SOLIGENIX, INC.
Form 10-K
March 27, 2012

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)
x ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the Fiscal Year Ended December 31, 2011

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the transition period from _____ to _____

Commission File No. 000-16929

SOLIGENIX, INC.
(Exact name of registrant as specified in its charter)

Delaware	41-1505029
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
29 EMMONS DRIVE, SUITE C-10 PRINCETON, NJ (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	OTCBB

Securities registered under Section 12(g) of the Exchange Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes £ No R

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 R

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this 10-K or any amendments to this Form 10-K. þ

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

Large accelerated filer £	Accelerated filer £	Non-accelerated filer £	Smaller reporting company R

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

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $4,420,330 (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 March 21, 2012.

As of March 21, 2012, 11,122,199 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, 2011

Table of Contents

PART I

Item 1. Business

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

Our Business Overview

Soligenix, Inc. was incorporated in Delaware in 1987. We are a development stage biopharmaceutical company focused on developing products to treat the life-threatening side effects of cancer treatment and 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 BioDefense. Our BioTherapeutics business segment intends to develop orBec® (oral beclomethasone dipropionate, or oral BDP) and other biotherapeutic products, while the Company's collaboration partner, Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau") will commercialize orBec® and oral BDP in North America and Europe, if approved. 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"). Additionally, we are actively developing oral BDP in other therapeutic indications, such as pediatric Crohn's disease and radiation enteritis. Our Vaccines/BioDefense business segment includes RiVaxTM, our ricin toxin vaccine, and SGX204, our anthrax vaccine, and SGX202, our gastrointestinal acute radiation syndrome ("GI ARS") program. The advanced development of these programs will be supported by our heat stabilization technology under existing and on-going government grant funding.

Our business plan can be outlined as follows:

- Initiate a Phase 2 clinical trial of oral BDP known as SGX203 in pediatric Crohn's disease;
- Use RiVaxTM and SGX204 to support development efforts and establish proof of concept with our proprietary vaccine heat stabilization technology known as ThermoVax TM;
- Apply for and secure further government funding for development of our BioDefense programs, namely RiVax TM, SGX204, and SGX202 in GI ARS;
- Evaluate the effectiveness of orBec®/Oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal ("GI") tract such as prevention of acute radiation enteritis, prevention of acute GVHD, and treatment of chronic GI GVHD;
- Continue to secure additional government funding for each of our BioTherapeutics programs through grants;
- Acquire or in-license new clinical-stage compounds for development; and
- Explore other business development and 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
orBec®	Treatment of Acute GI GVHD	Pivotal Phase 3 trial stopped for futility; analyzing data
orBec®	Prevention of Acute GVHD	Phase 2 trial completed
orBec®	Treatment of Chronic GI GVHD	Potential Phase 2 trial under review
SGX201	Acute Radiation Enteritis	Phase 1/2 trial complete; safety and preliminary efficacy demonstrated
SGX203	Pediatric Crohn's disease	Phase 2 clinical program planned
LPM™ Leuprolide	Endometriosis and Prostate Cancer	Pre-clinical

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 enrollment complete; complete results expected in 2012
SGX202	Therapeutic against GI ARS	Initial pre-clinical study complete; successful protection of dogs

BioTherapeutics Overview

orBec® and Oral BDP

orBec® represents a first-of-its-kind oral, locally acting therapy tailored to treat the gastrointestinal manifestation of acute GVHD, the organ system where GVHD is most frequently encountered and highly problematic. orBec® is intended to reduce the need for systemic immunosuppressive drugs to treat acute GI GVHD. The active ingredient in orBec® is beclomethasone dipropionate ("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® 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 data from the prior Phase 3 study of orBec®, the current confirmatory Phase 3 study was a highly powered, double-blind, randomized, placebo-controlled, multi-center trial and that enrolled 140 patients. This trial is supported in part by a $1.2 million FDA Orphan Products grant awarded to Soligenix. The primary endpoint is the treatment failure rate at Study Day 80. This trial was stopped in September 2011 at the recommendation of an independent Data Safety Monitoring Board (DSMB) because it was highly unlikely to achieve the predetermined primary endpoint of efficacy based on the interim results. The DSMB had no safety concerns with the trial. The data from the Phase 3 trial is currently being analyzed to determine the factors resulting in its termination.

In addition to issued patents and pending worldwide patent applications held by or exclusively licensed to us, orBec® would benefit from orphan drug designations in the U.S. and in Europe for the treatment of GI GVHD, as well as an orphan drug designation in the U.S for the treatment of chronic GI GVHD. Orphan drug designations provide for 7 and 10 years of market exclusivity upon approval in the U.S and Europe, respectively.

Commercialization and Market

On February 11, 2009, we entered into a collaboration and supply agreement with Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau") for the commercialization of orBec®/oral BDP. Sigma-Tau is a pharmaceutical company that develops novel therapies for the unmet needs of patients with rare diseases. Pursuant to this agreement, Sigma-Tau has an exclusive license to commercialize orBec®/oral BDP in the U.S., Canada and Mexico (the "Territory"). Sigma-Tau is obligated to make payments upon the attainment of significant milestones, as set forth in the agreement. The first milestone payment of $1 million was made in connection with the enrollment of the first patient in our confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD in September 2009. Total additional milestone payments due from Sigma-Tau for orBec® under the agreement could reach up to $9 million. Sigma-Tau will pay us a 35% royalty (Soligenix to provide finished drug product) on net sales in the Territory as well as pay for commercialization expenses, including launch activities. In connection with the execution of the collaboration and supply agreement, we entered into a common stock purchase agreement with Sigma-Tau pursuant to which we sold 1.25 million shares of our common stock to Sigma-Tau for $3.60 per share, for an aggregate price of $4,500,000. The purchase price is equal to one hundred fifty percent (150%) of the average trading price of our common stock over the five trading days prior to February 11, 2009.

The Collaboration and Supply Agreement dated February 11, 2009 between us and Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau") expires on a country-by-country basis on the later of: (i) 10 years after the date of the first commercial sale of oral beclomethasone dipropionate ("orBec®") by Sigma-Tau in such country; or (ii) the expiration of the last to expire of the Company's patents and patent applications relating to orBec® in such country. Upon the expiration of the initial term, on a country-by-country basis, the agreement is automatically renewed for periods of five years. During such renewal periods, we and Sigma-Tau have the right to terminate the agreement for convenience upon six months and 18 months, respectively, prior written notice. If we terminates the agreement for convenience, we are required to transfer to Sigma-Tau or its designee, for no consideration, the U.S. Food and Drug Administration (the "FDA") and European Medicines Agency ("EMEA") authorizations which are necessary for the marketing, use, distribution and sale of orBec® and all relevant data and know-how necessary to manufacture and commercialize orBec® in the country and grant to Sigma-Tau a royalty-free, fully paid, perpetual and irrevocable license, with the right to sublicense, to the trademark "orBec" and such know-how.

Either party may terminate the agreement: (i) in the event the other party breaches any material obligation; or (ii) upon the initiation of a proceeding in bankruptcy (voluntary or involuntary), reorganization, dissolution, liquidation or similar proceeding or occurrence. We also have the right to terminate the agreement in the event that Sigma-Tau challenges or assists any third party in the challenge of the validity of any of our patents or patent applications relating to orBec®.

Upon termination other than for breach by Sigma-Tau, Sigma-Tau has the right to process and sell its inventory for a period of three months following the date of termination, subject to the payment of the amounts owed under the agreement, to us and continued compliance with the terms of the agreement.

On July 28, 2011, we announced the expansion and amendment of our North American licensing partnership with Sigma-Tau for the development and commercialization of orBec®/oral BDP into the "European Territory", as defined in the amendment. Pursuant to this amendment, we received an up-front non-refundable payment of $5 million and

granted Sigma-Tau an exclusive license to commercialize orBec®/oral BDP in the European territory. The amendment requires Sigma-Tau to make additional payments to us in the aggregate amount of $11 million upon the achievement of certain milestones. The amendment also requires Sigma-Tau to pay us a 40% royalty (Soligenix to provide finished drug product) on net sales in the European Territory and pay for all commercialization expenses, including launch activities.

We believe the potential worldwide market for orBec®/oral BDP is in excess of $500 million for all GI applications, namely, Crohn’s disease, radiation enteritis, GI ARS, and all GVHD applications.

