2) Audit and (3) Nominating and Corporate Governance. Our Board of Directors has adopted a written charter for each of these committees, which are available on our website at www.soligenix.com under the “Investors” section.

Director	**Audit Committee**	**Compensation Committee**	**Nominating and Corporate Governance Committee**
Keith L. Brownlie, CPA			
Marco M. Brughera, DVM			
Gregg A. Lapointe, CPA			
Robert J. Rubin, MD			
Jerome B. Zeldis, MD, PhD			

– Committee Chair

– Member

Audit Committee

Our Board of Directors has an Audit Committee, which is comprised of Mr. Brownlie (Chair), Mr. Lapointe and Dr. Rubin. The Audit Committee assists our Board of Directors in monitoring the financial reporting process, the internal control structure and the independent registered public accountants. Its primary duties are to serve as an independent and objective party to monitor the financial reporting process and internal control system, to review and appraise the audit effort of the independent registered public accountants and to provide an open avenue of communication among the independent registered public accountants, financial and senior management, and our Board of Directors. Our Board of Directors has determined that Mr. Brownlie, Mr. Lapointe and Dr. Rubin are "independent" directors, within the meaning of applicable listing standards of The Nasdaq Stock Market LLC ("Nasdaq") and the Exchange Act and the rules and regulations thereunder. Our Board of Directors has also determined that the members of the Audit Committee are qualified to serve on the committee and have the experience and knowledge to perform the duties required of the committee and that Mr. Brownlie qualifies as an "audit committee financial expert" as that term is defined in the applicable regulations of the Exchange Act.

Compensation Committee

Our Board of Directors has a Compensation Committee, which is comprised of Dr. Rubin (Chair), Dr. Brughera and Dr. Zeldis. The Compensation Committee is responsible for reviewing and approving the executive compensation program, assessing executive performance, setting salary, making grants of annual incentive compensation and approving certain employment agreements. Our Board of Directors has determined that Dr. Brughera, Dr. Rubin, and Dr. Zeldis are "independent" directors within the meaning of applicable listing standards of Nasdaq and the Exchange Act and the rules and regulations thereunder.

Nominating and Corporate Governance Committee

Our Board of Directors has a Nominating and Corporate Governance Committee ("Nominating Committee"), which is comprised of Dr. Zeldis (Chair), Mr. Brownlie and Mr. Lapointe. The Nominating Committee makes recommendations to the Board of Directors regarding the size and composition of our Board of Directors, establishes procedures for the nomination process, identifies and recommends candidates for election to our Board of Directors. Our Board of Directors has determined that Dr. Zeldis, Mr. Brownlie and Mr. Lapointe are "independent" directors, as such term is defined by the applicable Nasdaq listing standards.

Code of Ethics

We have adopted a code of ethics that applies to all of our executive officers and senior financial officers (including our chief executive officer, chief financial officer, chief accounting officer and any person performing similar functions). A copy of our code of ethics is publicly available on our website at www.soligenix.com under the "Investors" section. If we make any substantive amendments to our code of ethics or grant any waiver, including any implicit waiver, from a provision of the code to our chief executive officer, chief financial officer or chief accounting officer, we will disclose the nature of such amendment or waiver in a Current Report on Form 8-K.

Diversity Considerations in Identifying Director Nominees

We do not have a formal diversity policy or set of guidelines in selecting and appointing directors that comprise our Board of Directors. However, when making recommendations to our Board of Directors regarding the size and composition of our Board of Directors, our Nominating Committee does consider each individual director's qualifications, skills, business experience and capacity to serve as a director and the diversity of these attributes for the Board of Directors as a whole.

Compensation Committee Interlocks and Insider Participation

No member of our Compensation Committee is or has at any time during the past year been one of our officers or employees. None of our executive officers currently serves or in the past year has served as a member of the Board of Directors or Compensation Committee of any entity that has one or more executive officers serving on our Board of Directors or Compensation Committee.

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Item 11. Executive Compensation

Summary Compensation

The following table contains information concerning the compensation paid during each of the two years ended December 31, 2016 to our Chief Executive Officer and each of the two other most highly compensated executive officers during 2016 (collectively, the "Named Executive Officers").

Summary Compensation

Name	Position	Year	Salary	Bonus	Option Awards	All Other Compensation	Total
Christopher J. Schaber[1]	CEO & President	2016	$434,969	$121,792		$ 41,511	$598,272
		2015	$424,360	$101,846	$158,200	$ 36,201	$720,607
Karen Krumeich[2]	CFO & Senior VP	2016	$120,250	$23,976	$74,000	$ 7,849	$226,075
		2015	-	-	-	-	-
Richard C. Straube[3]	CMO & Senior VP	2016	$316,725	$68,413		$ 27,919	$413,057
		2015	$309,000	$58,401	$79,100	$ 25,656	$472,157
Joseph M. Warusz[4]	Former VP & Acting CFO	2016	$151,236			$ 20,472	$171,708
		2015	$196,730	$38,362	$62,150	$ 24,676	$321,918

[1] Dr. Schaber's 2016 bonus payment of $121,792 was deferred until April 1, 2017. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by the Company.

[2] On June 16, 2016 Ms. Krumeich was appointed Senior Vice President and Chief Financial Officer. Ms. Krumeich deferred the payment of her 2016 bonus of $23,976 until January 15, 2017. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by the Company.

[3] Dr. Straube deferred the payment of his 2016 bonus of $68,413 until January 15, 2017. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation

represents health insurance costs paid by the Company.

4 Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by the Company. Other compensation represents health insurance costs paid by the Company. On June 30, 2016, Mr. Warusz retired from the Company.

Employment and Severance Agreements

In August 2006, we entered into a three-year employment agreement with Christopher J. Schaber, PhD. Pursuant to this employment agreement we agreed to pay Dr. Schaber a base salary of $300,000 per year and a minimum annual bonus of $100,000. Dr. Schaber's employment agreement automatically renews every three years, unless otherwise terminated, and was automatically renewed in December 2007, December 2010, December 2013 and December 2016 for an additional term of three years. We agreed to issue him options to purchase 12,500 shares of our common stock, with one third immediately vesting and the remainder vesting over three years. Upon termination without "Just Cause" as defined by this agreement, we would pay Dr. Schaber nine months of severance, as well as any accrued bonuses, accrued vacation, and we would provide health insurance and life insurance benefits for Dr. Schaber and his dependents. No unvested options shall vest beyond the termination date. Dr. Schaber's monetary compensation (base salary of $300,000 and bonus of $100,000) remained unchanged from 2006 with the 2007 renewal. Upon a change in control of the Company due to merger or acquisition, all of Dr. Schaber's options shall become fully vested, and be exercisable for a period of five years after such change in control (unless they would have expired sooner pursuant to their terms). In the event of his death during the term of the agreement, all of his unvested options shall immediately vest and remain exercisable for the remainder of their term and become the property of Dr. Schaber's immediate family.

In February 2007, our Board of Directors authorized the issuance of 5,000 shares to Dr. Schaber immediately prior to the completion of a transaction, or series or a combination of related transactions negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of our assets are transferred from the Company and/or our stockholders to a third party. The amended agreement with Dr. Schaber includes our obligation to issue such shares to him if such event occurs.

On June 22, 2011, the Compensation Committee eliminated his fixed minimum annual bonus payable and revised it to an annual targeted bonus of 40% of his annual base salary. On December 4, 2014, the Compensation Committee approved an increase in salary for Dr. Schaber to $424,360. On December 10, 2015, the Compensation Committee approved an increase in salary for Dr. Schaber to $434,969. On December 14, 2016, the Compensation Committee approved an increase in salary for Dr. Schaber to $443,668.

In May 2011, we entered into a one-year employment agreement with Mr. Joseph M. Warusz, our Acting Chief Financial Officer, Vice President Finance and Chief Accounting Officer. Pursuant to the agreement, we have agreed to pay Mr. Warusz $175,000 per year and a targeted annual bonus of 30% of base salary. We also agreed to issue him options to purchase 4,000 shares of our common stock with one-third immediately vesting and the remainder vesting over three years. Mr. Warusz's employment agreement automatically renews each year, unless otherwise terminated, and was automatically renewed each year since execution, until Mr. Warusz retired from the Company effective June 30, 2016. In connection with his retirement, we agreed to provide Mr. Warusz three months of salary and three months of health insurance benefits and to accelerate the vesting and extend the exercise period of certain options. On December 4, 2014, the Compensation Committee approved an increase in salary for Mr. Warusz to $196,730. On December 10, 2015, the Compensation Committee approved an increase in salary for Mr. Warusz to $201,648. On June 30, 2016, Mr. Warusz retired from the Company. As defined in the employment agreement, we paid Mr. Warusz three months of severance, vacation, as well as insurance benefits to the term of his severance.

In December 2014, we entered into a one-year employment agreement with Richard C. Straube, MD, our Chief Medical Officer and Senior Vice President. Pursuant to the agreement, we have agreed to pay Dr. Straube $300,000 per year and a targeted annual bonus of 30% of base salary. We also agreed to issue him options to purchase 10,000 shares of our common stock with one-third immediately vesting and the remainder vesting over three years. Dr. Straube's employment agreement automatically renews each year, unless otherwise terminated, and has automatically renewed each year since execution. Upon termination without "Just Cause", as defined in Dr. Straube's employment agreement, we would pay Dr. Straube three months of severance, accrued bonuses and vacation, and health insurance benefits. No unvested options vest beyond the termination date. On December 4, 2014, the Compensation Committee approved an increase in salary for Dr. Straube to $309,000. On December 10, 2015, the Compensation Committee approved an increase in salary for Dr. Straube to $316,725. On December 14, 2016, the Compensation Committee approved an increase in salary for Dr. Straube to $323,060.

On June 16, 2016, we entered into a one-year employment agreement with Karen Krumeich, our Senior Vice President and Chief Financial Officer. Pursuant to the agreement, we have agreed to pay Ms. Krumeich $222,000 per

year and a targeted annual bonus of 30% of base salary. We also agreed to issue her options to purchase 10,000 shares of our common stock with one-quarter immediately vesting and the remainder vesting over three years. Ms. Krumeich's employment agreement automatically renews each year, unless otherwise terminated. Upon termination without "Just Cause", as defined in Ms. Krumeich's employment agreement, we would pay Ms. Krumeich three months of severance, accrued bonuses and vacation, and health insurance benefits. No unvested options vest beyond the termination date. On December 14, 2016, the Compensation Committee approved an increase in salary for Ms. Krumeich to $226,440.

Outstanding Equity Awards at Fiscal Year-End

The following table contains information concerning unexercised options, stock that has not vested, and equity incentive plan awards for the Named Executive Officers outstanding at December 31, 2016, as adjusted for the reverse stock split of one-for-ten effective October 7, 2016. We have never issued Stock Appreciation Rights.

