

SOLIGENIX, INC.  
Form 10-K  
February 26, 2013

---

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, 2012

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

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

Edgar Filing: SOLIGENIX, INC. - Form 10-K

Act. Yes  No

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

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  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  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.

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

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

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately \$14,840,800 (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 February 22, 2013.

As of February 22, 2013, 11,179,968 shares of the registrant's Common Stock, par value \$0.001 per share, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: None.

SOLIGENIX, INC.

ANNUAL REPORT ON FORM 10-K  
For the Year Ended December 31, 2012

## Table of Contents

Item	Description	Page
Part I		
1.	Business	3
1A.	Risk Factors	19
1B.	Unresolved Staff Comments	27
2.	Properties	27
3.	Legal Proceedings	27
Part II		
5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	28
6.	Selected Financial Data	28
7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	28
8.	Financial Statements and Supplementary Data	34
9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	34
9A.	Controls and Procedures	34
9B.	Other Information	35
Part III		
10.	Directors, Executive Officers and Corporate Governance	36
11.	Executive Compensation	40
12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	44
13.	Certain Relationships and Related Transactions and Director Independence	45
14.	Principal Accountant Fees and Services	46
Part IV		
15.	Exhibits and Financial Statement Schedules	47
Signatures		50
Consolidated Financial Statements		F-1

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

Soligenix, Inc. was incorporated in Delaware in 1987. We are a development stage biopharmaceutical company that is focused on developing products to treat serious inflammatory diseases and biodefense countermeasures where there remains an unmet medical need. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense.

Our BioTherapeutics business segment is developing 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), acute radiation enteritis (SGX201) and chronic Graft-versus-Host disease (orBec®), as well as developing our novel innate defense regulator (“IDR”) technology (SGX942) for the treatment of oral mucositis.

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine, VeloThrax™, our anthrax vaccine, and OrbeShield™, our gastrointestinal acute radiation syndrome (“GI ARS”) therapeutic. The advanced development of our vaccine programs is currently supported by our heat stabilization technology, known as ThermoVax™, under existing and on-going government grant funding.

An outline for our business strategy follows:

- Initiate a Phase 1/2 clinical trial of oral BDP, known as SGX203 for the treatment of pediatric Crohn’s disease;
- Initiate a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;
- Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as prevention of acute radiation enteritis, prevention of acute radiation syndrome, and treatment of chronic graft-versus-host disease (“GVHD”);
- Develop RiVax™ and VeloThrax™ in combination with our proprietary vaccine heat stabilization technology, known as ThermoVax™, to develop new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas;
- Continue to apply for and secure additional government funding for each of our BioTherapeutics and Vaccines/BioDefense programs through grants, contracts and/or procurements; and
- Explore other business development and merger/acquisition strategies.

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 Products in Development

The following tables summarize the products that we are currently developing:

BioTherapeutic Products

Soligenix Product	Therapeutic Indication	Stage of Development
SGX942	Oral Mucositis in Head and Neck Cancer	IND clearance and Phase 2 trial planned
SGX203	Pediatric Crohn's disease	Phase 1/2 clinical trial planned
SGX201	Acute Radiation Enteritis	Phase 1/2 clinical trial complete; safety and preliminary efficacy demonstrated
orBec®	Treatment of Chronic GI GVHD	Phase 2 trial planned

Vaccine Thermostability Platform

Soligenix Product	Indication	Stage of Development
ThermoVax™	Thermostability of aluminum adjuvanted vaccines	Pre-clinical

BioDefense Products

Soligenix Product	Indication	Stage of Development
RiVax™	Vaccine against Ricin Toxin Poisoning	Phase 1B trial complete; safety and neutralizing antibodies for protection demonstrated
VeloThrax™	Vaccine against Anthrax Poisoning	Pre-clinical
OrbeShield™	Therapeutic against GI ARS	Follow-on pre-clinical study initiated; Initial pre-clinical study complete; successful protection in canines

BioTherapeutics Overview

SGX94

In December 2012, we acquired a novel drug technology, we refer to as SGX94, representing a unique approach to modulation of the innate immune system. SGX94 is an IDR that regulates the innate immune system to simultaneously reduce inflammation, eliminate infection and enhance tissue healing. 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 the University of British Columbia ("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.

SGX94 is the research name for the active ingredient in SGX942, which is the research name for the finished drug product being studied in oral mucositis. It is 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 provide 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 are 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.

We have a strong worldwide IP position on SGX94 and related analogs including composition of matter. SGX94 was developed pursuant to discoveries made by Professors B. Brett Finlay and Robert Hancock of the University of British Columbia, Canada and approximately \$40 million has been invested towards its development to date, inclusive of government grants.

SGX94 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. SGX94 showed a strong safety profile when administered by IV over 7 days and was consistent with safety results seen in pre-clinical studies. SGX94 is the subject of an open Investigational New Drug (“IND”) application which has been cleared by the United States Food and Drug Administration (“FDA”). Market opportunities include, but are not limited to, mucositis and bacterial infections.

#### SGX942 – for Treating Oral Mucositis in Head and Neck Cancer

SGX942 is poised to start a Phase 2 clinical study in 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.

#### About 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. Mucositis affects approximately 500,000 people in the United States (“U.S.”) per year and occurs in 40% of patients receiving chemotherapy. Mucositis almost always occurs in patients with head and neck cancer treated with radiation therapy (>80% incidence of severe mucositis) and is common (40-100% incidence) in patients undergoing high dose chemotherapy and hematopoietic cell transplantation, where the incidence and severity of mucositis depends greatly on the nature of the conditioning regimen used for myeloablation. Mucositis can be severely debilitating and can lead to infection, sepsis, the need for parenteral nutrition and narcotic analgesia. The gastro-intestinal 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 now regarded as a secondary consequence of dysregulated local inflammation triggered by therapy-induced cell death, rather than as the primary cause of the lesions.

#### Oral BDP

Oral BDP (beclomethasone 17,21-dipropionate) represents a first-of-its-kind oral, locally acting therapy tailored to treat gastrointestinal 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 have an issued U.S. patent 8,263,582 claiming the use of oral BDP as a method of treating inflammatory disorders of the gastrointestinal tract, including Crohn's disease, and an issued U.S. patent 6,096,731 claiming the use of oral BDP as a method for preventing and treating the tissue damage that is associated with both GI GVHD following hematopoietic cell transplantation, as well as GVHD which also occurs following organ allograft transplantation. 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. We are planning to pursue development programs in the treatment of pediatric Crohn's disease, acute radiation enteritis, chronic GI GVHD 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 believe the potential worldwide market for oral BDP is in excess of \$500 million for all GI applications, namely, pediatric Crohn's disease, radiation enteritis, GI ARS, and chronic GI GVHD.

In addition to issued patents and pending worldwide patent applications held by or exclusively licensed to us, oral BDP would benefit from orphan drug designations in the U.S. and in Europe. Orphan drug designations provide for 7 and 10 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 awarded SGX203 Orphan Drug designation for the treatment of pediatric Crohn's disease as well as Fast Track designation. 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 New Drug Application ("NDA") for SGX203 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, which implies an abbreviated review time of six months.

We plan to initiate a Phase 1/2 pharmacokinetic clinical trial in pediatric Crohn's disease in 2013.

#### About Pediatric Crohn's Disease

Crohn's disease is an ongoing disorder that 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. Pediatric Crohn's disease is a subpopulation of approximately 80,000 patients in the U.S.. Crohn's disease tends to be both severe and extensive in the pediatric population and a relatively high proportion (~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.

6

---

### SGX201 –for Preventing Acute Radiation Enteritis

SGX201 is a delayed-release formulation of BDP specifically designed for oral use. 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 (“NCI”) 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 are currently working with our Radiation Enteritis medical advisory board to determine potential next steps forward with the clinical development program.

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

### About 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 2-6 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.

There are over 100,000 patients annually in the U.S. who receive abdominal or pelvic external beam radiation treatment for cancer, and these patients are at risk of developing acute and chronic radiation enteritis.

### orBec® –for Treating Chronic GI GVHD

orBec® is a two tablet delivery system of BDP specifically designed for oral use that allows for delivery of immediate and delayed release BDP to treat the gastrointestinal manifestation of chronic GVHD, the organ system where GVHD is most frequently encountered and highly problematic. orBec® is intended to reduce the need for systemic immunosuppressive drugs such as prednisone to treat chronic GI GVHD. The active ingredient in orBec® is BDP, a highly potent, topically active corticosteroid that has a local effect on inflamed tissue. 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. orBec® has been awarded orphan

drug designations in the U.S. and in Europe for the treatment of GI GVHD. In September 2012, we received a \$300,000 two-year SBIR grant awarded by the NIH to support a Phase 2 study for the treatment of chronic GI GVHD.

## About Chronic GVHD

GVHD is a major complication of allogeneic hematopoietic cell transplantation. GVHD is an inflammatory disease initiated by T cells in the donor graft that recognize histocompatibility and other tissue antigens of the host, and is mediated by a variety of effector cells and inflammatory cytokines. GVHD presents in both acute and chronic forms. The symptoms of chronic GVHD typically present at between 100 days and three years post-transplant.

Chronic GVHD has features resembling autoimmune and other immunologic disorders such as scleroderma, Sjögren syndrome, primary biliary cirrhosis, wasting syndrome, bronchiolitis obliterans, immune cytopenias and chronic immunodeficiency. The manifestations of chronic GVHD may be restricted to a single organ or tissue or may be widespread. Chronic GVHD can lead to debilitating consequences, e.g., joint contractures, loss of sight, end-stage lung disease, or mortality resulting from profound chronic immune suppression leading to recurrent or life-threatening infections.

Treatment of chronic GVHD is a challenge because it can be refractory to frontline immunosuppression. High-dose systemic corticosteroids are used with some success but carry significant toxicity. The risks of prolonged immunosuppression include local and disseminated infections, Epstein-Barr virus associated lymphoproliferative disease, hypothalamic-pituitary-adrenal (“HPA”) axis suppression, myopathy, glucose intolerance, neuropsychiatric disease and bone demineralization.

## 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. The World Health Organization (“WHO”) reports that 50% of all vaccines around the world are wasted due to thermostability issues. 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. The savings realized from the elimination of cold chain costs and related product losses would in turn significantly increase the profitability of vaccine products. Elimination of the cold chain would also 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 is being supported pursuant to our \$9.4 million National Institute of Allergy and Infectious Diseases (“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™, made under precise lyophilization conditions using excipients that aid in maintaining native protein structure of the ricin A chain, the immunogenic compound of the vaccine. When RiVax™ was kept at 40 degrees C for over three months, all of the animals vaccinated with the lyophilized RiVax™ vaccine developed potent and high titer neutralizing antibodies. Confirmatory results have extended the stability to more than three months when the vaccine is kept at 40 degrees C. 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.

Near term progress with ThermoVax™ will allow us to seek out potential partnerships with companies marketing FDA/ex-U.S. health authority approved Alum adjuvanted vaccines that are interested in eliminating the need for cold chain for their products. ThermoVax™ will further enable Soligenix to expand its 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).

ThermoVax™ is the subject of U.S. patent application number 12/532,225 filed January 29, 2010 entitled “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 entitled “Thermostable Vaccine Compositions and Methods of Preparing Same.” These patents and their corresponding foreign filings are pending and licensed to Soligenix 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.

#### RiVax™ – Ricin Toxin Vaccine

RiVax™ is our proprietary vaccine developed to protect against exposure to ricin toxin, and is the first ricin. With RiVax™, we are a world leader in ricin toxin vaccine research. 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. Two Phase 1 human clinical trials have been completed. The development of RiVax™ has been sponsored through a series of overlapping challenge grants, UC1, and cooperative grants, U01, from the NIH, granted to Soligenix and to the University of Texas Southwestern Medical Center (“UTSW”) where the vaccine originated. The second clinical trial was supported by a grant from the FDA's Office of Orphan Products to UTSW. Soligenix and UTSW have collectively received approximately \$25 million in grant funding from the NIH for RiVax™. Results of the first Phase 1 human trial of RiVax™ established that the immunogen was safe and induced antibodies anticipated to 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, PNAS, 105:2268-2273). The second trial, sponsored by UTSW, evaluated a more potent formulation of RiVax™ that contained an aluminum adjuvant (Alum), was completed in September 2012. 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, Clin. Vaccine Immunol. 10:1697-9). We have adapted the original manufacturing process for the immunogen contained in RiVax™ for large scale manufacturing and are further establishing correlates of the human immune response in non-human primates.

RiVax™ is the subject of three issued U.S. patent numbers 6,566,500, 6,960,652, and 7,829,668, all entitled “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 entitled “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. RiVax™ has also been granted Orphan Drug designation by the FDA for the prevention of ricin intoxication.



## About 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 Investigations Bioterror report released in November 2007 entitled 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](http://www.fbi.gov/stats-services/publications/terrorism-2002-2005/terror02_05.pdf)).

The Centers for Disease Control (“CDC”) 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. 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.

In January of 2012, a Request for Information (“RFI”) was issued by the Chemical Biological Medical Systems – Joint Vaccine Acquisition Program (“CBMS-JVAP”) of the Department of Defense (“DoD”). This RFI was entitled “Development of a Ricin Toxin Vaccine to FDA Approval”, and marks the first time any agency of the U.S. government has specifically indicated an interest in development of a vaccine against ricin toxin. We intend to pursue this avenue of funding to the fullest extent.

