SOLIGENIX, INC.
Form 10-K
March 30, 2011

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

FORM 10-K

(Mark One)
xANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the Fiscal Year Ended December 31, 2010

oTRANSITION 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 þ

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

Act. Yes o No þ

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

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

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $37,573,936 (assuming, for this purpose, that executive officers, directors and holders of 10% or more of the common stock are affiliates), based on the closing price of the registrant's common stock as reported on the Over-the-Counter Bulletin Board on June 30, 2010.

As of March 25, 2011, 217,411,160 shares of the registrant's Common Stock, par value $0.001 per share, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: None.

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SOLIGENIX, INC.

ANNUAL REPORT ON FORM 10-K
For the Year Ended December 31, 2010

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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 late-stage research and development 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, including LPMTM - Leuprolide, while our collaboration partner, Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau"), will commercialize orBec® in North America once approved by the U.S. Food and Drug Administration (the "FDA"). Our BioDefense business segment intends to use RiVaxTM, our ricin toxin vaccine, to support development efforts in the area of our heat stabilization technology and SGX202, our radiation injury program, to convert from early stage development to advanced development and manufacturing with the assistance of ongoing government grant funding.

Our business strategy can be outlined as follows:

complete the confirmatory Phase 3 clinical trial for orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease ("GI GVHD");

identify a development and marketing partner for orBec® for territories outside of North America, as we have granted an exclusive license to Sigma-Tau to commercialize orBec® in the U.S., Canada and Mexico;

complete the Phase1/2 clinical trial for SGX201 (oral BDP) in the prevention of acute radiation enteritis;

evaluate and/or initiate additional trials to explore the effectiveness of orBec®/oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal ("GI") tract such as prevention of acute GVHD, treatment of chronic GVHD, radiation injury, and Crohn's disease;

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

use RiVaxTM to support development efforts with our heat stabilization technology into the development of new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas;

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.

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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 confirmatory trial enrolling; expected to complete in 2H 2011
orBec®	Prevention of Acute GI GVHD	Phase 2 trial completed
orBec®	Treatment of Chronic GI GVHD	Phase 2 trial potentially to be initiated in 2H 2011
SGX201	Acute Radiation Enteritis	Phase 1/2 trial enrolling; expected to complete in 1H 2011
LPM™ Leuprolide	Endometriosis and Prostate Cancer	Pre-clinical

BioDefense Products

Soligenix Product	Indication	Stage of Development
RiVax™	Vaccine against Ricin Toxin Poisoning	Phase 1B trial enrollment complete; data expected in 1H 2011
SGX202	Radiation Injury	Pre-clinical

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 1970's 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 is a highly powered, double-blind, randomized, placebo-controlled, multi-center trial and will seek to enroll an estimated 166 patients. This trial is supported in part by a $1.2 million FDA Orphan Products grant. The primary endpoint is the treatment failure rate at Study Day 80. This endpoint was successfully measured as a secondary endpoint (p-value 0.005) in the previous Phase 3 study as a key measure of durability following a 50-day course of treatment with orBec® (i.e., 30 days following cessation of treatment).

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.

Historical Background

Two prior randomized, double-blind, placebo-controlled Phase 2 and 3 clinical trials support the ability of orBec® to provide clinically meaningful outcomes when compared with the current standard of care, including a lowered exposure to systemic corticosteroids following allogeneic transplantation. Currently, there are no approved products to treat GI GVHD. The first trial was a 60-patient Phase 2 single-center clinical trial conducted at the Fred Hutchinson Cancer Research Center (“FHCRC”) in Seattle, Washington. The second trial was a 129-patient pivotal Phase 3 multi-center clinical trial of orBec® conducted at 16 leading bone marrow/stem cell transplantation centers in the U.S. and France. Although orBec® did not achieve statistical significance in the primary endpoint of its pivotal trial, namely median time-to-treatment failure through Day 50 (p-value 0.1177), orBec® did achieve statistical significance in other key secondary endpoints such as the proportion of patients free of GVHD at Day 50 (p-value 0.05) and Day 80 (p-value 0.005) and the median time-to-treatment failure through Day 80 (p-value 0.0226), as well as a 66% reduction in mortality among patients randomized to orBec® at 200 days post-transplant with only 5 patient (8%) deaths in the orBec® group compared to 16 patient (24%) deaths in the placebo group (p-value 0.0139). Within one year after randomization in the pivotal Phase 3 trial, 18 patients (29%) in the orBec® group and 28 patients (42%) in the placebo group died (46% reduction in mortality, p-value 0.04).

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In the Phase 2 study, the primary endpoint was the clinically relevant determination of whether GI GVHD patients at Day 30 (the end of treatment) had a durable GVHD treatment response as measured by whether or not they were able to consume at least 70% of their estimated caloric requirement. The GVHD treatment response at Day 30 was 22 of 31 (71%) vs. 12 of 29 (41%) in the orBec® and placebo groups, respectively (p-value 0.02). Additionally, the GVHD treatment response at Day 40 (10 days post cessation of therapy) was 16 of 31 (52%) vs. 5 of 29 (17%) in the orBec® and placebo groups, respectively (p-value 0.007).

Based on the data from the above referenced Phase 2 and Phase 3 studies, on September 21, 2006, we filed a new drug application ("NDA") for our lead product orBec® with the FDA for the treatment of acute GI GVHD. On October 18, 2007, we received a not approvable letter from the FDA in response to our NDA for orBec® for the treatment of acute GI GVHD. In the letter, the FDA requested additional clinical trial data to demonstrate the safety and efficacy of orBec®. The FDA also requested nonclinical and chemistry, manufacturing and controls information as part of this letter.

In December 2008, we reached agreement with the FDA on the design of a confirmatory, pivotal Phase 3 clinical trial evaluating orBec® for the treatment of acute GI GVHD under the FDA's Special Protocol Assessment ("SPA") procedure. An agreement via the SPA procedure is an agreement with the FDA that a Phase 3 clinical trial design (e.g., endpoints, sample size, control group and statistical analyses) is acceptable to support a regulatory submission seeking new drug approval. After the study begins, the FDA can only change a SPA for very limited reasons. Further, in June 2009, we received Protocol Assistance feedback from the European Medicines Agency ("EMEA") on the design of the Phase 3 clinical protocol for orBec®. The EMEA agreed that should the new confirmatory Phase 3 study produce positive results, the data would be sufficient to support a marketing authorization in all 27 European Union member states. The confirmatory Phase 3 trial is enrolling patients and is expected to complete in the second half of 2011.

If the confirmatory Phase 3 trial is successful, we will file a complete response to the FDA action letter. This response is expected to be designated a class II response with a corresponding FDA review time frame of 6 months.

Mortality Results

	Phase 3 Trial		Phase 2 Trial	
	orBec®	Placebo	orBec®	Placebo
Number of patients randomized	62	67	31	29
Number (%) who died	5 (8%)	16 (24%)	3 (10%)	6 (21%)
Hazard ratio (95% confidence interval)	0.33 (0.12, 0.89)		0.47 (0.12, 1.87)	
Death with infection*	3 (5%)	9 (13%)	2 (6%)	5 (17%)
Death with relapse*	3 (5%)	9 (13%)	1 (3%)	4 (14%)

*Some patients died with both infection and relapse of their underlying malignancy.

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Among the data from the Phase 3 clinical study of orBec® reported in the January 2007 issue of Blood, the peer-reviewed Journal of the American Society of Hematology, survival at the pre-specified endpoint of 200 days post-transplantation showed a clinically meaningful and statistically significant result. According to the manuscript, "the risk of mortality during the 200-day post-transplantation period was 67% lower with orBec® treatment compared to placebo treatment (hazard ratio 0.33; 95% CI: 0.12, 0.89; p-value 0.03, Wald chi-square test)." The most common proximate causes of death by transplantation day-200 were relapse of the underlying malignancy and infection. Relapse of the underlying hematologic malignancy had contributed to the deaths of 9/67 patients (13.4%) in the placebo arm and 3/62 patients (4.8%) in the BDP arm. Infection contributed to the deaths of 9/67 patients (13.4%) in the placebo arm and 3/62 (4.8%) in the BDP arm. Acute or chronic GVHD was the proximate cause of death in 3/67 patients (4.5%) in the placebo arm and in 1/62 (1.6%) in the BDP arm.

In addition, a subgroup analysis also revealed that patients dosed with orBec® who had received stem cells from unrelated donors had a 94% reduction in the risk of mortality 200 days post-transplantation.

In this Phase 3 study, orBec® showed continued survival benefit when compared to placebo one year after randomization. Overall, 18 patients (29%) in the orBec® group and 28 patients (42%) in the placebo group died within one year of randomization (46% reduction in mortality, p-value 0.04). Results from the Phase 2 trial also demonstrated enhanced long-term survival benefit with orBec® versus placebo. In that study, at one year after randomization, 6 of 31 patients (19%) in the orBec® group had died while 9 of 29 patients (31%) in the placebo group had died (45% reduction in mortality, p-value 0.26). Pooling the survival data from both trials demonstrated that the survival benefit of orBec® treatment was sustained long after orBec® was discontinued and extended well beyond 3 years after the transplantation. As of September 25, 2005, median follow-up of patients in the two trials was 3.5 years (placebo patients) and 3.6 years (orBec® patients), with a range of 10.6 months to 11.1 years. The risk of mortality was 37% lower for patients randomized to orBec® compared with placebo (p-value 0.03).

A retrospective analysis of survival at 200 days post-transplantation in the supportive Phase 2 clinical trial showed consistent response rates with the Phase 3 trial; three patients (10%) who had been randomized to orBec® had died, compared with six deaths (21%) among patients who had been randomized to placebo, leading to a reduced hazard of day-200 mortality, although not statistically significant. Detailed analysis of the likely proximate cause of death showed that mortality with infection or with relapse of underlying malignancy were both reduced in the same proportion after treatment with orBec® compared to placebo. By transplantation day-200, relapse of hematologic malignancy had contributed to the deaths of 1 of 31 patients (3%) in the orBec® arm and 4 of 29 patients (14%) in the placebo arm. Infection contributed to the deaths of 2 of 31 patients (6%) in the orBec® arm and 5 of 29 patients (17%) in the placebo arm.

Safety and Adverse Events

The frequencies of severe adverse events, adverse events related to study drug, and adverse events resulting in study drug discontinuation were all comparable to that of the placebo group in both trials. Patients who remained on orBec® until Day 50 in the Phase 3 study had a higher likelihood of having biochemical evidence of abnormal hypothalamic-pituitary-adrenal axis function compared to patients on placebo. This effect was far less pronounced than those seen in patients on high dose prednisone.

Commercialization and Market

We anticipate the market potential for orBec® for the treatment of acute GI GVHD to be approximately 50% of the more than 10,000 allogeneic bone marrow and stem cell transplantations that occur each year in the U.S.

On February 11, 2009, we entered into a collaboration and supply agreement with Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau") for the commercialization of orBec®. 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® 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 25 million shares of our common stock to Sigma-Tau for $0.18 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. On November 26, 2008, prior to entering the collaboration agreement, we sold Sigma-Tau 16,666,667 common shares at $0.09 per share (the market price at the time) for proceeds of $1,500,000 in exchange for the exclusive right to negotiate a collaboration deal with us until March 1, 2009.