About GVHD

GVHD occurs in patients following allogeneic stem cell transplantation in which tissues of the host, most frequently the gut, liver, and skin, are attacked by lymphocytes from the donor (graft) marrow. Patients with mild to moderate GI GVHD present to the clinic with early satiety, anorexia, nausea, vomiting and diarrhea. If left untreated, symptoms of GI GVHD persist and can progress to necrosis and exfoliation of most of the epithelial cells of the intestinal mucosa, frequently a fatal condition. Approximately 50% of the more than 10,000 annual allogeneic transplantation patients in the U.S. will develop some form of acute GI GVHD.

GI GVHD is one of the most common causes for the failure of stem cell transplantation. These procedures are being increasingly utilized to treat leukemia and other cancer patients with the prospect of eliminating residual disease and reducing the likelihood of relapse. Although systemic immunosuppressives are currently used to control GI GVHD, they substantially inhibit the highly desirable Graft-versus-Leukemia ("GVL") effect of stem cell transplantations, leading to high rates of aggressive forms of relapse, as well as substantial rates of mortality due to opportunistic infection.

About Allogeneic Hematopoietic Cell Transplantation

Allogeneic hematopoietic cell transplantation ("HCT") is considered a potentially curative option for many leukemias as well as other forms of blood cancer. In an allogeneic HCT procedure, hematopoietic stem cells are harvested from the blood or bone marrow of a closely matched relative or unrelated person, and are transplanted into the patient following either high-dose chemotherapy or intense immunosuppressive conditioning therapy. The curative potential of allogeneic HCT is now partly attributed to the GVL or Graft-versus-Tumor effects of the newly transplanted donor cells to recognize and destroy malignant cells in the recipient patient.

The use of allogeneic HCT has grown substantially over the last decade due to advances in human immunogenetics, the establishment of unrelated donor programs, the use of cord blood as a source of hematopoietic stem cells and the advent of non-myeloablative conditioning regimens, or mini-transplants, that avoid the side effects of high-dose chemotherapy. Based on the latest statistics available, it is estimated that there are more than 10,000 allogeneic HCT procedures annually in the U.S. and a comparable number in Europe. Estimates as to the current annual rate of increase in these procedures are as high as 20%. High rates of morbidity and mortality occur in this patient population. Clinical trials are also underway testing allogeneic HCT for treatment of some metastatic solid tumors such as breast cancer, renal cell carcinoma, melanoma and ovarian cancer. Allogeneic transplantation has also been studied as a curative therapy for several genetic disorders, including immunodeficiency syndromes, inborn errors of metabolism, and sickle cell disease. The primary toxicity of allogeneic HCT, however, is GVHD in which the newly transplanted donor cells damage cells in the recipient's gastrointestinal tract, liver and skin.

Future Potential Indications of orBec® and Oral BDP

Based on its pharmacological characteristics, orBec®/oral BDP may have utility in treating other conditions of the gastrointestinal tract having an inflammatory component. We have 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 HCT, as well as GVHD which also occurs following organ allograft transplantation. We also have an issued U.S. patent 7,704,985 claiming the use of oral BDP to treat IBS, a painful gastrointestinal condition that affects approximately 15% of the population in the industrialized world. 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 and European patent EP 1830857 claiming oral BDP in conjunction with a short duration of high-dose prednisone with a rapid taper for the reduction of mortality associated with GVHD and leukemia. We are exploring the possibility of testing oral BDP (the active ingredient in orBec®) for

local inflammation associated with radiation enteritis, pediatric Crohn's disease, and GI ARS, among other indications.

SGX201- Oral BDP for Preventing Acute Radiation Enteritis

SGX201 is a delayed-release formulation of BDP specifically designed for oral use. We recently 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 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 Research (“SBIR”) grant awarded by the NIH. These data are currently under review 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 radiation enteritis. 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 an NDA for SGX201 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.

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.

SGX203 – Oral BDP for Treating Pediatric Crohn’s Disease

SGX203 is a two pill delivery system of a delayed release formulation of BDP specifically designed for oral use that allows for delivery 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. We plan to initiate a Phase 2 clinical trial in pediatric Crohn’s disease in 2012.

About Pediatric Crohn's Disease

Crohn's disease is an ongoing disorder that causes inflammation of the gastrointestinal (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 Ashkenazy 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 United States. Crohn’s disease tends to be both severe and extensive in the pediatric population and a relatively high proportion (25-40%) 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.

orBec® – Oral BDP for Preventing Acute GVHD

A trial was completed under an investigator-initiated Investigational New Drug (“IND”) application by Paul Martin, MD, at the Fred Hutchinson Cancer Research Center. It was an exploratory, randomized, double blind, placebo-controlled, Phase 2 proof-of-concept clinical trial of orBec® for the prevention of acute GVHD in patients undergoing myeloablative conditioning regimens with initiation of dosing prior to hematopoietic cell transplantation (HCT) and continuing through the post-transplantation period. This study was supported, in large part, by a grant from the National Institutes of Health. We did not receive any direct monetary benefit from this grant.

The Phase 2 trial enrolled 140 patients with a 2:1 (orBec®:placebo) randomization plan. Results from this estimation study indicate that orBec® appears safe and well tolerated in this patient population, but did not achieve statistical significance in the primary endpoint, which was the proportion of patients who developed acute GVHD with severity sufficient to require systemic immunosuppressive treatment on or before day 90 after transplantation. This result was possibly due to poor patient compliance with administration of study drug which was lower than anticipated with only 54% of patients taking at least 90% of study drug within 4 weeks of transplantation. It was noted that poor compliance in the study may be associated with the incidence of oral mucositis, as a lower severity of oral mucositis was highly correlated with better compliance ($p < 0.0001$). Compliance was also better in patients who did not require systemic treatment for GVHD in the orBec® arm ($p = 0.001$) compared to those in the placebo arm ($p = 0.98$), consistent with the possibility that reduced adherence may have compromised the orBec® treatment effect. Among the 50 orBec® patients with at least 90% compliance, 54% required systemic treatment for GVHD, versus 65% of the 26 placebo patients with at least 90% compliance. The mean cumulative dose of prednisone was 28.8 mg/kg among all orBec®

patients with at least 90% compliance, versus 37.1 mg/kg among all placebo patients with at least 90% compliance. For the group with less than 90% compliance, the mean cumulative prednisone dose was the same in both arms.

The use of orBec® also resulted in fewer cases of more severe acute GVHD grades IIb-IV (21% vs. 33% of patients receiving placebo), although this difference was not statistically significant. This result has the potential to be clinically relevant because GVHD grades IIb-IV are associated with more severe disease involving the skin and liver as well as being associated with poorer outcomes, including mortality rates that approach 100% in the grade IV patient population. The outcome of this study was published online in Biology of Blood and Marrow Transplantation (Martin et al., 2011, ASBMT:1-8)

LPM™ – Leuprolide for Endometriosis and Prostate Cancer

Our Lipid Polymer Micelle ("LPM™") oral drug delivery system is a proprietary platform technology designed to allow for the oral administration of peptide drugs that are water-soluble but poorly permeable through the gastrointestinal tract. We have previously demonstrated in pre-clinical animal models that the LPM™ technology is adaptable to oral delivery of peptide drugs and that high systemic levels after intestinal absorption can be achieved with the peptide hormone drug leuprolide. The LPM™ system utilizes a lipid based delivery system that can incorporate the peptide of interest in a thermodynamically stable configuration called a "reverse micelle" that, through oral administration, can promote intestinal absorption. Reverse micelles are structures that form when certain classes of lipids come in contact with small amounts of water. This results in a drug delivery system in which a stable clear dispersion of the water soluble drug can be evenly dispersed within the lipid phase. LPM™ is thought to promote intestinal absorption due to the ability of the micelles to open up small channels through the epithelial layer of the intestines that allow only molecules of a certain dimension to pass through while excluding extremely large molecules such as bacteria and viruses. The reverse micelles also structurally prevent the rapid inactivation of peptides by enzymes in the upper gastrointestinal tract via a non-specific enzyme inhibition by surfactant(s) in the formulation.

In pre-clinical studies, the LPM™ delivery technology significantly enhanced the ability of leuprolide to pass through the intestinal epithelium in comparison to leuprolide alone. Leuprolide is a synthetic peptide agonist of gonadotropin releasing hormone, which is used in the treatment of prostate cancer in men and endometriosis in women. Leuprolide exhibits poor intestinal absorption from an aqueous solution with the oral bioavailability being less than 5%. Utilizing LPM™ in rats and dogs, the bioavailability of leuprolide averaged 30% compared to 2.2% for the control oral solution. Based on these promising pre-clinical data, we anticipate preparing for a Phase 1 study in humans to confirm these findings, pending further funding.