## VeloThrax™ – Anthrax Vaccine

VeloThrax™ is our newly acquired proprietary vaccine based on a recombinant Protective Antigen (“rPA) derivative intended for use against anthrax. Soligenix has entered into an exclusive license option with Harvard College to license VeloThrax™ (also known as DNI for dominant negative inhibitor). VeloThrax™ is a translocation-deficient mutant of PA with double mutations of K397D and D425K that impede the conformational changes necessary for endosomal membrane translocation into the cell cytoplasm. In the absence of that PA translocation step, anthrax toxin trafficking and function cease. VeloThrax™ is also considered a more immunogenic candidate than native rPA. This apparent increase in immunogenicity suggests that the DNI rPA is processed and presented to the immune system more efficiently by cellular antigen processing pathways, which is consistent with known properties of the molecule.

DNI versions of rPA such as VeloThrax™ are also capable of inducing antibodies that neutralize the activity of the anthrax toxin complex. Unlike fully-functional rPA, VeloThrax™ might be given to a patient post-exposure without risk of enhancing intoxication during an infection, although clinical tests involving intravenous administration of potentially therapeutic levels of DNI rPA resulted in serious adverse events and so further development of this product as a therapeutic biological for blocking the effects of infection by *B. anthracis* was discontinued. Soligenix intends to test VeloThrax™ at a 1,000 fold lower dose than previously tested for an intramuscular or intradermal vaccine.

VeloThrax™’s greater immunogenicity could lead to a vaccine that can be administered in the fewest possible doses to induce the highest level of toxin neutralizing antibodies. Utilizing ThermoVax™, we believe that we will be able to develop VeloThrax™ into a vaccine with an improved stability profile, an issue that has proven challenging in the development of other anthrax vaccines. Extended stability at ambient temperatures would be a significant improvement for stockpiled vaccines and one which is not expected from conventional vaccines. Further, a large-scale, Good Manufacturing Practice (“cGMP”) production methodology has already been completed. Assuming long-term stability can be met, VeloThrax™ could be stockpiled for general prophylactic as well as a post exposure use.





The overall objective of the VeloThrax™ program is to rapidly and efficiently develop a next generation anthrax vaccine which combines a well established, safe and relatively low risk vaccine development and dosing approach with targeted, proven innovative strategies. VeloThrax™ will potentially be a combination of a stable, readily manufactured mutant rPA subunit antigen with next generation, clinically compatible adjuvants which have been demonstrated to enhance potency and reduce the time and number of vaccine doses required to achieve protective titer using a variety of vaccine antigens. This blend of proven yet innovative technologies will provide the Public Health Emergency Medical Countermeasures Enterprise (“PHEMCE”) and the DoD with a safe and stable alternative to the existing licensed anthrax vaccine product. Soligenix also proposes to adapt newly developed glassification technology (initially developed under an ongoing NIAID grant to stabilize exceptionally unstable ricin toxin/adjuvant formulations) to enable a thermostable, dried, single vial, pre-formulated adjuvanted rPA vaccine which is suitable for both long term storage and field use without typical cold chain constraints.

#### About Anthrax

Anthrax is an acute infectious disease that is easily transmitted to humans by environmentally durable spores that are produced by *Bacillus anthracis*. Because the spores are robust and contagious, anthrax is considered a Category A bioterror threat. Anthrax infection can occur in three forms: cutaneous (skin), inhalation, and gastrointestinal. Inhaled spores can cause a rapidly progressing form of anthrax since the spores are transported to lymph nodes near the lungs where they germinate, releasing vegetative bacteria into the bloodstream. Bacteria synthesize a complex series of toxin components that make up anthrax toxin, resulting in overwhelming toxemia that causes shock and organ failure. Treatment of anthrax involves long-term antibiotic therapy, since ungerminated spores can lie dormant in the lungs for up to 60 days. Only a few inhaled spores can cause inhalational anthrax. Once the toxin has entered the bloodstream, antibiotics are ineffective, and only toxin-specific therapy is effective. Passively transferred antibodies can neutralize anthrax toxins and can be used post-exposure in conjunction with antibiotics. Because of the long residence time of spores in the lung, it is possible to vaccinate post-exposure, but the onset of neutralizing antibodies must occur during the period of antibiotic therapy.

#### OrbeShield™ –for Treating GI ARS

OrbeShield™ (an oral immediate and delayed release formulation of the topically active corticosteroid BDP) is being developed for the treatment of GI ARS. Corticosteroids are the best understood and most 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 2 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. This is the same type of toxicity that occurs in Soligenix’s acute radiation enteritis clinical program with SGX201. As a result, there is a dual avenue of development for Soligenix, and OrbeShield™ is potentially a “dual use” compound, a desirable characteristic which is a specific priority of Biomedical Advanced Research and Development Authority (“BARDA”) for ARS and other medical countermeasure indications. BARDA recently invited Soligenix to submit a full contract proposal for a potential multi-year, multi-million dollar contract to develop OrbeShield™ from its

current level of technical readiness to potential FDA approval. In response, Soligenix submitted its contract proposal in February 2013. We expect a response in the second half of 2013.

The FDA has cleared the Investigational New Drug (“IND”) application for OrbeShield™ for the mitigation of morbidity and mortality associated with GI ARS. Previously, development of OrbeShield™ had been largely supported by a \$1 million NIH grant to Soligenix’s academic partner, the Fred Hutchinson Cancer Research Center. In July 2012, the Company 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 awarded OrbeShield™ Orphan Drug and Fast Track designation for the prevention of death following a potentially lethal dose of total body irradiation during or after a radiation disaster.

## About GI ARS

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 >2 Gy 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 in 5-15 days. The GI tract is highly sensitive due to the requirement for incessant proliferation of 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. Therefore, there is an urgent need to develop specific medical counter measures against the lethal pathophysiological manifestations of radiation-induced GI injury.

## The Drug Approval Process

Before marketing, each of our products must undergo an extensive regulatory approval process conducted by the FDA and applicable agencies in other countries. Testing, manufacturing, commercialization, advertising, promotion, export and marketing, among other things, of the proposed products are subject to extensive regulation by government authorities in the U.S. and other countries. All products must go through a series of tests, including advanced human clinical trials, which the FDA is allowed to suspend as it deems necessary to protect the safety of patients.

Our products will require regulatory clearance by the FDA and by comparable agencies in other countries, prior to commercialization. The nature and extent of regulation differs with respect to different products. In order to test, produce and market certain therapeutic products in the U.S., mandatory procedures and safety standards, approval processes, manufacturing and marketing practices established by the FDA must be satisfied.

An IND application is required before human clinical testing in the U.S. of a new drug compound or biological product can commence. 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 an NDA for approval of a drug. 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, 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. 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 products. 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 Federal Food, Drug, and Cosmetic Act, 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 Federal Food, Drug, and Cosmetic Act 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.

### Marketing Strategies

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, the Company has agreed to pay Sigma-Tau: (a) a royalty amount equal to 3% of all net sales of oral BDP made directly by the Company, 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 the Company’s patents and patent applications relating to oral BDP in such country; and (b) 15% of all up-front payments, milestone payments and any other consideration (exclusive of equity payments) received by the Company and/or a potential partner from the Company’s 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.



We intend to seek partners to out-license all or portions of our programs. We are keen to advance our products through development and into the market in as many indications as possible.

We have had and are having strategic discussions with a number of pharmaceutical companies regarding the partnering or sale of our biodefense vaccine products. We may market our biodefense vaccine products directly to government agencies. 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.

## Competition

Our competitors are pharmaceutical and biotechnology companies, most of whom have considerably greater financial, technical, and marketing resources than we currently have. Another source of competing technologies is universities and other research institutions, including the U.S. Army Medical Research Institute of Infectious Diseases, and we face competition from other companies to acquire rights to those technologies.

### SGX94/942 Competition

SGX94 has a unique mechanism of action in combating bacterial infections and is complementary to the use of antibiotics. Thus 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 (e.g. Celtaxsys, Innaxon Therapeutics, Innate Pharma).

There is currently one drug approved for the treatment of oral mucositis in hematological cancer only (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 at least 5 drugs in clinical development for oral mucositis – 1 in phase 3 (under development by Daewoong Pharmaceutical Co., Ltd), 3 in phase 2 (under development by ActoGenix N.V., BioAlliance Pharma S.A. and Alder Biopharmaceuticals Inc.) and 1 in phase 1 (under development by PolyMedix, Inc.). 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; however, none of these devices are biologically based.

### Oral BDP Competition

There are currently approximately 41 compounds either on the market or in clinical development for Crohn's disease of which 14 are biologics, 6 immunomodulators, 3 cell-based therapies, 2 steroids, 2 anti-inflammatory, 2 5-ASAs, 1 antibiotic, and 11 others that are unclassified. In the U.S., there are 24 compounds on market or in development including 4 compounds in Phase 3.

There are 4 compounds currently in development or on the market specifically for pediatric Crohn's disease. Of these, Remicade (infliximab) is the only compound currently with an indication in pediatric Crohn's disease. There are two other marketed biologics, Cimzia (certolizumab) and Tysabri (natalizumab), in Phase 2 for pediatric Crohn's. Entocort (enteric-coated budesonide) is also currently in Phase 3 trials in pediatric Crohn's disease. We believe that SGX203's unique release characteristics, intended to deliver topically active therapy to both the upper and lower gastrointestinal systems, should make SGX203 an attractive alternative to existing therapies for inflammatory diseases of the gastrointestinal tract.





Competition is also intense in the gastroenterology and transplant areas. Companies are attempting to develop technologies to treat GVHD by suppressing the immune system through various mechanisms. Some companies, including Osiris, Abgenix, and PDL BioPharma, Inc., are developing monoclonal antibodies to treat GVHD. Novartis, Medimmune, and Ariad are developing both gene therapy products and small molecules to treat GVHD. All of these products are in various stages of development. Kiadis Pharma is also developing products for the treatment of GVHD. In addition, there are investigator-sponsored clinical trials exploring the use of approved drugs such as Enbrel®, which has been approved by the FDA for the treatment of rheumatoid arthritis, in the treatment of GVHD.

Additionally, Chiesi Pharmaceuticals markets, in certain countries in Europe, a delayed-release oral formulation of beclomethasone dipropionate, the active ingredient of orBec®, called CLIPPER™ for ulcerative colitis.

#### ThermoVax™ Competition

Multiple groups and companies are working to address the unmet need of vaccine thermostability using a variety of technologies. In addition, both non-governmental organizations such as the Bill and Melinda Gates Foundation and PATH, as well as academic organizations such as the Kansas University Macromolecular and Vaccine Stabilization Center have programs designed to advance technologies which may address this need.

The majority of 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 and synthetic polymers such as Pluronic F127 (Endo Pharmaceuticals under Gates Foundation funding). VBI (Variation Biotechnologies, Inc) intends to employ a lipid system (resembling liposomes) to stabilize viral antigens, including virus-like particles (VLPs), and apply it to a conventional influenza vaccine among others

Other approaches involve process variations to freeze-dry live virus vaccines. For example, PaxVax intends 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 has the capacity 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), 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. Another Soligenix competitor, Endo Pharmaceuticals is working to identify Pluronic polymer-based formulations that stabilize measles and hepatitis B vaccines from -10°C to 45°C.

Additionally, companies like Pharmathene, Panacea Biotech, and Compass Biotech 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 currently available anthrax vaccine known as BioThrax® (Anthrax Vaccine Adsorbed or AVA) marketed by Emergent BioSolutions, Inc. was developed nearly 50 years ago from a culture filtrate derived from anthrax bacteria. Consequently, it contains a number of different proteins, some of which are believed to potentially contribute to the adverse events that have been reported in the literature (up to 7-8% serious adverse events) and which prompted

agencies like the Institute of Medicine to recommend adoption of newer and safer anthrax vaccines. BioThrax® is FDA approved for the prevention of anthrax infection, but requires five doses over a period of eighteen months to achieve protective immunity.

With respect to the development of PA-based vaccines and therapeutics such as VeloThrax™, there are a number of other companies in preclinical and clinical development including Emergent, Pharmathene, Dynavax, Panacea Biotech, Paxvax, Elusys, and Pfenex.

Cangene is currently developing an anthrax immune globulin therapeutic based on plasma collected from military personnel who have been vaccinated with BioThrax®. Human Genome Sciences is developing a monoclonal antibody to Bacillus anthracis, referred to as ABthrax™, as a post-exposure therapeutic for anthrax infection. Elusys Therapeutics is developing a monoclonal antibody to Bacillus anthracis, known as Anthim™, as a pre-exposure and post-exposure prophylaxis against anthrax infection, as well as an active treatment of the disease. Pharmathene and Medarex are collaborating to develop a human antibody to anthrax, known as Valortim™. Bavarian Nordic is developing a multivalent combination vaccine against both anthrax and smallpox.

The only potential competition to RiVax™ is being developed by the U.S. Army Medical Research Institute of Infectious Diseases (“USAMRIID”), the DoD’s lead laboratory for medical research to counter biological threats. Development of this product, known as RVEc™, is proceeding under a program led by Dr. Len Smith, who has been working for many years to develop a ricin vaccine candidate. Similar to RiVax™, 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 successfully conducted to evaluate RVEc™’s safety as well as its immunogenicity.