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Additionally, orBec® is sold through Named Patient Access Programs ("NPAPs") in South Korea, Latin America, Canada, Australia, South Africa, New Zealand and the ASEAN countries. The NPAPs are compassionate use drug supply programs under which medical practitioners can legally supply investigational drugs to their eligible patients. Under this program, drugs can be administered to patients who are suffering from serious illnesses prior to the drug being approved by the various regional regulatory authorities. The activity under NPAP programs is currently minimal.

We believe the potential worldwide market for orBec® to be approximately $400 million for all GVHD applications, namely, treatment of acute and chronic GI GVHD and prevention of acute GVHD.

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. orBec® represents a first-of-its-kind oral, locally acting therapy tailored to treat the gastrointestinal manifestation of GVHD, the organ system where GVHD is most frequently encountered and highly problematic. orBec® is intended to reduce the need for systemic immunosuppressives to treat acute GI GVHD. Currently used systemic immunosuppressives utilized to control GI GVHD 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.

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Future Potential Indications of orBec® and oral BDP

Based on its pharmacological characteristics, orBec® 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 recently completed a Phase 2 trial of orBec® in the prevention of acute GVHD and have announced preliminary results from the study. We are targeting to begin a Phase 2 clinical trial in chronic GI GVHD in the second half of 2011, pending further funding. In addition, we are exploring the possibility of testing oral BDP (the active ingredient in orBec®) for local inflammation associated with Crohn's Disease, Lymphocytic Colitis, IBS, Ulcerative Colitis, among other indications.

Prevention of Acute GVHD

We have recently completed 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. The trial was conducted under an investigator-initiated IND by Paul Martin, MD, at the FHCRC and 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. Preliminary 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. However, the use of orBec® 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. Further analysis of the complete dataset continues and is aimed at identifying other potential effects seen with orBec® in preventing acute GVHD.

SGX201- Time Release Formulation of oral BDP

We are currently enrolling patients in a Phase 1/2 clinical trial in acute radiation enteritis for which we have received "Fast Track" designation from the FDA. 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.

SGX201 contains 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 inhalation products for the treatment of patients with allergic rhinitis and asthma. BDP is also the active ingredient in

orBec®, currently in Phase 3 and Phase 2 development by Soligenix for the treatment and prevention of GI GVHD, respectively. SGX201 is a time-release formulation of BDP specifically designed for oral use.

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Patients with rectal cancer who are scheduled to undergo concurrent radiation and chemotherapy prior to surgery will be enrolled in four dose groups. The objectives of the study are 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. This program is supported in part by a $500,000 two-year Small Business Innovation Research ("SBIR") grant awarded by the NIH.

The study is expected to be completed in the first half of 2011.

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.

LPM™ – Leuprolide

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.

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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.

BioDefense Overview

RiVax™

RiVax™ is our proprietary vaccine developed to protect against exposure to ricin toxin, and is the first and only ricin toxin vaccine to be clinically tested in humans. The vaccine is comprised of a recombinant nontoxic derivative of ricin A chain which induces antibodies after immunization. Ricin is a potent glycoprotein toxin, derived from the beans of castor plants. It 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 Centers for Disease Control ("CDC") has classified ricin 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.

The initial Phase 1 clinical trial of RiVax™ was conducted by Ellen Vitetta, PhD at the University of Texas Southwestern Medical Center ("UTSW") at Dallas, Soligenix's academic partner. The trial demonstrated that RiVax™ is well tolerated and induces antibodies in humans that neutralize the ricin toxin. The functional activity of the antibodies was confirmed by animal challenge studies in mice which survived exposure to ricin toxin after being injected with serum samples from the volunteers. The outcome of the study was published in the Proceedings of the National Academy of Sciences. A second Phase 1 trial supported by an FDA Orphan Products grant to UTSW has completed enrollment utilizing an adjuvant formulation of RiVax™. Preliminary results indicate that RiVax™ appears safe at all doses tested in volunteers. Analysis of human immunogenicity and complementary non-human primate efficacy is expected during the first half of 2011. We initiated a comprehensive program to evaluate the efficiency of RiVax™ in non-human primates. This study is ongoing at the Tulane University Health Sciences Center and will provide data that will further aid in the interpretation of immunogenicity data obtained in the human vaccination trials.

The National Institute of Allergy and Infectious Diseases ("NIAID"), a division of the National Institutes of Health ("NIH"), has previously awarded us two grants: one for $6.4 million and one for $5.2 million for a total of $11.6 million for the development of RiVax™ covering process development, scale-up and current Good Manufacturing Practice ("cGMP") manufacturing, and pre-clinical toxicology testing pursuant to the FDA's "animal rule," which has supported our research from 2004 to present.

In September 2009, we were awarded a $9.4 million grant from NIAID. The grant will fund, over a five-year period, the development of formulation and manufacturing processes for vaccines, including RiVax™, that are stable at elevated temperatures. The grant will also fund the development of improved thermostable adjuvants expected to result in rapidly acting vaccines that can be given with fewer injections over shorter intervals.

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In January 2011, we entered into a definitive license agreement with the University of Colorado ("CU") for novel technology for use in the development of subunit vaccines with long-term stability, including stability at elevated temperatures. This "heat stabilization" technology is the subject of the $9.4 million grant from NIAID. It is also the subject of several United States and foreign patent applications that 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. The novel technology involves the use of several unique process and formulation steps that fix sensitive vaccine ingredients in native configuration. For biodefense indications, we are using the stabilization technology to advance RiVax™, and a subunit vaccine for anthrax prevention. The underlying technology has been developed by Drs. Amber Clausi, John Carpenter and Theodore Randolph at CU-Boulder.

The development of heat-stable vaccines will combine several novel formulation processes with well characterized adjuvants that have been evaluated in numerous vaccine field trials. The formulation and process technology funded by the grant will be applied to the further development of RiVax™, a subunit vaccine for prevention of ricin toxin lethality and morbidity. The grant will also address the development of manufacturing processes and animal model systems necessary for the pre-clinical characterization of vaccine formulations. Further, the grant will fund the concurrent development of at least one other protein subunit vaccine, which is currently expected to be an anthrax vaccine. This could lead to new subunit vaccines that would bypass current cold chain requirements for storage and distribution. Vaccines to be stored in the Strategic National Stockpile ("SNS") and used under emergency situations for biodefense are expected to have long-term shelf life.

In December 2010, the United States Patent and Trademark Office ("USPTO") granted patent #7,829,668 entitled "Compositions and methods for modifying toxic effects of proteinaceous compounds." This patent includes composition claims for the modified ricin toxin A chain, which is the immunogen contained in RiVax™. The issued patent contains claims that describe alteration of sequences within the ricin A chain that affect vascular leak, one of the deadly toxicities caused by ricin toxin.

In January 2011, the FDA granted Orphan Drug Designation to RiVax™ for the prevention of ricin intoxication.

SGX202 – Oral BDP for GI Radiation Injury

In September 2007, we announced that our academic partner, the FHCRC, received a $1 million grant from the NIH to conduct pre-clinical studies of oral BDP, also the active ingredient in orBec®, for the treatment of GI radiation injury. While we will not receive any monetary benefit from this grant, we will benefit if this work is successful and it will enhance the value of our oral BDP programs.

The purpose of the studies funded by the grant, entitled "Improving Gastrointestinal Recovery after Radiation," is to evaluate the ability of three promising clinical-grade drugs, including oral BDP, given alone or in combination, that are likely to significantly mitigate the damage to the gastrointestinal epithelium caused by exposure to high doses of radiation using a well-established dog model. 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 type of therapy, if successful, would benefit cancer patients undergoing radiation, chemotherapy, or victims of nuclear-terrorism. In most radiation scenarios, injury to the hematopoietic (blood) system and gastrointestinal tract are the main determinants of survival. The studies will compare overall survival and markers of intestinal cell regeneration when the drug regimens are added to supportive care intended to boost proliferation of blood cells. The principal investigator of the study is George E. Georges, MD, Associate Member of the FHCRC. Our rights to the use of SGX202 are through our license with George B. McDonald, MD.

In January 2011, we released promising preliminary results from a preclinical study of SGX202 in a canine gastrointestinal acute radiation syndrome (GARS) model. The results indicate that dogs treated with SGX202 demonstrated statistically significant (p=0.04) improvement in survival after exposure to lethal doses of total body irradiation ("TBI") when compared to control dogs. The aim of the study was to determine whether SGX202 could improve survival and GI recovery after TBI using a well-established GARS dog model. Six dogs were exposed to TBI (12 Gy administered at 70 cGy/min), and then given autologous bone marrow and SGX202 with supportive care; four dogs were used as controls and not treated with SGX202. Autologous bone marrow was given to reduce the duration and impact of the radiation-induced hematopoietic syndrome and allow for a focus on measures to treat the GI effects of TBI. SGX202 was administered two hours after TBI and daily until GI recovery (up to day 100 post exposure). Median survival post exposure in the control group was 8 days, compared to greater than 100 days in the SGX202 treated group. These results demonstrate that SGX202 has the potential to reduce the local inflammation in the radiation damaged GI tract.

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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 Investigational New Drug (“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.

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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 and Mexico. We are actively seeking a commercialization partner for orBec® and oral BDP outside of North America

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.

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orBec® Competition

Competition is 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 Sangstat, 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. For example, Novartis currently markets Cyclosporin, and Sangstat currently markets Thymoglobulin for transplant-related therapeutics. We face potential competition from Osiris Therapeutics if its product Prochymal for the treatment of GVHD is successful in reaching the market. 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.

Competition is also intense in the therapeutic area of inflammatory bowel disease. Several companies, including Centocor, Immunex, and Celgene, have products that are currently FDA approved. For example, Centocor, a subsidiary of Johnson & Johnson, markets the drug product RemicadeTM for Crohn's disease. Other drugs used to treat inflammatory bowel disease include another oral locally active corticosteroid called budesonide, which is being marketed by AstraZeneca in Europe and Canada and by Prometheus Pharmaceuticals in the U.S. under the tradename of Entocort®. Entocort® is structurally similar to beclomethasone dipropionate, and the FDA-approved Entocort® for Crohn's disease late in 2001. In addition, Salix Pharmaceuticals, Inc. markets an FDA-approved therapy for ulcerative colitis called Colazal®. Chiesi Pharmaceuticals ("Chiesi") markets a delayed-release oral formulation of beclomethasone dipropionate, the active ingredient of orBec®, called CLIPPERTM for ulcerative colitis.

Several companies have also established various colonic drug delivery systems to deliver therapeutic drugs to the colon for treatment of Crohn's disease. These companies include Ivax Corporation, Inkine Pharmaceutical Corporation, and Elan Pharmaceuticals, Inc. Other approaches to treat gastrointestinal disorders include antisense and gene therapy. Isis Pharmaceuticals, Inc. is in the process of developing antisense therapy to treat Crohn's disease.