An oral version of leuprolide may provide a significant advantage over the currently marketed "depot" formulations. Leuprolide is one of the most widely used anti-cancer agents for advanced prostate cancer in men. Injectable forms of leuprolide marketed under trade names such as Lupron® and Eligard® had worldwide annual sales of more than $1 billion in recent years. Injectable leuprolide is also widely used in non-cancer indications, such as endometriosis in women (a common condition in which cells normally found in the uterus become implanted in other areas of the body), uterine fibroids in women (noncancerous growths in the uterus) and central precocious puberty in children (a condition causing children to enter puberty too soon). Leuprolide is currently available only in injectable, injectable depot and subcutaneous implant routes of delivery which limits its use and utility.

Vaccines/BioDefense Overview

ThermVax™ - Thermo-stability Technology

Soligenix's Thermostability technology, ThermoVax™, is a novel method of rendering aluminum salt, 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. On the Vaccines/BioDefense side, ThermoVax™ has the potential to facilitate easier storage and distribution of strategic national stockpile vaccines in emergency settings.

Initial proof-of-concept preclinical studies with ThermoVaxTM 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 Soligenix's 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 one month, all of the animals vaccinated with the lyophilized RiVax™ vaccine developed potent and high titer neutralizing antibodies. In contrast, animals that were vaccinated with the liquid RiVax™ vaccine kept at 40 degrees C did not develop neutralizing antibodies and were not protected against ricin exposure. The ricin A chain is extremely sensitive to temperature and rapidly loses the ability to induce neutralizing antibodies when exposed to temperatures higher than 8 degrees C.

Near term progress with ThermoVax™ will allow Soligenix 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 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 University of Colorado 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.

SGX204 – Anthrax Vaccine

SGX204 is Soligenix's 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 SGX204 (also known as DNI for dominant negative inhibitor). SGX204 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. SGX204 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 SGX204 are also capable of inducing antibodies that neutralize the activity of the anthrax toxin complex. Unlike fully-functional rPA, SGX204 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 SGX204 at a 1,000 fold lower dose than previously tested for an intramuscular or intradermal vaccine.

Initial development work on SGX204 has begun and will be conducted pursuant to Soligenix's $9.4 million NIAID grant enabling development of thermo-stable ricin and anthrax vaccines. SGX204'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 ThermoVaxTM, Soligenix believes that it will be able to develop SGX204 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, cGMP production methodology has already been completed. Assuming long-term stability can be met, SGX204 could be stockpiled for general prophylactic as well as

a post exposure use.

The overall objective of the SGX204 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. SGX204 will potentially be a combination of a stable, readily manufactured mutant rPA subunit antigen with next generation, clinically compatible adjuvants from Infectious Disease Research Institute (IDRI) 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 Department of Defense (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.

RiVax™ - Ricin Toxin Vcaccine

RiVax™ is Soligenix’s proprietary vaccine developed to protect against exposure to ricin toxin. With RiVax™, Soligenix is 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. One Phase 1 human clinical trial was completed, and a second trial is currently being conducted. 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 is being supported by a grant from the FDA's Office of Orphan Products to UTSW. Soligenix and UTSW have collectively received approximately $15 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 the 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, is currently evaluating a more potent formulation of RiVax™ that contains a conventional adjuvant (salts of aluminum), anticipated to result in higher antibody titers of longer duration in human subjects. This trial is expected to complete in the 2H 2012. Soligenix has adapted the original manufacturing process for the immunogen contained in RiVax™ for large scale manufacturing and is further establishing correlates of the human immune response in non-human primates.

11

RiVaxTM 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. RiVaxTM 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). 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.

SGX202 – Oral BDP for Gastrointestinal Acute Radiation Syndrome (GI ARS)

SGX202 (an oral immediate and delayed release formulation of the topically active corticosteroid beclomethasone dipropionate (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.

SGX202 has demonstrated positive preclinical results in a canine GI ARS model which indicate that dogs treated with SGX202 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. SGX202 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 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 radiation-induced GI ARS. As a result, there is a dual avenue of development for Soligenix, and SGX202 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.

The application of SGX202 to acute GI ARS originated from other programs for oral BDP and is based on the properties of BDP to act locally in the GI to modulate local inflammation and epithelial cellular apoptosis.

Development of SGX202 for GI ARS is a natural extension of Soligenix's radiation enteritis clinical program with SGX201. Killing cancer cells with radiation therapy or chemotherapy must be done in ways that minimize toxicity to the rest of the body, but often leads to an inflammatory condition in the GI tract when administered in that general vicinity. In most radiation scenarios, injury to the hematopoietic (blood) system and GI tract are the main determinants of survival.

To date, development of SGX202 has been largely supported by a $1 million NIH grant to Soligenix's academic partner, the Fred Hutchinson Cancer Research Center.

About GI ARS

The potential occurrence of industrial radiation accidents and the threat of terrorist events involving radioactive material mandate the development and implementation of effective treatments of radiation injury. The GI tract is highly sensitive to radiation damage. Substantial injury to the GI tract after radiation exposure results in death. In most radiation scenarios, injury to the hematopoietic system and gastrointestinal tract are the main determinants of survival. There is an urgent need to develop specific countermeasures against the lethality caused by intestinal exposure to radiation and against the pathophysiological manifestations of radiation-induced gastrointestinal 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 the development of biodefense vaccines, such as RiVax™, 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

Pursuant to the collaboration and supply agreement with Sigma-Tau, we granted an exclusive license to Sigma-Tau to commercialize orBec® in the U.S., Canada, Mexico and Europe.

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.

orBec®/Oral BDP Competition

There are currently 41 compounds either on 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 other 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 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 (budesonide) is also currently in Phase 3 trials in pediatric Crohn's.

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 Genzyme, 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. We believe that orBec®'s unique release characteristics, intended to deliver topically active therapy to both the upper and lower gastrointestinal systems, should make orBec® an attractive alternative to existing therapies for inflammatory diseases of the gastrointestinal tract.

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

ThermoVaxTM 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 ThermoVaxTM technology, and variations in drying cycles during lyophilization, as does the ThermoVaxTM 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 the 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 SGX204, 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 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 RiVaxTM 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 RVEcTM, 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 RiVaxTM, RVEcTM 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 RVEcTM's safety as well as its immunogenicity.

In the area of radiation-protective antidotes such as SGX202, various companies, such as Cleveland Biolabs, Aeolus Pharmaceuticals, Boulder Biotechnology, RxBio, Inc., 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 SGX202, even though their approaches to such treatment are different.

Only RxBio 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. 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 an issued U.S. patent that covers the use of oral BDP for the prevention and treatment of GI GVHD. 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 and European patent EP 1830857 claiming oral BDP in conjunction with a short duration of high-dose prednisone with a rapid taper for the reduction of mortality associated with GVHD and leukemia.

In addition to issued and pending patents, we also have “Orphan Drug” designations for orBec® in the U.S. and in Europe. Our Orphan Drug designations provide for seven years of post approval marketing exclusivity in the U.S. and ten years exclusivity in Europe for the use of orBec® in the treatment of GI GVHD. We have pending patent applications for this indication that, if granted, may extend our anticipated marketing exclusivity beyond the seven year post-approval exclusivity provided by the Orphan Drug Act of 1983.

orBec®/Oral BDP License Agreement

On November 24, 1998, the Company, 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®. 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 it 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.

ThermoVaxTM License Agreement

On September 1, 2009, we executed a worldwide exclusive option to license patent applications with the University of Colorado ("UC") for ThermoVaxTM 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 University of Texas Southwestern Medical Center ("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™.

SGX204 License Option Agreement

In December of 2011, we optioned a license to the SGX204 patent from the President and Fellows of Harvard College. SGX204 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 $6.3 million and $6.0 million in the years ended December 31, 2011 and 2010, respectively, on research and development. The amounts we spent on research and development per product during the years ended December 31, 2011 and 2010 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, 2011, we had 13 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.

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, 2011, we have approximately $6.0 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 2013.

We have sufficient funds through our existing biodefense grant facilities from the National Institute of Allergy and Infectious Diseases (“NIAID”), a division of the National Institutes of Health (“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. 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. We expect that our existing NIH biodefense grants will cover approximately $600,000 of such fixed overhead costs over the next several years.