In the area of radiation-protective antidotes such as OrbeShield™, various companies, such as Cleveland Biolabs, Aeolus Pharmaceuticals, Boulder Biotechnology, RxBio, Inc., Avaxia Biologics, Exponential Biotherapies Inc., Osiris Therapeutics, Inc., ImmuneRegen BioSciences, Inc., Neumedicines, Inc., Cellerant Therapeutics, Onconova Therapeutics, Inc., Araim Pharmaceuticals, Inc., EVA Pharmaceuticals, Terapio, 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’s 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.



We are the exclusive licensee of 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. 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.

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.

Recently, we have 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.

In addition to issued and pending patents, we also have “Orphan Drug” designations for SGX203 in the U.S. for pediatric Crohn’s disease, OrbeShield™ in the U.S. for GI ARS, orBec® in the U.S. and Europe (E.U.) for GI GVHD, 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. 10 year post-approval exclusivity provided by Orphan Drug legislation.

#### 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 orBec®/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. In consideration for the license, the Company has paid to Dr. McDonald a license fee in the amount of \$20,000 and 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 a milestone payment in the amount of \$300,000; (iii) issue Dr. McDonald shares of common stock equal to 8% of the Company’s outstanding common stock as of November 24, 1998, with certain anti-dilution protection, and (iv) pay Dr. McDonald royalty payments equal to 6% of net sales of the covered products.

Additionally, in the event that the Company sublicenses its rights under this license agreement, the Company will be required to pay Dr. McDonald 25% of any sublicense fees and royalty payments paid by the sublicense to the Company.

The term of this agreement expires upon the expiration of the licensed patent applications or patents. After five years from the date of the agreement, Dr. McDonald has the right to terminate this 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.

On July 26, 2011, the Company, Enteron, and Dr. McDonald entered into an amendment to their exclusive license agreement. Under the license agreement, Dr. McDonald would have been entitled to receive (i) \$1,250,000 upon the closing of the July 26, 2011 amendment executed by the Company and Sigma-Tau; and (ii) \$250,000 upon an approval of orBec® by the EMEA. Pursuant to the amendment, the Company agreed to pay Dr. McDonald (i) \$612,500 in cash and \$400,000 in common stock of the Company (based upon the closing price of the Company's common stock on July 26, 2011) upon the closing of the amendment between the Company and Sigma-Tau and (ii) \$400,000 in cash upon an approval of orBec® by the EMEA.

On December 20, 2012, the Company, Enteron, and Dr. McDonald entered into an amendment to their exclusive license agreement. Under the license agreement, Dr. McDonald would have been entitled to receive (i) royalty payments equal to 6% of net sales of the covered products, and (ii) 25% of any sublicense fees and royalty payments paid by the sublicense to the Company. Pursuant to the amendment, the Company agreed to pay Dr. McDonald (i) royalty payments equal to 3% of the net sales of the covered products and (ii) 10% of any sublicense fees and royalty payments paid by the sublicense to the Company.

#### SGX 94 License Agreements

On December 18, 2012, we announced the acquisition of a novel drug technology, known as SGX94, representing a unique 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, Soligenix 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.

#### ThermoVax™ License Agreement

On September 1, 2009, we executed a worldwide exclusive option to license patent applications with the UC for ThermoVax™ which is the subject of U.S. patent application number 60/896,429 filed on March 22, 2007 entitled "Method of Preparing an Immunologically-Active Adjuvant-Bound Dried Vaccine Composition." This patent and its corresponding foreign filings are pending and licensed to Soligenix by the UC and they address the use of adjuvants in conjunction with vaccines that are formulated to resist thermal inactivation. The license agreement also covers thermostable vaccines for biodefense as well as other potential vaccine indications. In addition, Soligenix in conjunction with UC, filed a provisional patent application number 61/487,206 on May 17, 2011 entitled: "Thermostable Vaccine Compositions and Methods of Preparing Same."

#### RiVax™ License Agreement

In January 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. Our license obligates us to pay \$50,000 in annual license fees. Through this license, we have rights to the issued patent number 7,175,848 entitled "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™.

#### VeloThrax™ License Option Agreement



In December of 2011, we optioned a license to the VeloThrax™ patent from the President and Fellows of Harvard College. VeloThrax™ is the subject of U.S. patent No. 7,037,503, issued on May 2, 2006 and entitled, “Compounds and Methods for the Treatment and Prevention of Bacterial Infection”, along with any reissue, renewal, reexamination, substitution or extension thereof. The PCT application patent was filed in May 2001 and will expire in May 2021 (barring any patent term extensions).

## Research and Development Expenditure

We spent approximately \$2.6 million and \$6.3 million in the years ended December 31, 2012 and 2011, respectively, on research and development. The amounts we spent on research and development per product during the years ended December 31, 2012 and 2011 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, 2012, we had 10 full-time employees, 4 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](mailto:info@soligenix.com).

## Item 1A. Risk factors

You should carefully consider the risks, uncertainties and other factors described below before you decide whether to buy shares of our common stock. Any of the factors could materially and adversely affect our business, financial condition, operating results and prospects and could negatively impact the market price of our common stock. Below are the significant risks and uncertainties of which we are aware. 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.

### 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 have a significant accumulated deficit. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of December 31, 2012, we have approximately \$3.4 million in cash available. Based on our projected budgetary needs and funding from existing grants over the next two years, we expect to be able to maintain the current level of our operations into the second quarter of 2014.

We have sufficient funds through our existing biodefense grant facilities from the NIAID, a division of the NIH, to finance our biodefense projects for the next several years. In September 2009, we received a NIAID grant for approximately \$9.4 million for the development of our biodefense programs and recently received an additional SBIR grant from NIAD for \$600,000. Our biodefense grants have an overhead component that allows us an agency-approved percentage over our incurred costs. We estimate that the overhead component, which is approximately 21% above our subcontracted expenses, will finance some fixed costs for direct employees working on the grants and other administrative costs.



Our products are positioned for or are currently in clinical trials, and we have not yet generated any significant revenues from sales or licensing of them. From inception through December 2012, we have expended approximately \$46.7 million developing our current product candidates for pre-clinical research and development and clinical trials, and we currently expect to spend at least \$3 million over the next two years in connection with the development of our therapeutic and vaccine products, licenses, employment agreements, and consulting agreements. 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 unsuccessful in developing our products, our ability to generate revenues will be significantly impaired.

To be profitable, our organization must, along with corporate partners and collaborators, successfully research, develop and commercialize our technologies or product candidates. Our current product candidates are in various stages of 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 unsuccessful in our efforts to secure profitable procurement contracts 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.

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 not be able to successfully 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.

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 U.S., 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 and require the expenditure of substantial capital and other resources. For example, our confirmatory Phase 3 clinical trial for orBec® (oral BDP) in the treatment of GI GVHD was stopped on September 15, 2011 at the recommendation of an independent Data Safety Monitoring Board (“DSMB”) as it was highly unlikely to achieve the predetermined end point of efficacy based on the interim results. Although no safety concerns were raised by the DSMB, preliminary findings indicated that there were no significant differences between the orBec® group and placebo group for the primary endpoint or for the pre-specified secondary endpoints. Given the outcome of the Phase 3 study, the Company terminated the development of orBec® for the treatment of acute GI GVHD. Although we hope to obtain FDA approval for oral BDP in similar indications, such as treatment of chronic GI GVHD, treatment of pediatric Crohn's disease acute radiation enteritis, and GI ARS, there can be no assurances that the FDA will ever approve oral BDP for market launch in any of these indications.

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 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. 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.

We will be 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 successful 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.

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 are anticipating 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 successfully produce and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or 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.

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

We do not have 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.

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.

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.

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 are currently separately billed. 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. We cannot speculate on the potential sales impact to orBec® based on the new rule.

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 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.

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 \$5 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 not be able to compete successfully with our 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 successfully with our existing and future competitors.

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 success depends 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 have obtained, or may obtain 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 regarding the breadth of claims allowed in biotechnology patents.

In addition, because patent applications in the U.S. are maintained in secrecy until 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 Patent and Trademark Office 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 patented technologies may infringe on patents or other rights owned by others, licenses to which may not be available to us. We may not be successful in our efforts 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.

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 only 10 employees and we depend upon these employees 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 will not be successful if our management team cannot effectively manage and operate our business.

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 months, there has been substantial volatility in financial markets due at least in part to the uncertainty with regard to the global economic environment and the potential impact of the so-called “fiscal cliff” arising from the combination of tax increases and automatic spending cuts scheduled to take effect at the end of calendar 2012 and in early calendar 2013 in the U.S. 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.

## Risks Related to our Common Stock

Our common stock price is highly volatile.

The market price of our common stock, like that of many other research and development public pharmaceutical and biotechnology companies, has been highly volatile and may continue to be so 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, 2012, the closing stock price (split adjusted) has fluctuated between a high of \$2.05 per share to a low of \$0.23 per share. As of February 19, 2013, our common stock closed at \$1.88 per share. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance. In addition, potential dilutive effects of future sales of shares of common stock 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.

Our common stock trades on the Over-the-Counter Bulletin Board.

Our common stock trades on the OTCQB securities market under the symbol "SNGX." The OTCQB is a decentralized market regulated by the Financial Industry Regulatory Authority in which securities are traded via an electronic quotation system that serves more than 3,000 companies. On the OTCQB, securities are traded by a network of brokers or dealers who carry inventories of securities to facilitate the buy and sell orders of investors, rather than providing the order matchmaking service seen in specialist exchanges. OTCQB securities include national, regional, and foreign equity issues. Companies traded on the OTCQB must be current in their reports filed with the SEC and other regulatory authorities.

If our common stock is not listed on a national exchange or market, the trading market for our common stock may become illiquid. Our common stock is subject to the penny stock rules of the SEC, which generally are applicable to equity securities with a price of less than \$5.00 per share, other than securities registered on certain national securities exchanges provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with bid and ask quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules require that, before a transaction in a penny stock that is not otherwise exempt from such rules, the broker-dealer must make a special written determination

that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. As a result of these requirements, our common stock could be priced at a lower price and our stockholders could find it more difficult to sell their shares.



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

We have a number of agreements or obligations that may result in dilution to investors. These include:

warrants to purchase a total of approximately 2,843,338 shares of our common stock at a current weighted average exercise price of approximately \$3.13; and  
options to purchase approximately 1,457,724 shares of our common stock at a current weighted average exercise price of approximately \$3.20.

To the extent that warrants or options are exercised, our stockholders will experience dilution and our stock price may decrease.

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

Our common stock has from time to time been "thinly-traded," meaning that the number of persons interested in purchasing our common stock 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 will develop or be sustained, or that current trading levels will be sustained.

#### Item 1B. Unresolved Staff Comments

None.

#### Item 2. Properties

We currently lease approximately 5,250 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. On February 7, 2012, we entered into a

lease agreement through March 31, 2015 for our existing office space. The rent for the first 12 months is approximately \$8,000 per month, or approximately \$18.25 per square foot on an annualized basis. This rent increases to approximately \$8,310 per month, or approximately \$19.00 per square foot on an annualized basis, for the remaining 24 months. 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 OTCQB under the symbol "SNGX." The following table sets forth, as adjusted for the reverse stock split of 1-for-20 effective February 1, 2012, for the periods indicated, the high and low sales prices per share of our common stock as reported by the OTCQB.

Period	Price Range	
	High	Low
Year Ended December 31, 2011:		
First Quarter	\$ 4.40	\$ 3.20
Second Quarter	\$ 5.20	\$ 3.60
Third Quarter	\$ 6.80	\$ 0.80
Fourth Quarter	\$ 1.00	\$ 0.60
Year Ended December 31, 2012:		
First Quarter	\$ 1.01	\$ 0.44
Second Quarter	\$ 0.53	\$ 0.23
Third Quarter	\$ 0.55	\$ 0.26
Fourth Quarter	\$ 0.77	\$ 0.38

As of February 19, 2013, the last reported price of our common stock quoted on the OTCQB was \$1.88 per share. The OTCQB 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. As of February 19, 2013, we have approximately 940 stockholders of record of our common stock.

## 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," "will," "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

Soligenix, Inc. was incorporated in Delaware in 1987. We are a development stage biopharmaceutical company that is focused on developing products to treat serious gastrointestinal diseases where there remains an unmet medical need, as well as developing several biodefense vaccines and therapeutics. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense.

Our BioTherapeutics business segment intends to develop oral beclomethasone dipropionate (“oral BDP”) indications such as pediatric Crohn’s disease and acute radiation enteritis. Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine, and VeloThrax™, our anthrax vaccine, and OrbeShield™, our gastrointestinal acute radiation syndrome (“GI ARS”) therapeutic. The advanced development of our vaccine programs is currently supported by our heat stabilization technology, known as ThermoVax™, under existing and on-going government grant funding.