BioDefense Vaccine Competition

We face competition in the area of biodefense vaccines 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. Acambis, Inc., Dynavax, Emergent Biosolutions (formerly Bioport Corporation), VaxGen, Inc., Chimerix, Inc., Human Genome Sciences, Inc., Coley Pharmaceuticals, Inc., Avanir Pharmaceuticals, Inc., Dynport Vaccine Company, LLC., Pharmathene, SIGA Pharmaceuticals and others have announced vaccine or countermeasure development programs for biodefense. Some of these companies have substantially greater human and financial resources than we do, and many of them have already received grants or government contracts to develop anti-toxins and vaccines against bioterrorism. For example, Avecia Biotechnology, Inc. has received NIH contracts to develop a next generation injectable anthrax vaccine. Several companies have received development grants from the NIH for biodefense products. For example, Coley Pharmaceuticals, Inc. has received a $6 million Department of Defense ("DOD") grant to develop vaccine enhancement technology. Dynport Vaccine Company, LLC, a prime contractor with the DOD, currently has a $200 million contract to develop vaccines for the U.S. military, including a multivalent botulinum toxin vaccine. Although we have received significant grant funding to date for product development, we have not yet been obtained contract awards for government procurement of products.

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.

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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 orBec® 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® License Agreement

In November 1998, we entered into an exclusive, worldwide, royalty bearing license agreement with George B. McDonald, MD, including the right to grant sublicenses, for the rights to the intellectual property and know-how relating to orBec®. In addition, Dr. McDonald receives $80,000 per annum as a consultant.

We also executed an exclusive license to patent applications for "Use of Anti-Inflammatories to Treat Irritable Bowel Syndrome" from the University of Texas Medical Branch-Galveston. Under the license agreements, we will be obligated to make performance-based milestone payments, as well as royalty payments on any net sales of oral BDP. Pursuant to this license, we 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.

RiVax™ Intellectual Property

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™.

Research and Development Expenditure

We spent approximately $5.7 million and $4.5 million in the years ended December 31, 2010 and 2009, respectively, on research and development. The amounts we spent on research and development per product during the years ended December 31, 2010 and 2009 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, 2010, we had 15 full-time employees, 5 of whom are PhDs.

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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, 2010, we had $7.5 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 2012 and complete the pivotal Phase 3 confirmatory clinical trial of orBec® for the treatment of acute GI GVHD.

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 22% 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 March 2011, we have expended approximately $37.8 million developing our current product candidates for pre-clinical research and development and clinical trials, and we currently expect to spend at least $10 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.

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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.

We received a “not approvable letter” from the FDA for our lead product candidate orBec®.

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 has been initiated and is expected to complete in the second half of 2011.

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Although we intend 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.

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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, 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.

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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, the University of Texas Medical Branch at Galveston, 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.

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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 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.

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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 15 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. Several members of our board of directors are associated with other companies in the biopharmaceutical industry. Stockholders should not expect an obligation on the part of these board members to present product opportunities to us of which they become aware outside of their capacity as members of our board of directors.

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.

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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, 2010, our stock price has fluctuated over the last year between a high of $0.30 per share to a low of $0.15 per share. As of March 25, 2011, our common stock traded at $0.21 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.

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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 54,076,373 shares of our common stock at a current weighted average exercise price of approximately $0.22; and
- options to purchase approximately 26,161,039 shares of our common stock at a current weighted average exercise price of approximately $0.24.

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

The sale of our common stock to Fusion Capital may cause dilution and the sale of the shares of common stock acquired by Fusion Capital could cause the price of our common stock to decline.

On February 14, 2008, we entered into an $8,500,000 common stock purchase agreement with Fusion Capital. The Fusion Capital facility, as amended, allows us to require Fusion Capital to purchase between $80,000 and $1.0 million, depending on certain conditions, of our common stock up to an aggregate of $8.5 million over approximately a 43-month period, ending on October 31, 2011. As part of that agreement, we issued Fusion Capital 1,275,000 shares of common stock as a commitment fee. In connection with the execution of the common stock purchase agreement, Fusion Capital purchased 2,777,778 common shares and a four-year warrant to purchase 1,388,889 shares of common stock at $0.22 per share, for an aggregate price of $500,000. From February 14, 2008 through March 25, 2011, we have issued an additional 2,609,090 shares of common stock, a five-year warrant to purchase 100,000 shares of common stock at $0.303 per share and received an additional $392,500 in proceeds from the Fusion Capital facility.

In connection with entering into the agreement, we authorized the sale to Fusion Capital of up to 25,327,778 shares of our common stock. The number of shares ultimately offered for sale by Fusion Capital is dependent upon the number of shares purchased by Fusion Capital under the agreement. The purchase price for the common stock to be sold to Fusion Capital pursuant to the common stock purchase agreement will fluctuate based on the price of our common stock. All 25,327,778 shares registered by us for sale by Fusion Capital are freely tradable. It is anticipated that those shares will be sold over a period of up to 18 months from April 30, 2010, the date of the prospectus covering the Fusion Capital shares. Depending upon market liquidity at the time, a sale of these shares under the registration statement at any given time could cause the trading price of our common stock to decline. Fusion Capital may ultimately purchase all, some or none of the approximately 18 million shares of common stock not yet issued. After it has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to Fusion Capital by us under the agreement may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of any sales of our shares to Fusion Capital and the agreement may be terminated by us at any time at our discretion without any cost to us.

The common stock purchase agreement with Fusion Capital also may be terminated in the event of a default under the agreement. In addition, we cannot require Fusion Capital to purchase any shares of our common stock if the purchase price is less than $0.10 per share. Thus, we may be unable to sell shares of our common stock to Fusion Capital when we need the funds, and that could severely harm our business and financial condition and our ability to continue to develop and commercialize our products. The closing price of our common stock on March 25, 2011 was $0.21 per share.

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.

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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.

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.

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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." Prior to September 30, 2009, around the time of our corporate name change, our stock was quoted under the symbol "DORB." The following table sets forth, 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, 2009:		
First Quarter	$ 0.18	$ 0.06
Second Quarter	$ 0.24	$ 0.09
Third Quarter	$ 0.38	$ 0.17
Fourth Quarter	$ 0.36	$ 0.18
Year Ended December 31, 2010:		
First Quarter	$ 0.29	$ 0.23
Second Quarter	$ 0.30	$ 0.24
Third Quarter	$ 0.26	$ 0.18
Fourth Quarter	$ 0.23	$ 0.15

As of March 25, 2011, the last reported price of our common stock quoted on the OTCBB was $0.21 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 25, 2011, 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.

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

Cautionary Note Regarding Forward-Looking Statements

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

Our Business Overview

Soligenix, Inc. was incorporated in Delaware in 1987. We are a late-stage research and development 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, including LPMTM-Leuprolide, while our collaboration partner, Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau") will commercialize orBec® in North America once approved by the FDA. Our BioDefense business segment intends to use RiVaxTM, our ricin toxin vaccine, to support development efforts in the area of our heat stabilization technology and SGX202, our radiation injury program, to convert from early stage development to advanced development and manufacturing with the assistance of ongoing government grant funding.

Our business strategy can be outlined as follows:

- complete the confirmatory Phase 3 clinical trial for orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease ("GI GVHD");
- identify a development and marketing partner for orBec® for territories outside of North America, as we have granted an exclusive license to Sigma-Tau to commercialize orBec® in the U.S., Canada and Mexico;
- complete the Phase 1/2 clinical trial for SGX201 (oral BDP) in the prevention of acute radiation enteritis;
- evaluate and/or initiate additional trials to explore the effectiveness of orBec®/oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal ("GI") tract such as prevention of acute GVHD, treatment of chronic GVHD, radiation injury, and Crohn's disease;
- continue to secure additional government funding for each of our BioDefense programs through grants, contracts and/or procurements;
- use RiVaxTM to support development efforts with our heat stabilization technology into the development of new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas;
- acquire or in-license new clinical-stage compounds for development; and
- explore other business development and acquisition strategies.

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

We capitalize and amortize intangibles over their expected useful life – generally a period of 11 to 16 years. We capitalize legal costs associated with the protection and maintenance 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 designed to protect, preserve, maintain and perhaps extend the lives of the patents. Therefore, our policy is to capitalize these costs and amortize them over the remaining useful life of the patents. 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.

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.

Revenue Recognition

Our revenues are generated from NIH grants, the achievement of licensing milestones, and Named Patient Access Program ("NPAP") sales of orBec®. 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. Revenue from NPAP sales of orBec® are recorded when the product is shipped.

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 equity for 2010 and 2009.

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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, 2010 Compared to 2009

For the year ended December 31, 2010, we had a net loss of $7,386,579 as compared to a net loss of $6,034,453 for the prior year, representing an additional loss of $1,352,126, or 22%. This increase in the net loss is primarily attributed to increased spending of $1,160,934 in research and development for the year ended December 31, 2010 over 2009 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, 2010, there was a decrease in general and administrative expenses of $349,458, which reflects decreases in compensation associated with severance, benefits and board fees in 2010.

For the year ended December 31, 2010, revenues and associated costs relate to NIH grants awarded in support of our ricin, botulinum and thermostable vaccines development and from the NPAP sales of orBec®. For the year ended December 31, 2010, we had revenues of $1,947,628 as compared to $2,816,037 for the prior year, representing a decrease of $868,409, or 31%. During 2009, we received a $1 million clinical milestone payment from Sigma-Tau, our collaborative partner on the orBec® Phase 3 study, which did no reoccur in 2010. Included in those revenue figures for the year ended December 31, 2010, we also recorded revenues of $72,000 from NPAP sales of orBec®, compared to $56,000 recorded in the prior year.

We incurred costs related to that revenue in the year ended December 31, 2010 and 2009 of $1,638,402 and $1,438,641, respectively, representing an increase of $199,761, or 14%. This increase follows from the increase in NIH grant revenues discussed above.

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Our gross profit for the year ended December 31, 2010 was $309,226 as compared to $1,332,396 for the prior year, representing a decrease of $1,023,170, or 77%. This decrease is almost entirely comprised of the $1 million clinical milestone revenue recorded in 2009 for which there were no corresponding costs.

Research and development spending increased by $1,160,934, or 26%, to $5,684,309, for the year ended December 31, 2010 as compared to $4,523,375 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 decreased $349,458, or 15%, to $1,931,793 for the year ended December 31, 2010, as compared to $2,281,251 for the prior year reflecting decreases in compensation associated with severance, benefits and board fees in 2010.

Stock-based compensation expenses related to research and development increased $91,262, or 43%, to $302,096 for the year ended December 31, 2010, as compared to $210,834 for the prior year. Stock-based compensation expenses related to general and administrative decreased $98,783, or 27%, to $269,449 for the year ended December 31, 2010, as compared to $368,232 for the prior year. These increases were related to stock options that were issued to new employees hired in 2010 and for options issued in the last quarter of 2009, all of which began their service periods largely in 2010.

Net interest income for the year ended December 31, 2010 was $12,074 as compared to $21,920 for the prior year, representing a decrease of $9,846, or 45%. This decrease was due to substantially lower interest rates earned on cash balances in 2010 versus the prior year.