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 2011, we have expended approximately $44.1 million developing our current product candidates for pre-clinical research and development and clinical trials, and we currently expect to spend at least $2 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 orBec®, our lead product candidate, or another 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 confirmatory Phase 3 clinical trial for orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease ("GI GVHD") was stopped on September 15, 2011 at the recommendation of an independent Data Safety Monitoring Board ("DSMB").

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.

On October 18, 2007, we received a "not approvable letter" from the FDA for our lead product candidate, orBec®, for the treatment of acute GI GVHD. The letter stated that the FDA requested data from additional clinical trials to demonstrate the safety and efficacy of orBec®. The FDA also requested nonclinical and chemistry, manufacturing and controls information as part of the not approvable letter. On October 19, 2007, we requested an "End of Review Conference" with the FDA to further understand the letter and gain clarity regarding the next steps. On December 7, 2007, we announced the following guidance from that meeting: (1) a single, confirmatory, Phase 3 clinical trial could provide sufficient evidence of efficacy provided that it is well designed, well executed and provides clinically and statistically meaningful findings; (2) we anticipated working quickly with the FDA to finalize the design of the confirmatory trial under the Agency's "Special Protocol Assessment" process; and (3) the FDA would be agreeable to reviewing a plan for a Treatment Investigational New Drug ("Treatment IND") as long as it does not interfere with patient accrual in a confirmatory trial, such as potentially enrolling patients that would not be eligible for the Phase 3 study.

On January 5, 2009, we reached an agreement with the FDA on the design of a confirmatory, pivotal Phase 3 clinical trial evaluating our lead product orBec® for the treatment of acute GI GVHD. The agreement was made under the FDA's Special Protocol Assessment procedure. The confirmatory Phase 3 clinical trial for the treatment of acute GI GVHD commenced on October 15, 2009. The trial was stopped on September 15, 2011 at the recommendation of the DSMB because it is highly unlikely to achieve the predetermined end point of efficacy based on the interim results. The data from the Phase 3 trial is currently being analyzed to determine the factors resulting in its termination.

Although we hope to obtain FDA approval for orBec®, there can be no assurances that the FDA will ever approve orBec® for market launch. Furthermore, the FDA may mandate additional testing or data, which may take additional time and expense to provide.

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

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. 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 dependant on our ability to adhere to the terms and provisions of the original grant documents and other regulations.

21

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

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

We 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. Although we have a collaboration agreement with Sigma-Tau for the sales and marketing of orBec® in North America and Europe, we may be unable to establish additional satisfactory arrangements for marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for orBec® or our other product candidates. In addition, Sigma-Tau may not be able to effectively commercialize orBec® if it is approved. To obtain the expertise necessary to successfully market and sell orBec®, or any other product, potentially will require the development of our own commercial infrastructure and/or collaborative commercial arrangements and partnerships. 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, such as orBec® for the treatment of acute and chronic GI GVHD and prevention of GVHD.

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, 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, or 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.

23

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. If our collaboration agreement with Sigma-Tau were to be terminated, we would need to establish and build our own sales force in North America and Europe or enter into an agreement for the commercialization of orBec® with another company. 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 9 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 and a decline in financial markets due at least in part to the deteriorating global economic environment. In addition, there has been substantial uncertainty in the capital markets and access to additional financing is uncertain. Moreover, customer spending habits may be adversely affected by the current economic crisis. 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, 2011, our stock price (split adjusted) has fluctuated over the last year between a high of $6.80 per share to a low of $0.60 per share. As of March 21, 2012, our common stock closed at $0.54 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, and subsequent 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 Over-The-Counter Bulletin Board (“OTCBB”) securities market under the symbol “SNGX.” The OTCBB 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 OTCBB, 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. OTCBB securities include national, regional, and foreign equity issues. Companies traded on the OTCBB must be current in their reports filed with the Securities and Exchange Commission (“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 2,701,569 shares of our common stock at a current weighted average exercise price of approximately $4.40; and
- options to purchase approximately 1,544,242 shares of our common stock at a current weighted average exercise price of approximately $3.75.

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

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. We currently pay rent of approximately $7,650 per month, or approximately $17.50 per square foot on an annualized basis, pursuant to the lease that we entered into on April 1, 2009 and that expires on March 31, 2012. Our office space is sufficient to satisfy our current needs. 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.

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. We are not a party to any legal proceedings at this time.

27

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 Over-the-Counter Bulletin Board ("OTCBB") 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 OTCBB.

	Price Range	
Period	High	Low
Year Ended December 31, 2010:		
First Quarter	$ 5.80	$ 4.60
Second Quarter	$ 6.00	$ 4.80
Third Quarter	$ 5.20	$ 3.60
Fourth Quarter	$ 4.60	$ 3.00
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

As of March 21, 2012, the last reported price of our common stock quoted on the OTCBB was $0.54 per share. The OTCBB 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 March 21, 2012, we have approximately 950 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," "ma "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 focused on developing products to treat the life-threatening side effects of cancer treatment and 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 orBec® (oral beclomethasone dipropionate, or oral BDP) and other biotherapeutic products, including LPMTM-Leuprolide, while our collaboration partner, Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau") will commercialize orBec® in North America and Europe, if approved. 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"). Additionally, we are actively developing oral BDP in other therapeutic indications, such as pediatric Crohn's disease and radiation enteritis. Our Vaccines/BioDefense business segment includes RiVaxTM, our ricin toxin vaccine, and SGX204, our anthrax vaccine, and SGX202, our gastrointestinal acute radiation syndrome ("GI ARS") program. The advanced development of these programs will be supported by our heat stabilization technology under existing and on-going government grant.
Our business plan can be outlined as follows:

- Initiate a Phase 2A clinical trial of oral BDP knows as SGX203 in pediatric Crohn's disease;
- Use RiVaxTM and SGX204 to support development efforts and establish proof of concept with our proprietary vaccine heat stabilization technology known as ThermoVaxTM;
- Apply for and secure further government funding for development of our BioDefense programs, namely RiVaxTM, SGX204, and SGX202 in GI ARS;
- Evaluate the effectiveness of orBec®/Oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal ("GI") tract such as prevention of acute radiation enteritis, prevention of acute GVHD, and treatment of chronic GI GVHD;
- Continue to secure additional government funding for each of our BioTherapeutics and Vaccines/BioDefense programs through grants, contracts and/or procurements;
- Acquire or in-license new clinical-stage compounds for development; and
- Explore other business development and acquisition strategies.

29

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 applicable outside legal and filing costs incurred in the procurement of patents.

We capitalize legal costs associated with the issuance and filings of new patents and expense annual maintenance costs of our patents and rights for our current products in both the domestic and international markets. As a late stage research and development company with drug and vaccine products in an often lengthy clinical research process, we believe that patent rights are one of our most valuable assets. Patents and patent applications are a key currency 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. The legal costs incurred for these patents consist of work associated with filing new patents and perhaps extending the lives of the patents. Therefore, our policy is to capitalize these costs and amortize them over the remaining useful life of the patents, generally a period of 11 to 16 years. We capitalize intangible assets' alternative future use as referred to in FASB ASC 350, Intangibles – Goodwill and Other and FASB ASC 730, Research and Development.

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 the carrying value of the related asset or group of assets.

Revenue Recognition

Our revenues are generated from NIH grants, licensing activities and the achievement of licensing milestones. The revenue from NIH grants are 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 milestone revenues are recorded when earned.

Research and Development Costs

Research and development costs are charged to expense when incurred. 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 and 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.

30

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 2011 and 2010.

Stock-Based Compensation

From time to time, we issue 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.

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.

New Accounting Pronouncements

See Note 2, New Accounting Pronouncements, of the financial statements for a discussion of new accounting pronouncements.

Material Changes in Results of Operations

Year Ended December 31, 2011 Compared to 2010

For the year ended December 31, 2011, we had a net loss of $2,378,594 as compared to a net loss of $7,386,579 for the prior year, representing a decreased loss of $5,007,985 or 68%. This decrease in the net loss is primarily attributable to the receipt of $5,000,000 from Sigma-Tau as payment on the execution of our expanded license agreement into the European territory (the "Sigma-Tau Agreement") offset by increased spending of $286,211 in research and development for the year ended December 31, 2011 over 2010 related to the conduct of the confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD. For the year ended December 31, 2011, there was a slight increase in general and administrative expenses of $40,930.