An outline of our business strategy follows:

- Initiate a Phase 1/2 clinical trial of oral BDP, known as SGX203 for the treatment of pediatric Crohn’s disease;
- Initiate a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;
- Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal (“GI”) tract such as prevention of acute radiation enteritis, prevention of acute radiation syndrome, and treatment of chronic graft-versus-host disease (“GVHD”);
- Develop RiVax™ and VeloThrax™ in combination with our proprietary vaccine heat stabilization technology, known as ThermoVax™, to develop new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas;
- Continue to apply for and secure additional government funding for each of our BioTherapeutics and Vaccines/BioDefense programs through grants, contracts and/or procurements; and
- Explore other business development and merger/acquisition strategies.

## 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 rights for our current products in both the domestic and international markets. We believe that patent rights are one of our most valuable assets. Patents and patent applications are key components 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 industrial partners. These rights can also be sold or sub-licensed as part of our strategy to partner our 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, maintain and perhaps extending the lives of the patents. Therefore, our policy is to

capitalize these costs and amortize intangibles 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.

#### 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 stock 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.

#### Revenue Recognition

Principally our revenues are generated from National Institutes of Health (“NIH”) grants and revenues from licensing activities and the achievement of licensing milestones (in prior periods). Recording of revenue is applied in accordance with FASB ASC 605, Revenue Recognition, ASC 605-25 and/or Accounting Standard Update, ASU, 2009-13, Revenue Recognition – Multiple Element Arrangements. The revenue from NIH grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the grant, plus a facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized when expenses have been incurred by subcontractors or when we incur internal expenses that are related to the grant. Licensing and associated milestone revenues are recorded when earned.

#### 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 warrants’ provisions and determined that they were indexed to our own stock and therefore to be accounted for as an equity instrument for 2012 and 2011.

#### Stock-Based Compensation

From time to time, we issue restricted shares of common stock to vendors and consultants as compensation for services performed. These shares are typically issued as restricted stock, unless issued to non-affiliates under the 2005 Equity Incentive Plan, where the stock may be issued as unrestricted. The restricted stock can only have the restrictive legend removed if the shares underlying the certificate are sold pursuant to an effective registration statement, which we must file and have approved by the SEC, if the shares underlying the certificate are sold pursuant to Rule 144, provided certain conditions are satisfied, or if the shares are sold pursuant to another exemption from the registration requirements of the Securities Act of 1933, as amended (the “Securities Act”).

We determine stock-based compensation expense for options, warrants and shares of common stock granted to non-employees in accordance with FASB ASC 718, Stock Compensation, 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 option’s price is remeasured using the Black-Scholes model at the end of each quarterly reporting period. Stock-based compensation expense recognized

during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period.



## Material Changes in Results of Operations

### Year Ended December 31, 2012 Compared to 2011

For the year ended December 31, 2012, we had a net loss of \$4,163,008 as compared to a net loss of \$2,378,594 for the prior year, representing an increased loss of \$1,784,414 or 75%. This increase in the net loss is attributable to a decrease in revenue of \$4,518,202 primarily related to receipt in 2011 of \$5,000,000 from Sigma-Tau Pharmaceuticals, Inc. (“Sigma-Tau”) as payment on the execution of our expanded license agreement into the European territory (the “Sigma-Tau Agreement”), decreased expenses in research and development related to the conduct of the confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD in 2011 and an increase in general and administrative expenses of \$390,799 related to professional fees and non-cash expenses for replacing previously issued warrants to Sigma-Tau upon reacquiring the rights to orBec® and accelerating the vesting of certain stock options issued to a former employee.

For the year ended December 31, 2012, revenues and associated costs relate to NIH grants awarded in support of the development of ThermoVax™, GI-ARS and orBec®. For the year ended December 31, 2012, we had revenues of \$3,144,620 as compared to \$7,662,822 for the prior year, representing a decrease of \$4,518,202. The decrease in revenues were a result of \$5,000,000 received in 2011 relating to the Sigma-Tau Agreement offset by increases in NIH drawdowns and the associated development work underlying them. Grant revenues increased by \$481,798 or 18%, relating to ThermoVax™ and recently awarded SBIR grants for GI-ARS and Chronic GI GVHD.

We incurred costs related to grant revenue in the year ended December 31, 2012 and 2011 of \$2,593,075 and \$2,108,228, respectively, representing an increase of \$484,847, or 23%. These costs primarily relate to payments made to subcontractors in connection with research performed pursuant to grants. The cost changes are due to work performed on the NIH grant revenues discussed above.

Our gross profit for the year ended December 31, 2012 was \$551,545 as compared to \$5,554,594 for the prior year, representing a decrease of \$5,003,049. This decrease is due primarily to the Sigma-Tau Agreement and a 2011 reimbursement of certain period salary costs for which there is no current period cost.

Research and development spending decreased by \$3,663,375 or 58%, to \$2,609,241 for the year ended December 31, 2012 as compared to \$6,272,616 for the prior year. This decrease is primarily related to expenses incurred in 2011 for the confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD.

General and administrative expenses increased by \$390,799, or 17%, to \$2,632,972 for the year ended December 31, 2012, as compared to \$2,242,173 for the prior year. This increase related to professional fees and non-cash expenses for replacing previously issued warrants to Sigma-Tau upon reacquiring the rights to orBec® and accelerating the vesting of certain stock options issued to a former employee. These non-cash charges totaled \$268,128.

Net interest income for the year ended December 31, 2012 was \$6,202 as compared to \$7,444 for the prior year, representing a decrease of \$1,242, or 17%. This decrease was due to reductions in our cash position during 2012.

During the year ended December 31, 2012, 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 net operating loss (“NOL”) carryforwards to other New Jersey-based corporate taxpayers based in New Jersey, we sold New Jersey NOL carryforwards, resulting in the recognition of \$521,458 of income tax benefit, net of transaction costs. 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 year ended December 31, 2012 and December 31, 2011: Vaccines/BioDefense and BioTherapeutics.

Revenues for the Vaccines/BioDefense business segment for the year ended December 31, 2012 were \$2,919,677 as compared to \$2,010,234 for the year ended December 31, 2011, representing an increase of 909,443 or 45%. This increase is attributable to NIH grant revenue for work towards our ThermoVax™ vaccine technology and GI-ARS. Revenues for the BioTherapeutics business segment for the year ended December 31, 2012 were \$224,943 as compared to \$5,652,588 for the year ended December 31, 2011, representing a decrease of \$5,427,645. This significant decrease is primarily related to the \$5,000,000 received for the Sigma-Tau Agreement and a decrease in NIH grant revenue related to the orBec® Orphan grant.

Loss from operations for the Vaccines/BioDefense business segment for the year ended December 31, 2012 was \$33,636 as compared to \$154,395 for the year ended December 31, 2011, representing a decreased loss of \$120,759. This decrease is primarily attributed to NIH grant revenue for work towards our ThermoVax™ vaccine technology and GI-ARS. Loss from operations for the BioTherapeutics business segment for the year ended December 31, 2012 was \$2,203,721 as compared to \$1,278,156 for the year ended December 31, 2011, representing an increase of \$925,565. This increased loss is due to a significant decrease in research and development spending and the receipt in 2011 of \$5,000,000 relating to the Sigma-Tau Agreement.

Amortization and depreciation expense for the Vaccines/BioDefense business segment for the year ended December 31, 2012 was \$38,589 as compared to \$42,640 for the year ended December 31, 2011, representing a decrease of \$4,051, or 10%. Amortization and depreciation expense for the BioTherapeutics business segment for the year ended December 31, 2012 was \$190,003 as compared to \$181,213 for the year ended December 31, 2011, representing an increase of \$8,790, or 5%.

## Financial Condition and Liquidity

### Cash and Working Capital

As of December 31, 2012, we had cash and cash equivalents of \$3,356,380 as compared to \$5,996,668 as of December 31, 2011, representing a decrease of \$2,640,228 or 44%. As of December 31, 2012, we had working capital of \$2,682,383 as compared to working capital of \$5,696,444 as of December 31, 2011, representing a decrease of \$3,014,061 or 53%. The decrease in working capital was the result of the cash used in operating and investing activities over the period. For the year ended December 31, 2012, our cash used in operating activities was \$2,635,533, as compared to \$1,951,738 for the same period in 2011. Excluding the proceeds of \$5,000,000 received from Sigma-Tau for the European territory license in the third quarter of 2011, for the year ended December 31, 2012, we experienced a decrease in cash used in operating activities of \$4,316,205. This decrease was attributable to the decrease in research and development expenses related to the 2011 orBec® Phase 3 clinical trial.

Based on our current rate of cash outflows, cash on hand, proceeds from our grant-funded programs, reductions in headcount and expected proceeds from the State of New Jersey Technology Business Tax Certificate Transfer Program, management believes that our current cash will be sufficient to meet our anticipated cash needs for working capital and capital expenditures into the second quarter of 2014.

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

We have instituted a cost reduction plan which has reduced headcount and will continue to reduce costs wherever possible.

We have approximately \$3.8 million in active grant funding still available to support our associated research programs in 2014 and beyond. We plan to submit additional 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 \$521,458 in proceeds from the sale of NJ NOL in 2012, we expect to participate in this program during 2013 and beyond as the program is available; 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 financing opportunities 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.

### Reverse Stock Split

On February 1, 2012, we completed a reverse stock split of its issued and outstanding shares of common stock at a ratio of 1-for-20, whereby, every 20 shares of our common stock was exchanged for one share of our common stock. Our common stock began trading on the OTCQB on a reverse split basis on February 2, 2012. All share and per share data have been restated to reflect this reverse stock split.

### 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 \$3.8 million before any grant reimbursements, of which \$1.2 million relates to the BioTherapeutics business and \$2.6 million relates to the Vaccines/BioDefense business. We anticipate grant revenues in the next 12 months of approximately \$3.0 million to offset research and development expenses, primarily for the development of our ThermoVax™ vaccine technology.

The table below details our costs for research and development by program and amounts reimbursed for the years ended December 31, 2012 and 2011:

	2012	2011
<b>Research &amp; Development Expenses</b>		
orBec®	\$ 903,820	\$ 3,935,737
RiVax™ & ThermoVax™ Vaccines	1,307,589	1,831,593
SGX94/Other	397,832	505,286
<b>Total</b>	<b>\$ 2,609,241</b>	<b>\$ 6,272,616</b>
<b>Reimbursed under NIH Grants</b>		
orBec®	\$ 209,152	\$ 616,783
RiVax™ & ThermoVax™ Vaccines	2,383,923	1,491,445
<b>Total</b>	<b>\$ 2,593,075</b>	<b>\$ 2,108,228</b>
<b>Grand Total</b>	<b>\$ 5,202,316</b>	<b>\$ 8,380,844</b>

### Contractual Obligations

We have commitments of approximately \$425,000 at December 31, 2012 for several licensing agreements with consultants and universities, which upon clinical or commercialization success may require the payment of milestones and/or royalties if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

On February 7, 2012, we entered into a lease agreement through March 31, 2015 for our existing office space. The rent for the first 12 months is approximately \$8,000 per month, or approximately \$18.25 per square foot. This rent increases to approximately \$8,310 per month, or approximately \$19.00 per square foot on, for the remaining 24 months. Rent expense is recognized on a straight-line basis.

In February 2007, our Board of Directors authorized the issuance of the following number of shares to each of Dr. Schaber and Dr. Brey immediately prior to 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: 50,000 common shares to Dr. Schaber; and 10,000 common shares to Dr. Brey. The amended agreement with Dr. Schaber includes our obligation to issue shares if such event occurs.

Employees with employment contracts have severance agreements that will provide separation benefits from the Company if they are involuntarily separated from employment. On February 15, 2012, Mr. Myrianthopoulos' employment agreement was terminated. However, he continues to serve the Company as a consultant on business development and other related matters.

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
2013	\$ 100,000	\$ 105,000	\$ 205,000
2014	100,000	101,200	201,200
2015	75,000	25,000	100,000
2016	75,000	-	75,000
2017	75,000	-	75,000
Total	\$ 425,000	\$ 231,200	\$ 656,200

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

The information required by this Item 8 is contained on pages F-1 through F-22 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, 2012. 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.

Based on our assessment, management has concluded that, as of December 31, 2012, the Company's internal control over financial reporting is effective.

This report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the SEC that permit us to provide only management's report in this report.

## 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.

On February 15, 2012, the employment agreement of Mr. Myriantopoulos, Chief Financial Officer and Senior Vice-President was terminated and Mr. Joseph M. Warusz was appointed the Acting Chief Financial Officer.

## 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 February 22, 2013:

Name	Age	Position
Christopher J. Schaber, PhD	46	Chairman of the Board, Chief Executive Officer and President
Keith L. Brownlie, CPA	60	Director
Gregg A. Lapointe, CPA	54	Director
Robert J. Rubin, MD	67	Director
Jerome Zeldis, MD, PhD	62	Director
Robert N. Brey, PhD	62	Chief Scientific Officer and Senior Vice President
Kevin J. Horgan, MD	53	Chief Medical Officer and Senior Vice President
Joseph M. Warusz, CPA	56	Vice President of Finance, Acting Chief Financial Officer and Corporate Secretary

Christopher J. Schaber, PhD has over 23 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 is 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. During his tenure at Discovery Laboratories, Inc., Dr. Schaber played a significant role in raising over \$150 million through both public offerings and private placements. 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 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, a position he has held since April 2011. Mr. Brownlie also 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 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 where he was involved with over 100 public and private financings and M&A transactions. 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 a publicly traded specialty pharmaceutical and biotechnology companies.