Name	**Number of Securities Underlying Unexercised Options (#)**		Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	**Option Exercise Price ($)**	Option Expiration Date
	Exercisable	Unexercisable			
Christopher J. Schaber	2,500	-	-	$ 54.00	8/9/2017
	4,500	-	-	$ 94.00	8/9/2017
	14,000	-	-	$ 12.00	12/17/2018
	11,000	-	-	$ 46.40	6/30/2020
	11,219	-	-	$ 6.40	11/30/2021
	13,000	-	-	$ 6.80	12/04/2022
	10,000	-	-	$ 20.10	12/04/2023
	7,500	2,500	2,500	$ 15.00	12/04/2024
	7,000	7,000	7,000	$ 11.30	12/30/2025
Richard C. Straube	9,375	625	625	$ 20.10	1/06/2024
	3,754	1,246	1,246	$ 15.00	12/04/2024
	3,502	3,498	3,498	$ 11.30	12/30/2025
Joseph M. Warusz[1]	4,000	-	-	$ 6.40	5/30/2021
	2,531	-	-	$ 6.80	11/30/2021
	5,500	-	-	$ 20.10	12/04/2022
	4,500	-	-	$ 15.00	12/04/2023
	4,500	-	-	$ 11.30	12/04/2024
	5,500	-	-	$ 6.40	12/30/2025
Karen Krumeich	3,750	6,250	6,250	$ 7.40	6/15/2016

[1] On June 30, 2016, Mr. Warusz retired from the Company and all unvested options immediately vested.

Compensation of Directors

The following table contains information concerning the compensation of the non-employee directors during the fiscal year ended December 31, 2016.

Name	**Fees Earned Paid in Cash[1]**	**Option Awards[2]**	Total
Keith L .Brownlie	$55,500	$ 30,000	$85,000
Marco M. Brughera	$40,000	$ 30,000	$70,000
Gregg A. Lapointe	$47,500	$ 30,000	$77,500
Robert J. Rubin	$52,500	$ 30,000	$82,500
Jerome B. Zeldis	$50,000	$ 30,000	$80,000

1 Directors who are compensated as full-time employees receive no additional compensation for service on our Board of Directors. Each independent director who is not a full-time employee is paid $35,000 annually, on a prorated basis, for their service on our Board of Directors, the chairman of our Audit Committee is paid $15,000 annually, on a prorated basis, and the chairmen of our Compensation and Nominating Committees will be paid $10,000 annually, on a prorated basis. Additionally, Audit Committee members are paid $7,500 annually and Compensation and Nominating Committee members are paid $5,000 annually. This compensation is paid quarterly.

2 We maintain a stock option grant program pursuant to the nonqualified stock option plan, whereby members of our Board of Directors or its committees who are not full-time employees receive an initial grant of fully vested options to purchase 1,500 shares of common stock. Upon re-election to the Board, each Board member will receive stock options with a value of $30,000, calculated using the closing price of the common stock on the trading day prior to the date of the annual meeting of the Company’s stockholders, which vest at the rate of 25% per quarter, commencing with the first quarter after each annual meeting of stockholders.

Stock Ownership Policy

In April 2012, our Board of Directors adopted a stock ownership policy applicable to our non-employee directors to strengthen the link between director and stockholder interests. Pursuant to the stock ownership policy, each non-employee director is required to hold a minimum ownership position in the common stock equal to the annual cash compensation paid for service on the Board of Directors, exclusive of cash compensation paid for service as a chair or member of any committees of the Board of Directors.

Stock counted toward the ownership requirement includes common stock held by the director, unvested and vested restricted stock, and all shares of common stock beneficially owned by the director held in a trust and by a spouse and/or minor children of the director. The policy provides that the ownership requirement must be attained within three years after the later of June 21, 2012 and the date a director is first elected or appointed to the Board of Directors. To monitor progress toward meeting the requirement, the Nominating Committee will review director ownership levels at the end of March of each year. Non-employee directors are prohibited from selling any shares of common stock unless such director is in compliance with the stock ownership policy. A copy of our director compensation and stock ownership policy is publicly available on our website at www.soligenix.com under the “Investors” section.

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

The table below provides information regarding the beneficial ownership of the common stock as of March 17, 2017, of (1) each person or entity who owns beneficially 5% or more of the shares of our outstanding common stock, (2) each of our directors, (3) each of the Named Executive Officers, and (4) our directors and officers as a group. Except as otherwise indicated, and subject to applicable community property laws, we believe the persons named in the table have sole voting and investment power with respect to all shares of common stock held by them.

Beneficial Ownership

Name of Beneficial Owner	**Shares of Common Stock Beneficially Owned**	**Percent of Class**
Randall J. Kirk (1)	686,783	12.00 %

NRM VII Holdings I, LLC (1)	583,334	10.19	%
SciClone Pharmaceuticals, Inc (2)	352,942	6.45	%
Paolo Cavazza (3)	337,998	6.13	%
Sigma-Tau Pharmaceuticals, Inc (3)	306,847	5.57	%
Christopher J. Schaber (4)	127,566	2.29	%
Keith L. Brownlie (5)	15,061	*	
Marco M. Brughera (6)	12,399	*	
Gregg A. Lapointe (7)	18,691	*	
Robert J. Rubin (8)	21,777	*	
Jerome B. Zeldis (9)	16,144	*	
Richard Straube (10)	18,007	*	
Oreola Donini (11)	17,382	*	
Karen Krumeich (12)	5,675	*	
All directors and executive officers as a group (9 persons)	252,702	4.45	%

(1) On June 26, 2013, Randal J. Kirk, on his own behalf and on behalf of Third Security, LLC, NRM VII Holdings I, LLC and Intrexon, filed Amendment No. 1 to Schedule 13D with the Securities and Exchange Commission (the "SEC"), which amends the Schedule 13D filed May 9, 2013 with the SEC (as amended, "Schedule 13D"). The Schedule 13D states that Mr. Kirk is Senior Managing Director of, and controls, Third Security, LLC, which is the Manager of an affiliate that manages NRM VII Holdings I, LLC, and that Mr. Kirk serves as the Chairman and Chief Executive Officer of Intrexon. The Schedule 13D indicates that (a) Mr. Kirk, Third Security, LLC and NRM VII Holdings I, LLC have sole voting and dispositive power with respect to 333,333 shares of Common Stock and warrants to purchase 250,000 shares of Common Stock exercisable within 60 days of March 17, 2017 held by NRM VII Holdings I, LLC, and (b) Mr. Kirk and Intrexon have shared voting and dispositive power with respect to 103,449 shares of Common Stock held by Intrexon Corporation. The address of the principal business office of Mr. Kirk is 2875 South Ocean Boulevard, Suite 214, Palm Beach, Florida 33480. The address of the principal business office of NRM VII Holdings I, LLC is c/o Third Security, LLC, 1881 Grove Avenue, Redford, Virginia 24141. The address of the principal business office of Intrexon Corporation is 20358 Seneca Meadows Parkway, Germantown, Maryland 20876.

(2) On September 19, 2016, SciClone Pharmaceuticals, Inc., filed a Schedule 13G with the SEC (the "Schedule 13G"). The Schedule 13G indicates that SciClone Pharmaceuticals, Inc. has sole voting and dispositive power with respect to the 352,942 shares held by SciClone Pharmaceuticals International China Holding Ltd. SciClone Pharmaceuticals International China Holding Ltd. is an indirect wholly-owned subsidiary of SciClone Pharmaceuticals, Inc.

(3) On May 16, 2013, Paolo Cavazza, on his own behalf and on behalf of Sigma-Tau Finanziaria S.p.A., Sigma-Tau International S.A., Sigma-Tau America S.A. and Sigma-Tau Pharmaceuticals,, filed Amendment No. 4 to Schedule 13D with the SEC, which amends the Schedule 13D filed with the SEC on February 20, 2009 as amended by Amendment No. 1 filed with the SEC on October 2, 2009, Amendment No. 2 filed with the SEC on June 28, 2010 and Amendment No. 3 filed with the SEC on January 2, 2013 (the "Schedule 13D"). The Schedule 13D indicates that (a) Mr. Cavazza has sole voting and dispositive power with respect to (i) 5,954 shares held by Mr. Paolo Cavazza and (ii) 16,415 shares of common stock and warrants to purchase 8,781 shares held by SINAF SA, and (b) Mr. Cavazza, Sigma-Tau Finanziaria S.p.A., Sigma-Tau International S.A., Sigma-Tau America S.A. and Sigma-Tau Pharmaceuticals, Inc. have shared voting and dispositive power with respect to 271,140 shares of common stock and warrants to purchase 35,707 shares of common stock exercisable within 60 days of the date of March 17, 2017 held by Sigma-Tau Pharmaceuticals, Inc. Sigma-Tau Pharmaceuticals, Inc. is a direct wholly-owned subsidiary of Sigma-Tau America S.A., which is a direct wholly-owned subsidiary of Sigma-Tau International S.A., which is a direct wholly-owned subsidiary of Sigma-Tau Finanziaria S.p.A. Mr. Paolo Cavazza directly and indirectly owns 38% of Sigma-Tau Finanziaria S.p.A. SINAF SA is an indirect wholly owned subsidiary of Aptafin S.p.A., which is owned by Mr. Paolo Cavazza and members of his family. Mr. Paolo Cavazza's address is Via Tesserte, 10, Lugano, Switzerland. The business address of Sigma-Tau Finanziaria S.p.A. is Via Sudafrica, 20, Rome, Italy 00144. The business address of Sigma-Tau Pharmaceuticals, Inc. is 9841 Washingtonian Boulevard, Suite 500, Gaithersburg, Maryland 20878.

(4) Includes 25,095 shares of common stock owned by Dr. Schaber, options to purchase 82,220 shares of common stock exercisable within 60 days of March 17, 2017, and warrants to purchase 20,251 shares of common stock exercisable within 60 days of March 17, 2017. The address of Dr. Schaber is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540

(5) Includes 5,000 shares of common stock and options to purchase 10,061 shares of common stock exercisable within 60 days of the March 17, 2017. The address of Mr. Brownlie is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(6) Includes 2,750 shares of common stock, options to purchase 7,149 shares of common stock exercisable within 60 days of March 17, 2017, and warrants to purchase 2,500 shares of common stock exercisable within 60 days of March 17, 2017. The address of Dr. Brughera is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(7) Includes 7,379 shares of common stock and options to purchase 11,312 shares of common stock exercisable within 60 days of March 17, 2017. The address of Mr. Lapointe is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(8) Includes 4,385 shares of common stock, options to purchase 13,436 shares of common stock exercisable within 60 days of March 17, 2017, and warrants to purchase 3,956 shares of common stock exercisable within 60 days of March 17, 2017. The address of Dr. Rubin is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(9) Includes 6,917 shares of common stock and options to purchase 9,227 shares of common stock exercisable within 60 days of March 17, 2017. The address of Dr. Zeldis is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(10) Includes options to purchase 18,007 shares of common stock exercisable within 60 days of March 17, 2017. The address of Dr. Straube is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(11) Includes options to purchase 12,382 shares of common stock owned by Dr. Donini exercisable within 60 days of March 17, 2017 and warrants to purchase 5,000 shares of common stock exercisable within 60 days of March 17, 2017. The address of Dr. Donini is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(12) Includes 1,300 shares of common stock and options to purchase 4,375 shares of common stock owned by Ms. Krumeich exercisable within 60 days of the date of March 17, 2017. The address of Ms. Krumeich is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

* Indicates less than 1%.

** Beneficial ownership is determined in accordance with the rules of the SEC. Shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days of March 17, 2017 are deemed outstanding for computing the percentage ownership of the stockholder holding the options or warrants, but are not deemed outstanding for computing the percentage ownership of any other stockholder. Percentage of ownership is based on 5,472,532 shares of common stock outstanding as of March 17, 2017.