For the year ended December 31, 2011, revenues and associated costs relate to NIH grants awarded in support of the development of ThermoVax™ as well as our ricin toxin vaccine, OrBec® and the Sigma-Tau Agreement. For the year ended December 31, 2011, we had revenues of $7,662,822 as compared to $1,947,628 for the prior year, representing an increase of $5,715,194. The increased revenues were a result of $5,000,000 received relating to the Sigma-Tau Agreement and increases in NIH drawdowns and the associated development work underlying them.

We incurred costs related to that revenue in the year ended December 31, 2011 and 2010 of $2,108,228 and $1,638,402, respectively, representing an increase of $469,826, or 29%. 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, 2011 was $5,554,594 as compared to $309,226 for the prior year, representing an increase of $5,245,368. This increase is almost entirely due to the Sigma-Tau Agreement and increase in grant revenues discussed above and a 2011 reimbursement of certain period salary costs which there is no current period cost. Excluding the license revenue associated with the Sigma-Tau Agreement, gross profit would have been $554,594 for the year ended December 31, 2011.

Research and development spending increased by $286,211, or 5%, to $6,272,616 for the year ended December 31, 2011 as compared to $5,986,405 for the prior year. This increase is primarily related to the conduct of the confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD.

General and administrative expenses slightly increased by $40,930, or 2%, to $2,242,172 for the year ended December 31, 2011, as compared to $2,201,242 for the prior year.

Net interest income (expense) for the year ended December 31, 2011 was $7,444 as compared to $11,332 for the prior year, representing a decrease of $3,888, or 34%. This decrease was due to substantially lower interest rates earned on cash balances in 2011 versus the prior year.

Other income (expense) for the year ended December 31, 2010 included $234,700 of proceeds, net of transaction costs, from grants in response to an application submitted for qualified investments in qualifying therapeutic discovery projects under Section 48D of the Internal Revenue Code. The qualifying therapeutic discovery project program was not renewed in 2011.

During the year ended December 31, 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 ("NOL") carryforwards to other New Jersey-based corporate taxpayers based in New Jersey, we sold New Jersey NOL carryforwards, resulting in the recognition of $574,157 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, 2011 and December 31, 2010: Vaccines/BioDefense and BioTherapeutics.

Revenues for the Vaccines/BioDefense business segment for the year ended December 31, 2011 were $2,010,234 as compared to $1,441,228 for the year ended December 31, 2010, representing an increase of $569,006 or 39%. This increase is primarily attributed to NIH grant revenue for work towards our ThermoVax™ vaccine technology. Revenues for the BioTherapeutics business segment for the year ended December 31, 2011 were $5,652,588 as compared to $506,400 for the year ended December 31, 2010, representing an increase of $5,146,188. This significant increase is a result of $5,000,000 received relating to the Sigma-Tau Agreement.

Loss from operations for the Vaccines/BioDefense business segment for the year ended December 31, 2011 was $154,395 as compared to $1,204,824 for the year ended December 31, 2010, representing a decreased loss of $1,050,429. This decrease is primarily attributed to NIH grant revenue for work towards our ThermoVax™ vaccine technology and a 2011 reimbursement of certain period salary costs which there is no current period cost. In 2010 we took a one time patent write-off cost of $378,501 in connection to the return of the botulinum toxic vaccine to Thomas Jefferson University. Loss from operations for the BioTherapeutics business segment for the year ended December 31, 2011 was $1,278,156 as compared to $5,018,090 for the year ended December 31, 2010, representing a decrease of $3,739,934. This decreased loss is primarily attributed to the $5,000,000 received relating to the Sigma-Tau Agreement offset by the conduct of the confirmatory Phase 3 clinical trial of orBec® in 2011.

Amortization and depreciation expense for the Vaccines/BioDefense business segment for the year ended December 31, 2011 was $42,640 as compared to $36,843 for the year ended December 31, 2010, representing an increase of $5,797, or 16%, primarily related to newly capitalized patent costs in 2011. Amortization and depreciation expense for the BioTherapeutics business segment for the year ended December 31, 2011 was $181,213 as compared to $146,832 for the year ended December 31, 2010, representing an increase of $34,381, or 23%, primarily related to newly capitalized patent costs in 2011.

Financial Condition and Liquidity

Cash and Working Capital

As of December 31, 2011, we had cash and cash equivalents of $5,996,668 as compared to $7,451,714 as of December 31, 2010, representing a decrease of $1,455,046 or 20%. As of December 31, 2011, we had working capital of $5,696,444 as compared to working capital of $6,101,103 as of December 31, 2010, representing a decrease of $404,659 or 7%. The decrease in working capital was the result of the cash used in operating and investing activities over the period, offset by the proceeds of $5,000,000 received from the Sigma-Tau Agreement in July 2011, as well as option exercise proceeds and proceeds from the sale of stock under the Fusion equity line. For the year ended December 31, 2011, our cash used in operating activities was $1,951,738, as compared to $5,730,582 for the same period in 2010. This decrease is due to proceeds of $5,000,00 received from the Sigma-Tau Agreement offset by spending attributable to the conduct of the confirmatory Phase 3 clinical trial of orBec® in the treatment of acute GI GVHD.

Based on our current rate of cash outflows, cash on hand, the timely collection of milestone payments under collaboration agreements, proceeds from our grant-funded programs, reductions in headcount and expected proceeds from the State of New Jersey Technology Business Tax Certificate Transfer Program, we believe that our current cash will be sufficient to meet our anticipated cash needs for working capital and capital expenditures into the second quarter of 2013.

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 2013 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 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 $574,157 in proceeds pursuant to NOL sales in 2011, we expect to participate in this program during 2012 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.

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 research and development expenditures for the next 12 months to be approximately $3.8 million before any grant reimbursements, of which $1.6 million relates to the BioTherapeutics business and $2.2 million relates to the Vaccines/BioDefense business. We anticipate grant revenues in the next 12 months of approximately $2.6 million to offset research and development expenses, primarily for the development of our ThermoVax™ vaccine technology and very limited contribution to the wind down costs of the Phase 3 clinical trial of orBec® in the treatment of acute GI GVHD.

33

The table below details our costs by program for the years ended December 31, 2011 and 2010:

	2011	2010
Research & Development Expenses		
orBec®	$ 3,935,737	$ 3,425,757
RiVax™ & ThermoVax™ Vaccines	1,831,593	1,871,474
BT-VACC™	-	378,501
Oraprine™	-	6,000
LPM™ Leuprolide	-	2,577
Total	$ 5,767,330	$ 5,684,309
Reimbursed under NIH Grants		
orBec®	$ 616,783	$ 460,279
RiVax™ & ThermoVax™ Vaccines	1,491,445	962,716
BT-VACC™	-	215,407
Total	$ 2,108,228	$ 1,638,402
Grand Total	$ 7,875,558	$ 7,322,711

Effects of Inflation and Foreign Currency Fluctuations

We do not believe that inflation or foreign currency fluctuations significantly affected our financial position and results of operations as of and for the years ended December 31, 2011 or 2010.

Contractual Obligations

We have a contractual obligation of approximately $80,000 as of December 31, 2011 resulting from a collaboration agreement with Numoda Corporation for the electronic data capture in connection with our confirmatory Phase 3 clinical trial of orBec® that began in September 2009 and is expected to complete in April 2012. Additionally, we have 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 April 1, 2009, we entered into a sublease agreement through March 31, 2012 for office space in Princeton, New Jersey. We were required to provide 4 months of rent as a security deposit. The rent for the first 18 months was approximately $7,500 per month, or approximately $17.00 per square foot on an annualized basis. This rent increased to approximately $7,650 per month, or approximately $17.50 per square foot on an annualized basis, for the remaining 18 months. 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.

In February 2007, our Board of Directors authorized the issuance of the following shares to Dr. Schaber and Dr. Brey upon the completion of a transaction, or series or a combination of related transactions negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of our assets are transferred from us and/or our stockholders to a third party: 50,000 common shares to Dr. Schaber; and 10,000 common shares to Dr. Brey. The employment agreement with Dr. Schaber has been amended to reflect this obligation.

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 member of the Board of Directors.