Gregg Lapointe, CPA has been a director since March 2009. Mr. Lapointe has served on the Board of Directors of the Pharmaceuticals Research and Manufacturers of America (“PhRMA”) and SciClone Pharmaceuticals, Inc., and has been a member of the Corporate Council of NORD for several years. He previously served in varying roles for Sigma-Tau Pharmaceuticals, Inc, a private biopharmaceutical company, from September 2001 through March 2012, including Chief Operating Officer from November 2003 to April 2008 and Chief Executive Officer from April 2008 to March 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 and a Chartered Accountant in Ontario, Canada. 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 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 the Assistant Surgeon General in the United States Public Health Service. Dr. Rubin has served on the Board of 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 Zeldis, MD, PhD has been a director since June 2011. Dr. Zeldis is currently Chief Executive Officer of Celgene Global Health and Chief Medical Officer of Celgene Corporation, a publicly traded, fully integrated biopharmaceutical company, where he has been employed since 1997. 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. 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 M Phil, 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. He has published 116 peer reviewed articles and 24 reviews, book chapters, and editorials. 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.



Robert N. Brey, PhD has been with the Company since January 1996 and is currently our Chief Scientific Officer and Senior Vice President. He has also held the positions of Vice President Vaccine Development and Vice President of Research and Development. He also has held Scientific, Management and Project Management positions in the Lederle-Praxis division of American Cyanamid, now a division of Wyeth, in which he participated in the successful development of a vaccine for Haemophilus influenza meningitis, and a vaccine for pneumonia. While at Lederle-Praxis, Dr. Brey was Manager of Molecular Biology Research for vaccines and Project Manager for development of oral vaccines from 1985 through 1993. From 1993 through 1994, Dr. Brey served as Director of Research and Development of Vaxcel, in which he was responsible for developing adjuvant technology and formulations for improved vaccines. From 1994 through 1996, Dr. Brey established an independent consulting group, Vaccine Design Group, to identify and develop novel vaccine technologies and platforms. Before entering into drug and vaccine delivery, he held senior scientific positions at Genex Corporation from 1982 through 1986. Dr. Brey received a B.S. degree in Biology from Trinity College in Hartford, Connecticut, his PhD degree in Microbiology from the University of Virginia and performed postdoctoral studies at MIT with Nobel Laureate Salvador Luria.

Kevin J. Horgan, MD has been with the Company since January 2011 and is currently our Chief Medical Officer. Dr. Horgan is a board-certified gastroenterologist with more than 25 years academic and pharmaceutical experience. He has conducted research in cellular immunology and has experience in the care of patients with inflammatory bowel disease, including GVHD. Prior to joining Soligenix, Dr. Horgan served from 1997 to 2005 as Senior Director of Clinical Research at Merck & Co., Inc., where he led the development of the first neurokinin-1 receptor antagonist, EMEND® , which was approved for the prevention of chemotherapy-induced nausea and vomiting. From 2006 to 2008, he was Vice President of Clinical Immunology at Centocor Ortho Biotech Inc., where he designed and conducted gastroenterology clinical studies for new compounds and indications including REMICADE™. From 2008 until joining Soligenix, Dr. Horgan was Head of Internal Medicine Research and Development in medical imaging with specific focus on oncology and neuroscience with GE Healthcare (a unit of General Electric Company). Dr. Horgan received his medical degree from University College, Cork, Ireland and completed training in internal medicine with Queen Elizabeth Hospital, Birmingham, United Kingdom and Johns Hopkins Hospital, Baltimore, MD, followed by an immunology research fellowship with the National Cancer Institute in Bethesda, MD. His research on human T-cell differentiation, activation and migration with emphasis on integrin adhesion molecules provided a framework for subsequent validation of three therapeutic targets. Dr. Horgan then did a fellowship in gastroenterology with University of California at Los Angeles and was then an Assistant Professor of Medicine there, where his research focus was gastrointestinal inflammatory disorders.

Joseph M. Warusz, CPA has more than 28 years of financial management experience in public and private life science companies as well as large pharma. Prior to joining Soligenix on June 1, 2011 as Vice President of Administration and Controller, he held senior financial positions with Amicus Therapeutics, Inc., Orchid Cellmark, Inc., and NexMed, Inc., as well as consulting assignments at Ardea BioSciences, Inc., and NovaDel Pharma, Inc., all R&D-focused companies in the biotechnology and specialty pharmaceuticals arenas. On February 15, 2012, he was appointed Acting Chief Financial Officer of the Company. Prior to 1998, Mr. Warusz also held management positions in financial analysis, accounting, reporting and auditing at Bristol-Myers Squibb and Peat Marwick Main & Company. He received his BS in accounting and MBA in finance at Drexel University and is a Certified Public Accountant.

#### 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.

38

---

Messrs. Brownlie, Lapointe 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 meeting 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, provides the Chairman with input regarding agenda items for Board of Directors and Committee meetings, and coordinates 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 Securities Exchange Act of 1934.

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, 2012, our officers, directors and significant stockholders have timely filed the appropriate form under Section 16(a) of the Exchange Act.

#### 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 <http://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.

#### Audit Committee Financial Expert

We have an audit committee comprised of Messrs. Brownlie (Chair) and Lapointe and Dr. Rubin. The board of directors has determined that Mr. Brownlie qualifies as an "audit committee financial expert," as defined under the rules of the Securities and Exchange Commission. The 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.



The board of directors has determined that Messrs. Brownlie and Lapointe and Dr. Rubin are “independent directors” within the meaning of The NASDAQ Stock Market LLC (“Nasdaq”) corporate governance rules and the regulations under the Securities Exchange Act of 1934 (“Exchange Act”) applicable to audit committees.

## Item 11. Executive Compensation

## Summary Compensation

The following table contains information concerning the compensation paid during each of the two years ended December 31, 2012 to our Chief Executive Officer and each of the four other most highly compensated executive officers during 2012 (collectively, the “Named Executive Officers”).

Summary Compensation							
Name	Position	Year	Salary	Bonus	Option Awards	All Other Compensation	Total
Christopher J. Schaber <sup>1</sup>	CEO & President	2012	\$ 390,000	-	-	\$ 38,006	\$ 428,006
		2011	\$ 370,000	\$ 50,000	\$ 68,400	\$ 35,529	\$ 523,929
Robert N. Brey <sup>2</sup>	CSO & Senior VP	2012	\$ 210,000	-	-	\$ 23,375	\$ 233,375
		2011	\$ 210,000	\$ 13,000	\$ 19,950	\$ 21,853	\$ 264,803
Kevin J. Horgan <sup>3</sup>	CMO & Senior VP	2012	\$ 290,000	-	-	\$ 26,214	\$ 316,214
		2011	\$ 281,589	\$ 16,000	\$ 203,575	\$ 22,543	\$ 523,707
Joseph M. Warusz <sup>4</sup>	VP & Acting CFO	2012	\$ 180,000	-	-	\$ 38,006	\$ 218,006
		2011	\$ 104,028	\$ 7,000	\$ 152,620	\$ 19,627	\$ 283,275

<sup>1</sup>Dr. Schaber deferred payment of his 2011 annual bonus of \$50,000 until January 15, 2012. 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. In 2012, no bonus was awarded or option awards issued.

<sup>2</sup>Dr. Brey deferred payment of his 2011 annual bonus of \$13,000 until January 15, 2012. 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. In 2012, no bonus was awarded or option awards issued.

<sup>3</sup>Dr. Horgan deferred payment of his 2011 annual bonus of \$13,000 until January 15, 2012. 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. In 2012, no bonus was awarded or option awards issued.

<sup>4</sup>Mr. Warusz deferred payment of his 2011 annual bonus of \$7,000 until January 15, 2012. 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. In 2012, no bonus was awarded or option awards issued.

## 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. This employment agreement was renewed in December 27, 2007 for an additional term of three years. We agreed to issue him options to purchase 125,000 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 dependants. 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. This agreement automatically renewed in December 2010 for an additional term of three years.

On June 22, 2011, the Compensation Committee approved the increase in salary for Dr. Schaber to \$390,000. Additionally, his fixed minimum annual bonus payable was eliminated and revised to an annual targeted bonus of his annual base salary. Dr. Schaber's targeted bonus is 40%. On December 6, 2012, the Compensation Committee approved the increase in salary for Dr. Schaber to \$402,000.

In January 2011, we entered into a two-year employment agreement with Dr. Kevin J. Horgan. Pursuant to this employment agreement we agreed to pay Dr. Horgan a base salary of \$290,000 per year, a one-time signing bonus of \$15,000 and a targeted annual bonus of 30% of base salary. We agreed to issue him options to purchase 62,500 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. Horgan six months of severance, as well as any accrued bonuses, accrued vacation, and we would provide health insurance benefits for Dr. Horgan and his dependants. No unvested options shall vest beyond the termination date. On December 6, 2012, the Compensation Committee approved the increase in salary for Dr. Horgan to \$300,000.

We do not currently have an employment agreement with Dr. Robert N. Brey, our Chief Scientific Officer and Senior Vice President. Dr. Brey's compensation is determined by our Board of Directors and our Compensation Committee. On December 6, 2012, the Compensation Committee approved the increase in salary for Dr. Brey to \$214,000.

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 20% of base salary. We also agreed to issue him options to purchase 40,000 shares of our common stock with one-third immediately vesting and the remainder vesting over three years. Upon termination without "Just Cause", as defined in this agreement, we would pay Mr. Warusz three months of severance, accrued bonuses and vacation, and health insurance benefits. No unvested options vest beyond the termination date. On December 1, 2011, the Compensation Committee increased the salary of Mr. Warusz to \$180,000. On December 6, 2012, the Compensation Committee approved the increase in salary for Mr. Warusz to \$186,000.

In February 2007, our Board of Directors authorized the issuance of the following number of shares to each of Dr. Schaber and Dr. Brey 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: 50,000 common shares to Dr. Schaber and 10,000 common shares to Dr. Brey. The amended agreement with Dr. Schaber includes our obligation to issue such shares to him if such event occurs.

## 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, 2012. We have never issued Stock Appreciation Rights.

## Outstanding Equity Awards at Fiscal Year-End

Name	Number of Securities Underlying Unexercised Options (#)		Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Option Expiration Date
	Exercisable	Unexercisable	Options (#)		
Christopher J. Schaber	125,000	-	-	\$ 5.40	8/28/2016
	45,000	-	-	\$ 9.40	8/9/2017
	140,000	-	-	\$ 1.20	12/17/2018
	89,375	20,625	20,625	\$ 4.64	6/30/2020
	60,000	60,000	60,000	\$ 0.64	11/30/2021
Robert N. Brey	30,000	-	-	\$ 6.60	5/10/2016
	10,000	-	-	\$ 9.40	8/9/2017
	40,000	-	-	\$ 1.20	12/17/2018
	34,529	7,971	7,971	\$ 4.64	6/30/2020
	17,502	17,498	17,498	\$ 0.64	11/30/2021
Kevin J. Horgan	42,976	19,533	19,533	\$ 3.44	1/30/2021
	30,000	30,000	30,000	\$ 0.64	11/30/2021
Joseph M. Warusz	25,000	15,000	15,000	\$ 4.10	5/30/2021
	15,000	15,000	15,000	\$ 0.64	11/30/2021

## Compensation of Directors

The following table contains information concerning the compensation of the non-employee directors during the fiscal year ended December 31, 2012.

## Compensation of Directors

Name	Fees Earned		Total
	Paid in Cash <sup>1</sup>	Option Awards <sup>2</sup>	
Keith Brownlie	\$ 56,250	\$ 7,500	\$ 63,750
Tamar D. Howson <sup>3</sup>	\$ 22,500	-	\$ 22,500
Gregg A. Lapointe	\$ 42,500	\$ 7,500	\$ 50,000
Robert J. Rubin	\$ 54,375	\$ 7,500	\$ 61,875
Virgil D. Thompson <sup>3</sup>	\$ 24,375	-	\$ 24,375
Jerry Zeldis	\$ 47,500	\$ 7,500	\$ 55,500

<sup>1</sup> 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.

<sup>2</sup> 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 15,000 shares of common stock. Upon re-election to the Board, each Board member will receive 25,000 stock options which vest at the rate of 25% per quarter, commencing with the first quarter after each annual meeting of stockholders.