Other income (expense) for the year ended December 31, 2010 includes $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.

During the year ended December 31, 2010, 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 $245,810 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, 2010 and December 31, 2009: BioDefense and BioTherapeutics.

Revenues for the BioDefense business segment for the year ended December 31, 2010 were $1,441,228 as compared to $1,670,536 for the year ended December 31, 2009, representing a decrease of $229,308, or 14%. This decrease is primarily attributed to a reduction in NIH grant revenues as we reached the end of our earlier NIH grants focusing on RiVax™ and botulinum vaccines before the work under our new thermostable vaccine technology grant had commenced. Revenues for the BioTherapeutics business segment for the year ended December 31, 2010 were $506,400 as compared to $1,145,501 for the year ended December 31, 2009, representing a decrease of $639,101, or 56%. This substantial decrease is a result of the receipt of a $1 million clinical milestone payment from Sigma-Tau in 2009 upon the initiation of enrollment in the confirmatory Phase 3 clinical trial of orBec®, offset by new revenues earned in 2010 on orBec® related NIH grants.

Loss from operations for the BioDefense business segment for the year ended December 31, 2010 was $1,204,824 as compared to $389,157 for the year ended December 31, 2009, representing an increase of $815,667, or 210%. This increase is primarily attributed to a reduction in NIH grant revenues as we reached the end of our earlier NIH grants focusing on RiVax™ and botulinum vaccines before the work under our new thermostable vaccine technology grant had commenced. Loss from operations for the BioTherapeutics business segment for the year ended December 31, 2010 was $5,018,090 as compared to $3,444,838 for the year ended December 31, 2009, representing an increase of $1,573,252, or 46%. This increase is primarily attributed to the conduct of the confirmatory Phase 3 clinical trial of orBec®, offset to some degree by the receipt of a $1 million clinical milestone payment from Sigma-Tau in 2009.

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Amortization and depreciation expense for the BioDefense business segment for the year ended December 31, 2010 was $36,843 as compared to $91,420 for the year ended December 31, 2009, representing a decrease of $54,577, or 60%, primarily related to the write-off of Botulinum related intangibles in March 2010, offset by newly capitalized patent support costs in 2010. Amortization and depreciation expense for the BioTherapeutics business segment for the year ended December 31, 2010 was $146,832 as compared to $77,496 for the year ended December 31, 2009, representing an increase of $69,336, or 89%, primarily related to newly capitalized patent support costs in 2010.

Financial Condition and Liquidity

Cash and Working Capital

As of December 31, 2010, we had cash and cash equivalents of $7,451,714 as compared to $7,692,011 as of December 31, 2009, representing a marginal decrease of $240,297 or 3%. As of December 31, 2010, we had working capital of $6,101,103 as compared to working capital of $6,689,765 as of December 31, 2009, representing a decrease of $588,662 or 9%. The decrease in working capital was the result of the cash used in operating and investing activities over the period, offset by the proceeds raised in the private placement of common stock and warrants completed in June 2010, as well as option and warrant exercise proceeds and proceeds from the sale of stock under the Fusion equity line. For the year ended December 31, 2010, our cash used in operating activities was $5,730,582, as compared to $4,603,189 for the same period in 2009. The increase in spending was 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, and proceeds expected from the Fusion Capital transaction, 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 2012.

Our plans with respect to our liquidity management include the following:

- We have approximately $9.5 million in active grant funding still available to support our research programs in 2011 and beyond. Additionally, we have submitted additional grant applications for further support of these programs and others with various funding agencies, and have received encouraging feedback to date on the likelihood of funding;
- We have approximately $7.6 million in available capacity under our Fusion Capital equity facility through October 2011. Although we have historically drawn down modest amounts under this agreement, we could draw more within certain contractual parameters;
- We will pursue Net Operating Losses (“NOLs”) sales in the State of New Jersey. Based on the receipt of $245,810 in proceeds pursuant to NOLs sales in 2010, we expect to participate in the expanded program during 2011 and beyond;
- We will seek non-dilutive funding through completion of partnerships for our orBec®/oral BDP programs in territories outside North America;
- 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; 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.

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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 $6.6 million before any grant reimbursements, of which $6.1 million relates to the BioTherapeutics business and $0.5 million relates to the BioDefense business. We anticipate grant revenues in the next 12 months to offset research and development expenses for the development of our thermostable vaccine technology, the confirmatory Phase 3 clinical trial of orBec® in the treatment of acute GI GVHD, and the development of SGX201 in acute radiation enteritis in the amount of approximately $1.7 million.

The table below details our costs by program for the years ended December 31, 2010 and 2009:

	2010	2009
Research & Development Expenses		
orBec®	$3,425,757	$3,211,682
RiVax™ & Thermostable Vaccines	1,871,474	1,264,218
BT-VACC™	378,501	31,167
Oraprine™	6,000	6,000
LPM™ Leuprolide	2,577	10,308
Total	$5,684,309	$4,523,375
Reimbursed under NIH Grants		
orBec®	$460,279	$162,106
RiVax™ & Thermostable Vaccines	962,716	1,321,535
BT-VACC™	215,407	-
Total	$ 1,638,402	$1,483,641
Grand Total	$ 7,322,711	$6,007,016

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, 2010 or 2009.

Contractual Obligations

We have a contractual obligation of approximately $860,000 as of December 31, 2010 in connection with 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 second half of 2011.

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.

In February 2007, our Board of Directors authorized the issuance of the following shares to Dr. Schaber, Mr. Myrianthopoulos, Dr. Brey and certain other employees and a consultant, 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: 1,000,000 common shares to Dr. Schaber; 750,000 common shares to Mr. Myrianthopoulos; 200,000 common shares to Dr. Brey; and 450,000 common shares to employees and a consultant shall be issued. The employment agreements with Dr. Schaber and Mr. Myrianthopoulos have 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.

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

Year	Research and Development	Property and Other Leases	Total
2011	$ 895,000	$99,017	$994,017
2012	275,000	28,761	303,761
2013	75,000	5,793	80,793
2014	75,000	1,448	76,448
2015	75,000	-	75,000
Total	$ 1,395,000	$135,019	$1,530,019

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.

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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, 2010. 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, 2010, 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.

Item 9B. Other Information

None.

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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 25, 2011:

Name	Age	Position
Christopher J. Schaber, PhD	44	Chairman of the Board, Chief Executive Officer and President
Gregg A. Lapointe, CPA	52	Director
Robert J. Rubin, MD	65	Director
Tamar D. Howson	62	Director
Virgil D. Thompson	71	Director
Evan Myrianthopoulos	46	Chief Financial Officer, Senior Vice President and Director
Kevin J. Horgan, MD	51	Chief Medical Officer and Senior Vice President
Robert N. Brey, PhD	60	Chief Scientific Officer and Senior Vice President
Christopher P. Schnittker, CPA	42	Vice President of Administration, Controller and Corporate Secretary

Christopher J. Schaber, PhD has over 21 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 interim 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.

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 since April 2008. 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.

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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.

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.

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.

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Evan Myrianthopoulos has been a director since 2002 and is currently our Chief Financial Officer and Senior Vice President, after joining us in November of 2004 as President and Acting Chief Executive Officer. 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.

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.

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 influenzae 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.

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Christopher P. Schnittker, CPA has been our Vice President of Administration, Controller and Corporate Secretary since July 2009. He has more than 20 years of financial management experience primarily in publicly-held life science companies. From June 2000 until joining Soligenix, Mr. Schnittker was a Vice President and Chief Financial Officer of several publicly-held biotechnology and specialty pharmaceutical companies, including: VioQuest Pharmaceuticals Inc. (from July 2008 until joining Soligenix); Micromet, Inc. (from October 2006 through December 2007); Cytogen Corporation (from September 2003 through May 2006); and Genaera Corporation (from June 2000 through August 2003). From December 1997 through June 2000, he was Director of Finance and Controller of GSI Commerce, an e-commerce technology company. From June 1995 through December 1997, he served in various financial reporting and internal control manager roles with Rhône-Poulenc Rorer Pharmaceuticals Inc. (now part of the Sanofi Aventis Group). From September 1990 through June 1995, he was a member of the Audit and Assurance Services division at Price Waterhouse LLP (now PricewaterhouseCoopers LLP), working largely with the firm's pharmaceutical and technology clients. Mr. Schnittker received his Bachelor's degree in Economics and Business, with a concentration in Accounting, from Lafayette College in 1990 and is a currently-licensed Certified Public Accountant in the State of New Jersey.

Board Leadership Structure

Our Board of Directors believes that Dr. Schaber's service as both our Interim 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. Thompson, Ms. Howson and Dr. Rubin 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, 2010, 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.

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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. Thompson (Chair) and Lapointe and Dr. Rubin. The board of directors has determined that both Messrs. Thompson and Lapointe qualify 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 Mr. 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. However, the board of directors has determined that, although Mr. 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 is 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. Notwithstanding Mr. Lapointe's relationship with Sigma-Tau, the board of directors believes that it is in the best interest of the Company and its shareholders for Mr. Lapointe to continue to serve as a member of the Audit Committee.

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Item 11. Executive Compensation

Summary Compensation

The following table contains information concerning the compensation paid during each of the two years ended December 31, 2010 to our Chief Executive Officer and each of the two other most highly compensated executive officers during 2010 (collectively, the "Named Executive Officers").

Summary Compensation

Name	Position	Year	Salary	Bonus	Option Awards	All Other Compensation	Total
Christopher J. Schaber1	CEO & President	2010	$350,981	$100,000	$408,908	$27,529	$887,419
		2009	$337,709	$120,000	-	$24,737	$482,446
Evan Myrianthopoulos2	CFO & Senior VP	2010	$230,723	$50,000	$195,161	$27,677	$503,561
		2009	$202,605	$70,000	-	$24,811	$297,416
Robert N. Brey3	CSO & Senior VP	2010	$210,000	$40,000	$157,987	$11,955	$419,942
		2009	$197,592	$60,000	-	$14,322	$271,914

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1 Dr. Schaber deferred payment of his 2009 annual bonus of $120,000 until January 15, 2010 and his 2010 annual bonus of $100,000 until January 15, 2011. 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 2009 annual bonus of $70,000 until January 15, 2010 and his 2010 annual bonus of $50,000 until January 15, 2011. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by the Company.

3 Dr. Brey deferred payment of his 2009 annual bonus of $60,000 until January 15, 2010 and his 2010 annual bonus of $40,000 until January 15, 2011. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation for 2010 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 2,500,000 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.

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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 500,000 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 150,000 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.

In February 2007, our Board of Directors authorized the issuance of the following number of shares to each of Dr. Schaber, Mr. Myrianthopoulos 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: 1,000,000 common shares to Dr. Schaber and 750,000 common shares to Mr. Myrianthopoulos. 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.

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.

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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, 2010. We have never issued Stock Appreciation Rights.