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	Severance	Total
2012	$ 235,000	$ 100,621	$ 154,362	$ 489,983
2013	75,000	104,559	-	179,559
2014	75,000	101,198	-	176,198
2015	75,000	24,938	-	99,938
2016	75,000	-	-	75,000
Total	$ 535,000	$ 331,316	$ 154,362	$ 1,020,678

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, 2011. 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, 2011, 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. Myrianthopoulos, 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 March 21, 2012:

Name	Age	Position
Christopher J. Schaber, PhD	45	Chairman of the Board, Chief Executive Officer and President
Keith L. Brownlie, CPA	59	Director
Tamar D. Howson	63	Director
Gregg A. Lapointe, CPA	53	Director
Evan Myrianthopoulos	47	Director
Robert J. Rubin, MD	66	Director
Virgil D. Thompson	72	Director
Jerome Zeldis, MD, PhD	61	Director
Robert N. Brey, PhD	61	Chief Scientific Officer and Senior Vice President
Kevin J. Horgan, MD	52	Chief Medical Officer and Senior Vice President
Joseph M. Warusz, CPA	55	Vice President of Finance, Acting Chief Financial Officer and Corporate Secretary

Christopher J. Schaber, PhD has over 22 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. 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.

Tamar D. Howson has been a director since September 2010. She is currently a partner with JSB-Partners, LP, a transaction advisory firm serving the life sciences industry. From 2007 to 2008, Ms. Howson served as Executive Vice President of Corporate Development for Lexicon Pharmaceuticals, Inc. From 2001 to 2007, she served as Senior Vice President of Corporate and Business Development and was a member of the executive committee at Bristol-Myers Squibb Company. During her tenure at Bristol-Myers, Ms. Howson was responsible for leading the company's efforts in external alliances, licensing and acquisitions. In 2000 and 2001, Ms. Howson served as a business development and strategy consultant to biotechnology companies in the United States and in Europe. During this period, she served on the Boards of Skye Pharma, plc., Ariad, NPS, and Targacept Pharmaceuticals. From 1991 to 2000, Ms. Howson served as Senior Vice President and Director of Business Development at SmithKline Beecham plc. She also managed SR One Ltd., a $100 million venture capital fund of SmithKline Beecham, plc. From 1990 to 1991, Ms. Howson held the position of Vice President, Venture Investments at Johnston Associates, Inc., a venture capital firm, and from 1987 to 1990, she served as Director of Worldwide Business Development and Licensing for Squibb Corporation. Ms. Howson serves on the boards of OXIGENE, Inc., a publicly traded, clinical-stage, biopharmaceutical company developing therapeutics to treat cancer and eye diseases; Idenix Pharmaceuticals, Inc., a publicly traded, biopharmaceutical company developing drugs for the treatment of human viral diseases; and S*Bio Pte Ltd., a private drug discovery company developing small molecule anti-cancer drugs. She also serves as a consultant to Bay City Capital and is a member of the advisory board to Triana Venture Partners, Inc. She previously served on the board of the Healthcare Businesswomen's Association. Ms. Howson received her MBA in finance and international business from Columbia University. She holds a MS from the City College of New York and a BS from Technion in Israel.

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 has served in varying roles for Sigma-Tau, a private biopharmaceutical company, since September 2001, 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.

Evan Myrianthopoulos has been a director since 2002, after joining us in November of 2004 as President and Acting Chief Executive Officer until August of 2006. He then was our Chief Financial Officer and Senior Vice President until February 2012. From November 2001 to November 2004, he was President and founder of CVL Advisors Group Inc., a financial consulting firm specializing in the biotechnology sector. Prior to founding CVL Advisors Group, Inc., Mr. Myrianthopoulos was a co-founder of Discovery Laboratories, Inc. During his tenure at Discovery Laboratories, Inc. from June 1996 to November 2001, Mr. Myrianthopoulos held the positions of Chief Financial Officer and Vice President of Finance, where he was responsible for raising approximately $55 million in four private placements. He also helped negotiate and manage Discovery Laboratories, Inc.'s mergers with Ansan Pharmaceuticals and Acute Therapeutics, Inc. Prior to co-founding Discovery Laboratories, Inc., Mr. Myrianthopoulos was a Technology Associate at Paramount Capital Investments, L.L.C., a New York City based biotechnology venture capital and investment banking firm from October 1995 to December 1997. Prior to joining Paramount Capital Investments, LLC, Mr. Myrianthopoulos was a managing partner at a hedge fund and also held senior positions in the treasury department at the National Australia Bank where he was employed as a spot and derivatives currency trader. Mr.

Myrianthopoulos holds a B.A. degree in Economics and Psychology from Emory University. Mr. Myrianthopoulos was selected to serve as a member of our Board of Directors because of his experience as principal financial officer and principal executive officer of our Company and Discovery Laboratories and his experience in raising capital.

Robert J. Rubin, MD has been a director since October 2009. Dr. Rubin has also been a clinical professor of medicine at Georgetown University since 1995. 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.

Virgil D. Thompson has been a director since September 2010. Mr. Thompson currently serves as Chairman of the Board of Directors of Aradigm Corporation, a publicly traded specialty pharmaceutical company (director since June 1995); Chairman of the Board of Directors of Questcor Pharmaceuticals, Inc., a publicly traded pharmaceutical company (director since 1996); a director of Savient Pharmaceuticals, Inc., a publicly traded specialty pharmaceutical company; and Chief Executive Officer and a director of Spinnaker Biosciences, Inc., a private ophthalmic drug delivery company. He served as the President, Chief Executive Officer and as a Director of Angstrom Pharmaceuticals, Inc. from 2002 until 2007. From 2000 to 2002, Mr. Thompson was President, Chief Executive Officer and a director of Chimeric Therapies, Inc. From 1999 to 2000, Mr. Thompson was President, Chief Operating Officer and a director of Bio-Technology General Corporation, a pharmaceutical company (now Savient Pharmaceuticals, Inc.). From 1996 to 1999, Mr. Thompson was President and Chief Executive Officer and a director of Cytel Corporation, a publicly traded biopharmaceutical company that was subsequently acquired by IDM Pharma, Inc. From 1994 to 1996, Mr. Thompson was President and Chief Executive Officer of Cibus Pharmaceuticals, Inc., a privately held drug delivery device company. From 1969 to 1993, Mr. Thompson was employed by Syntex Corporation, a publicly traded pharmaceutical company where his employment included Vice President, Corporate Regulatory Affairs, Executive Vice President and Chief Operating Officer, and President of Syntex Laboratories, Inc., the U.S. subsidiary. Mr. Thompson holds a BS degree in pharmacy from Kansas University and a JD degree from The George Washington University Law School.

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, and the Castleman's Disease Organization. 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.

39

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 Haemophilius nfluenza 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 graft-versus-host disease (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.

Mr. Brownlie, Ms. Howson, Dr. Rubin, Mr. Thompson 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, 2011, 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, controller, 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 Thompson 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 Thompson 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, 2011 to our Chief Executive Officer and each of the three other most highly compensated executive officers during 2011 (collectively, the "Named Executive Officers").

Summary Compensation

Name	Position	Year	Salary	Bonus	Option Awards	All Other Compensation	Total
Christopher J. Schaber1	CEO & President	2011	$ 370,000	$ 50,000	$ 68,400	$ 35,529	$ 455,529
		2010	$ 350,981	$ 100,000	$ 408,908	$ 27,529	$ 887,419
Evan Myrianthopoulos2	CFO & Senior VP	2011	$ 242,500	$ 25,000	$ 34,200	$ 35,529	$ 303,029
		2010	$ 230,723	$ 50,000	$ 195,161	$ 27,677	$ 503,561
Robert N. Brey3	CSO & Senior VP	2011	$ 210,000	$ 13,000	$ 19,950	$ 21,853	$ 244,853
		2010	$ 210,000	$ 40,000	$ 157,987	$ 11,955	$ 419,942
Kevin J. Horgan4	CMO & Senior VP	2011	$ 281,589	$ 16,000	$ 203,575	$ 22,543	$ 320,132
Joseph M. Warusz5	VP & Controller	2011	$ 104,028	$ 7,000	$ 152,620	$ 19,627	$ 130,655

1 Dr. Schaber deferred payment of his 2010 annual bonus of $100,000 until January 15, 2011 and 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.

2 Mr. Myrianthopoulos deferred payment of his 2010 annual bonus of $50,000 until January 15, 2011 and his 2011 annual bonus of $25,000 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. On February 15, 2012, Mr. Myrianthopoulos' employment agreement with the Company was terminated.

3 Dr. Brey deferred payment of his 2010 annual bonus of $40,000 until January 15, 2011 and 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.

4 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.

5 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.

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. He will be paid nine months of severance upon termination of employment. 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 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.