<sup>3</sup> Ms. Howson and Mr. Thompson did not stand for re-election to the Board of Directors at our June 21, 2012 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](http://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 April 1, 2013, 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	
Paolo Cavazza <sup>1</sup>	3,379,952	29.08	%
Claudio Cavazza (deceased) <sup>2</sup>	3,068,461	26.60	%
Sigma-Tau Pharmaceuticals, Inc. <sup>3</sup>	3,068,461	26.6.0	%
Christopher J. Schaber <sup>4</sup>	532,759	4.57	%
Gregg A. Lapointe <sup>5</sup>	132,636	*	
Robert N. Brey <sup>6</sup>	139,531	*	
Robert J. Rubin <sup>7</sup>	70,349	*	
Joseph Warusz <sup>8</sup>	44,375	*	
Kevin J. Horgan <sup>9</sup>	80,623	*	
Keith Brownlie <sup>10</sup>	33,750	*	
Jerry Zeldis <sup>11</sup>	33,750	*	
All directors and executive officers as a group (8 persons)	1,067,773	8.80	%

<sup>1</sup> Includes (a) 2,711,392 shares of common stock and warrants to purchase 357,069 shares of common stock exercisable within 60 days of January 31, 2013 held by Sigma-Tau Pharmaceuticals, Inc., (b) 223,685 shares of common stock and warrants to purchase 87,854 shares held by SINAF SA, and (c) 59,539 shares held by Mr. Paolo Cavazza. 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. Accordingly, Mr. Paolo Cavazza may be deemed to beneficially own the shares beneficially owned by Sigma-Tau Pharmaceuticals, Inc. and Chaumiere Sarl. Mr. Paolo Cavazza's address is Via Tesserte, 10, Lugano, Switzerland.

<sup>2</sup> Includes 2,711,392 shares of common stock and warrants to purchase 357,072 shares of common stock exercisable within 60 days of January 31, 2013 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. Claudio Cavazza directly and indirectly owns 57% of Sigma-Tau Finanziaria S.p.A. Accordingly, Mr. Claudio Cavazza may be deemed to beneficially own the shares beneficially owned by Sigma-Tau Pharmaceuticals, Inc. Mr. Claudio Cavazza's address is Via Sudafrica, 20, Rome, Italy 00144. The address of Sigma-Tau Pharmaceuticals, Inc. is c/o Sigma-Tau Pharmaceuticals, Inc., 9841 Washingtonian Boulevard, Suite 500, Gaithersburg, Maryland 20878.



- Includes 2,280,962 shares of common stock and warrants to purchase 98,814 shares of common stock exercisable within 60 days of January 31, 2013. The amount does not include 77,344 shares of common stock held by Paolo Cavazza, one of the principal owners of Sigma-Tau. The address of Sigma-Tau Pharmaceuticals, Inc. is c/o Sigma-Tau Pharmaceuticals, Inc., 9841 Washingtonian Boulevard, Suite 500, Gaithersburg, Maryland 20878.
- 4Includes 50,158 shares of common stock owned by Dr. Schaber, options to purchase 480,625 shares of common stock exercisable within 60 days of January 31, 2013, and warrants to purchase 1,976 shares of common stock exercisable within 60 days of January 31, 2013. The address of Dr. Schaber is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- 5Includes 48,781 shares of common stock, options to purchase 50,837 shares of common stock exercisable within 60 days of January 31, 2013, and warrants to purchase 29,268 shares of common stock exercisable within 60 days of January 31, 2013. The address of Mr. Lapointe is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- 6Includes options to purchase 139,531 shares of common stock exercisable within 60 days of January 31, 2013. The address of Dr. Brey is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- 7Includes 12,195 shares of common stock, options to purchase 50,837 shares of common stock exercisable within 60 days of January 31, 2013, and warrants to purchase 7,317 shares of common stock exercisable within 60 days of January 31, 2013. The address of Dr. Rubin is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- 8Includes options to purchase 44,375 shares of common stock owned by Mr. Warusz exercisable within 60 days of January 31, 2013. The address of Mr. Warusz is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- 9Includes options to purchase 80,623 shares of common stock owned by Dr. Horgan exercisable within 60 days of January 31, 2013. The address of Dr. Horgan is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- 10Includes options to purchase 33,750 shares of common stock exercisable within 60 days of January 31, 2013. The address of Mr. Brownlie is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540

11 Includes options to purchase 33,750 shares of common stock exercisable within 60 days of January 31, 2012. The address of Mr. Zeldis 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 January 31, 2013 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 11,179,968 shares of common stock outstanding as of January 31, 2013.

### 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 2007, 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 1,000,000 shares, bringing the total shares reserved for issuance under the plan to 2,000,000 shares. In September 2010, our stockholders approved a second 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 750,000 shares, bringing the total shares reserved for issuance under the plan to 1,750,000 shares. The following table provides information, as of December 31, 2012 with respect to options outstanding under our 1995 Amended and Restated Omnibus Incentive Plan and our 2005 Equity Incentive Plan.

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 <sup>1</sup>	1,457,724	\$ 3.20	129,711
Equity compensation plans not approved by security holders	-	-	-
<b>Total</b>	<b>1,457,724</b>	<b>\$ 3.20</b>	<b>129,711</b>

<sup>1</sup> Includes our 1995 Amended and Restated Omnibus Incentive Plan and our 2005 Equity Incentive Plan. Our 1995 Plan expired in 2005 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

Other than the employment agreements and compensation paid to our directors, we did not engage in any transactions with related parties since January 1, 2011. 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 Keith Brownlie, Gregg Lapointe, Dr. Robert Rubin and Dr. Jerome 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.

Item 14. Principal Accountant Fees and Services

The following table highlights the aggregate fees billed during each of the two years ended December 31, 2012 by EisnerAmper, LLP.

	2012	2011
Audit fees	\$ 121,590	\$ 137,847
Tax fees	8,400	8,524
Total	\$ 129,990	\$ 146,371

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 ended December 31, 2012.

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:

Consolidated Balance Sheets as of December 31, 2012 and 2011	F-2
Consolidated Statements of Operations for the Years Ended December 31, 2012 and 2011	F-3
Consolidated Statements of Stockholders' Deficiency for the Years Ended December 31, 2012 and 2011	F-4
Consolidated Statements of Cash Flows for the Years Ended December 31, 2012 and 2011	F-5
Notes to Consolidated Financial Statements	F-6
Reports of Independent Registered Public Accounting Firms	F-20

## (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).
- 4.1 Rights Agreement dated June 22, 2007, between the Company and American Stock Transfer & Trust Company, as Rights Agent (incorporated by reference to Exhibit 4.1 included in our current report on Form 8-K filed on June 22, 2007).
- 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).
- 10.1 Amended and Restated 1995 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.1 included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended September 30, 2003). \*\*

- 10.2 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).
- 10.3 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).
- 10.4 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).
- 10.5 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).
- 10.6 2005 Equity Incentive Plan (incorporated by reference to Appendix D to our Proxy Statement filed December 12, 2005). \*\*
- 10.7 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).
- 10.8 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).
- 10.9 Letter from Sigma-Tau Pharmaceuticals, Inc. dated February 21, 2007 (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on February 23, 2007).
- 10.10 Letter dated May 3, 2007 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 May 4, 2007).
- 10.11 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). \*\*
- 10.12 Employment Agreement dated December 27, 2007, between Evan Myriantopoulos and the Company (incorporated by reference to Exhibit 10.31 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008). \*\*
- 10.13 Common Stock Purchase Agreement dated February 14, 2008, between the Company and Fusion Capital Fund II, LLC (incorporated by reference to Exhibit 10.35 included in our Registration Statement on Form S-1 filed on February 14, 2008).
- 10.14 Registration Rights Agreement dated February 14, 2008, between the Company and Fusion Capital Fund II, LLC (incorporated by reference to Exhibit 10.35 included in our Registration Statement on Form S-1 (File No. 333-149239) filed on February 14, 2008).
- 10.15 Letter dated December 1, 2008, 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 December 1, 2008).

10.16 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).

10.17 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). †



10.18 First Amendment to Common Stock Purchase Agreement dated April 19, 2010 between the Company and Fusion Capital Fund II, LLC (incorporated by reference to Exhibit 10.34 included in our Post-Effective Amendment to Registration Statement on Form S-1 (File No. 333-149239) filed on April 20, 2010).

10.19 Amendment to Employment Agreement dated as of January 4, 2011, between The Company and Evan Myrianthopoulos (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on January 6, 2011). \*\*

10.20 Employment Agreement dated as of January 31, 2011 between Kevin Horgan, M.D., and The Company (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on February 2, 2011). \*\*

10.21 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). \*\*

10.22 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). \*\*

10.23 Second Amendment to Employment Agreement dated as of July 12, 2011, between The Company and Evan Myrianthopoulos (incorporated by reference to Exhibit 10.2 of our current report on Form 8-K filed on July 14, 2011). \*\*

10.24 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).

10.25 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).

10.26 Lease Agreement dated as of February 7, 2012, between CPP II, LLC and The Company (incorporated by reference to Exhibit 10.40 included in our Annual Report on Form 10-K filed March 27, 2012, for the fiscal year ended December 31, 2011).

10.27 Separation Agreement dated February 15, 2012, between Evan Myrianthopoulos and The Company (incorporated by reference to Exhibit 10.28 included in our Registration Statement on Form S-1 (File No. 333-184762) filed on November 5, 2012). \*\*

10.28 First Amendment to Separation Agreement dated July 2, 2012, between Evan Myrianthopoulos and The Company (incorporated by reference to Exhibit 10.29 included in our Registration Statement on Form S-1 (File No. 333-184762) filed on November 5, 2012). \*\*

10.29 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). †

10.30 Warrant dated December 20, 2012 and issued to Sigma-Tau to purchase 357,069 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).

10.31 Warrant dated December 20, 2012 and issued to SINAF S.A. to purchase 87,804 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).

10.32 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).

10.33 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).

10.34 Warrant dated December 20, 2012 and issued to McDonald to purchase 280,000 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).

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: February 26, 2013

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)	February 26, 2013
/s/ Keith L. Brownlie Keith L. Brownlie, CPA	Director	February 26, 2013
/s/ Gregg A. Lapointe Gregg A. Lapointe, CPA	Director	February 26, 2013
/s/ Robert J. Rubin Robert J. Rubin, MD	Director	February 26, 2013
/s/ Jerome Zeldis Jerome Zeldis, MD, PhD	Director	February 26, 2013
/s/ Joseph M. Warusz Joseph M. Warusz, CPA	Vice President of Finance, Acting Chief Financial Officer and Corporate Secretary (principal accounting officer)	February 26, 2013

SOLIGENIX, INC. AND SUBSIDIARIES  
CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

	Page
Consolidated Balance Sheets as of December 31, 2012 and 2011	F-2
Consolidated Statements of Operations for the Years Ended December 31, 2012 and 2011	F-3
Consolidated Statements of Changes in Shareholders' Equity for the Years Ended December 31, 2012 and 2011	F-4
Consolidated Statements of Cash Flows for the Years Ended December 31, 2012 and 2011	F-5
Notes to Consolidated Financial Statements	F-6
Report of Independent Registered Public Accounting Firm	F-19

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

	2012	2011
Assets		
Current assets:		
Cash and cash equivalents	\$ 3,356,380	\$ 5,996,668
Grants receivable	339,308	362,473
Taxes receivable	-	574,157
Prepaid expenses	140,693	195,762
Total current assets	3,836,381	7,129,060
Office furniture and equipment, net	12,995	15,032
Intangible assets, net	855,728	1,079,566
Total assets	\$ 4,705,104	\$ 8,223,658
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 1,124,503	\$ 1,303,555
Accrued compensation	29,495	129,061
Total current liabilities	1,153,998	1,432,616
Commitments and contingencies		
Shareholders' equity:		
Preferred stock; 250,000 shares authorized; none issued or outstanding	-	-
Common stock, \$.001 par value; 50,000,000 and 20,000,000 shares authorized in 2012 and 2011, respectively; 11,168,905 shares and 11,105,532 shares issued and outstanding in 2012 and 2011, respectively (1)	11,169	11,106
Additional paid-in capital (1)	125,820,318	124,897,309
Accumulated deficit	(122,280,381)	(118,117,373)
Total shareholders' equity	3,551,106	6,791,042
Total liabilities and shareholders' equity	\$ 4,705,104	\$ 8,223,658

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

(1) Adjusted to reflect the reverse stock split of 1 for 20 effective February 1, 2012.

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

	2012	2011
Revenues:		
License revenue	\$-	\$5,000,000
Grant revenue	3,144,620	2,662,822
Total revenues	3,144,620	7,662,822
Cost of grant revenues	(2,593,075 )	(2,108,228 )
Gross profit	551,545	5,554,594
Operating expenses:		
Research and development	2,609,241	6,272,616
General and administrative	2,632,972	2,242,173
Total operating expenses	5,242,213	8,514,789
Loss from operations	(4,690,668 )	(2,960,195 )
Other income:		
Interest income	6,202	7,444
Total other income	6,202	7,444
Net loss before income taxes	(4,684,466 )	(2,952,751 )
Income tax benefit	521,458	574,157
Net loss	\$(4,163,008 )	\$(2,378,594 )
Basic and diluted net loss per share	\$(0.37 )	\$(0.22 )
Basic and diluted weighted average common shares outstanding(1)	11,136,484	10,957,676

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

(1) Adjusted to reflect the reverse stock split of 1 for 20 effective February 1, 2012.