Outstanding Equity Awards at Fiscal Year-End

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Christopher J. Schaber	2,500,000	-	-	$0.27	8/28/2016
	900,000	-	-	$0.47	8/9/2017
	2,100,000	700,000	700,000	$0.06	12/17/2018
	687,500	1,512,500	1,512,500	$0.232	6/30/2020
Evan Myrianthopoulos	150,000	-	-	$0.35	11/14/2012
	50,000	-	-	$0.90	9/15/2013
	50,000	-	-	$0.58	6/11/2014
	150,000	-	-	$0.47	11/10/2014
	500,000	-	-	$0.49	12/13/2014
	400,000	-	-	$0.35	5/10/2016
	550,000	-	-	$0.47	8/9/2017
	900,000	300,000	300,000	$0.06	12/17/2018
	328,125	721,875	721,875	$0.232	6/30/2020
Robert N. Brey	600,000	-	-	$0.33	5/9/2016
	200,000	-	-	$0.47	8/9/2017
	600,000	200,000	200,000	$0.06	12/17/2018
	265,625	584,375	584,375	$0.232	6/30/2020

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Compensation of Directors

The following table contains information concerning the compensation of the non-employee directors during the fiscal year ended December 31, 2010.

Compensation of Directors

Name	Fees Earned Paid in Cash1	Option Awards2	Total
Gregg A. Lapointe	$20,626	$30,721	$51,347
Cyrille F. Buhrman3	$10,000	-	$10,000
Robert J. Rubin	$22,500	$24,577	$47,077
Tamar D. Howson	-	$49,153	$49,153
Virgil D. Thompson	-	$49,153	$49,153

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 $7,500 annually, on a prorated basis, and the chairman of our Compensation and Nominating Committees will be paid $5,000 annually, on a prorated basis. 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 300,000 shares of common stock, and subsequent prorated annual grants of fully vested options to purchase 150,000 shares of common stock after re-election to our Board of Directors. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718.

3 Mr. Buhrman did not stand for re-election at our September 23, 2010 Annual Meeting of Stockholders.

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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 25, 2011 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	67,599,044	29.87%
Claudio Cavazza2	61,369,248	27.33%
Sigma-Tau Pharmaceuticals, Inc. 3	61,369,248	27.33%
Hal Mintz 4	23,992,569	10.84%
Ross Berman 4	23,992,569	10.84%
Adam Stern 4	23,992,569	10.84%
Mark Friedman 4	23,992,569	10.84%
BAM Management, LLC 4	23,992,569	10.84%
AM Investment Partners, LLC 4	23,992,569	10.84%
BAM Capital, LLC 4	23,992,569	10.84%
BAM Opportunity Fund, LP 4	23,992,569	10.84%
Biotex Pharma Investments, LLC 5	17,395,000	8.00%
Christopher J. Schaber 6	7,148,843	3.19%
Evan Myrianthopoulos 7	3,509,155	1.59%
Gregg A. Lapointe 8	2,085,976	*
Robert N. Brey 9	1,471,875	*
Robert J. Rubin 10	840,243	*
Christopher P. Schnittker 11	821,875	*
Kevin J. Horgan 12	390,625	*
Tamar D. Howson 13	300,000	*
Virgil D. Thompson 14	300,000	*
All directors and executive officers as a group (9 persons)	16,868,592	7.26%

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1 Includes (a) 54,227,817 shares of common stock and warrants to purchase 7,141,432 shares of common stock exercisable within 60 days of March 25, 2011 held by Sigma-Tau Pharmaceuticals, Inc., (b) 3,282,929 shares of common stock and warrants to purchase 1,756,097 shares held by Chaumiere Sarl, and (c) 1,190,770 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 54,227,817 shares of common stock and warrants to purchase 7,141,432 shares of common stock exercisable within 60 days of March 25, 2011 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. Sigma-Tau Pharmaceuticals, Inc.'s address is 9841 Washingtonian Boulevard, Suite 500, Gaithersburg, Maryland 20878.

3 Includes 45,619,237 shares of common stock and warrants to purchase 1,976,284 shares of common stock exercisable within 60 days of March 25, 2011. The amount does not include 1,546,870 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.

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4 Includes 20,040,000 shares of common stock and warrants to purchase 3,952,569 shares of common stock exercisable within 60 days of March 25, 2011. The address of BAM Management, LLC and related entities is 44 Wall Street, Suite 1603, New York, NY 10005.

5 Includes 17,395,000 shares of common stock. The address of Biotex Pharma Investments, LLC is c/o Biotex Pharma Investments, LLC, 220 West 42nd Street 6th Floor New York, New York 10036.

6 Includes 471,817 shares of common stock owned by Dr. Schaber, options to purchase 6,637,500 shares of common stock exercisable within 60 days of March 25, 2011, and warrants to purchase 39,526 shares of common stock exercisable within 60 days of March 25, 2011. The address of Dr. Schaber is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

7 Includes 224,780 shares of common stock owned by Mr. Myrianthopoulos and his wife and options to purchase 3,284,375 shares of common stock exercisable within 60 days of March 25, 2011. The address of Mr. Myrianthopoulos is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

8 Includes 975,610 shares of common stock, options to purchase 525,000 shares of common stock exercisable within 60 days of March 25, 2011, and warrants to purchase 585,366 shares of common stock exercisable within 60 days of March 25, 2011. The address of Mr. Lapointe is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

9 Includes options to purchase 1,471,875 shares of common stock exercisable within 60 days of March 25, 2011. The address of Dr. Brey is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

10 Includes 243,902 shares of common stock, options to purchase 450,000 shares of common stock exercisable within 60 days of March 25, 2011, and warrants to purchase 146,341 shares of common stock exercisable within 60 days of March 25, 2011. The address of Dr. Rubin is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

11 Includes options to purchase 821,875 shares of common stock owned by Mr. Schnittker exercisable within 60 days of March 25, 2011. The address of Mr. Schnittker is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

12 Includes options to purchase 390,625 shares of common stock owned by Dr. Horgan exercisable within 60 days of March 25, 2011. The address of Dr. Horgan is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

13 Includes options to purchase 300,000 shares of common stock exercisable within 60 days of March 25, 2011. The address of Ms. Howson is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

14 Includes options to purchase 300,000 shares of common stock exercisable within 60 days of March 25, 2011. The address of Mr. Thompson 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 25, 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 217,4115160 shares of common stock outstanding as of March 25, 2011.

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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 10,000,000 shares, bringing the total shares reserved for issuance under the plan to 20,000,000 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 15,000,000 shares, bringing the total shares reserved for issuance under the plan to 35,000,000 shares. The following table provides information, as of December 31, 2010, 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	26,161,039	$ 0.24	7,924,456
Equity compensation plans not approved by security holders	-	-	-
Total	26,161,039	$ 0.24	7,924,456

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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. Under the amended 2005 equity incentive plan, we have issued 1,482,669 shares to individuals as payment for services in the amount of $380,342 as allowed in the plan.

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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 Tamar Howson, Virgil Thompson and Robert Rubin 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 is 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.

Item 14. Principal Accountant Fees and Services

The following table highlights the aggregate fees billed during each of the two years ended December 31, 2010 by Amper, Politziner & Mattia, LLP (“Amper,” our principal accountants in 2009 through August 16, 2010) and EisnerAmper, LLP (“EisnerAmper,” our principal accountants commencing August 16, 2010).

	EisnerAmper 2010	Amper 2010	2009
Audit fees1	$14,280	$82,625	$96,900
Audit related fees	1,500	19,795	15,600
Tax fees	-	5,464	2,210
Total	$15,780	$107,884	$114,710

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1 Relates to services performed during the audit of each of those years and reviews of our financial statements included in our Quarterly Reports on Form 10-Q during those years. Although Amper was engaged for the December 31, 2008 audit, our fees related to that audit were incurred in 2009.

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, 2010.

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.

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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).

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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 10.8 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).
10.3	License Agreement between the Company and 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).

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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).

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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). **
21.1	Subsidiaries of the Company.*
23.1	Consent of EisnerAmper LLP.*
31.1	Certification of the Chief Executive Officer pursuant to Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002).*
31.2	Certification of the Chief Financial Officer pursuant to Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002).*
32.1	Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
32.2	Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *

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* Filed herewith.

** Indicates management contract or compensatory plan.

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

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SIGNATURES

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

SOLIGENIX, INC.

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

Date: March 29, 2011

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

Name	Capacity	Date
/s/ Christopher J. Schaber Christopher J. Schaber, PhD	Chairman of the Board, Chief Executive Officer and President (principal executive officer)	March 29, 2011
/s/ Tamar D. Howson Tamar D. Howson	Director	March 29, 2011
/s/ Gregg A. Lapointe Gregg A. Lapointe, CPA	Director	March 29, 2011
/s/ Robert J. Rubin Robert J. Rubin, MD	Director	March 29, 2011
/s/ Virgil D. Thompson Virgil D. Thompson	Director	March 29, 2011
/s/ Evan Myrianthopoulos Evan Myrianthopoulos	Chief Financial Officer, Senior Vice President and Director (principal financial officer)	March 29, 2011
/s/ Christopher P. Schnittker Christopher P. Schnittker, CPA	Vice President of Administration, Controller and Corporate Secretary (principal accounting officer)	March 29, 2011

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SOLIGENIX, INC. AND SUBSIDIARIES
CONSOLIDATED FINANCIAL STATEMENTS

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

	2010	2009
Assets		
Current assets:		
Cash and cash equivalents	$7,451,714	$7,692,011
Grants receivable	120,787	23,632
Taxes receivable	251,864	-
Inventory, net	-	42,865
Prepaid expenses	187,494	141,313
Total current assets	8,011,859	7,899,821
Office furniture and equipment, net	20,699	21,172
Intangible assets, net	1,235,989	1,463,289
Total assets	$9,268,547	$9,384,282
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$1,674,175	$844,857
Accrued compensation	236,581	365,199
Total current liabilities	1,910,756	1,210,056
Commitments and contingencies		
Shareholders' equity:		
Preferred stock; 5,000,000 shares authorized; none issued or outstanding	-	-
Common stock, $.001 par value; 400,000,000 shares authorized; 216,192,360 shares and 185,655,720 shares issued and outstanding in 2010 and 2009, respectively	216,192	185,656
Additional paid-in capital	122,880,378	116,340,770
Accumulated deficit	(115,738,779)	(108,352,200)
Total shareholders' equity	7,357,791	8,174,226
Total liabilities and shareholders' equity	$9,268,547	$9,384,282

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

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

	2010	2009
Revenues, principally from grants	$1,947,628	$2,816,037
Cost of revenues	(1,638,402)	(1,483,641)
Gross profit	309,226	1,332,396
Operating expenses:		
Research and development	5,684,309	4,523,375
General and administrative	1,931,793	2,281,251
Stock-based compensation - research and development	302,096	210,834
Stock-based compensation - general and administrative	269,449	368,232
Total operating expenses	8,187,647	7,383,692
Loss from operations	(7,878,421)	(6,051,296)
Other income (expense):		
Interest income	12,074	21,920
Interest expense	(742)	(2,678)
Other income (expense), principally net proceeds from QTDP grant	234,700	(2,399)
Total other income (expense)	246,032	16,843
Net loss before income taxes	(7,632,389)	(6,034,453)
Income tax benefit	245,810	-
Net loss	$(7,386,579)	$(6,034,453)
Basic and diluted net loss per share	$(0.04)	$(0.04)
Basic and diluted weighted average common shares outstanding	202,406,476	167,515,043