Equity Compensation Plan Information

In December 2005, our Board of Directors approved the 2005 Equity Incentive Plan, which was approved by stockholders on December 29, 2005. In September 2013, our stockholders approved an amendment to the 2005 Equity Incentive Plan to increase the maximum number of shares of our common stock available for issuance under the plan by 125,000 shares, bringing the total shares reserved for issuance under the plan to 300,000 shares. In April 2015, our Board of Directors approved the 2015 Equity Incentive Plan, which was approved by stockholders on June 18, 2015. A maximum of 300,000 shares of our common stock are available for issuance under the 2015 Equity Incentive Plan. The following table provides information, as of December 31, 2016 with respect to options outstanding under our 2005 Equity Incentive Plan and our 2015 Equity Incentive Plan. All share numbers in this paragraph and in the following table have been adjusted for the one-for-ten reverse stock split effective October 7, 2016.

Plan Category	**Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights**	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	**Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in the first column)**
Equity compensation plans approved by security holders[1]	330,605	$ 17.07	185,769
Equity compensation plans not approved by security holders	-	-	-
Total	330,605	$ 17.07	185,769

[1] Includes our 2005 Equity Incentive Plan and our 2015 Equity Incentive Plan. Our 2005 Plan expired in 2015 and thus no securities remain available for future issuance under that plan.

Item 13. Certain Relationships and Related Transactions and Director Independence

Related Party Transactions

Our audit committee is responsible for the review, approval and ratification of related party transactions. The audit committee reviews these transactions under our Code of Ethics, which governs conflicts of interests, among other matters, and is applicable to our employees, officers and directors.

We are party to a common stock purchase agreement with Sigma-Tau Pharmaceuticals, Inc. (“Sigma-Tau Pharmaceuticals”), a corporation of which Paolo Cavazza, who beneficially owns 5% or more of the shares of our outstanding common stock, indirectly owns 37.2%. The agreement provides that Sigma-Tau Pharmaceuticals has the right to require that we register its shares under the Securities Act of 1933 (the “Securities Act”) for sale to the public, on not more than one occasion during any twelve-month rolling period, and not more than two occasions in the aggregate. We must pay all expenses incurred in connection with the exercise of these demand registration rights. Additionally, the agreement required us to use our best efforts to secure the election of a Sigma-Tau Pharmaceuticals’ designee to our Board of Directors as long as Sigma-Tau Pharmaceuticals beneficially owned at least 10% of our issued and outstanding shares of common stock. As of the date of this filing, Sigma-Tau Pharmaceuticals beneficially owned 5.57% of our outstanding common stock, and our obligation with respect to the election of a Sigma-Tau Pharmaceuticals designee to our Board of Directors has expired.

In addition, Sigma-Tau Pharmaceuticals has piggyback registration rights, which means that they have the right to include their shares in any registration that we effect under the Securities Act, subject to specified exceptions. We must pay all expenses incurred in connection with these piggyback registration rights.

We are party to a stock issuance agreement with Intrexon Corporation (“Intrexon”), a corporation of which Randall J. Kirk, who beneficially owns 5% or more of the shares of our outstanding common stock, serves as the Chairman and Chief Executive Officer. Under the agreement, Intrexon has piggyback registration rights, which means that it has the right to include its shares in any registration that we effect under the Securities Act, subject to specified exceptions. We must pay all expenses, except any broker or similar commissions, incurred in connection with these piggyback registration rights.

We are party to a common stock purchase agreement with SciClone Pharmaceuticals, Inc. (“SciClone”), which beneficially owns 5% or more of the shares of our outstanding common stock. Under the agreement, SciClone has demand registration rights, which means that SciClone has the right to require that we register its shares under the Securities Act for sale to the public, on not more than one occasion, subject to specified exceptions. We must pay all expenses incurred in connection with the exercise of these demand registration rights.

We are unable to estimate the dollar value of the registration rights to the holders of these rights. The amount of reimbursable expenses under the agreements depends on a number of variables, including whether registration rights are exercised incident to a primary offering by us, the form on which we are eligible to register such a transaction, and whether we have a shelf registration in place at the time of a future offering.

In our June 2013 public offering, we issued warrants that contained provisions protecting holders from a decline in the issue price of our common stock (or “down-round” provision) and contained net settlement provisions. As a result, we accounted for these warrants as liabilities instead of equity instruments. During November 2016, we entered into amendments with the holders of those warrants pursuant to which we agreed to reduce the exercise price (after giving effect to the one-for-ten reverse stock split effective October 7, 2016) from $5.10 per share to $0.80 per share and permit those warrants to be exercised on a “cashless exercise” basis, and we eliminated the “down round” provision of those warrants not immediately exercised. As a result of the amendments, the warrant liability was remeasured as of the date of the modification, which resulted in an approximate $1,541,000 decrease in the carrying value of the warrant liability, which was recognized in the statement of operations for the year ended December 31, 2016. The warrant liability related to the warrants not immediately exercised was then reclassified to equity as the amended terms of the warrants qualified them to be accounted for as equity instruments. Of the 303,694 shares of common stock that remained issuable upon the exercise of such warrants as of September 30, 2016, warrants to purchase a total of 250,000 shares were held by NRM VII Holdings I, LLC, an entity the manager of which is indirectly controlled by Mr. Kirk.

Other than as described above, the employment agreements and compensation paid to our directors, we did not engage in any transactions with related parties since January 1, 2016. For a discussion of our employment agreements and compensation paid to our directors, see “Item 11. Executive Compensation”.

Director Independence

The Board of Directors has determined that Messrs. Brownlie and Lapointe, Dr. Brughera, Dr. Rubin, and Dr. Zeldis are “independent” as such term is defined by the applicable listing standards of Nasdaq. Our Board of Directors based this determination primarily on a review of the responses of the Directors to questionnaires regarding their employment, affiliations and family and other relationships.

62

Item 14. Principal Accountant Fees and Services

The following table highlights the aggregate fees billed during each of the two years ended December 31, 2016 by EisnerAmper LLP.

	2016	2015
Audit fees	$237,563	$167,365
Tax fees	9,660	10,000
Other fees	-	27,500
Total	$247,223	$204,865

Other Fees

Our principal accountants did not bill us for any services or products other than as reported above in this Item 14 during each of the two years. Other services include billing for an IT security assessment project that commenced during the year ended December 31, 2015.

Pre-Approval Policies and Procedures

The audit committee has adopted a policy that requires advance approval of all audit services and permitted non-audit services to be provided by the independent auditor as required by the Exchange Act. The audit committee must approve the permitted service before the independent auditor is engaged to perform it. The audit committee approved all of the services described above in accordance with its pre-approval policies and procedures.

Part IV

Item 15. Exhibits and Financial Statements Schedules

a. (1) Consolidated Financial Statements:

The financial statements required to be filed by Item 8 of this Annual Report on Form 10-K and filed in this Item 15, are as follows:

(2) Financial Statement Schedules

Schedules are omitted because they are not applicable, or are not required, or because the information is included in the consolidated financial statements and notes thereto.

(3) Exhibits:

2.1 Agreement and Plan of Merger, dated May 10, 2006 by and among the Company, Corporate Technology Development, Inc., Enteron Pharmaceuticals, Inc. and CTD Acquisition, Inc. (incorporated by reference to Exhibit 2.1 included in our Registration Statement on Form SB-2 (File No. 333-133975) filed on May 10, 2006).

3.1 Second Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 included in our current report on Form 8-K filed on June 22, 2012).

3.2 By-laws (incorporated by reference to Exhibit 3.1 included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended June 30, 2003).

3.3 Certificate of Amendment to Second Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 included in our current report on Form 8-K filed on June 22, 2016).

3.4	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 included in our current report on Form 8-K filed on October 7, 2016).
4.2	Form of Right Certificate (incorporated by reference to Exhibit 4.2 included in our current report on Form 8-K filed on June 22, 2007).
4.3	Form of Warrant issued to each investor in the January 2009 private placement (incorporated by reference to Exhibit 4.18 included in our Registration Statement on Form S-1 (File No. 333-149239) filed on February 14, 2008).
4.4	Form of Warrant issued to each investor in the September 2009 private placement (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on September 29, 2009).
4.5	Warrant dated April 19, 2010, issued to Fusion Capital Fund II, LLC (incorporated by reference to Exhibit 4.10 included in our Post-Effective Amendment to Registration Statement on Form S-1 filed on April 20, 2010).
4.6	Form of Common Stock Purchase Warrant issued to each investor in the June 2010 private placement (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on June 18, 2010).
4.7	Warrant dated December 20, 2012 and issued to Sigma-Tau to purchase 35,707 shares of the Company’s common stock (incorporated by reference to Exhibit 10.2 of our current report on Form 8-K filed on December 27, 2012).
4.8	Warrant dated December 20, 2012 and issued to SINAF S.A. to purchase 8,781 shares of the Company’s common stock (incorporated by reference to Exhibit 10.3 of our current report on Form 8-K filed on December 27, 2012).

4.9	Warrant dated December 20, 2012 and issued to McDonald to purchase 28,000 shares of the Company's common stock (incorporated by reference to Exhibit 10.6 of our current report on Form 8-K filed on December 27, 2012).
4.10	Form of Common Stock Purchase Warrant issued to each investor in the June 2013 registered public offering (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on June 24, 2013).
4.11	Form of Warrant issued to Maxim Group LLC (incorporated by reference to Exhibit 10.4 included in our current report on Form 8-K filed on June 24, 2013).
4.12	Form of Warrant to Purchase Common Stock issued to each investor in the December 2014 registered public offering (incorporated by reference to Exhibit 4.12 included in our Registration Statement on Form S-1 (File No. 333-199761) filed on December 17, 2014).
4.13	Form of Warrant to Purchase Common Stock issued to Roth Capital Partners, LLC (incorporated by reference to Exhibit 4.13 included in our Registration Statement on Form S-1 (File No. 333-199761) filed on December 17, 2014).
4.14	Warrant Agency Agreement by and between the Company and American Stock Transfer & Trust Company, LLC (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on December 16, 2016).
4.15	Representative's Warrant (incorporated by reference to Exhibit 4.15 included in our Registration Statement on Form S-1 (File No. 333-214038) filed on November 14, 2016).
10.1	License Agreement between the Company and the University of Texas Southwestern Medical Center (incorporated by reference to Exhibit 10.9 included in our Annual Report on Form 10-KSB filed March 30, 2004, as amended, for the fiscal year ended December 31, 2004).
10.2	License Agreement between the Company and Thomas Jefferson University (incorporated by reference to Exhibit 10.9 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).
10.3	License Agreement between the Company and the University of Texas Medical Branch (incorporated by reference to Exhibit 10.10 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).
10.4	Consulting Agreement between the Company and Lance Simpson of Thomas Jefferson University. (incorporated by reference to Exhibit 10.43 included in our Annual Report on Form 10-KSB as amended for the fiscal year ended December 31, 2002).
10.5	2005 Equity Incentive Plan, as amended on September 25, 2013 (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on September 30, 2013). **
10.6	Form S-8 Registration of Stock Options Plan dated December 30, 2005 (incorporated by reference to our registration statement on Form S-8 filed on December 30, 2005).