Soligenix, Inc. and Subsidiaries  
Consolidated Statements of Changes in Shareholders' Equity  
For the Years Ended December 31, 2012 and 2011

	Common Stock		Additional	Accumulated	Total
	Shares (1)	Par Value (1)	Paid-In Capital (1)	Deficit	
Balance, December 31, 2010	10,813,087	10,813	123,085,757	(115,738,779)	7,357,791
Issuance of common stock from collaboration agreement	66,890	67	399,933	-	400,000
Fair value of common stock warrants to vendors	-	-	11,184	-	11,184
Issuance of common stock pursuant to Fusion equity line	90,789	91	354,909	-	355,000
Issuance of common stock to vendors	29,297	29	14,971	-	15,000
Issuance of common stock to employee as severance	25,625	26	20,474	-	20,500
Settlement of broker fees associated with 2010 financing	-	-	40,743	-	40,743
Issuance of common stock for option and warrant exercises	79,844	80	253,533	-	253,613
Stock-based compensation expense	-	-	715,805	-	715,805
Net loss	-	-	-	(2,378,594 )	(2,378,594)
Balance, December 31, 2011	11,105,532	\$ 11,106	\$ 124,897,309	\$ (118,117,373)	\$ 6,791,042
Issuance of common stock to vendors	46,706	46	20,954	-	21,000
Issuance of common stock to employee	16,667	17	9,983	-	10,000
Fair value of common stock warrants to vendors	-	-	429,902	-	429,902
Stock-based compensation expense	-	-	462,170	-	462,170
Net loss	-	-	-	(4,163,008 )	(4,163,008)
Balance, December 31, 2012	11,168,905	\$ 11,169	\$ 125,820,318	\$ (122,280,381)	\$ 3,551,106

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

(1) Adjusted to reflect the reverse stock split of 1 for 20 effective February 1, 2012.

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

	2012	2011
Operating activities:		
Net loss	\$(4,163,008)	\$(2,378,594)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	230,630	226,027
Common stock issued for amended license agreement	-	400,000
Common stock issued to employee	10,000	20,500
Common stock issued in exchange for services	21,000	26,184
Warrants replaced in exchange for renegotiated agreement	429,902	-
Stock-based compensation	462,170	715,805
Capitalized patent write-off	-	88,727
Change in operating assets and liabilities:		
Grants receivable	23,165	(241,686 )
Taxes receivable	574,157	(322,293 )
Prepaid expenses	55,069	(8,268 )
Accounts payable	(179,053 )	(370,620 )
Accrued compensation	(99,565 )	(107,520 )
Total adjustments	1,527,475	426,856
Net cash used in operating activities	(2,635,533)	(1,951,738)
Investing activities:		
Acquisition of intangible assets	-	(151,086 )
Purchase of office equipment	(4,755 )	(1,578 )
Net cash used in investing activities	(4,755 )	(152,664 )
Financing activities:		
Net proceeds from sale of common stock	-	-
Settlement of broker fees associated with 2010 financing	-	40,743
Proceeds from sale of common stock pursuant to equity line	-	355,000
Proceeds from exercise of options and warrants	-	253,613
Net cash provided by financing activities	-	649,356
Net decrease in cash and cash equivalents	(2,640,288)	(1,455,046)
Cash and cash equivalents at beginning of period	5,996,668	7,451,714
Cash and cash equivalents at end of period	\$3,356,380	\$5,996,668
Supplemental information:		
Cash paid for state income taxes	\$2,730	\$2,750

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 development stage biopharmaceutical company that was incorporated in 1987 and is focused on developing products to treat the life-threatening side effects of cancer treatments and serious gastrointestinal diseases where there remains an unmet medical need, as well as developing several biodefense vaccines and therapeutics. The Company maintains two active business segments: BioTherapeutics and Vaccines/BioDefense. Soligenix’s BioTherapeutics business segment is developing 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), acute radiation enteritis (SGX201) and chronic Graft-versus-Host disease (orBec®), as well as developing our novel innate defense regulator (“IDR”) technology (SGX942) for the treatment of oral mucositis. On September 15, 2011 the Company’s confirmatory Phase 3 clinical trial for orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease (“GI GVHD”) was stopped at the recommendation of an independent Data Safety Monitoring Board (“DSMB”). Our Vaccines/BioDefense business segment includes RiVax™, our ricin toxin vaccine, and VeloThrax™, our anthrax vaccine, and OrbeShield™, our gastrointestinal acute radiation syndrome (“GI ARS”) program. The advanced development of these programs will be supported by our existing and on-going government grants, including our National Institutes of Health (“NIH”) grant for our heat stabilization technology ThermoVax™.

The Company generates revenues primarily from the NIH under four active grants.

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 FDA regulations, litigation, and product liability.

Liquidity

As of December 31, 2012, the Company had cash and cash equivalents of \$3,356,380 as compared to \$5,996,668 as of December 31, 2011, representing a decrease of \$2,640,288 or 44%. As of December 31, 2012, the Company had working capital of \$2,682,383 as compared to working capital of \$5,696,444 as of December 31, 2011, representing a decrease of \$3,014,061 or 53%. The decrease in working capital was primarily the result of the cash used in operating and investing activities over the period. For the year ended December 31, 2012, the Company’s cash used in operating activities was \$2,635,533 as compared to \$1,951,738 for the same period in 2011, representing an increase of \$683,795. Excluding the proceeds of \$5,000,000 received from Sigma-Tau for the European territory license in the third quarter of 2011, for the year ended December 31, 2012, the Company experienced a decrease in cash used in operating activities of \$4,316,205. This decrease was attributable to the decrease in research and development expenses related to the 2011 orBec® Phase 3 clinical trial. Based on the Company’s current rate of cash outflows, cash on hand and proceeds from its grant programs, 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 into the second quarter of 2014.

Management’s business plan can be outlined as follows:

- Initiate a Phase 1/2 clinical trial of oral BDP, known as SGX203 for the treatment of pediatric Crohn’s disease;
- Initiate a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;

Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as prevention of acute radiation enteritis, prevention of acute radiation syndrome, and treatment of chronic GVHD;

F-6

---

Develop RiVax™ and VeloThrax™ in combination with our proprietary vaccine heat stabilization technology, known as ThermoVax™, to develop new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas;

Continue to apply for and secure additional government funding for each of our BioTherapeutics and Vaccines/BioDefense programs through grants, contracts and/or procurements; and

Explore other business development and merger/acquisition strategies.

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

The Company has approximately \$3.8 million in active grant funding still available to support its associated research programs through 2014 and beyond. The Company plans to submit additional 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 Losses ("NOLs") sales in the State of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of \$521,458 in proceeds pursuant to NOLs sales in 2012, the Company expects to participate in the program during 2013 and beyond; and

The Company may seek additional capital in the private and/or public equity markets to continue its operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. The Company is currently evaluating additional equity financing opportunities 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 February 1, 2012, the Company completed a reverse stock split of its issued and outstanding shares of common stock at a ratio of 1-for-20, whereby, once effective, every 20 shares of its common stock was exchanged for one share of its common stock. Its common stock began trading on the OTCBB on a reverse split basis at the market opening on February 2, 2012. All share and per share data reflects 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.

##### Grants Receivable

Grants receivable consist of unbilled amounts due from various grants from the NIH for costs incurred prior to the period end under reimbursement contracts. The amounts were billed to the NIH 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.

F-7

---

## 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 industrial 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 and perhaps extending the lives of the patents. The Company capitalizes such costs and amortizes intangibles over their expected useful life – generally a period of 11 to 16 years.

The Company did not incur any capitalized patent related costs during the year ended December 31, 2012. The Company capitalized \$151,086 in patent related costs during the year ended December 31, 2011.

During the year ended December 31, 2011, the Company incurred an \$88,727 patent write off cost due to abandonment of patents related to Azathioprine. These costs are reflected in research and development expense in the consolidated statement of operations.

## Impairment of Long-Lived Assets

Office furniture and equipment and intangible assets 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, 2012 or 2011, except for the patent write-offs discussed in Note 3.

## Fair Value of Financial Instruments

Accounting principles generally accepted in the U.S. require that fair values be disclosed for the Company’s financial instruments. The carrying amounts of the Company’s financial instruments, which include grants receivable and current liabilities, are considered to be representative of their respective fair values.

## Revenue Recognition

Principally the Company’s revenues are generated from NIH grants and revenues from licensing activities and the achievement of licensing milestones (in prior periods). Recording of revenue is applied in accordance with FASB ASC 605, Revenue Recognition, ASC 605-25 and/or Accounting Standard Update, ASU, 2009-13, Revenue Recognition – Multiple Element Arrangements. The revenue from NIH grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the grants, plus a facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized when expenses have been incurred by subcontractors

or when the Company incurs internal expenses that are related to the grant.

Licensing and associated milestone revenues are recorded when earned. On September 15, 2011, as a result of stopping the confirmatory Phase 3 clinical trial as well as no future clinical development or performance obligations associated with the Sigma-Tau Agreement, the Company recognized license revenue of \$5,000,000 relating to the execution of an expanded license agreement with Sigma-Tau for the European territory.

F-8

---

## 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 stock 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.

## Stock-Based Compensation

From time to time, the Company issues restricted shares of common stock to vendors and consultants as compensation for services performed. Stock-based compensation expense recognized during the period is based on the fair value of the portion of share-based payment awards that is ultimately expected to vest during the period. Typically these instruments vest upon issuance and therefore the entire stock compensation expense is recognized upon issuance to the vendors and/or consultants.

Stock options are issued with an exercise price equal to the market price on the date of issuance. 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 vest 25% immediately as of 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.

Stock compensation expense for options, warrants and shares of common stock granted to non-employees has been determined in accordance with FASB ASC 718, Stock Compensation, 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-employee directors is amortized as the options vest. The option's price is re-measured using the Black-Scholes model at the end of each three month reporting period.

The fair value of options in accordance with FASB ASC 718, Stock Compensation, was estimated using the Black-Scholes option-pricing model and the following assumptions:

- a dividend yield of 0%;
- an expected life of 4 years;
- volatilities of 160% for 2012 and ranging from 123% to 160% for 2011;
- forfeitures at a rate of 12%; and
- risk-free interest rates of 0.51% for 2012 and 0.69% to 1.47% in 2011.

The fair value of each option grant made during 2012 and 2011 was estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option's 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 bases. 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, 2012 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 2012 and 2011. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at December 31, 2012 and 2011. Tax years beginning in 2009 for federal purposes are generally subject to examination by taxing authorities, although net operating losses from those years are subject to examinations and adjustments for at least three years following the year in which the tax attributes are utilized.

F-9

---



## 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. No options and warrants were included in the 2012 and 2011 computations of diluted earnings per share because their effect would be anti-dilutive as a result of losses or options and warrants for which the strike price exceeds the quoted market value at period end.

	For the Year Ended December 31, 2012			For the Year Ended December 31, 2011		
	Net Loss	Shares	EPS	Net Loss	Shares	EPS
Basic & Diluted EPS	\$(4,163,008)	11,136,484	\$(0.37 )	\$(2,378,594)	10,957,676	\$(0.22 )

Shares issuable upon the exercise of options and warrants outstanding at December 31, 2012 and 2011 were 1,457,724 and 1,544,242 shares issuable upon the exercise of options, and 2,843,338 and 2,701,569 shares issuable upon the exercise of warrants, respectively. The weighted average exercise price of the Company’s stock options and warrants outstanding at December 31, 2012 were \$3.20 and \$3.13 per share, respectively. No options or warrants were included in the 2012 and 2011 computations of diluted earnings per share because their effect would be anti-dilutive as a result of losses in each of those years.

## 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, 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.

## Note 3. Intangible Assets

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

	Weighted Average Amortization period (years)	Cost	Accumulated Amortization	Net Book Value
December 31, 2012				
Licenses	7.72	\$462,234	\$ 252,019	\$210,215
Patents	3.3	1,893,185	1,247,672	645,513
Total	4.2	\$2,355,419	\$ 1,499,691	\$855,728
December 31, 2011				
Licenses	8.72	\$462,234	\$ 224,708	\$237,526
Patents	3.3	1,893,185	1,051,145	842,040
Total	4.4	\$2,355,419	\$ 1,275,853	\$1,079,566

Amortization expense was \$223,838 and \$218,782 in 2012 and 2011, respectively.

During the year ended December 31, 2011, the Company incurred an \$88,727 patent write off cost due to abandonment of patents related to Azathioprine. These costs are reflected in research and development expense in the consolidated statement of operations.

Based on the balance of licenses and patents at December 31, 2012, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

Year	Amortization Expense
2013	\$ 222,800
2014	\$ 222,800
2015	\$ 173,800
2016	\$ 61,800
2017	\$ 20,800

License fees and royalty payments are expensed annually as incurred as the Company does not attribute any future benefits other than within that period.

## Note 4. Income Taxes

Deferred tax assets consisted of the following as of December 31:

	2012	2011
Net operating loss carry forwards	\$27,872,000	\$26,001,000
Orphan drug and research and development credit carry forwards	3,068,000	2,818,000
Other	1,443,000	1,615,000
Total	32,383,000	30,434,000
Valuation allowance	(32,383,000)	(30,434,000)
Net deferred tax assets	\$-	\$-

At December 31, 2012, the Company had NOL carry forwards of approximately \$79,463,000 for federal tax purposes and approximately \$9,498,000 of New Jersey NOL carry forwards remaining after the sale of unused net operating loss carry forwards, portions of which are currently expiring each year through 2032. In addition, the Company has \$3,068,000 of various tax credits that expire from 2013 to 2032. The Company may be able to utilize their 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.

F-11

---

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. The Company is no longer subject to Federal income tax assessment for years before 2008 for Federal and 2007 for New Jersey income tax assessment. However, since the Company has incurred net operating losses in every tax year since inception, all its income tax returns are subject to examination and adjustments by the Internal Revenue Service for at least three years following the year in which the tax attributes are utilized.