In December 2004, we entered into a three-year employment agreement with Evan Myrianthopoulos. Pursuant to this employment agreement we agreed to pay Mr. Myrianthopoulos a base salary of $185,000 per year. After one year of service Mr. Myrianthopoulos would be entitled to a minimum annual bonus of $50,000. This employment agreement was renewed on December 27, 2007 for an additional term of three years. We agreed to issue him options to purchase 25,000 shares of our common stock, with the options vesting over three years. Upon termination without "Just Cause" as defined by this agreement, we would pay Mr. Myrianthopoulos six months of severance subject to set off, as well as any unpaid bonuses and accrued vacation would become payable. No unvested options shall vest beyond the termination date. Mr. Myrianthopoulos also received 7,500 options, vested immediately when he was hired in November 2004, as President and Acting Chief Executive Officer. Mr. Myrianthopoulos' monetary compensation (base salary of $200,000 and bonus of $50,000) remained unchanged from 2006 with the 2007 renewal. He will be paid six months of severance upon termination of employment. Upon a change in control of the Company due to merger or acquisition, all of Mr. Myrianthopoulos' options shall become fully vested, and be exercisable for a period of three years after such change in control (unless they would have expired sooner pursuant to their terms). In the event of his death during term of contract, all of his unvested options shall immediately vest and remain exercisable for the remainder of their term and become property of Mr. Myrianthopoulos' immediate family. This employment agreement was amended on January 4, 2011, extending his employment for an additional two years, and thereafter the term of employment automatically renews for a period of two years, unless the Company or Mr. Myrianthopoulos deliver three months notice of an election not to renew the term. On February 15, 2012, Mr. Myrianthopoulos' employment agreement was terminated, however he continues to serve as a member of our Board of Directors.

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 agreements include our obligation to issue such shares to the executives if such event occurs.

On March 27, 2009, the Compensation Committee approved the increase in salaries for Dr. Schaber to $350,000 and Mr. Myrianthopoulos to $230,000.

On June 22, 2011, the Compensation Committee approved the increase in salaries for Dr. Schaber to $390,000 and Mr. Myrianthopoulos to $255,000. Additionally, their fixed minimum annual bonus payable was eliminated and revised to an annual targeted bonus of their respective annual base salary. Dr. Schaber and Mr. Myrianthopoulos targeted bonus is 40% and 30%, respectively.

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.

We do not currently have an employment agreement with 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.

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 February 15, 2012, Mr. Myrianthopoulos’ employment agreement was terminated, however he continues to serve as a member of our Board of Directors. As defined in the employment agreement, we will pay Mr. Myrianthopoulos six months of severance, accrued bonus and vacation as well as insurance benefits to the term of his severance.

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, 2011 as adjusted for the reverse stock split of 1-for-20 effective February 1, 2012. We have never issued Stock Appreciation Rights.

Outstanding Equity Awards at Fiscal Year-End

	Number of Securities Underlying Unexercised Options (#)		Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned	Option Exercise	Option Expiration
Name	Exercisable	Unexercisable	Options (#)	Price ($)	Date
Christopher J. Schaber	125,000	-	-	$ 5.40	8/28/2016
	45,000	-	-	$ 9.40	8/9/2017
	140,000	-	-	$ 1.20	12/17/2018
	61,875	48,125	48,125	$ 4.64	6/30/2020
	30,000	90,000	90,000	$ 0.64	11/30/2021
Evan Myrianthopoulos	7,500	-	-	$ 7.00	11/14/2012
	2,500	-	-	$ 18.00	9/15/2013
	2,500	-	-	$ 11.60	6/11/2014
	7,500	-	-	$ 9.40	11/10/2014
	25,000	-	-	$ 9.80	12/13/2014
	20,000	-	-	$ 7.00	5/10/2016
	27,500	-	-	$ 9.40	8/9/2017
	60,000	-	-	$ 1.20	12/17/2018
	29,531	22,969	22,969	$ 4.64	6/30/2020
	15,000	45,000	45,000	$ 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
	23,906	18,594	18,594	$ 4.64	6/30/2020
	8,750	26,250	26,250	$ 0.64	11/30/2021
Kevin J. Horgan	27,344	35,156	35,156	$ 3.44	1/30/2021
	15,000	45,000	45,000	$ 0.64	11/30/2021
Joseph M. Warusz	15,000	25,000	25,000	$ 4.10	5/30/2021
	7,500	22,500	22,500	$ 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, 2011.

Compensation of Directors

Name	Fees Earned Paid in Cash1	Option Awards2	Total
Keith Brownlie	$9,245	$46,944	$56,189
Tamar D. Howson	$23,073	$30,001	$53,074
Gregg A. Lapointe	$26,497	$30,001	$56,498
Robert J. Rubin	$29,746	$30,001	$59,747
Virgil D. Thompson	$29,507	$30,001	$59,508
Jerry Zeldis	$5,495	$46,944	$52,439

1 Directors who are compensated as full-time employees receive no additional compensation for service on our Board of Directors. Each independent director who is not a full-time employee is paid $20,000 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, in arrears.

2 We maintain a stock option grant program pursuant to the nonqualified stock option plan, whereby members of our Board of Directors or its committees who are not full-time employees receive an initial grant of fully vested options to purchase 15,000 shares of common stock. Upon re-election to the Board, each Board member will receive stock options with a value of $30,000 based upon the Black Scholes valuation method. Furthermore, all stock options would vest at the rate of 25% per quarter, commencing with the first quarter after each annual meeting of stockholders.

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

The table below provides information regarding the beneficial ownership of the common stock as of March 31, 2012, as adjusted for the reverse stock split of 1-for-20 effective February 1, 2012, 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 Cavazza1	3,379,953	29.22	%
Claudio Cavazza2	3,068,464	26.73	%
Sigma-Tau Pharmaceuticals, Inc. 3	3,068,464	26.73	%
Christopher J. Schaber 4	458,483	3.97	%
Evan Myrianthopoulos 5	204,052	*	
Gregg A. Lapointe 6	111,489	*	
Robert N. Brey 7	117,501	*	
Robert J. Rubin 8	49,202	*	
Joseph Warusz 9	26,875	*	
Kevin J. Horgan 10	50,000	*	
Tamar D. Howson 11	22,163	*	
Virgil D. Thompson 12	22,163	*	
Keith Brownlie13	15,000	*	
Jerry Zeldis 14	15,000	*	
All directors and executive officers as a group (11 persons)	1,091,928	9.02	%

1 Includes (a) 2,711,392 shares of common stock and warrants to purchase 357,072 shares of common stock exercisable within 60 days of January 31, 2012 held by Sigma-Tau Pharmaceuticals, Inc., (b) 223,685 shares of common stock and warrants to purchase 87,854 shares held by Chaumiere Sarl, 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. Chaumiere Sarl 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.

2 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, 2012 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.

3 Includes 2,280,962 shares of common stock and warrants to purchase 98,814 shares of common stock exercisable within 60 days of March 31, 2012. 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.

4 Includes 40,257 shares of common stock owned by Dr. Schaber, options to purchase 416,250 shares of common stock exercisable within 60 days of January 31, 2011, and warrants to purchase 1,976 shares of common stock exercisable within 60 days of January 31, 2012. The address of Dr. Schaber is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

5 Includes 11,239 shares of common stock owned by Mr. Myrianthopoulos and his wife and options to purchase 192,813 shares of common stock exercisable within 60 days of January 31, 2012. The address of Mr. Myrianthopoulos is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

6 Includes 48,781 shares of common stock, options to purchase 33,440 shares of common stock exercisable within 60 days of January 31, 2012, and warrants to purchase 29,268 shares of common stock exercisable within 60 days of January 31, 2012. The address of Mr. Lapointe is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

7 Includes options to purchase 117,501 shares of common stock exercisable within 60 days of January 31, 2012. The address of Dr. Brey is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

8 Includes 12,195 shares of common stock, options to purchase 29,690 shares of common stock exercisable within 60 days of January 31, 2012, and warrants to purchase 7,317 shares of common stock exercisable within 60 days of January 31, 2011. The address of Dr. Rubin is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

9 Includes options to purchase 26,875 shares of common stock owned by Mr. Warusz exercisable within 60 days of January 31, 2012. The address of Mr. Warusz is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

10 Includes options to purchase 50,000 shares of common stock owned by Dr. Horgan exercisable within 60 days of January 31, 2012. The address of Dr. Horgan is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

11 Includes options to purchase 22,163 shares of common stock exercisable within 60 days of January 31, 2012. The address of Ms. Howson is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

12 Includes options to purchase 22,163 shares of common stock exercisable within 60 days of January 31, 2012. The address of Mr. Thompson is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

13 Includes options to purchase 15,000 shares of common stock exercisable within 60 days of January 31, 2012. The address of Mr. Brownlie is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540

14 Includes options to purchase 15,000 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 March 31, 2011 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 11,120,874 shares of common stock outstanding as of January 31, 2011 on a 20-1 post split basis.