10.7	Letter of Intent dated January 3, 2007 by and between the Company and Sigma-Tau Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on January 4, 2007).
10.8	Employment Agreement dated December 27, 2007, between Christopher J. Schaber, PhD and the Company (incorporated by reference to Exhibit 10.30 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008). **
10.9	Exclusive License Agreement dated November 24, 1998, between Enteron Pharmaceuticals, Inc. and George B. McDonald, MD and amendments (incorporated by reference to Exhibit 10.42 included in our Registration Statement on Form S-1 (File No. 333-157322) filed on February 13, 2009).
10.10	Collaboration and Supply Agreement dated February 11, 2009, between the Company and Sigma-Tau Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.43 included in our Registration Statement on Form S-1 (File No. 333-157322) filed on February 13, 2009). †

10.11	Employment Agreement dated as of May 31, 2011, between Joseph M. Warusz and the Company (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on May 31, 2011).**
10.12	First Amendment to Employment Agreement dated as of July 12, 2011, between the Company and Christopher J. Schaber, PhD (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on July 14, 2011).**
10.13	Amendment to the Collaboration and Supply Agreement dated July 26, 2011, between Sigma-Tau Pharmaceuticals, Inc. and the Company (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on July 28, 2011).
10.14	Amendment to the Exclusive License Agreement dated as of July 26, 2011, between George McDonald, MD and the Company (incorporated by reference to Exhibit 10.2 of our current report on Form 8-K filed on July 28, 2011).
10.15	Amendment No. 2 to the Collaboration and Supply Agreement between the Company, Enteron and Sigma-Tau dated as of December 20, 2012 (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on December 27, 2012). †
10.16	Amendment to Exclusive License Agreement dated as of December 20, 2012 between Enteron and McDonald (incorporated by reference to Exhibit 10.4 of our current report on Form 8-K filed on December 27, 2012).
10.17	Amendment to Consulting Agreement dated as of December 20, 2012 between Enteron and McDonald (incorporated by reference to Exhibit 10.5 of our current report on Form 8-K filed on December 27, 2012).
10.18	Contract HHSO100201300023C dated September 18, 2013 between the Company and the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on September 24, 2013). †
10.19	Contract HHSN272201300030C dated September 24, 2013 by and between the Company and the National Institutes of Health (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on September 30, 2013). †
10.20	Purchase Agreement dated as of November 18, 2013 between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on November 21, 2013).
10.21	Registration Rights Agreement dated as of November 18, 2013 between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.2 of our current report on Form 8-K filed on November 21, 2013)
10.22	Employment Agreement dated as of January 6, 2014 between the Company and Richard Straube, M.D. (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on January

	8, 2014). **
10.23	Asset Purchase Agreement dated September 3, 2014 between the Company and Hy Biopharma, Inc. (incorporated by reference to Exhibit 10.1 of our current report on Form 8-k filed on September 5, 2014). †
10.24	Registration Rights Agreement dated September 3, 2014 between the Company and Hy Biopharma, Inc. (incorporated by reference to Exhibit 10.2 of our current report on Form 8-k filed on September 5, 2014).
10.25	Contract HHSN272201400039C dated September 17, 2014 by and between the Company and the National Institutes of Health (incorporated by reference to Exhibit 10.1 of our current report on Form 8-k filed on September 23, 2014). †
10.26	Lease Agreement dated November 21, 2014, between the Company and CPP II, LLC (incorporated by reference to Exhibit 10.31 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014).
10.27	2015 Equity Incentive Plan, as amended on June 9, 2015 (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on June 19, 2015).
10.28	Form of Equity Purchase Agreement dated as of July 29, 2015 between the Company and Kodiak Capital Group, LLC, Kingsbrook Opportunities Master Fund LP and River North Equity, LLC (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on July 31, 2015).
10.29	Form of Registration Rights Agreement dated as of July 29, 2015 between the Company and Kodiak Capital Group, LLC, Kingsbrook Opportunities Master Fund LP and River North Equity, LLC (incorporated by reference to Exhibit 10.2 of our current report on Form 8-K filed on July 31, 2015).

10.30	Form of Promissory Note dated as of July 29, 2015 made by the Company in favor of Kodiak Capital Group, LLC, Kingsbrook Opportunities Master Fund LP and River North Equity, LLC (incorporated by reference to Exhibit 10.3 of our current report on Form 8-K filed on July 31, 2015).
10.31	Purchase Agreement dated as of March 22, 2016 between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.30 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015).
10.32	Registration Rights Agreement dated as of March 22, 2016 between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.31 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015).
10.33	Employment Agreement dated as of June 16, 2016 between the Company and Karen R. Krumeich (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on June 22, 2016).
10.34	Common Stock Purchase Agreement dated September 9, 2016 between Soligenix, Inc. and SciClone Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on September 12, 2016).
21.1	Subsidiaries of the Company. *
23.1	Consent of EisnerAmper LLP. *
31.1	Certification of the Chief Executive Officer pursuant to Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002). *
31.2	Certification of the Chief Financial Officer pursuant to Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002). *
32.1	Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
32.2	Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *

* Filed herewith.

** Indicates management contract or compensatory plan.

† Portions of this exhibit have been omitted pursuant to a request for confidential treatment.

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SOLIGENIX, INC.

By: /s/ Christopher J. Schaber
Christopher J. Schaber, PhD
Chief Executive Officer and President

Date: March 27, 2017

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated and on the dates indicated.

Name	Capacity	Date
/s/ Christopher J. Schaber **Christopher J. Schaber, PhD**	Chairman of the Board, Chief Executive Officer and President (principal executive officer)	March 27, 2017
/s/ Keith L. Brownlie **Keith L. Brownlie, CPA**	Director	March 27, 2017
/s/ Marco M. Brughera **Marco M. Brughera, DVM**	Director	March 27, 2017
/s/ Gregg A. Lapointe **Gregg A. Lapointe, CPA**	Director	March 27, 2017
/s/ Robert J. Rubin **Robert J. Rubin, MD**	Director	March 27, 2017
/s/ Jerome B. Zeldis **Jerome B. Zeldis, MD, PhD**	Director	March 27, 2017
/s/ Karen Krumeich		March 27, 2017

Karen Krumeich	Chief Financial Officer, Senior Vice President, and Corporate Secretary (principal accounting officer)

SOLIGENIX, INC. AND SUBSIDIARIES
CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

Soligenix, Inc. and Subsidiaries
Consolidated Balance Sheets
As of December 31,

	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	$8,772,567	$4,921,545
Contracts and grants receivable	1,206,777	1,985,212
Prepaid expenses	134,431	244,267
Total current assets	10,113,775	7,151,024
Office furniture and equipment, net	26,702	47,366
Intangible assets, net	126,628	188,732
Total assets	$10,267,105	$7,387,122
Liabilities and shareholders' equity (deficiency)		
Current liabilities:		
Accounts payable	$1,708,091	$2,869,392
Accrued expenses	806,118	1,510,544
Notes payable	-	292,719
Warrant liability	-	2,434,101
Accrued compensation	355,648	298,675
Total current liabilities	2,869,857	7,405,431
Commitments and contingencies		
Shareholders' equity (deficiency):		
Preferred stock: 350,000 shares authorized; none issued or outstanding	-	-
Common stock, $.001 par value; 10,000,000 shares and 5,000,000 shares authorized at December 31, 2016 and 2015, respectively; 5,470,032 and 3,126,952 shares issued and outstanding in 2016 and 2015, respectively	5,470	3,127
Additional paid-in capital[(1)]	157,514,740	146,856,143
Accumulated deficit	(150,122,962)	(146,877,579)
Total shareholders' equity (deficiency)	7,397,248	(18,309)
Total liabilities and shareholders' equity (deficiency)	$10,267,105	$7,387,122

(1) Adjusted to reflect the reverse stock split of one-for-ten effective October 7, 2016.

The accompanying notes are an integral part of these consolidated financial statements.

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Operations
For the Years Ended December 31,

	2016	2015
Revenues:		
Contract revenue	$10,448,794	$8,641,348
Grant revenue	-	127,042
Total revenues	10,448,794	8,768,390
Cost of revenues	(8,433,671)	(6,882,204)
Gross profit	2,015,123	1,886,186
Operating expenses:		
Research and development	4,295,867	5,399,839
General and administrative	3,428,838	3,596,623
Total operating expenses	7,724,705	8,996,462
Loss from operations	(5,709,582)	(7,110,276)
Other income (expense):		
Change in fair value of warrant liability	1,541,241	(1,201,870)
Gain on settlement of liability	390,599	-
Interest income (expense)	2,216	(8,017)
Total other income (expense)	1,934,056	(1,209,887)
Net loss before income taxes	(3,775,526)	(8,320,163)
Income tax benefit	530,143	488,933
Net loss	$(3,245,383)	(7,831,230)
Basic net loss per share[(1)]	$(0.93)	$(3.00)
Diluted net loss per share[(1)]	$(1.34)	$(3.00)
Basic weighted average common shares outstanding[(1)]	3,481,460	2,606,577
Diluted weighted average common shares outstanding[(1)]	3,583,587	2,606,577

(1) Adjusted to reflect the reverse stock split of one-for-ten effective October 7, 2016.

The accompanying notes are an integral part of these consolidated financial statements.

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Changes in Shareholders' Equity (Deficiency)
For the Years Ended December 31, 2016 and 2015

	Common Stock		Additional Paid–In	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance, December 31, 2014	2,393,657	$2,394	$138,890,066	$(139,046,349)	$(153,889)
Issuance of common stock pursuant to Lincoln Park Equity line	84,135	84	1,339,093	-	1,339,177
Issuance of common stock pursuant to Equity Line Purchase Agreement	454,577	455	2,499,545	-	2,500,000
Stock issuance costs associated with Equity Line Purchase Agreement	-	-	(453,162)	-	(453,162)
Issuance of common stock to vendors	16,628	16	232,196	-	232,212
Issuance of shares from exercise of stock options	3,312	3	19,247	-	19,250
Issuance of shares for exercise of warrants	174,643	175	1,117,346	-	1,117,521
Reclassification of warrant liability upon partial exercise of warrants issued in unit offering	-	-	2,557,331	-	2,557,331
Share-based compensation expense	-	-	654,481	-	654,481
Net loss	-	-	-	(7,831,230)	(7,831,230)
Balance, December 31, 2015	3,126,952	$3,127	$146,856,143	$(146,877,579)	$(18,309)
Issuance of common stock and warrants in public offering	1,670,000	1,670	5,277,270	-	5,278,940
Stock issuance costs associated with public offering	-	-	(809,277)	-	(809,277)
Issuance of common stock pursuant to Lincoln Park Equity Line	277,135	277	1,712,043	-	1,712,320
Cost associated with Lincoln Park Equity Line	-	-	(41,381)	-	(41,381)
Issuance of common stock in reverse stock split	1,525	1	-	-	1
Issuance of common stock to SciClone	352,942	353	2,999,647	-	3,000,000
Cashless exercise of warrants and reclassification of warrant liability to equity	33,978	34	892,826	-	892,860
Issuance of common stock to vendors	7,500	8	52,492	-	52,500
Share-based compensation expense	-	-	574,977	-	574,977
Net loss	-	-	-	(3,245,383)	(3,245,383)
Balance, December 31, 2016	5,470,032	$5,470	$157,514,740	$(150,122,962)	$7,397,248

Adjusted to reflect the reverse stock split of one-for-ten effective October 7, 2016.

The accompanying notes are an integral part of these consolidated financial statements.