The net change in the valuation allowance for the years ended December 31, 2012 and December 31, 2011 was an increase of approximately \$1,949,000 and a decrease of approximately \$1,115,000, respectively, resulting primarily from net operating losses expiring and generated. As a result of the Company's continuing tax losses, the Company has recorded a full valuation allowance against a net deferred tax asset.

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, 2012 and 2011 was as follows:

	2012		2011
Income tax loss at federal statutory rate	(34.00	) %	(34.00 ) %
State tax benefits, plus sale of NJ NOLs, net of federal benefit	(6.00	)	(6.00 )
Subtotal	(40.00	)	(40.00 )
Valuation allowance	28.87		20.56
Income tax benefit	(11.13	) %	(19.44 ) %

During the years ended December 31, 2012 and 2011, 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 net operating loss carryforwards to other New Jersey-based corporate taxpayers based in New Jersey, the Company sold New Jersey net operating loss carryforwards, resulting in the recognition of \$521,458 and \$574,157 of income tax benefit, net of transaction costs, respectively. There can be no assurance as to the continuation or magnitude of this program in future.

The Company follows FASB ASC 740-10, Uncertainty in Income Taxes. This standard prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Company did not have any unrecognized tax benefits or a liability for uncertain tax positions at December 31, 2012 and 2011. The Company does not expect to have any unrecognized tax benefits within the next twelve months. 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 2012 and 2011.

#### Note 5. Shareholders' Equity

##### Preferred Stock

The Company has 250,000 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, 2012:

In January 2012, the Company issued 16,667 shares of common stock as part of an employee's 2011 bonus from the Company.

In four separate transactions, the Company issued 46,706 shares of common stock as part of consideration for services performed.

The following items represent transactions in the Company's common stock for the year ended December 31, 2011:

In sixteen separate transactions during 2011, the Company issued an aggregate of 90,789 shares of common stock under its existing Fusion Capital equity facility. The Company received an aggregate of \$355,000 in proceeds which approximated the shares' fair market value on the date of issuance.

As a result of stock option exercises, 79,844 shares were issued during 2011. The Company received an aggregate of \$253,613 in proceeds from these exercises.

As a result of granting Sigma-Tau an exclusive license to commercialize orBec® in the European territory, the Company amended the license agreement with Dr. George McDonald and issued 66,890 shares of Company stock in lieu of \$400,000 cash obligation. Stock price used for share calculation was \$5.98, closing price at July 29, 2011.

In December 2011, the Company issued 25,625 shares of common stock as part of an employee's severance from the Company.

In December 2011, the Company issued 29,297 shares of common stock as part of consideration for services performed.

## Warrants

During 2012, the Company issued warrants to purchase 50,000 shares of common stock to a consultant in exchange for services. Additionally, in December 2012, the Company replaced previously issued warrants to purchase 724,873 shares of common stock for new warrants. These new warrants were issued to Sigma Tau upon the Company reacquiring the rights to orBec® and to Dr. George McDonald upon the renegotiation of our orBec® license agreement. During 2011, the Company issued warrants to purchase 4,750 shares of common stock to consultants in exchange for their services.

Expense charges of \$429,902 and \$11,184 were recorded during the years ended December 31, 2012 and 2011, respectively, as a result of these issuances which represented the estimated fair value of services performed and renegotiated agreements with Sigma-Tau and Dr. McDonald pertaining to the rights of orBec®.

## Equity Line

In February 2008, the Company entered into a common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"). The Fusion Capital equity facility allows the Company to require Fusion Capital to purchase between \$80,000 and \$1.0 million of the Company's common stock every two business days, up to an aggregate of \$8.0 million over approximately a 25-month period depending on certain conditions, including the quoted market price of the Company's common stock on such date. As part of the agreement, the Company issued Fusion Capital 63,750 shares of common stock as a commitment fee. In connection with the execution of the common stock purchase agreement, Fusion Capital made an initial purchase of 138,889 common shares and received a four year warrant to purchase 69,445 shares of common stock for \$4.40 per share, representing an aggregate price of \$500,000. The Company issued an additional 3,750 shares of common stock as a commitment fee in connection with this \$500,000

purchase.

If the Company's stock price exceeds \$3.00, then the amount required to be purchased may be increased under certain conditions as the price of the Company's common stock increases. The Company cannot require Fusion Capital to purchase any shares of the Company's common stock on any trading days that the market price of the Company's common stock is less than \$2.00 per share. Furthermore, for each additional purchase by Fusion, additional commitment shares in commensurate amounts up to a total of 63,750 shares will be issued based upon the relative proportion of purchases compared to the total commitment maximum of 925,000 shares. The total issuance of common stock related to commitment shares for 2008 was 68,456 shares, which were issued to Fusion Capital and consisted of 63,750 shares as a commitment fee, 3,750 shares as a commitment fee for the \$500,000 invested, and 957 shares for the commitment fee shares on the equity line draws totaling \$127,500.

F-13

---

During the year ended December 31, 2011, the Company issued 90,789 shares of common stock under the Fusion Capital equity facility. In connection with these issuances, the Company received \$355,000 in proceeds which approximated the shares' fair market value on the dates of issuance.

The Fusion equity line expired in October 2011.

#### Note 6. Stock Option Plans and Warrants to Purchase Common Stock

##### Stock Option Plans

The Amended and Restated 1995 Omnibus Plan was replaced by the 2005 Equity Incentive 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,
- 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") 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 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.

In addition, under the 2005 Plan, the Board may elect to pay certain consultants, directors, and employees in common stock. The 2005 Plan was amended in September 2007 to increase the number of options available under the plan to 1,000,000 and again in 2010 to increase the number of shares under the plan to 1,750,000.

The table below only accounts for transactions occurring as part of the amended 2005 Equity Incentive Plan.

	December 31,	
	2012	2011
Shares available for grant at beginning of year	60,692	396,223
Increase in shares available for the plan	-	-
Options granted	(100,000)	(523,344)
Options forfeited or expired	169,019	187,813
Shares available for grant at end of year	129,711	60,692





The total option activity for the 1995 plan and the amended 2005 plan for the years ended December 31, 2012 and 2011 was as follows:

	Options	Weighted Average Options Exercise Price
Balance at December 31, 2010	1,308,056	4.84
Granted	523,344	1.68
Exercised	(79,844 )	3.18
Forfeited	(207,314 )	1.88
Balance at December 31, 2011	1,544,242	\$ 3.75
Granted	100,000	0.30
Exercised	-	-
Forfeited	(186,518 )	6.22
Balance at December 31, 2012	1,457,724	\$ 3.19

The Company awarded 100,000 and 523,344 stock options to new employees and new and existing Board members during 2012 and 2011, respectively. The 2012 grants were issued to Board members on June 21, 2012 under the 2005 Equity Incentive Plan.

The weighted-average exercise price, by price range, for outstanding options to purchase common stock at December 31, 2012 was:

Price Range	Weighted Average Remaining Contractual Life in Years	Outstanding Options	Exercisable Options
\$0.30-\$2.20	7.9	738,300	542,050
\$2.80-\$4.10	8.1	186,674	151,283
\$4.64-\$8.60	5.9	426,500	391,891
\$9.40-\$11.60	4.1	97,500	97,500
\$18.00-\$25.60	0.7	8,750	8,750
Total	7.0	1,457,724	1,191,474

The Company's share-based compensation for the years ended December 31, 2012 and 2011 was \$462,170 and \$715,805, respectively. At December 31, 2012, the total compensation cost for stock options not yet recognized was approximately \$245,000 and will be expensed over the next three years.

## Warrants to Purchase Common stock

Warrant activity for the years ended December 31, 2012 and 2011 was as follows:

	Warrants	Weighted Average Warrant Exercise Price
Balance at December 31, 2010	2,703,819	\$ 4.40
Granted	4,750	3.85
Exercised	-	-
Expired/Cancelled	(7,000 )	0.66
Balance at December 31, 2011	2,701,569	\$ 4.40
Granted	774,873	0.56
Exercised	-	-
Expired/Cancelled	(633,104 )	5.40
Balance at December 31, 2012	2,843,338	\$ 3.13

During 2012, the Company issued warrants to purchase 50,000 shares of common stock, with an exercise price of \$0.68, to a consultant in exchange for services. Additional warrants to purchase 724,873 were issued relating to reacquiring the rights to orBec® and renegotiation of our orBec® license agreement, with exercise prices ranging from \$0.53 to \$0.58. Expense charges of \$429,902 were recorded to reflect these issuances. Warrants of 633,104 had either expired or were cancelled by the Company with exercise prices ranging from \$2.20 to \$5.60.

The weighted-average exercise price, by price range, for outstanding warrants at December 31, 2010 was:

Price Range	Weighted Average Remaining Contractual Life in Years	Outstanding Warrants	Exercisable Warrants
\$0.53-\$2.00	5.0	777,373	777,373
\$2.80-\$3.96	1.1	1,103,202	1,103,202
\$5.00-\$6.06	2.2	962,763	962,763
Total	2.5	2,843,338	2,843,338

During 2013, warrants to purchase approximately 1,250 shares of the Company's common stock will expire.

## Note 7. Concentrations

At December 31, 2012 and 2011, 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. The excess amounts at December 31, 2012 and 2011 were \$2,356,380 and \$4,996,668, respectively.

## Note 8. Commitments and Contingencies

The Company has commitments of approximately \$425,000 at December 31, 2012 for several licensing agreements with consultants and universities, which upon clinical or commercialization success may require the payment of milestones and/or royalties if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

On February 7, 2012, the Company entered into a lease agreement through March 31, 2015 for existing office space. The rent for the first 12 months is approximately \$8,000 per month, or approximately \$18.25 per square foot. This rent increases to approximately \$8,310 per month, or approximately \$19.00 per square foot, for the remaining 24 months.

F-16

---

In February 2007, the Company's Board of Directors authorized the issuance of the following number of shares to each of Dr. Schaber and Dr. Brey 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: 50,000 common shares to Dr. Schaber and 10,000 common shares to Dr. Brey. The amended agreement with Dr. Schaber includes its obligation to issue such shares if such event occurs.

Employees with employment contracts have severance agreements that will provide separation benefits from the Company if they are involuntarily separated from employment. On February 15, 2012, Mr. Myriantopoulos' employment agreement was terminated. The Company recognized an expense of \$95,625 at March 31, 2012 and at December 31, 2012 there are no severance and healthcare benefits due to Mr. Myriantopoulos. In connection with the termination of Mr. Myriantopoulos' employment agreement, we accelerated the vesting of options to purchase 53,908 shares of common stock and Mr. Myriantopoulos forfeited options to purchase 72,500 shares of common stock, resulting in Mr. Myriantopoulos holding vested options to purchase 192,500 shares of common stock with expiration dates ranging from November 14, 2012 to November 30, 2021. In connection with the acceleration of vesting, the Company recognized \$68,032 of stock-based compensation expense during the year ended December 31, 2012.

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
2013	\$ 100,000	\$ 105,000	\$ 205,000
2014	100,000	101,200	201,200
2015	75,000	25,000	100,000
2016	75,000	-	75,000
2017	75,000	-	75,000
Total	\$ 425,000	\$ 231,200	\$ 656,200

## Note 9. 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 Year Ended December 31,	
	2012	2011
<b>Revenues</b>		
Vaccines/BioDefense	\$2,919,677	\$ 2,010,234
BioTherapeutics 1	224,943	5,652,588
Total	\$3,144,620	\$ 7,662,822
<b>Loss from Operations</b>		
Vaccines/BioDefense	\$(33,636 )	\$ (154,395 )
BioTherapeutics	(2,203,721)	(1,278,156)
Corporate	(2,453,311)	(1,527,644)
Total	\$(4,690,668)	\$ (2,960,195)
<b>Amortization and Depreciation Expense</b>		
Vaccines/BioDefense	\$38,589	\$ 42,640
BioTherapeutics	190,003	181,213
Corporate	2,038	2,174
Total	\$230,630	\$ 226,027
<b>Interest Income</b>		
Corporate	\$6,202	\$ 7,444
<b>Stock-Based Compensation</b>		
Vaccines/BioDefense	\$44,484	\$ 78,622
BioTherapeutics	84,020	426,666
Corporate	333,666	210,517
Total	\$462,170	\$ 715,805
<b>Identifiable Assets</b>		
As of December 31,		
	2012	2011
Vaccines/BioDefense	\$628,494	\$ 689,266
BioTherapeutics	566,111	753,767
Corporate	3,510,499	6,780,625
Total	\$4,705,104	\$ 8,223,658

1 BioTherapeutics revenues for 2011 includes the receipt of a \$5 million licensing fee from Sigma-Tau in July 2011.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders,

We have audited the accompanying consolidated balance sheets of Soligenix, Inc. and subsidiaries (the "Company") as of December 31, 2012 and 2011, and the related consolidated statements of operations, changes in shareholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2012. 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, 2012 and 2011, and the consolidated results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2012, in conformity with accounting principles generally accepted in the United States of America.

/s/ EisnerAmper LLP

Jenkintown, PA  
February 25, 2013

F-19

---