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, 2011 as adjusted for the reverse stock split of 1-for-20 effective February 1, 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 holders1	1,095,242	$ 4.41	60,692
Equity compensation plans not approved by security holders	-	-	-
Total	1,095,242	$ 4.41	60,692

1 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, compensation paid to our directors and our collaboration and supply agreement with Sigma-Tau, we did not engage in any transactions with related parties since January 1, 2010. For a discussion of our employment agreements and compensation paid to our directors, see "Item 11. Executive Compensation." For a discussion of our collaboration and supply agreement with Sigma-Tau, see "Item 1. Business – BioTherapeutics Overview – orBec® and oral BDP – Commercialization and Market."

Director Independence

The Board of Directors has determined that Keith Brownlie, Tamar Howson, Virgil Thompson, 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. The board of Directors has also determined that, although Gregg Lapointe is an "independent director" within the meaning of the regulations under the Exchange Act applicable to audit committees, Mr. Lapointe is not an "independent director" under Nasdaq's rules because he was the Chief Executive Officer of Sigma-Tau, which made a milestone payment of $1 million to us pursuant to our collaboration and supply agreement with Sigma-Tau. Additionally, in July 2011 we received an up-front non-refundable payment of $5 million and granted Sigma-Tau an exclusive license to commercialize orBec®/oral BDP in the European territory.

Item 14. Principal Accountant Fees and Services

The following table highlights the aggregate fees billed during each of the two years ended December 31, 2011 by EisnerAmper, LLP ("EisnerAmper," our principal accountants commencing August 16, 2010), Amper, Politziner & Mattia, LLP ("Amper," were our principal accountants in 2010 through August 16, 2010).

	EisnerAmper 2011	EisnerAmper 2010	Amper 2010
Audit fees	$ 105,347	$ 14,280	$ 82,625
Audit related fees	32,500	1,500	19,795
Tax fees	8,524	-	5,464
Total	$ 146,371	$ 15,780	$ 107,884

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, 2011.

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.

49

PART IV

Item 15. Exhibits and Financial Statements Schedules

a. (1) Consolidated Financial Statements:

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

(2) Financial Statement Schedules

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

(3) Exhibits:

2.1	Agreement and Plan of Merger, dated May 10, 2006 by and among the Company, Corporate Technology Development, Inc., Enteron Pharmaceuticals, Inc. and CTD Acquisition, Inc. (incorporated by reference to Exhibit 2.1 included in our Registration Statement on Form SB-2 (File No. 333-133975) filed on May 10, 2006).
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended September 30, 2003).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 4.2 included in our Registration Statement on Form S-8 (File No. 333-130801) filed on December 30, 2005).
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Annex A to our Proxy Statement filed December 12, 2006).
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.4 included in our Registration Statement on Form S-1 (File No. 333-162375) filed on October 7, 2009).
3.5	Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 included in our current report on Form 8-K filed on September 30, 2009).
3.6	Certificate of Designations of Series A Junior Participating Preferred Stock (incorporated by reference to Exhibit 3.1 included in our current report on Form 8-K filed on June 22, 2007).

3.7	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	Form of Warrant issued to each investor in the April 2006 private placement (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on April 7, 2006).
4.2	Form of Warrant issued to finders in connection with the February 2007 private placement (incorporated by reference to Exhibit 4.14 included in our Registration Statement on Form SB-2 filed on April 16, 2007).

4.3	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).
4.4	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).
4.5	Warrant dated February 14, 2008, issued to Fusion Capital Fund II, LLC (incorporated by reference to Exhibit 4.17 included in our Registration Statement on Form S-1 (File No. 333-149239) filed on February 14, 2008).
4.6	Form of Warrant issued to each investor in the February 2008 private placement (incorporated by reference to Exhibit 10.2 in our current report on Form 8-K filed on January 21, 2009).
4.7	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).
4.8	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).
4.9	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).
4.10	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 Myrianthopoulos 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	Form of Securities Purchase Agreement between the Company and each investor dated February 14, 2008 (incorporated by reference to Exhibit 10.37 included in our Registration Statement on Form S-1 (File No. 333-149239) filed on February 14, 2008).
10.17	Common Stock Purchase Agreement dated January 12, 2009, between the Company and accredited investors (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on January 21, 2009).
10.18	Registration Rights Agreement dated January 12, 2009, between the Company and accredited investors (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on January 21, 2009).
10.19	Registration Rights Agreement dated January 12, 2009, between the Company and accredited investors (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on January 21, 2009).
10.20	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).
10.21	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). †
10.22	Common Stock Purchase Agreement dated February 11, 2009, between the Company and Sigma-Tau Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.44 included in our Registration Statement on Form S-1 (File No. 333-157322) filed on February 13, 2009).

10.23	Sublease Agreement dated April 1, 2009, between the Company and BioWa, Inc. (incorporated by reference to Exhibit 10.43 included in our Registration Statement on Form S-1/A (File No. 333-157322) filed on April 14, 2009).
10.24	Employment Agreement, dated as of July 1, 2009, between Christopher P. Schnittker, CPA and the Company. (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on July 7, 2009).

10.25	Securities Purchase Agreement dated September 23, 2009 among the Company and the investors named therein (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on September 29, 2009).
10.26	Registration Rights Agreement dated September 23, 2009 among the Company and the investors named therein (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on September 29, 2009).
10.27	Letter Agreement dated September 25, 2009 between the Company and BAM Opportunity Fund, L.P. (incorporated by reference to Exhibit 10.32 included in our Registration Statement on Form S-1 (File No. 333-162375) filed on October 7, 2009).
10.28	Letter Agreement dated September 23, 2009 between the Company and Iroquois Master Fund, Ltd. (incorporated by reference to Exhibit 10.32 included in our Registration Statement on Form S-1 (File No. 333-162375) filed on October 7, 2009).
10.29	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).
10.30	Securities Purchase Agreement dated June 15, 2010 among the Company and the investors (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on June 18, 2010).
10.31	Registration Rights Agreement dated June 15, 2010 among the Company and the investors (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on June 18, 2010).
10.32	Waiver of Registration Rights dated July 8, 2010 by Sigma-Tau Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.37 included in our Amendment to Registration Statement on Form S-1 (File No. 333-167792) filed on July 9, 2010).
10.33	Waiver of Registration Rights dated July 8, 2010 by Gregg A. Lapointe (incorporated by reference to Exhibit 10.38 included in our Amendment to Registration Statement on Form S-1 (File No. 333- 167792) filed on July 9, 2010).
10.34	Waiver of Registration Rights dated July 8, 2010 by Robert J. Rubin (incorporated by reference to Exhibit 10.39 included in our Amendment to Registration Statement on Form S-1 (File No. 333- 167792) filed on July 9, 2010).
10.35	Amendment to Employment Agreement dated as of January 4, 2011, between Soligenix, Inc. and Evan Myrianthopoulos (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on January 6, 2011). **
10.36	Employment Agreement dated as of January 31, 2011 between Kevin Horgan, M.D., and Soligenix, Inc. (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on February 2, 2011). **
10.37	Employment Agreement dated as of May 31, 2011, between Joseph M. Warusz and Soligenix, Inc. (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on May 31, 2011).**

10.38	Amendment to the Collaboration and Supply Agreement dated July 26, 2011, between Sigma-Tau Pharmaceuticals, Inc. and Soligenix, Inc. (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on July 28, 2011).
10.39	Amendment to the Exclusive License Agreement dated as of July 26, 2011, between George McDonald, MD and Soligenix, Inc. (incorporated by reference to Exhibit 10.2 of our current report on Form 8-K filed on July 28, 2011).
10.40	Lease Agreement dated as of February 7, 2012, between CPP II , LLC and Soligenix, Inc. *
10.41	Separation Agreement dated February 15, 2012, between Evan Myrianthopoulos and Soligenix, Inc. (included in our current report on Form 8-K filed on February 17, 2012).

21.1	Subsidiaries of the Company. *
23.1	Consent of EisnerAmper LLP. *
31.1	Certification of the Chief Executive Officer pursuant to Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002). *
31.2	Certification of the Chief Financial Officer pursuant to Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002). *
32.1	Certification of the Chief Executive Officer pursuant to Se