F-4

Soligenix, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

For the Years Ended December 31,

	2016	2015
Operating activities:		
Net loss	$(3,245,383)	$(7,831,230)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	89,928	247,458
Amortization of discount on debt	7,281	10,648
Share-based compensation	574,977	654,481
Gain on settlement of liability	(390,599)	-
Issuance of common stock for services	52,500	232,212
Change in fair value of warrant liability	(1,541,241)	1,201,870
Change in operating assets and liabilities:		
Contracts and grants receivable	778,435	(1,190,445)
Prepaid expenses	109,836	(71,339)
Accounts payable and accrued expenses	(1,475,128)	1,376,391
Accrued compensation	56,973	(16,354)
Total adjustments	(1,737,038)	2,444,922
Net cash used in operating activities	(4,982,421)	(5,386,308)
Investing activities:		
Purchases of office furniture and equipment	(7,159)	(22,098)
Net cash used in investing activities	(7,159)	(22,098)
Financing activities:		
Proceeds from issuance of common stock and warrants from public offering	5,278,940	-
Stock issuance costs associated with public offering	(809,277)	-
Proceeds from issuance of common stock pursuant to the equity lines	1,712,320	3,839,177
Stock issuance cost associated with equity lines	(41,381)	(171,091)
Repayment of notes payable	(300,000)	-
Proceeds from issuance of common stock to SciClone	3,000,000	-
Proceeds from exercise of options and warrants	-	1,136,771
Net cash provided by financing activities	8,840,602	4,804,857
Net increase (decrease) in cash and cash equivalents	3,851,022	(603,549)
Cash and cash equivalents at beginning of period	4,921,545	5,525,094
Cash and cash equivalents at end of period	$8,772,567	$4,921,545
Supplemental disclosure of non cash financing activities:		
Reclassification of warrant liability to additional paid-in capital	$892,860	$2,557,331
Notes payable issued in connection with Equity Purchase Agreement	$-	$282,071
Supplemental information:		

Cash paid for state income taxes	$5,030	$7,542

The accompanying notes are an integral part of these consolidated financial statements.

Soligenix, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

Note 1. Nature of Business

Basis of Presentation

Soligenix, Inc. (the "Company") is a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. The Company maintains two active business segments: BioTherapeutics and Vaccines/BioDefense.

The Company's BioTherapeutics business segment is developing a novel photodynamic therapy (SGX301) utilizing topical synthetic hypericin activated with safe visible florescent light for the treatment of cutaneous T-cell lymphoma ("CTCL"), its first-in-class innate defense regulator ("IDR") technology, dusquetide (SGX942) for the treatment of oral mucositis in head and neck cancer, and proprietary formulations of oral beclomethasone 17,21-dipropionate ("BDP") for the prevention/treatment of gastrointestinal ("GI") disorders characterized by severe inflammation, including pediatric Crohn's disease (SGX203) and acute radiation enteritis (SGX201).

The Company's Vaccines/BioDefense business segment includes active development programs for RiVax™, its ricin toxin vaccine candidate, OrbeShield®, a GI acute radiation syndrome ("GI ARS") therapeutic candidate and SGX943, a melioidosis therapeutic candidate. The development of the vaccine program is currently supported by the heat stabilization technology, known as ThermoVax®, under existing and on-going government contract funding. With the government contract from the National Institute of Allergy and Infectious Diseases ("NIAID"), the Company will attempt to advance the development of RiVax™ to protect against exposure to ricin toxin. We had advanced the development of OrbeShield® for the treatment of GI ARS with funds received under our awarded government contracts with the Biomedical Advanced Research and Development Authority ("BARDA") and NIAID. We will continue to pursue additional government funding support.

The Company generates revenues under government grants primarily from the National Institutes of Health (the "NIH") and government contracts from BARDA and NIAID. The NIAID contract will be completed during the first quarter of 2017 along with the BARDA contract base period, with BARDA electing not to extend the current contract beyond the base period. We will continue to apply for additional government funding.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, development of new technological innovations, dependence on key personnel, protections of proprietary technology, compliance with the United States Food and Drug Administration (the U.S. “FDA”) regulations, and other regulatory authorities, litigation, and product liability.

Liquidity

In accordance with Accounting Standards Codification 205-40, Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date the consolidated financial statements are issued. As of December 31, 2016, the Company had an accumulated deficit of $150,122,962. During the year ended December 31, 2016, the Company incurred a loss of $3,245,383 and used $4,982,421 of cash in operations. The Company expects to continue to generate losses in the foreseeable future. The Company’s liquidity needs will be largely determined by the budgeted operational expenditures incurred in regards to the progression of its product candidates. The Company’s plans to meet its liquidity needs primarily include its ability to control the timing and spending on its research and development programs and raising additional funds through potential partnership and/or financings. Based on the Company’s approved operating budget, management believes that it will have sufficient capital to meet the anticipated cash needs for working capital and capital expenditures through at least March 31, 2018. Based on the Company’s current rate of cash outflows, cash on hand, proceeds from government contract and grant programs, proceeds available from the equity line with Lincoln Park, LLC (“Lincoln Park”) and proceeds from the State of New Jersey Technology Business Tax Certificate Transfer Program, management believes that its current cash will be sufficient to meet the anticipated cash needs for working capital and capital expenditures for at least the next twelve months following the issuance of this report.

As of December 31, 2016, the Company had cash and cash equivalents of $8,772,567 as compared to $4,921,545 as of December 31, 2015, representing an increase of $3,851,022 or 78%. The increase in cash was primarily the result of net proceeds received from financing activities of $8,840,602, primarily from a public offering of the Company’s stock and the Company’s stock purchase agreement with SciClone Pharmaceuticals, Inc. This was partially offset by cash used in operations of $4,982,421. As of December 31, 2016, the Company had working capital of $7,243,918 as compared to working capital of $2,179,694, which excludes a non-cash warrant liability of $2,434,101, as of December 31, 2015, representing an increase of $5,064,224 or 232%. The increase in working capital was primarily the result of the increase in cash received from our financing activities.

Management's business strategy can be outlined as follows:

Complete enrollment and report preliminary results in the pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL;
Obtain agreement from the FDA on a pivotal Phase 3 protocol of SGX942 for the treatment of oral mucositis in head and neck cancer patients and initiate the trial;
Initiate a pivotal Phase 3 clinical trial of SGX203 for the treatment of pediatric Crohn's disease;
Continue development of RiVax™ in combination with the Company's ThermoVax® technology, to develop new heat stable vaccines in biodefense with NIAID support;
Advance the preclinical and manufacturing development of OrbeShield® as a biodefense medical countermeasure for the treatment of GI ARS contingent upon government funding support;
Continue to apply for and secure additional government funding for each of the Company's BioTherapeutics and Vaccines/BioDefense programs through grants, contracts and/or procurements;
Pursue business development opportunities for the Company's pipeline programs, as well as explore merger/acquisition strategies; and
Acquire or in-license new clinical-stage compounds for development.

The Company's plans with respect to its liquidity management include, but are not limited to the following:

The Company has up to $17.3 million in active government contract and grant funding still available to support its associated research programs through 2017 and beyond provided the federal agencies exercise all options and do not elect to terminate the contracts or grants for convenience. The Company plans to submit additional contract and grant applications for further support of its programs with various funding agencies;
The Company has continued to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners and expects to continue to do so for the foreseeable future;
The Company will pursue Net Operating Loss ("NOL") sales in the state of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of $530,143 in proceeds from the sale from NJ NOL in 2016, the Company expects to participate in the program during 2017 and beyond as long as the program is available;
The Company plans to pursue potential partnerships for pipeline programs. However, there can be no assurances that we can consummate such transactions;
The Company has $10.3 million available from an equity facility expiring in March 2019; and
The Company may seek additional capital in the private and/or public equity markets, pursue government contracts and grants as well as business development activities to continue its operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. The Company evaluates additional equity/debt financing opportunities on an ongoing basis and may execute them when appropriate. However, there can be no assurances that the Company can consummate such a transaction, or consummate a transaction at favorable pricing.

Reverse Stock Split

On October 7, 2016, the Company completed a reverse stock split of its issued and outstanding shares of common stock at a ratio of one-for-ten, whereby, once effective, every ten shares of its common stock was exchanged for one share of its common stock. The Company's common stock began trading on the OTCQB on a reverse split basis at the market opening on October 7, 2016. All share and per share data have been restated to reflect this reverse stock split.

Note 2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include Soligenix, Inc., and its wholly and majority owned subsidiaries. All significant intercompany accounts and transactions have been eliminated as a result of consolidation.

Operating Segments

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the chief operating decision maker, or decision making group, in deciding how to allocate resources to an individual segment and in assessing the performance of the segment. The Company divides its operations into two operating segments: BioTherapeutics and Vaccines/BioDefense.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents.

Contracts and Grants Receivable

Contracts and grants receivable consist of amounts due from various grants from the NIH and contracts from BARDA and NIAID, an institute of NIH, for costs incurred prior to the period end under reimbursement contracts. The amounts were billed to the respective governmental agencies in the month subsequent to period end and collected shortly thereafter. Accordingly, no allowance for doubtful amounts has been established. If amounts become uncollectible, they are charged to operations.

Intangible Assets

One of the most significant estimates or judgments that the Company makes is whether to capitalize or expense patent and license costs. The Company makes this judgment based on whether the technology has alternative future uses, as defined in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 730, *Research and Development*. Based on this consideration, the Company capitalizes payments made to legal firms that are engaged in filing and protecting rights to intellectual property and rights for its current products in both the domestic and international markets. The Company believes that patent rights are one of its most valuable assets. Patents and patent applications are a key component of intellectual property, especially in the early stage of product development, as their purchase and maintenance gives the Company access to key product development rights from Soligenix's academic and industry partners. These rights can also be sold or sub-licensed as part of its strategy to partner its products at each stage of development as the intangible assets have alternative future use. The legal costs incurred for these patents consist of work associated with filing new patents designed to protect, preserve and maintain the Company's rights, and perhaps extend the lives of the patents. The Company capitalizes such costs and amortizes intangibles on a straight-line basis over their expected useful life – generally a period of 11 to 16 years.

The Company did not capitalize any patent related costs during the years ended December 31, 2016 or 2015.

These intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable or if the underlying program is no longer being pursued. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and carrying value of the related asset or group of assets. No such write downs have occurred during the years ended December 31, 2016 and 2015.

Impairment of Long-Lived Assets

Office furniture and equipment and intangible assets with finite lives are evaluated and reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The Company recognizes impairment of long-lived assets in the event the net book value of such assets exceeds the estimated future undiscounted cash flows attributable to such assets. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and the carrying value of the related asset or group of assets. Such analyses necessarily involve significant judgment.

The Company did not record any impairment of long-lived assets for the years ended December 31, 2016 or 2015.

Fair Value of Financial Instruments

FASB ASC 820 — *Fair Value Measurements and Disclosures,* defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. FASB ASC 820 requires disclosures about the fair value of all financial instruments, whether or not recognized, for financial statement purposes. Disclosures about the fair value of financial instruments are based on pertinent information available to the Company on December 31, 2016. Accordingly, the estimates presented in these financial statements are not necessarily indicative of the amounts that could be realized on disposition of the financial instruments.

FASB ASC 820 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

The three levels of the fair value hierarchy are as follows:

Level 1 — Quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.

Level 2 — Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 includes financial instruments that are valued using models or other valuation methodologies. These models consider various assumptions, including volatility factors, current market prices and contractual prices for the underlying financial instruments. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.

Level 3 — Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable.

The carrying amounts reported in the consolidated balance sheet for cash and cash equivalents, contracts and grants receivable, accounts payable, accrued expenses, notes payable and accrued compensation approximate their fair value based on the short-term maturity of these instruments. The Company recognizes all derivative financial instruments as assets or liabilities in the financial statements and measures them at fair value with changes in fair value reflected as current period income or loss unless the derivatives qualify as hedges. As a result, certain warrants issued in connection with the Company's June 2013 registered public offering were accounted for as derivatives. See Note 5, *Warrant Liability*.