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

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Soligenix, Inc. and Subsidiaries
Consolidated Statements of Changes in Shareholders' Equity (Deficit)
For the Years Ended December 31, 2010 and 2009

	Common Stock		Additional	Accumulated	
	Shares	Par Value	Paid–In Capital	Deficit	Total
Balance, December 31, 2008	118,610,704	$ 118,610	$ 104,176,253	$ (102,317,747)	$ 1,977,116
Issuance of common stock pursuant to private placements, net of $347,000 in expenses	38,266,602	38,267	6,488,995	-	6,527,262
Issuance of common stock for collaboration and supply agreement with Sigma-Tau	25,000,000	25,000	4,375,000	-	4,400,000
Issuance of common stock pursuant to Fusion equity line	708,989	709	114,292	-	115,001
Issuance of common stock to vendors	2,500,000	2,500	297,500	-	300,000
Issuance of common stock warrants to vendors	-	-	190,655	-	190,655
Issuance of common stock to former employee	569,425	570	119,009	-	119,579
Stock-based compensation expense	-	-	579,066	-	579,066
Net loss	-	-	-	(6,034,453)	(6,034,453)
Balance, December 31, 2009	185,655,720	185,656	116,340,770	(108,352,200)	8,174,226
Issuance of common stock pursuant to private placement, net of $224,421 in expenses	28,801,351	28,801	5,651,055	-	5,679,856
Issuance of common stock pursuant to Fusion equity line	294,091	294	69,706	-	70,000
Issuance of common stock to vendors	403,225	403	104,435	-	104,838
Issuance of common stock warrants to vendors	-	-	67,052	-	67,052
Issuance of common stock for option and warrant exercises	1,080,875	1,081	75,772	-	76,853
Shares retired	(42,902)	(43)	43		-
Stock-based compensation expense	-	-	571,545	-	571,545
Net loss	-	-	-	(7,386,579)	(7,386,579)
Balance, December 31, 2010	216,192,360	$ 216,192	$ 122,880,378	$ (115,738,779)	$ 7,357,791

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

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

	2010	2009
Operating activities:		
Net loss	$ (7,386,579)	$(6,034,453)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	185,696	175,604
Inventory reserve	-	50,000
Stock or warrants issued in exchange for services	171,890	490,654
Stock-based compensation	571,545	579,066
Capitalized patent write-off	378,501	-
Stock issued to former employee	-	119,579
Loss on disposal of fixed assets	-	2,399
Change in operating assets and liabilities:		
Grants receivable	(97,155)	254,684
Taxes receivable	(251,864)	-
Inventory	42,865	(10,683)
Prepaid expenses	(46,181)	(54,476)
Accounts payable	829,318	(170,148)
Accrued compensation	(128,618)	(5,415)
Total adjustments	1,655,997	1,431,264
Net cash used in operating activities	(5,730,582)	(4,603,189)
Investing activities:		
Acquisition of intangible assets	(330,163)	(206,799)
Purchase of office equipment	(6,261)	(15,730)
Net cash used in investing activities	(336,424)	(222,529)
Financing activities:		
Net proceeds from sale of common stock	5,679,856	10,927,262
Proceeds from sale of common stock pursuant to Fusion equity line	70,000	115,001
Proceeds from exercise of stock options and warrants	76,853	-
Net cash provided by financing activities	5,826,709	11,042,263
Net increase (decrease) in cash and cash equivalents	(240,297)	6,216,545
Cash and cash equivalents at beginning of year	7,692,011	1,475,466
Cash and cash equivalents at end of year	$ 7,451,714	$7,692,011
Supplemental information:		
Cash paid for state income taxes	$ $2,853	$$2,542
Shares retired	$ 43	$-

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

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Soligenix, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

Note 1. Nature of Business

Basis of Presentation

Soligenix, Inc. (the "Company") is a late-stage biopharmaceutical company that was incorporated in 1987 and is focused on developing products to treat the life-threatening side effects of cancer treatments and serious gastrointestinal diseases where there remains an unmet medical need, as well as developing several biodefense vaccines and therapeutics. The Company maintains two active business segments: BioTherapeutics and BioDefense. Soligenix's BioTherapeutics business segment intends to develop orBec® (oral beclomethasone dipropionate, or oral BDP) and other biotherapeutic products, including LPM™ Leuprolide, while the Company's collaboration partner, Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau") will commercialize orBec® in North America once approved. Soligenix's BioDefense business segment intends to convert its ricin toxin vaccine programs and radiation injury programs from early stage development to advanced development and manufacturing.

The Company generates revenues primarily from the National Institutes of Health under three active grants and from a licensing agreement with Sigma-Tau.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, development of new technological innovations, dependence on key personnel, protections of proprietary technology, compliance with FDA regulations, litigation, and product liability.

Liquidity

As of December 31, 2010, the Company had cash and cash equivalents of $7,451,714 as compared to $7,692,011 as of December 31, 2009, representing a marginal decrease of $240,297 or 3%. As of December 31, 2010, the Company had working capital of $6,101,103 as compared to working capital of $6,689,765 as of December 31, 2009, representing a decrease of $588,662 or 9%. The decrease in working capital was the result of the cash used in operating and investing activities over the period, offset by the proceeds raised in the private placement of common stock and warrants completed in June 2010, as well as option and warrant exercise proceeds and proceeds from the sale of stock under the Fusion equity line. For the year ended December 31, 2010, the Company's cash used in operating activities was $5,730,582, as compared to $4,603,189 for the same period in 2009. The increase in spending was attributable to the conduct of the confirmatory Phase 3 clinical trial of orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease ("GI GVHD").

Management's business strategy can be outlined as follows:

- complete the confirmatory Phase 3 clinical trial for orBec® in the treatment of acute gastrointestinal GI GVHD;
- identify a development and marketing partner for orBec® for territories outside of North America, as we have granted an exclusive license to Sigma-Tau to commercialize orBec® in the U.S., Canada and Mexico;
- complete the Phase 1/2 clinical trial for SGX201 (oral BDP) in the prevention of acute radiation enteritis;
- evaluate and/or initiate additional trials to explore the effectiveness of orBec®/oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal ("GI") tract such as prevention of acute GVHD, treatment of chronic GVHD, radiation injury, and Crohn's disease;
- continue to secure additional government funding for each of our BioTherapeutics and BioDefense programs through grants, contracts and/or procurements;

use RiVaxTM to support development efforts with our heat stabilization technology into the development of new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas;

acquire or in-license new clinical-stage compounds for development; and

explore other business development and acquisition strategies.

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Based on the Company's current rate of cash outflows, cash on hand, the timely collection of milestone payments under collaboration agreements, proceeds from our grant programs, and proceeds expected from the Fusion Capital transaction, management believes that its current cash will be sufficient to meet the anticipated cash needs for working capital and capital expenditures into the second quarter of 2012.

The Company's plans with respect to its liquidity management include the following:

- The Company has approximately $9.5 million in active grant funding still available to support its research programs through 2011 and beyond. Additionally, the Company has submitted additional grant applications for further support of these programs and others with various funding agencies;
- The Company has approximately $7.6 million in available capacity under the Company's Fusion Capital equity facility through October 2011. Although, the Company has historically drawn down modest amounts under this agreement, the Company could draw more within certain contractual parameters;
- The Company has continued to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners and expects to continue to do so for the foreseeable future;
- The Company will seek non-dilutive funding through completion of partnerships for our orBec®/oral BDP programs in territories outside North America;
- The Company will pursue Net Operating Losses ("NOLs") sales in the State of New Jersey. Based on the receipt of $245,810 in proceeds pursuant to NOLs sales in 2010, the Company expects to participate in the expanded program during 2011 and beyond; and
- The Company may seek additional capital in the private and/or public equity markets to continue its operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. The Company is currently evaluating additional equity financing opportunities and may execute them when appropriate. However, there can be no assurances that the Company can consummate such a transaction, or consummate a transaction at favorable pricing.

Note 2. Summary of Significant Accounting Policies

Principles of Consolidation

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

Operating Segments

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

Grants Receivable

Grants receivable consist of unbilled amounts due from various grants from the National Institutes of Health ("NIH") of the U.S. Federal Government for costs incurred prior to the period end under reimbursement contracts. The amounts were billed to the NIH in the month subsequent to period end and collected shortly thereafter. The Company considers the grants receivable to be fully collectible; accordingly, no allowance for doubtful amounts has been established. If amounts become uncollectible, they are charged to operations.

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Intangible Assets

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

The Company capitalized $330,163 and $206,799 in patent related costs during the years ended December 31, 2010 and 2009, respectively.

During the year ended December 31, 2010, the Company incurred $378,501 in expense as a result of a one-time patent write off related to its return of the botulinum toxin vaccine license and abandonment of related patents. This expense is reflected in research and development expense in the consolidated statement of operations.

Impairment of Long-Lived Assets

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

The Company did not record any impairment of long-lived assets for the years ended December 31, 2010 or 2009.

Inventory

Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out (FIFO) method and includes the cost of materials and overhead. Inventory consists of finished goods related to the orBec® NPAP. The Company records an allowance as needed for excess inventory. During 2009 an allowance of $150,000 was provided. During the year ended December 31, 2010 the Company disposed of its remaining inventory valued at $30,211 due to product expiration dates and expects to manufacture more product for the NPAP during early 2011.

Fair Value of Financial Instruments

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

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Revenue Recognition

Substantially all of the Company's revenues are generated from NIH grants. The Company also generates revenues from the achievement of licensing milestones (in prior periods), and from sales of orBec® under the NPAP. The revenue from NIH grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the grants, plus a facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized when expenses have been incurred by subcontractors or when the Company incurs internal expenses that are related to the grant. Licensing milestone revenues are recorded when earned. Revenue from NPAP sales of orBec® are recognized when the product is shipped.

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.

Stock-Based Compensation

From time to time, the Company issues restricted shares of common stock to vendors and consultants as compensation for services performed. Stock-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period.

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

Stock compensation expense for options, warrants and shares of common stock granted to non-employees has been determined in accordance with FASB ASC 718, Stock Compensation, and FASB ASC 505-50, Equity-Based Payments to Non-Employees, and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employees is amortized as the options vest. The option's price is re-measured using the Black-Scholes model at the end of each three month reporting period.

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

a dividend yield of 0%;
an expected life of 4 years;
volatilities ranging from 127% to 129% and 126% to 130% for 2010 and 2009, respectively; and
risk-free interest rates ranging from 0.77% and 1.91% and 1.51% to 2.24% in 2010 and 2009, respectively.

The Company estimates these values based on the assumptions that have been historically available. The fair value of each option grant made during 2010 and 2009 was estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option's vesting periods, which approximates the service period.

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Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including the Company's current and past performance, the market environment in which the Company operates, the utilization of past tax credits, and the length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. No current or deferred income taxes have been provided through December 31, 2010 due to the net operating losses incurred by the Company since its inception. The Company recognizes accrued interest and penalties associated with uncertain tax positions, if any, as part of income tax expense. There were no tax related interest and penalties recorded for 2010 and 2009. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at December 31, 2010 and 2009. The income tax returns for 2007, 2008 and 2009 are subject to examination by the IRS and other various taxing authorities, generally for three years after they were filed.