Revenue Recognition

The Company's revenues are primarily generated from government contracts and grants. The revenue from government contracts and grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the contracts and grants, plus a facilities and administrative rate that provides funding for overhead expenses and management fees. These revenues are recognized when expenses have been incurred by subcontractors or when the Company incurs reimbursable internal expenses that are related to the government contracts and grants.

Research and Development Costs

Research and development costs are charged to expense when incurred in accordance with FASB ASC 730, *Research and Development*. Research and development includes costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies and materials, salaries, share-based compensation, employee benefits, equipment depreciation and allocation of various corporate costs. Purchased in-process research and development expense represents the value assigned or paid for acquired research and development for which there is no alternative future use as of the date of acquisition.

Accounting for Warrants

The Company considered FASB ASC 815, *Evaluating Whether an Instrument is Considered Indexed to an Entity's Own Stock*, which provides guidance for determining whether an equity-linked financial instrument (or embedded feature) issued by an entity is indexed to the entity's stock, and, therefore, qualifying for the first part of the scope exception in paragraph 815-10-15. The Company evaluated the provisions and determined the warrants issued in connection with the Company's June 2013 registered public offering contains provisions that protect holders from a decline in the issue price of the Company's common stock (or "down-round" provisions) and contain net settlement provisions. Consequently, these warrants were recognized as liabilities at their fair value on the date of grant and remeasured at fair value on each reporting date. During November 2016, the Company entered into amendments with the holders of those warrants pursuant to which the Company agreed to reduce the exercise price (after giving effect to the one-for-ten reverse stock split effective October 7, 2016) from $5.10 per share to $0.80 per share and permit those warrants to be exercised on a "cashless exercise" basis, and the Company eliminated the "down-round" provision of those warrants not immediately exercised. As a result of the amendments, the fair value of the warrant liability was remeasured for the year ended December 31, 2016 and the change in fair value was recognized in the statement of operations. The warrant liability related to the warrants not immediately exercised was then reclassified to equity as the amended terms of the warrants qualified them to be accounted for as equity instruments. All other warrants that have been issued by the Company were indexed to the Company's stock and therefore are accounted for as equity instruments for 2016 and 2015.

Share-Based Compensation

Stock options are issued with an exercise price equal to the market price on the date of grant. Stock options issued to directors upon re-election vest quarterly for a period of one year (new director issuances are fully vested upon issuance). Stock options issued to employees generally vest 25% on the grant date, then 25% each subsequent year for a period of three years. These options have a ten year life for as long as the individuals remain employees or directors. In general, when an employee or director terminates their position, the options will expire within three months, unless otherwise extended by the Board.

From time to time, the Company issues restricted shares of common stock to vendors and consultants as compensation for services performed. Typically these instruments vest upon issuance and therefore the entire share-based compensation expense is recognized upon issuance to the vendors and/or consultants.

Share-based compensation expense for options, warrants and shares of common stock granted to non-employees has been determined in accordance with and FASB ASC 505-50, *Equity-Based Payments to Non-Employees*, and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employees is amortized as the options vest. The fair value is remeasured each reporting period until performance is complete.

For the year ended December 31, 2016, the Company issued 66,875 stock options at a weighted average exercise price of $5.30 per share. The fair value of options issued during the years ended December 31, 2016 and 2015 was estimated using the Black-Scholes option-pricing model and the following assumptions:

a dividend yield of 0%;
an expected life of 4 years;
volatility of 84% - 121% for 2016 and 121% - 141% for 2015;
forfeitures at a rate of 12%; and
risk-free interest rates ranging from 0.96% to 1.70% and 0.98% to 1.53% for 2016 and 2015, respectively.

The fair value of each option grant made during 2016 and 2015 was estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option vesting periods, which approximates the service period.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including the Company's current and past performance, the market environment in which the Company operates, the utilization of past tax credits, and the length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. No current or deferred income taxes have been provided through December 31, 2016 due to the net operating losses incurred by the Company since its inception. The Company recognizes accrued interest and penalties associated with uncertain tax positions, if any, as part of income tax expense. There were no tax related interest and penalties recorded for 2016 and 2015. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at December 31, 2016 and 2015.

Earnings Per Share

Basic earnings per share ("EPS") excludes dilution and is computed by dividing income (loss) available to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that shared in the earnings of the entity. Since there is a significant number of options and warrants outstanding, fluctuations in the actual market price can have a variety of

results for each period presented.

	For the Year Ended December 31, 2016	For the Year Ended December 31, 2015
Numerator:		
Net loss for basic earnings per share	$ (3,245,383)	$ (7,831,230)
Less change in fair value of warrant liability	1,541,241	-
Net loss for diluted earnings per share	$ (4,786,624)	$ (7,831,230)
Denominator:		
Weighted-average basic common shares outstanding	3,481,460	2,606,577
Assumed conversion of dilutive securities:		
Common stock purchase warrants	102,127	-
Denominator for diluted earnings per share – adjusted weighted-average shares	3,583,587	2,606,577
Basic net loss per share	($0.93)	($3.00)
Diluted net loss per share	($1.34)	($3.00)

The following table summarizes potentially dilutive adjustments to the weighted average number of common shares which were excluded from the calculation because their effect would be anti-dilutive.

	For the Year Ended December 31, 2016	For the Year Ended December 31, 2015
Common stock purchase warrants	2,853,575	492,612
Stock options	330,605	276,861
Total	3,184,180	769,473

The weighted average exercise price of the Company's stock options and warrants outstanding at December 31, 2016 were $17.07 and $4.13 per share, respectively.

Use of Estimates and Assumptions

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions such as the fair value of warrants and stock options and the useful life of intangibles that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ from those estimates.

Recently Issued Accounting Pronouncements

In August 2014, FASB issued Accounting Standards Update ("ASU") No. 2014-15, "Presentation of Financial Statements — Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." The amendments in this ASU are intended to define management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Specifically, this ASU provides a definition of the term substantial doubt and requires an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). It also requires certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans and requires an express statement and other disclosures when substantial doubt is not alleviated. The new standard is effective for annual periods ending after December 15, 2016, and interim periods thereafter. The Company adopted the new standard effective December 31, 2016, and the adoption of the standard did not have an impact on the Company's consolidated financial statements and disclosures.

In February 2016, the FASB issued ASU No. 2016-02, “Leases” (topic 842). The FASB issued this update to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The updated guidance is effective for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption of the update is permitted. The Company is evaluating the impact of the adoption of this update on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, “Improvements to Employee Share-Based Payment Accounting, which amends ASC Topic 718, and intends to simplify various aspects related to how share-based payments are accounted for and presented in the financial statements. It is effective for annual reporting periods beginning after December 15, 2016, and interim periods within that reporting period. Early adoption is permitted. The Company is currently evaluating the impact of adoption of this update on our consolidated financial statements and related disclosures.

Note 3. Intangible Assets

The following is a summary of intangible assets which consists of licenses and patents:

	Cost	Accumulated Amortization	Net Book Value
December 31, 2016			
Licenses	$462,234	$ 361,044	$101,190
Patents	1,893,185	1,867,747	25,438
Total	$2,355,419	$ 2,228,791	$126,628
December 31, 2015			
Licenses	$462,234	$ 333,732	$128,502
Patents	1,893,185	1,832,955	60,230
Total	$2,355,419	$ 2,166,687	$188,732

Amortization expense was $62,104 and $221,217 in 2016 and 2015, respectively.

Based on the balance of licenses and patents at December 31, 2016, future annual amortization expense is expected to be as follows:

Year	Amortization Expense
2017	$ 61,800
2018	$ 37,300
2019	$ 27,528

License fees and royalty payments are expensed annually as incurred, as the Company does not attribute any future benefits of such payments.

Note 4. Accrued Expenses

The following is a summary of the Company’s accrued expenses:

	For the Years Ended December 31,	
	2016	2015
Clinical trial expenses	$741,174	$1,168,021
Executive bonuses	-	275,355
Other	64,944	67,168
Total	$806,118	$1,510,544

Note 5. Notes Payable

On July 29, 2015, the Company entered into equity purchase agreements (the “Equity Line Purchase Agreements”) and registration rights agreements with certain accredited institutional investors (see Note 7). In consideration for entering into the Equity Line Purchase Agreements, the Company issued to the investors promissory notes having an aggregate principal amount of $300,000, which were recorded as stock issuance costs. The promissory notes had an issuance date present value of $282,071 and were repaid on April 15, 2016. The promissory notes did not include terms for interest, therefore the interest was imputed at 9%. Total discount amortization of $7,281 and $10,648 was recorded as interest expense for the years ended December 31, 2016 and 2015, respectively. The discount was accreted over the term of the promissory notes using the effective interest rate method.

Note 6. Warrant Liability

On June 25, 2013, the Company consummated a public offering in which the Company issued shares of common stock, together with warrants to purchase shares of common stock. These warrants contained provisions that protected holders from a decline in the issue price of the Company's common stock (or "down-round" provision) and contained net settlement provisions. As a result, the Company accounted for these warrants as liabilities instead of equity instruments. Down-round provisions reduce the exercise or conversion price of a warrant if the Company issues equity shares for a price that is lower than the exercise or conversion price of the warrants. Net settlement provisions allow the holder of the warrant to surrender shares underlying the warrant equal to the exercise price as payment of its exercise price, instead of exercising the warrant by paying cash. The Company evaluates whether warrants to acquire its common stock contain provisions that protect holders from declines in the stock price or otherwise could result in modification of the exercise price and/or the number of shares to be issued under the respective warrant agreements based on a variable that is not an input to the fair value of a "fixed for fixed" option. As a result of the Company's December 2014 registered public unit offering, the exercise price of warrants outstanding in connection with the public offering completed in June 2013 was adjusted to $6.10 per share. As a result of the Company's December 2015 drawings on the Equity Line Purchase Agreements, the exercise price of warrants outstanding in connection with the public offering conducted in June 2013 was adjusted to $5.10 per share. The Company recognized these warrants as liabilities at their fair value on the date of grant and remeasured them to fair value on each reporting date.

The Company recognized an initial warrant liability for the warrants issued in connection with the registered public offering completed in June 2013 totaling $4,827,788, which was based on the June 25, 2013 closing price of a share of the Company's common stock as reported on OTC Markets of $9.60. During November 2016, the Company entered into amendments with the holders of those warrants pursuant to which the Company agreed to reduce the exercise price (after giving effect to the one-for-ten reverse stock split effective October 7, 2016) from $5.10 per share to $0.80 per share and permit those warrants to be exercised on a "cashless exercise" basis, and the Company eliminated the "down round" provision of those warrants not immediately exercised. As a result of the amendments, the warrant liability was remeasured as of the date of the modification, which resulted in an approximate $1,541,000 decrease in the carrying value of the warrant liability, which was recognized in the statement of operations for the year ended December 31, 2016. The warrant liability related to the warrants not immediately exercised was then reclassified to equity as the amended terms of the warrants qualified them to be accounted for as equity instruments. Of the 303,694 shares of common stock that remained issuable upon the exercise of such warrants as of the amendment date, warrants to purchase a total of 42,444 shares were exercised on a cashless basis and as a result 33,978 shares of common stock were issued on November 9, 2016.

The assumptions used in the valuation of the warrants issued in the June 25, 2013 financing on November 9, 2016 using the Black Scholes model and for the year ended December 31, 2015 using the binomial method, respectively, were as follows:

	November 9, 2016	December 31, 2015
Number of shares underlying the warrants	303,694	303,694
Exercise price	$ 0.80	$ 5.10
Volatility	93 %	98 %
Risk-free interest rate	0.81 %	1.19 %
Expected dividend yield	0 %	0 %
Expected warrant life (years)	1.63	2.48
Stock price	$ 3.65	$ 11.30

Recurring Level 3 Activity and Reconciliation

The table below provides a reconciliation of the beginning and ending balances for the liability measured at fair value using significant unobservable inputs (Level 3).

Fair Value Measurements Using Significant Unobservable Inputs (Level 3):

	December 31, 2015	Decrease in Fair Value	Reclassification of warrant liability to equity in 2016	December 31, 2016
Warrant liability	$ 2,434,101	$(1,541,241)	$ (892,860)	$ 0

Note 7. Income Taxes

The income tax benefit consisted of the following for the years ended December 31, 2016 and December 31, 2015:

	2016	2015
Federal	$-	$-
State	(530,143)	(488,933)
Income tax benefit	$(530,143)	$(488,933)

The significant components of the Company's deferred tax assets and liabilities at December 31, 2016 and 2015 are as follows:

	2016	2015
Net operating loss carry forwards	$32,028,000	$31,216,000
Orphan drug and research and development credit carry forwards	6,374,000	4,909,000
Equity based compensation	1,943,000	1,923,000
Intangibles	1,921,000	2,090,000
Total	42,266,000	40,138,000
Valuation allowance	(42,266,000)	(40,138,000)
Net deferred tax assets	$-	$-

The Company had gross NOLs at December 31, 2016 of approximately $93,635,000 for federal tax purposes and approximately $3,233,000 of New Jersey NOL carry forwards remaining after the sale of unused net operating loss carry forwards, portions of which will begin to expire in 2018. In addition, the Company has $6,374,000 of various tax credits which expire from 2018 to 2035. The Company may be able to utilize its NOLs to reduce future federal and state income tax liabilities. However, these NOLs are subject to various limitations under Internal Revenue Code ("IRC") Section 382. IRC Section 382 limits the use of NOLs to the extent there has been an ownership change of more than 50 percentage points. In addition, the NOL carry forwards are subject to examination by the taxing authority and could be adjusted or disallowed due to such exams. Although the Company has not undergone an IRC Section 382 analysis, it is likely that the utilization of the NOLs may be substantially limited.

The Company and one or more of its subsidiaries files income tax returns in the U.S. Federal jurisdiction, and various state and local jurisdictions. During the years ended December 31, 2016 and 2015, in accordance with the State of New Jersey's Technology Business Tax Certificate Program, which allowed certain high technology and biotechnology companies to sell unused NOL carry forwards to other New Jersey-based corporate taxpayers, the Company sold New Jersey NOL carry forwards, resulting in the recognition of $530,143 and $488,933 of income tax benefit, net of transaction costs, respectively. There can be no assurance as to the continuation or magnitude of this

program in the future.

Reconciliations of the difference between income tax benefit computed at the federal and state statutory tax rates and the provision for income tax benefit for the years ended December 31, 2016 and 2015 were as follows:

	2016	2015
Income tax loss at federal statutory rate	(34.0)%	(34.0)%
State tax benefits, plus sale of NJ NOLs, net of federal benefit	(7.9)	(4.3)
Permanent differences	10.3	15.0
Orphan drug and research and development credits	(38.8)	(16.3)
Change in valuation allowance	56.4	33.7
Income tax benefit	(14.0)%	(5.9)%

Note 8. Shareholders' Deficiency

Preferred Stock

The Company has 350,000 shares of preferred stock authorized, none of which are issued or outstanding.

Common Stock

The following items represent transactions in the Company's common stock for the year ended December 31, 2016:

The Company issued Lincoln Park Capital Fund, LLC ("Lincoln Park") 277,135 shares of common stock pursuant to the equity line purchase agreement;
On May 31, 2016, the Company issued 5,000 shares of common stock to a vendor for partial consideration for services performed.
On August 29, 2016, the Company issued 2,500 shares of common stock to a vendor for partial consideration for services performed.
On September 9, 2016, the Company entered into a common stock purchase agreement with SciClone pursuant to which we sold 352,942 shares of the Company's common stock to SciClone for an aggregate price of $3,000,000.
In November 2016, warrants to purchase a total of 42,444 shares were exercised on a cashless basis and as a result 33,978 shares of common stock were issued.
On December 16, 2016, 1,670,000 shares of the Company's common stock and warrants to purchase 2,087,500 shares of the Company's common stock at a combined offering price of $3.16 were issued in a registered public offering. In addition, the underwriters partially exercised the over-allotment to purchase an additional 282,505 warrants. The

warrants have a per share exercise price of $3.95 and are exercisable immediately.

The following items represent transactions in the Company's common stock for the year ended December 31, 2015:

In February 2015, the Company issued 70,179 shares of common stock in connection with the exercise of stock warrants;
In March 2015, the Company issued 48,200 shares of common stock in connection with the exercise of stock warrants;
In March 2015, the Company issued 15,301 shares of common stock pursuant to the Lincoln Park facility;
In April 2015, the Company issued 35,679 shares of common stock in connection with the exercise of stock warrants;
In April 2015, the Company issued 812 shares of common stock in connection with the exercise of stock options;
In May 2015, the Company issued 7,636 shares of common stock pursuant to the Lincoln Park facility;
In June 2015, the Company issued 38,425 shares of common stock pursuant to the Lincoln Park facility;

In June 2015, the Company issued 19,871 shares of common stock in connection with the exercise of stock warrants;
In July 2015, the Company issued 714 shares of common stock in connection with the exercise of stock warrants;
In September 2015, the Company issued 60,954 shares of common stock pursuant to an Equity Line Purchase Agreement;
In September 2015, the Company issued 2,500 shares of common stock in connection with the exercise of stock options;
In October 2015, the Company issued 15,184 shares of common stock pursuant to the Lincoln Park facility;
In November 2015, the Company issued 7,589 shares of common stock pursuant to the Lincoln Park facility;
In December 2015, the Company issued 393,623 shares of common stock pursuant to an Equity Line Purchase Agreement;
In nine separate transactions, the Company issued 16,628 fully vested shares of common stock as partial consideration for services performed

Equity Line Purchase Agreement

On July 29, 2015, the Company entered into the Equity Line Purchase Agreements and registration rights agreements with accredited institutional investors, Kodiak Capital Group, LLC (“Kodiak Capital”), Kingsbrook Opportunities Master Fund LP (“Kingsbrook”) and River North Equity, LLC (“River North” and, together with Kodiak Capital and Kingsbrook, the “Investors”). Under the Equity Line Purchase Agreements, the Investors agreed to purchase from the Company up to an aggregate of $10 million worth of shares of common stock, from time to time. In accordance with the registration rights agreements, the Company has filed with the U.S. Securities and Exchange Commission (“SEC”) a registration statement to register for resale under the Securities Act of 1933, as amended, the shares of common stock that may be issued to the Investors under the Equity Line Purchase Agreements.

From the date that the SEC declared the registration statement effective in August 2015, the Company had the right to sell up to $5 million, $4 million and $1 million worth of shares of common stock to Kodiak Capital, Kingsbrook and River North, respectively. The purchase price of the shares was equal to eighty percent (80%) of the lowest daily volume weighted average price of the common stock for any trading day during the five consecutive trading days immediately following the date of the Company’s notice to the Investors requesting the purchase.

In consideration for entering into the Equity Line Purchase Agreements, the Company issued to each of the Investors a promissory note having a principal amount equal to 3% of the total amount committed by such Investor. The principal amount due under the promissory notes did not accrue interest and was payable by April 15, 2016. The promissory notes were repaid on April 15, 2016 (see Note 4).

The initial drawdown under the Equity Line Purchase Agreements was $500,000 offset by issuance cost of $453,162, which is included in the Consolidated Statements of Changes in Shareholders’ Deficiency for the year ended December 31, 2015. Issuance costs include professional fees, 3% commitment fee (promissory notes payable by April 15, 2016)

and SEC filing fees.

In December 2015, a second drawdown was made, whereby under the Equity Line Purchase Agreements, the Company issued 393,624 shares of common stock receiving proceeds of $2,000,000.

On March 7, 2016, in accordance with the terms of the Equity Line Purchase Agreements, the Company exercised its right to terminate the Purchase Agreements upon written notice to the Investors. The Company did not incur any penalties as a result of this termination.

Equity Line

In November 2013, the Company entered into a common stock purchase agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"). The Lincoln Park equity facility allowed the Company to require Lincoln Park to purchase up to $10.6 million of our common stock over a 36-month period depending on certain conditions. During the year ended December 31, 2015, the Company sold 82,500 shares of common stock and issued 1,635 commitment shares to Lincoln Park receiving net proceeds of $1,339,177. During the year ended December 31, 2016, there were no sales of common stock under the Lincoln Park 2013 equity facility. The 2013 Lincoln Park equity facility expired in November 2016 in accordance with the terms of the agreement.

In March 2016, the Company entered into a common stock purchase agreement with Lincoln Park. The 2016 Lincoln Park equity facility allows the Company to require Lincoln Park to purchase up to 10,000 shares ("Regular Purchase") of the Company's common stock every two business days, up to an aggregate of $12.0 million over approximately a 36-month period with such amounts increasing as the quoted stock price increases. The Regular Purchase may be increased up to 15,000 shares of common stock if the closing price of the common shares is not below $10.00, up to 20,000 shares of common stock if the closing price of the common shares is not below $15.00 and up to 25,000 shares of common stock if the closing price of the common shares is not below $20.00. The purchase price for the Regular Purchase shall be equal to the lesser of (i) the lowest sale price of the common shares during the purchase date, or (ii) the average of the three lowest closing sale prices of the common shares during the twelve business days prior to the purchase date. Each Regular Purchase shall not exceed $750,000. Furthermore, for each purchase by Lincoln Park, additional commitment shares in commensurate amounts up to a total of 50,000 shares will be issued based upon the relative proportion of the aggregate amount of $12.0 million. In addition to the Regular Purchase and provided that the closing price of the common shares is not below $7.50 on the purchase date, the Company in its sole discretion may direct Lincoln Park on each purchase date to purchase on the next stock trading day (Accelerated Purchase Date") additional shares of Company stock up to the lesser of (i) three times the number of shares purchased following a Regular Purchase or (ii) 30% of the trading volume of shares traded on the Accelerated Purchase Date at a price equal to the lesser of the closing sale price on the Accelerated Purchase Date or 95% of the Accelerated Purchase Date's volume weighted average price.

Upon entering into the agreement, the Company issued 10,000 shares of common stock as consideration for its commitment to purchase shares of the Company's common stock under the purchase agreement. The value of these shares on the date granted was $81,000, which was accounted for as a stock issuance cost.

During the year ended December 31, 2016, the Company sold 260,000 shares of common stock and issued 7,135 commitment shares and received proceeds of $1,712,320. The value of commitment shares on the date granted was $47,244 which was accounted for as a stock issuance cost.