Earnings Per Share

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

	For the Year Ended December 31, 2010			For the Year Ended December 31, 2009		
	Net Loss	Shares	EPS	Net Loss	Shares	EPS
Basic & Diluted EPS	$(7,386,579)	202,406,476	$(0.04)	$(6,034,453)	167,515,043	$(0.04)

Share issuable upon the exercise of options and warrants outstanding at December 31, 2010 and 2009 were 26,161,039 and 19,311,539 shares issuable upon the exercise of options, and 54,076,373 and 42,472,874 shares issuable upon the exercise of warrants, respectively. The weighted average exercise price of the Company's stock options and warrants outstanding at December 31, 2010 were $0.22 and $0.24 per share, respectively. No options and warrants were included in the 2010 and 2009 computations of diluted earnings per share because their effect would be anti-dilutive as a result of losses in each of those years.

Use of Estimates and Assumptions

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ from those estimates.

New Accounting Pronouncements

In April 2010, the FASB issued Accounting Standards Update ("ASU") 2010-12, Accounting for Certain Tax Effects of the 2010 Health Care Reform Acts, which clarifies the effect, if any, that the different signing dates of the Patient

Protection and Affordable Care Act (signed March 23, 2010) and the Health Care and Education Reconciliation Act of 2010 (signed March 30, 2010). ASU 2010-12 became effective for the Company upon issuance. The adoption of the standard did not have any impact on the Company's consolidated financial statements.

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Note 3. Office Furniture and Equipment

Office furniture and equipment are stated at cost. Depreciation is computed on a straight-line basis over five years. Office and laboratory equipment consisted of the following as of December 31:

	2010	2009
Office equipment	$37,828	$31,567
Office furniture	2,889	2,889
Laboratory equipment	-	-
	40,717	34,456
Less: Accumulated depreciation	(20,018)	(13,284)
Office furniture and equipment, net	$20,699	$21,172

Depreciation expense was $6,734 and $13,377 for the years ended December 31, 2010 and 2009, respectively.

Note 4. Intangible Assets

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

	Weighted Average Amortization period (years)	Cost	Accumulated Amortization	Net Book Value
December 31, 2010				
Licenses	9.7	$462,234	$197,469	$264,765
Patents	4.2	1,912,784	941,559	971,224
Total	5.3	$2,375,018	$1,139,028	$1,235,989
December 31, 2009				
Licenses	10.7	$462,234	$170,231	$292,003
Patents	6.2	2,077,401	906,115	1,171,286
Total	7.0	$2,539,635	$1,076,346	$1,463,289

Amortization expense was $178,962 and $162,227 in 2010 and 2009, respectively.

During the year ended December 31, 2010, the Company incurred $378,501 in a one-time patent write off cost related to its return of the botulinum toxin vaccine license and abandonment of related patents. This cost is reflected in research and development expense in the consolidated statement of operations.

Based on the balance of licenses and patents at December 31, 2010, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

Year	Amortization Expense
2011	$200,000
2012	$200,000
2013	$200,000
2014	$200,000
2015	$200,000

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

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Note 5. Income Taxes

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

	2010	2009
Net operating loss carry forwards	$26,294,000	$24,249,000
Orphan drug and research and development credit carry forwards	3,462,000	3,339,000
Other	1,796,000	2,312,000
Total	31,552,000	29,900,000
Valuation allowance	(31,552,000)	(29,900,000)
Net deferred tax assets	$-	$-

At December 31, 2010, the Company had net operating loss carry forwards ("NOLs") of approximately $74,000,000 for federal tax purposes and approximately $17,000,000 of New Jersey net operating loss carry forwards remaining after the sale of unused net operating loss carry forwards, portions of which are currently expiring each year until 2030. In addition, the Company had $3,462,000 of various tax credits that start expiring from December 2010 to December 2030. The Company may be able to utilize their NOLs to reduce future federal and state income tax liabilities. However, these NOLs are subject to various limitations under Internal Revenue Code ("IRC") Section 382. IRC Section 382 limits the use of NOLs to the extent there has been an ownership change of more than 50 percentage points. In addition, the NOL carryforwards are subject to examination by the taxing authority and could be adjusted or disallowed due to such exams. Although the Company has not undergone an IRC Section 382 analysis, it is likely that the utilization of the NOLs may be substantially limited.

The Company and one or more of its subsidiaries files income tax returns in the U.S. Federal jurisdiction, and various state and local jurisdictions. The Company is no longer subject to income tax assessment for years before 2005. However, since the Company has incurred net operating losses in every tax year since inception, all its income tax returns are subject to examination by the Internal Revenue Service and state authorities for purposes of determining the amount of net operating loss carryforward that can be used to reduce taxable income.

The net change in the valuation allowance for the year ended December 31, 2010 and December 31, 2009 was an increase of approximately $1,652,000 and decrease of $1,700,000, respectively, resulting primarily from net operating losses expiring and generated. As a result of the Company's continuing tax losses, the Company has recorded a full valuation allowance against a net deferred tax asset.

Reconciliations of the difference between income tax benefit computed at the federal and state statutory tax rates and the provision for income tax benefit for the years ended December 31, 2010 and 2009 was as follows:

	2010		2009	
Income tax loss at federal statutory rate	(34.00	) %	(34.00	) %
State tax benefits, plus sale of NJ NOLs, net of federal benefit	(6.50	)	(6.50	)
Subtotal	(40.50	)	(40.50	)
Valuation allowance	37.28		40.50	
Provision for income taxes (benefit)	(3.22	)%	-	%

The Company follows FASB ASC 740-10, Uncertainty in Income Taxes. This standard prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The adoption did not have an effect on the consolidated financial statements.

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In November 2010, the Company received $234,700 of cash 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, which is included in Other Income (Expense) for the year ended December 31, 2010.

During the year ended December 31, 2010, in accordance with the State of New Jersey's Technology Business Tax Certificate Program, which allowed certain high technology and biotechnology companies to sell unused net operating loss carryforwards to other New Jersey-based corporate taxpayers based in New Jersey, the Company sold New Jersey net operating loss carryforwards, resulting in the recognition of $245,810 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.

Note 6. Shareholders' Equity

Preferred Stock

The Company has 5 million authorized shares of preferred stock authorized, none of which are issued or outstanding.

Common Stock

The following items represent transactions in the Company's common stock for the year ended December 31, 2010:

In five separate transactions during 2010, the Company issued an aggregate of 294,091 shares of common stock under its existing Fusion Capital equity facility. The Company received an aggregate of $70,000 in proceeds which approximated the shares' fair market value on the date of issuance.

In January 2010, the Company issued 403,225 shares of common stock pursuant to the $400,000 ($300,000 of which was issued in 2009) common stock equity investment agreement with its Phase 3 electronic data capture partner, Numoda Corporation ("Numoda"). These shares were priced at the then current 5-day average market price of $0.25 per share. The Company recognized $104,838 of research and development expense during the year ended December 31, 2010 as a result of this transaction.

On June 15, 2010, the Company entered into a Securities Purchase Agreement totaling $5,904,277 (before expenses of the offering) with accredited investors, including members of the Company's Board of Directors and Sigma-Tau. Pursuant to the Purchase Agreement, on June 18, 2010, the Company completed the private placement to the investors of 28,801,351 shares of the Company's common stock and warrants to purchase up to 17,280,810 shares of the Company's common stock. The warrants are exercisable at a price of $0.28 per share for a period of five years commencing on June 18, 2010. The expiration date of the warrants is subject to acceleration if the closing sales price of the Company's common stock attains certain per share values. The Company paid an aggregate placement agent/finder's fee to three different entities of $162,977 in cash and issued warrants to purchase 941,348 shares of common stock having the same terms as the warrants issued to the investors in the private placement. Net proceeds to the Company of the offering were $5,679,856.

As a result of stock option and warrant exercises during 2010, 1,080,875 shares were issued for total proceeds of $76,853 to the Company.

The following items represent transactions in the Company's common stock for the year ended December 31, 2009:

In 11 separate transactions during 2009, the Company issued an aggregate of 708,989 shares of common stock under its existing Fusion Capital equity facility. The Company received an aggregate of $115,001 in proceeds which

approximated the shares' fair market value on the date of issuance.

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In September 2009, the Company received $4,390,200 from the completed private placement of common stock and warrants to accredited investors. Under the terms of the agreements, the Company sold 17,352,567 common shares together with five year warrants to purchase up to 8,676,284 shares of the Company's common stock at $0.278 per share, for an aggregate price of $4,390,200, or $0.253 per share, representing the market price as determined by the five-day average closing price of the Company's common stock prior to the date of the agreements. The expiration date of the warrants can be accelerated at the option of the Company if the Company's common stock meets certain price thresholds. The Company would receive additional gross proceeds of approximately $2,412,000 if they are all exercised. Sigma-Tau led this offering with an investment of $1 million.

In August 2009, 569,425 shares of the Company's common stock were issued to the former controller, treasurer and secretary of the Company in partial settlement of certain compensation and severance liabilities pursuant to the employee's employment agreement. The aggregate number of shares was subject to future adjustment for a six month period following the separation date should the market price fall below the original issuance price. The former employee was granted standard piggyback registration rights with respect to those shares. Compensation expense of $119,579 was recorded in General & Administrative Expense for 2009 related to this issuance, representing the fair market value of the shares at the date of issuance.

In March 2009, the Company issued 2,500,000 shares of common stock pursuant to the $400,000 ($300,000 of which was issued on this date) common stock equity investment agreement with its Phase 3 electronic data capture partner, Numoda. These shares were priced at the then current market price of $0.12 per share. The remaining $100,000 investment was completed in January 2010 and was paid in cash. The investment follows the collaboration between the Company and Numoda announced in June 2008 and represents partial payment by the Company under its collaboration agreement. The Company recognized $400,000 of research and development costs during March 2009 as a result of this transaction.

In February 2009, the Company entered into a collaboration and supply agreement with Sigma-Tau for the commercialization of orBec®. In connection with the execution of the collaboration agreement, the Company entered into a common stock purchase agreement with Sigma-Tau pursuant to which the Company sold 25,000,000 shares of common stock to Sigma-Tau for $0.18 per share, representing an aggregate price of $4,500,000. The purchase price was equal to one hundred fifty percent (150%) of the average trading price of the Company's common stock over the five trading days prior to closing. As part of the transaction, the Company granted Sigma-Tau certain demand and piggy-back registration rights.

In January 2009, the Company received $2,384,200 from the completed private placement of common stock and warrants to accredited investors. Under the terms of the agreement, the Company sold 20,914,035 common shares together with five year warrants to purchase up to 20,914,035 shares of the Company's common stock at $0.14 per share, for an aggregate price of $2,384,200, or $0.114 per share, representing a premium to the Company's common stock market price on the date of the agreements. The expiration date of the warrants can be accelerated if the Company's common stock meets certain price thresholds and the Company would receive additional gross proceeds of approximately $2,900,000 if they are all exercised.