Note 9. Stock Option Plans and Warrants to Purchase Common Stock

Stock Option Plans

The Amended and Restated 2005 Equity Incentive Plan was replaced by the 2015 Equity Incentive Plan ("2015 Plan"), approved in June 2015, with 300,000 shares available under the 2015 Plan, and is divided into four separate equity programs:

1) the Discretionary Option Grant Program, under which eligible persons may, at the discretion of the Plan Administrator, be granted options to purchase shares of common stock,
2) the Salary Investment Option Grant Program, under which eligible employees may elect to have a portion of their base salary invested each year in options to purchase shares of common stock,
3) the Automatic Option Grant Program, under which eligible nonemployee Board members will automatically receive options at periodic intervals to purchase shares of common stock, and
4) the Director Fee Option Grant Program, under which non-employee Board members may elect to have all, or any portion, of their annual retainer fee otherwise payable in cash applied to a special option grant.

The 2005 Equity Incentive Plan ("2005 Plan") also was divided into four separate equity programs:

1) the Discretionary Option Grant Program, under which eligible persons may, at the discretion of the Plan Administrator, be issued common stock or granted options to purchase shares of common stock,
2) the Salary Investment Option Grant Program, under which eligible employees may elect to have a portion of their base salary invested each year in options to purchase shares of common stock,
3) the Automatic Option Grant Program, under which eligible nonemployee Board members will automatically receive options at periodic intervals to purchase shares of common stock, and
4) the Director Fee Option Grant Program, under which non-employee Board members may elect to have all, or any portion, of their annual retainer fee otherwise payable in cash applied to a special option grant.

The 2005 Plan expired in 2015 and thus no securities remain available for future issuance under that plan.

The table below accounts only for transactions occurring as part of the 2015 Plan.

Shares available for grant at January 1, 2016	252,300
Options granted	(66,875)
Options forfeited	344
Shares available for grant at December 31, 2016	185,679

The total option activity for the amended 2005 Plan and the 2015 Plan for the years ended December 31, 2016 and 2015 was as follows:

	Options	Weighted Average Options Exercise Price
Balance outstanding at December 31, 2014	248,828	$ 24.00
Granted	60,534	11.90
Exercised	(3,312)	5.80
Forfeited	(29,189)	31.30
Balance outstanding at December 31, 2015	276,861	$ 21.30
Granted	66,875	5.30
Increase post reverse stock split	1,851	17.07
Exercised	-	-

Forfeited	(14,982)	48.52
Balance outstanding at December 31, 2016	330,605	$ 17.07

As of December 31, 2016, there were 258,996 options exercisable with a weighted average exercise price of $19.58, a weighted average remaining contractual term of 7.43 years and an intrinsic value of $0. The intrinsic value of options exercised during the year ended December 31, 2015 was $18,181. As of December 31, 2016, there were 330,605 options outstanding and expected to vest with a weighted average exercise price of $17.07, weighted average remaining term of 5.82 years and an intrinsic value of $0. The aggregate intrinsic value represents the total pre-tax intrinsic value (the difference between the closing price of our common stock on the last trading day on December 31, 2016 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2016. This amount changes based on the fair market value of our common stock.

The Company awarded 66,875 and 60,534 stock options to new employees and existing Board members during the years ended December 31, 2016 and 2015, respectively, which had a weighted average grant date fair value per share of $3.90 and $9.48, respectively. The weighted-average exercise price, by price range, for outstanding options to purchase common stock at December 31, 2016 was:

Price Range	Weighted Average Remaining Contractual Life in Years	Outstanding Options	Exercisable Options
$2.25-$19.50	6.14	235,475	165,144
$20.00-$41.00	6.36	63,080	61,802
$46.40-$94.00	2.43	32,050	32,050
Total	5.82	330,605	258,996

The Company’s share-based compensation expense for the years ended December 31, 2016 and 2015 was recognized as follows:

Share-based compensation	2016	2015
Research and development	$230,573	$260,204
General and administrative	344,404	394,277
Total	$574,977	$654,481

At December 31, 2016, the total compensation cost for stock options not yet recognized was approximately $407,520 and will be expensed over the next three years.

Warrants to Purchase Common Stock

As described in Note 5. Warrant Liability, during November 2016, the Company entered into amendments with the holders of the price protected warrants issued in the June 2013 registered public offering eliminating the “down round” provision and permitting those warrants to be exercised on a “cashless exercise” basis. Of the 303,694 shares of common stock that remained issuable on the date of the amendments upon the exercise of such warrants, warrants to purchase a total of 42,444 shares were exercised on a cashless basis on November 9, 2016. The fair value of the warrant liability of $892,860 related to the remaining 261,250 warrants outstanding after the amendment and exercises was reclassified to equity as the amended terms of the warrants qualified them to be accounted for as equity instruments.

On December 16, 2016, 1,670,000 shares of our common stock and warrants to purchase 2,087,500 shares of the Company's common stock at a combined offering price of $3.16 were issued in a registered public offering. In addition, the underwriters partially exercised the over-allotment to purchase an additional 282,505 warrants. Commencing on the date of issuance, holders of the warrants may exercise their right to acquire the common stock and pay an exercise price of $3.95 per share, prior to five years from the date of issuance, after which date any unexercised warrants will expire and have no further value. The warrants are traded on the Nasdaq Capital Market under the symbol "SNGXW".

In connection with the registered public offering, a warrant to purchase 33,400 shares of the Company's common stock was issued to the representative of the underwriters of the offering. The warrant is exercisable at $3.95 per share of common stock underlying the warrant for a four-year period commencing one year from the effective date of the offering.

Warrant activity for the years ended December 31, 2016 and 2015 was as follows:

	Warrants	Weighted Average Warrant Exercise Price
Balance at December 31, 2014	726,950	$ 11.50
Exercised	(174,643)	6.40
Expired	(59,693)	55.90
Balance at December 31, 2015	492,614	$ 7.40
Granted	2,403,405	3.95
Exercised	(42,444)	0.80
Balance at December 31, 2016	2,853,575	$ 4.13

The weighted-average remaining life, by grant date, for outstanding warrants at December 31, 2016 was:

Grant Date	**Exercise Price**	**Weighted Average Remaining Contractual Life in Years**	**Outstanding Warrants**	**Exercisable Warrants**
11/15/2012	$ 6.80	0.87	5,000	5,000
12/20/2012	5.30	0.97	44,488	44,488
12/20/2012	5.80	0.97	28,000	28,000
6/25/2013	0.80	1.48	261,250	261,250
12/5/2013	20.50	1.93	500	500
12/24/2014	14.80	2.98	110,932	110,932
12/16/2016	$ 3.95	4.96	2,403,405	2,370,005
	Total	4.45	2,853,575	2,820,175

Note 10. Concentrations

At December 31, 2016 and 2015, the Company had deposits in major financial institutions that exceeded the amount under protection by the Securities Investor Protection Corporation (“SIPC”). Currently, the Company is covered up to $1,000,000 by the SIPC and at times maintains cash balances in excess of the SIPC coverage.

Note 11. Commitments and Contingencies

The Company has commitments of approximately $500,000 at December 31, 2016 for several licensing agreements with consultants and universities. Additionally, the Company has collaboration and license agreements, which upon clinical or commercialization success, may require the payment of milestones of up to $7.9 million and/or royalties up to 6% of net sales of covered products, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur. As of December 31, 2016, no milestones or royalty payments have been paid or accrued.

In December 2014, the Company entered into a lease agreement through May 31, 2018 for existing and expanded office space. The rent for the first 12 months was approximately $12,300 per month, or approximately $20.85 per square foot. This rent increased to approximately $12,375 per month, or approximately $20.95 per square foot, for the next 12 months and will increase to approximately $12,460 per month, or approximately $21.13 per square foot for the remainder of the lease. Rent expense was $148,336 and $142,935 for 2016 and 2015, respectively.

On September 3, 2014, the Company entered into an asset purchase agreement with Hy Biopharma, Inc. ("Hy Biopharma") pursuant to which the Company acquired certain intangible assets, properties and rights of Hy Biopharma related to the development of Hy BioPharma's synthetic hypericin product. As consideration for the assets acquired, the Company paid $275,000 in cash and issued 184,912 shares of common stock with a fair value based on the Company's stock price on the date of grant of $3,750,000. These amounts were charged to research and development expense during the third quarter of 2014 as the assets will be used in the Company's research and development activities and do not have alternative future use pursuant to generally accepted accounting principles in the United States. Provided all future success-oriented milestones are attained, the Company will be required to make additional payments of up to $10.0 million, if and when achieved. Payments will be payable in restricted securities of the Company provided they do not exceed 19.9% ownership of the Company's outstanding stock. As of December 31, 2016, no milestone or royalty payments have been paid or accrued.

In February 2007, the Company's Board of Directors authorized the issuance of 5,000 shares of the Company's common stock to Dr. Schaber immediately prior to the completion of a transaction, or series or a combination of related transactions, negotiated by its Board of Directors whereby, directly or indirectly, a majority of its capital stock or a majority of its assets are transferred from the Company and/or its stockholders to a third party. Dr. Schaber's amended employment agreement includes the Company's obligation to issue such shares if such event occurs.

As a result of the above agreements, the Company has future contractual obligations over the next five years as follows:

Year	Research and Development	**Property and Other Leases**	**Total**
2017	$ 100,000	$151,000	$251,000
2018	100,000	52,000	152,000
2019	100,000	-	100,000
2020	100,000	-	100,000
2021	100,000	-	100,000
Total	$ 500,000	$203,000	$703,000

Note 12. Operating Segments

The Company maintains two active operating segments: BioTherapeutics and Vaccines/BioDefense. Each segment includes an element of overhead costs specifically associated with its operations, with its corporate shared services group responsible for support functions generic to both operating segments.

	For the Years Ended December 31,	
	2016	**2015**
Revenues		
Vaccines/BioDefense	**$10,448,794**	$8,754,418
BioTherapeutics	**-**	13,972
Total	**$10,448,794**	$8,768,390
Income (Loss) from Operations		
Vaccines/BioDefense	**$1,563,884**	$1,263,709
BioTherapeutics	**(3,399,933)**	(4,487,988)
Corporate	**(3,873,533)**	(3,885,997)
Total	**$(5,709,582)**	$(7,110,276)
Amortization and Depreciation Expense		
Vaccines/BioDefense	**$40,186**	$39,925
BioTherapeutics	**41,395**	199,661
Corporate	**8,347**	7,872
Total	**$89,928**	$247,458
Other Income (Expense), Net		
Corporate	**$1,934,056**	$(1,209,887)
Share-Based Compensation		
Vaccines/BioDefense	**$99,410**	$111,960
BioTherapeutics	**131,163**	148,244
Corporate	**344,404**	394,277
Total	**$574,977**	$654,481

	As of December 31,	
	2016	2015
Identifiable Assets		
Vaccines/BioDefense	$**1,297,986**	$2,123,676
BioTherapeutics	**49,422**	76,183
Corporate	**8,919,698**	5,187,263

Total	$**10,267,105**	$7,387,122

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders of
Soligenix, Inc.

We have audited the accompanying consolidated balance sheets of Soligenix, Inc. and Subsidiaries (the "Company") as of December 31, 2016 and 2015, and the related consolidated statements of operations, shareholders' equity (deficiency), and cash flows for each of the years then ended. The financial statements are the responsibility of the Company'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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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 financial statements referred to above present fairly, in all material respects, the consolidated financial position of Soligenix, Inc. and Subsidiaries as of December 31, 2016 and 2015, and the consolidated results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ EisnerAmper LLP

Philadelphia, PA
March 27, 2017