Warrants

During 2010, in addition to warrants issued above in the June private placement, the Company issued 540,000 warrants to purchase common stock shares to consultants in exchange for their services. Expense charges of $67,052 and $190,655 were recorded during the years ended December 31, 2010 and 2009, respectively, as a result of these issuances.

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Equity Line

In February 2008, the Company entered into a common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"). The Fusion Capital equity facility allows the Company to require Fusion Capital to purchase between $80,000 and $1.0 million of the Company's common stock every two business days, up to an aggregate of $8.0 million over approximately a 25-month period depending on certain conditions, including the quoted market price of the Company's common stock on such date. As part of the agreement, the Company issued Fusion Capital 1,275,000 shares of common stock as a commitment fee. In connection with the execution of the common stock purchase agreement, Fusion Capital made an initial purchase of 2,777,778 common shares and received a four year warrant to purchase 1,388,889 shares of common stock for $0.22 per share, representing an aggregate price of $500,000. The Company issued an additional 75,000 shares of common stock as a commitment fee in connection with this $500,000 purchase.

If the Company's stock price exceeds $0.15, then the amount required to be purchased may be increased under certain conditions as the price of the Company's common stock increases. The Company cannot require Fusion Capital to purchase any shares of the Company's common stock on any trading days that the market price of the Company's common stock is less than $0.10 per share. Furthermore, for each additional purchase by Fusion, additional commitment shares in commensurate amounts up to a total of 1,275,000 shares will be issued based upon the relative proportion of purchases compared to the total commitment maximum of 18.5 million shares. The total issuance of common stock related to commitment shares for 2008 was 1,369,125 shares, which were issued to Fusion Capital and consisted of 1,275,000 shares as a commitment fee, 75,000 shares as a commitment fee for the $500,000 invested, and 19,125 shares for the commitment fee shares on the equity line draws totaling $127,500.

During the year ended December 31, 2008, the Company issued 993,084 shares of common stock under the Fusion Capital equity facility. In connection with these issuances the Company received $127,500 in proceeds which approximated the shares' fair market value on the dates of issuance.

Note 7. Stock Option Plans and Warrants to Purchase Common Stock

Stock Option Plans

The Amended and Restated 1995 Omnibus Plan is divided into four separate equity programs:

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

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

1) the Discretionary Option Grant Program, under which eligible persons may, at the discretion of the Plan Administrator, be issued common stock or granted options to purchase shares of common stock,
2) the Salary Investment Option Grant Program, under which eligible employees may elect to have a portion of their base salary invested each year in options to purchase shares of common stock,
3)

the Automatic Option Grant Program, under which eligible nonemployee Board members will automatically receive options at periodic intervals to purchase shares of common stock, and

4) the Director Fee Option Grant Program, under which non-employee Board members may elect to have all, or any portion, of their annual retainer fee otherwise payable in cash applied to a special option grant.

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In addition, under the 2005 Plan, the Board may elect to pay certain consultants, directors, and employees in common stock. The 2005 Plan was amended in September 2007 to increase the number of options available under the plan to 20,000,000 and again in 2010 to increase the number of shares under the plan to 35,000,000.

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

December 31,	2010	2009
Shares available for grant at beginning of year	454,831	3,547,331
Increase in shares available for the plan	15,000,000	-
Options granted	(8,792,500)	(3,712,500)
Options forfeited or expired	1,262,125	620,000
Common stock payment for services	-	-
Shares available for grant at end of year	7,924,456	454,831

The total option activity for the 1995 plan and the amended 2005 plan for the years ended December 31, 2010 and 2009 was as follows:

	Options	Weighted Average Options Exercise Price
Balance at December 31, 2008	16,370,039	$ 0.27
Granted	3,712,500	0.17
Forfeited	(771,000)	0.51
Balance at December 31, 2009	19,311,539	0.24
Granted	8,792,500	0.23
Exercised	(680,875)	0.07
Forfeited	(1,262,125)	0.20
Balance at December 31, 2010	26,161,039	$ 0.24

The Company awarded 8,792,500 and 3,712,500 stock options to new employees and new and existing Board members during in 2010 and 2009, respectively. Of the 2010 grants, 7,335,000 stock options were issued to employees on July 1, 2010 subject to shareholder approval of an increase to the number of available shares under the 2005 Equity Incentive Plan at the Company’s annual meeting of stockholders. Expense reductions of $126,171 and $59,015 are included in Stock-based Compensation - Research & Development and - General & Administrative, respectively, for the year ended December 31, 2010, which represent the decrease in the fair value of the options between their grant date (and the original expense recorded using that date) and fair value of the options at the date of the shareholder approval of the increase to the number of shares available under the equity plan.

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The weighted-average exercise price, by price range, for outstanding options to purchase common stock at December 31, 2010 was:

Price Range	Weighted Average Remaining Contractual Life in Years	Outstanding Options	Exercisable Options
$0.06-$0.11	7.3	6,841,000	5,341,000
$0.14-$0.21	8.6	3,050,000	2,237,503
$0.23-$0.45	7.5	12,430,000	7,672,813
$0.47-$0.58	5.3	3,525,000	3,525,000
$0.74-$1.28	1.9	315,039	315,039
Total	7.2	26,161,039	19,091,355
Intrinsic Value		$-	$-

The intrinsic value was calculated as the difference between the Company's common stock closing price on the Over-The-Counter Bulletin Board at December 31, 2010 and the exercise price of the stock option issued multiplied by the number of stock options. The Company's common stock price at December 31, 2010 was $0.19.

The Company's share-based compensation for the years ended December 31, 2010 and 2009 was $571,545 and $579,066, respectively. At December 31, 2010, the total compensation cost for stock options not yet recognized was approximately $1,082,572 and will be expensed over the next three years.

Warrants to Purchase Common stock

Warrant activity for the years ended December 31, 2010 and 2009 was as follows:

	Warrants	Weighted Average Warrant Exercise Price
Balance at December 31, 2008	20,350,148	$0.41
Granted	32,906,540	0.18
Expired	(10,783,814)	1.13
Balance at December 31, 2009	42,472,874	$0.24
Granted	19,000,282	0.28
Exercised	(400,000)	0.08
Expired	(6,996,783)	0.99
Balance at December 31, 2010	54,076,373	$0.22

During 2010, the Company issued 540,000 warrants to purchase common stock shares to consultants in exchange for their services with exercise prices ranging from $0.25 to $0.30. Expense charges of $67,052 were recorded during 2010 to reflect these issuances.

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

Price Range	Weighted Average Remaining Contractual Life in Years	Outstanding Warrants	Exercisable Warrants
$0.10-$0.11	3.1	1,050,000	1,050,000
$0.14-$0.14	3.1	21,914,035	21,914,035
$0.20-$0.22	1.4	2,239,445	2,239,445
$0.25-$0.31	4.2	28,312,787	28,312,787
$0.59-$0.59	1.1	560,106	560,106
Total	3.6	54,076,373	54,076,373

During 2011, warrants to purchase approximately 45,000 shares of the Company's common stock will expire.

Note 8. Concentrations

At December 31, 2010 and 2009, the Company had deposits in major financial institutions that exceeded the amount under protection by the Securities Investor Protection Corporation ("SIPC"). Currently we are covered up to $1,000,000 by the SIPC. The excess amounts at December 31, 2010 and 2009 were $6,451,714 and $6,692,011, respectively.

Note 9. Commitments and Contingencies

The Company has a commitments of approximately $860,000 million as of December 31, 2010 in connection with an agreement with Numoda for 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 the second half of 2011.

The Company also has 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, the Company entered into a sub-lease agreement through March 31, 2012 for office space in Princeton, New Jersey. The Company was 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 $17.00 per square foot. This rent increased to approximately $7,650 per month, or $17.50 per square foot, for the remaining 18 months.

In February 2007, the Company's Board of Directors authorized the issuance of the following shares to Dr. Schaber, Mr. Myrianthopoulos, Dr. Brey and certain other employees and a consultant, upon the completion of a transaction, or series or a combination of related transactions negotiated by the Company's Board of Directors whereby, directly or indirectly, a majority of the Company's capital stock or a majority of its assets are transferred from the Company and/or its stockholders to a third party: 1,000,000 common shares to Dr. Schaber; 750,000 common shares to Mr. Myrianthopoulos; 200,000 common shares to Dr. Brey; and 450,000 common shares to employees and a consultant shall be issued.

Employees with employment contracts have severance agreements that will provide separation benefits from the Company if they are involuntarily separated from employment.

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

Year	Research and Development	Property and Other Leases	Total
2011	$ 895,000	$ 99,017	$ 994,017
2012	275,000	28,761	303,761
2013	75,000	5,793	80,793
2014	75,000	1,448	76,448
2015	75,000	-	75,000
Total	$ 1,395,000	$ 135,019	$ 1,530,019

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Note 10. Operating Segments

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

	For the Year Ended December 31,	
	2010	2009
Revenues		
BioDefense	$1,441,228	$1,670,536
BioTherapeutics 1	506,400	1,145,501
Total	$1,947,628	$2,816,037
Loss from Operations		
BioDefense	$(1,204,824)	$(389,157)
BioTherapeutics	(5,018,090)	(3,444,838)
Corporate	(1,655,507)	(2,217,301)
Total	$(7,878,421)	$(6,051,296)
Amortization and Depreciation Expense		
BioDefense	$36,843	$91,420
BioTherapeutics	146,832	77,496
Corporate	2,021	6,688
Total	$185,696	$175,604
Interest Income		
Corporate	$12,074	$21,920
Stock-Based Compensation		
BioDefense	$106,842	$66,434
BioTherapeutics	195,252	144,398
Corporate	269,451	368,234
Total	$571,545	$579,066
	As of December 31,	
	2010	2009
Identifiable Assets		
BioDefense	$480,995	$787,225
BioTherapeutics	927,973	784,282
Corporate	7,859,579	7,812,775
Total	$9,268,547	$9,384,282

1 BioTherapeutics revenues for 2009 include the receipt of a $1 million licensing milestone from Sigma-Tau in October 2009.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors of Soligenix, Inc.,

We have audited the accompanying consolidated balance sheet of Soligenix, Inc. and subsidiaries as of December 31, 2010 and the related consolidated statements of operations, changes in shareholders' equity and cash flows for the year ended December 31, 2010. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropri−ate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company at December 31, 2010, and the results of its operations and its cash flows for the year ended December 31, 2010, in conformity with U.S. generally accepted accounting principles.

/s/ EisnerAmper LLP

Edison, New Jersey
March 29, 2011

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors of Soligenix, Inc.,

We have audited the accompanying consolidated balance sheet of Soligenix, Inc. and subsidiaries as of December 31, 2009 and the related consolidated statements of operations, changes in shareholders' equity and cash flows for the year ended December 31, 2009. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropri−ate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company at December 31, 2009, and the results of its operations and its cash flows for the year ended December 31, 2009, in conformity with U.S. generally accepted accounting principles.

/s/ Amper, Politziner & Mattia, LLP

Edison, New Jersey
March 31, 2010